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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational ;	Total Number	Number of Pts	Fisher's					
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	Number of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL					www				
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	s49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19 .	0		0	ō	٥	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	•	1 (100%)	
· ·	. ≤49 Days (Group 1)	145	1 (<1%)	1.0000	1	0	0 1		0
	50-56 Days (Group 2)	40	0		0	0	0 .	1 (100%)	0
	57-63 Days (Group 3)	19	ō		Ö	Ö	0 ,	0	0
BART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	204	2 (<1%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	145	2 (1%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	40	0		Ô	0	0	0	0
	57-63 Days (Group 3)	19	0		0	ō	ŏ	. 0	0
TACHYCARDIA	≤63 Days (All)	204	2 (<1%)	1.0000	-				
	≤49 Days (Group 1)	145	2 (21%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	40	0		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
ASCULAR (EXTRACARDIAC) DISORDERS	,				-	-	v	· ·	v
ANY EVENT	≤63 Days (All)	204	. (
• ;	≤49 Days (Group 1)	204 145	1 (<1%)	1.0000	1	1 (100%),	4	0	0
Profession (Profession Control of Control o	50-56 Days (Group 2)		1 (<1%)		• 1	1 (100%)	/ O	0	0
	57-63 Days (Group 2)	40	0		0	0	0 ,	0	0
•	37-03 Days (Group 3)	19	0		0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational	Total Number	Number of Pts	Fisher's	Number		•		
Body System/Event [2]	Age Group [3]	of Pts	w/Event	exact p-value	of Events	Mild	Moderate	Severe	Unknown
VASCULAR (EXTRACARDIAC) DISORDERS (cont.)		1							
FLUSHING	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	. 0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	6 (3%)	0.4929	6	3 (50%)	2 (33%)	1 (17%)	0
	≤49 Days (Group 1)	145	6 (4%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	40	0		- 0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	204	2 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	2 (100%)	0	0	0
1	50-56 Days (Group 2)	40	0 :		0	0	0	: o	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RHINITIS	≤63 Days (All)	204	2 (<1%)	1.0000	2	0	1 (50%)	_i 1 (50%)	0
4 .	≤49 Days (Group 1)	145	2 (1%)		2	0	1 (50%)	1 (50%)	0
graph of the state	50-56 Days (Group 2)	40	0		• 0	o .i	. 0	'o	0
	57-63 Days (Group 3)	19	0		0	0	0,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational	Total	Number	Fisher's	M				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)					·	- <u> </u>			
SINUSITIS	≰63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≰63 Days (All)	204	8 (4%)	0.2089	8	3 (38%)	2 (25%)	3 (38%)	0
	≤49 Days (Group 1)	145	4 (3%)		4	0	2 (50%)	2 (50%)	0
	50 ¹ 56 Days (Group 2)	40	3 (8%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
ANAEMIA	s63 Days (All)	204	7 (3%)	0.5313	7	2 (29%)	2 (29%)	3 (43%)	0
	≰49 Days (Group 1)	145	4 (3%)		4	0	2 (50%)	2 (50%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	204	1 (<1%)	0.2892	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
,	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	• 0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
LATELET, BLEEDING & CLOTTING DISORDERS	•								
ANY EVENT	s63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0 · ∮ ′	a	0
	≰49 Days (Group 1)	145	1 (<1%)		. 1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	o .'	1 0	0	0
	57-63 Days (Group 3)	19	0		0	0 r	0 '	0	0
· ·	_	•				ļ	}		

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORS	DERS (cont.)		······································		· · · · · · · · · · · · · · · · · · ·				
EPISTAXIS	≤63 Days (All)	204	1 (<1%)	1.0000	. 1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50 56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19 .	0		0	0	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	. ≤63 Days (All)	204	3 (14)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	145	3 (2%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	40	0.		. 0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DYSURIA	≰63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	o	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
URINARY TRACT INFECTION	≰63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	Õ
· ·	50-56 Days (Group 2)	40	0		0	0	0	ō	0
	57-63 Days (Group 3)	19	0		0	0	0	0	o
URINE ABNORMAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
φ.	≤49 Days (Group 1)	145	1 (<1%)	2.2300	1	· .	1 (100%)	Ö	Ô
	50-56 Days (Group 2)	40	0		• 0	0 ;	0	Ö	ň
•	57-63 Days (Group 3)	19	ō		0	0	0	ŏ	0
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^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number				Severi	lty		
Body System/Event [2]	Group [3]	of Pts	w/Ev		p value	of Events	Mi	1 d	Mode	erate	•	ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE										-			****
ANY EVENT	≤63 Days (All)	204	29	(14%)	0.0012	33	10	(30%)	8	(24%)	15	(45%)	0
	≤49 Days (Group 1)	145	14	(10%)		16	5	(31%)	6	(38%)	5	(31%)	0
	50-56 Days (Group 2)	40	7	(18%)		8	4	(50%)	1	(13%)	3	(38%)	0
	57-63 Days (Group 3)	19 .	8	(42%)		9	1	(11%)	1	(11%)	7	(78%)	0
BREAST PAIN FEMALE	≤63 Days (All)	204	2	(<1%)	0.4958	2	1	(50%)	1	(50%)	0		0
1	≰49 Days (Group 1)	145	1	(<1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	40	1	(3%)		1	1	(100%)	0		0		0
	57 63 Days (Group 3)	19	0			. 0	0		0		0		0
CERVICAL DYSPLASIA	≤63 Days (All)	204	1	(<1 %)	1.0000	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	145	1	(<1%)		1	0		1	(100%)	0		0
1	50-56 Days (Group 2)	40	0			0	0		0		0		0
•	57-63 Days (Group 3)	19	0			0	0		0		0		0
ENDOMETRITIS	≤63 Days (All)	204	3	(1%)	1.0000	.3	1	(33%)	1	(33%)	1	(33%)	0
•	≰49 Days (Group 1)	145	3	(2%)		3	1	(33%)	1	(33%)	1	(33%)	0
	50-56 Days (Group 2)	40	0			0	0		0		0		0
•	57-63 Days (Group 3)	19	0			0	0		. 0		0		0
LEUKORRHOEA	s63 Days (All)	204	3	(1%)	1.0000	3	2	(67%)	1	(33%)	0		0
	s49 Days (Group 1)	145	3	(21)		3	2	(67%)	1	(33%)	0		0
ને	50-56 Days (Group 2)	40	0			0	0		. 0		0		0
1 1 4	57-63 Days (Group 3)	19	0			. 0	0	,i ^w	1	. व. ქ •	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational	Total	Numb		Fisher's								
Body System/Event [2]	Age Group (3)	Number of Pts	of P w/Ev		exact p-value	Number - of Events	Mil		Mod	Severi erate	•	ere	Unknown
					P 12								
REPRODUCTIVÉ DISORDERS, PENALE (cont.)									4				
OVARIAN DISORDER	≤63 Days (All)	204	1	(<1%)	0.2892	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	145	0			0	0		! 0		0		0
	50-56 Days (Group 2)	40	1	(3%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	19 -	0			0	0		0		0		0
SEXUAL FUNCTION ABNORMAL	≰63 Days (All)	204	1	(<1%)	0.2892	1	1 ((100%)	0		0		0
ı,	≤49 Days (Group 1)	145	0			0	0		0		0		0
	50-56 Days (Group 2)	40	1	(3%)		1	1 ((100%)	0		0		0
	57-63 Days (Group 3)	19	0			0	0		0		0		0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	14	(7%)	0.0004	14	0		1	(7%)	13	(93%)	0
	≤49 Days (Group 1)	145	5	(3%)		5	0		1	(20%)	4	(80%)	0
	50-56 Days (Group 2)	40	3	(8%)		3	0		0		3	(100%)	0
	57-63 Days (Group 3)	19	6	(32%)		6	0		0		6	(100%)	0
VAGINITIS	≤63 Days (All)	204		(4%)	0.0213	8	5	(63%)	2	(25%)	1	(13%)	0
	≤49 Days (Group 1)	145	3	(2%)		3	2	(67%)	1	(33%)	0		0
	50-56 Days (Group 2)	40	2	(5%)		2	2 ((100%)	0		0		0
	57-63 Days (Group 3)	19	3	(16%)		3	1	(33%)	1	(33%)	1	(33%)	0
TEOPLASM													
ANY EVENT	≤63 Days (All)	204	5	(2%)	0.5701	5	1	(20%)	3	(60%)	1	(20%)	0
- -	≤49 Days (Group 1)	145	3	(2%)	Ì	3	1	(33%)		(33%)	1	(33%)	0
	50-56 Days (Group 2)	40	2	(5%)	1	. 2	0	,i	2	(100%)	0		0
•	57-63 Days (Group 3)	19	0			0	0		0	•	0		0
								- [İ				

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number			.	Sever	itv		
Body System/Event [2]	Group [3]	of Pts	w/Ev	ent	p-value	of Events	Mi	1 d	Mode	rate	Sev	ere	Unknown
NEOPLASH (cont.)												······································	
CERVICAL SMEAR TEST POSITIVE	≤63 Days (All)	204	4	(2%)	0.3287	4	0		3	(75%)	1	(25%)	0
	≤49 Days (Group 1)	145	2	(1%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	40	2	(5%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	19	0			0	. 0		0		0		0
OVARIAN CYST	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0	1	0		0
1	. ≤49 Days (Group 1)	145	1	(<1%)		1	1	(100%)	0	, '	ġ		0
	50-56 Days (Group 2)	40	0			0	0		0		ó		0
	57-63 Days (Group 3)	19	0			. 0	0		0		0		0
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	s63 Days (All)	204	197	(97%)	0.4317	596	203	(34%)	231	(39%)	162	(27%)	0
	≤49 Days (Group 1)	145	138	(95%)		406	150	(37%)	153	(38%)	103	(25%)	0
	50-56 Days (Group 2)	40	40 (100%)		137	38	(28%)	58	(42%)	41	(30%)	0
	57-63 Days (Group 3)	19	19 (100%)		53	15	(28%)	20	(384)	18	(34%)	0
ABDOMINAL PAIN	≤63 Days (All)	204	195	(96%)	0.2077	527	171	(32%)	206	(39%)	150	(28%)	0
	s49 Days (Group 1)	145	136	(94%)		351	123	(35%)	133	(38%)	95	(27%)	0
,	50-56 Days (Group 2)	40	40 (100%)		128	35	(27%)	55	(43%)	38	(30%)	0
	57-63 Days (Group 3)	19	19 (100%)		48	13	(27%)	18	(38%)	17	(35%)	0
ASTHENIA	≤53 Days (All)	204	5	(21)	0.4316	5	1	(20%)	2	(40%)	2	(40%)	0
4 .	≤49 Days (Group 1)	145	3	(2%)		3	1	(33%)	. 2	(67%)	0		0
	50-56 Days (Group 2)	40	1	(3%)		. 1	0	į	, 0		1	(100%)	0
• • •	57-63 Days (Group 3)	19	1	(5%)		1	0	•	0	•	1	(100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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⁽⁴⁾ Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)		•						
BACK PAIN	≤63 Days (All)	204	14 (71	0.9015	22	7 (32%)	10 (45%)	5 (23%)	0
	≤49 Days (Group 1)	145	11 (89)	19	6 (32%)	9 (47%)	4 (21%)	0
	50-56 Days (Group 2)	40	2 (51)	2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	19	1 (5)	1	1 (100%)	0	0	0
CHEST PAIN	≤63 Days (All)	204	5 (29) 1.0000	6	3 (50%)	2 (33%)	1 (17%)	0
1	≤49 Days (Group 1)	145	4 (31)	5	2 (40%)	2 (40%)	1 (20%)	0
	50-56 Days (Group 2)	40	1 (31)	1	1 (100%)	0	0	Ō
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	204	12 (61) 0.7890	12	9 (75%)	2 (17%)	1 (8%)	0
	≤49 Days (Group 1)	145	10 (79)	10	7 (70%)	2 (20%)	1 (10%)	0
	50-56 Days (Group 2)	40	2 (51)	2	2 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FEVER	≤63 Days (All)	204	6 (31) 1.0000	7	3 (43%)	3 (43%)	1 (14%)	0
	<pre>s49 Days (Group 1)</pre>	145	5 (31)	6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	40	1 (31)	1	0	1 (100%)	0	0
,	57-63 Days (Group 3)	19	0	t .	0	0	0		0
HOT FLUSHES	≤63 Days (All)	204	1 (<1	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	ρ	0
÷.	50-56 Days (Group 2)	40	1 (31)	1	0 .	1 (100%)	þ	0
service of the servic	57-63 Days (Group 3)	19	0		. 0	o ,i "	0 1	Ь	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact				•	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
DY AS A WHÔLE - GENERAL DISORDERS (cont.)									
LEG PAIN	≰63 Days (All)	204	2 (<1%)	1.0000	2	2 (100%)	0	0	0
	≰49 Days (Group 1)	145	2 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	O
	57-63 Days (Group 3)	19	0		0	0	0	0	0
MALAISE	≤63 Days (All)	204	1 (<1%)	0.0931	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	145	0		0	0	0	0	0
·	50-56 Days (Group 2)	40	0		0	0	o :	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	o .	0	0
PAIN	≤63 Days (All)	204	3 (1%)	0.0411	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0 .	0	0	0
	57-63 Days (Group 3)	19	2 (11%)		2	0	2 (100%)	0	0
RIGORS	s63 Days (All)	204	4 (2%)	0.7159	5	3 (60%)	1 (20%)	1 (20%)	0
•	≤49 Days (Group 1)	145	4 (31)		5	3 (60%)	1 (20%)	1 (20%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	204	4 (2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
	≰49 Days (Group 1)	145	3 (2%)		3	2 (67%)	1 (33%)	0	0
v.	50-56 Days (Group 2)	40	1 (3%)		1	0 .	0 .	1 (100%)	0
	57-63 Days (Group 3)	19	0		. 0	0 , "	• 0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's	M				
Body System/Event [2]	Group [3]	of Pts	w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (COD	t.)	· · · · · · · · · · · · · · · · · · ·			******			· · · · · · · · · · · · · · · · · · ·	
TEMPERATURE CHANGED SENSATION	≰63 Days (All)	204	1 (<1%)	1.0000	. 1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	ō	1 (100%)	Ö	0
	50-56 Days (Group 2)	40	0		0	ō	0	0	0
	57-63 Days (Group 3)	19 .,	0		0	ō	o	ő	0
ESISTANCE NECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	204	5 (2%)	1.0000	5	5 (100%)	0 .	0	^
	s49 Days (Group 1)	145	4 (3%)		4	4 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		i	1 (100%)	Ō	0	0
	57-63 Days (Group 3)	19	0		0	0	0	ő	0
INFECTION BACTERIAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	•
	<49 Days (Group 1)	145	1 (<1%)	1.0000	i	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		•	0	0	0	0
	57-63 Days (Group 3)	19	0		0	ō	0	0	0
INFECTION VIRAL	s63 Days (All)	204	4 (2%)	1.0000		4 (100%)	•	•	_
	≤49 Days (Group 1)	145	3 (2%)	1.0000	,	3 (100%)	0	U	0
•	50-56 Days (Group 2)	40	1 (3%)		,	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0 0	0	0
ECONDARY TERMS		1							
ANY EVENT	≤63 Days (All)	204	2 (<1%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	145	2 (1%)		• 2	0 ;	2 (1001)	o	0
•	50-56 Days (Group 2)	40	0			0 .	0.	o	0
	57-63 Days (Group 3)	19	0		0	o r	0	0	0
·	1,0 (0200)	- -	-		J	Ĭ	1	v	v

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational	Total Number	Number of Pts	Fisher's exact			Severi		.
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
SECONDARY TERMS (cont.)									
INFLICTED INJURY	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
POST-OPERATIVE PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
·	50-56 Days (Group 2)	40	0		`o	0	0 '	0 -	0
	57-63 Days (Group 3)	19	0		0	0	0 .	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued)
Adverse Events [1] Sy Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational Aqe	Total Number		mber Pts	Fisher's exact	Number				Se	verity			
Body System/Event [2]	Group [3]	of Pts		Event	p value	of Events	Mi	ild	Mo	derate	•	vere	Unkno	own
•														
ANY EVENT	≤63 Days (All)	238	237	(>99%)	1.0000	1899	655	(34%)	7/3	7 (39)	506	(27%)	1	(<1%)
	≤49 Days (Group 1)	81	81	(100%)		598	226	(38%)	23	0 (38%) 141	(24%)	1	(<1%)
	50-56 Days (Group 2)	89	88	(99%)		694	251	(36%)	25	0 (36%) 193	(28%)	0	
	57-63 Days (Group 3)	68	68	(100%)		607	178	(29%)	25	7 (42%) 172	(28%)	0	
SKIN AND APPENDAGES DISORDERS														
ANY EVENT	. ≤63 Days (All)	238	9	(4%)	0.5823	10	2	(20%)		4 (40)) 4	(40%)	0	
	≤49 Days (Group 1)	81	2	(2%)		2	0			1 (50) 1	(50%)	0	
	50-56 Days (Group 2)	89	3	(3%)		. 4	1	(25%)		2 (50%) 1	(25%)	0	
	57-63 Days (Group 3)	68	4	(6%)		4	1	(25%)		1 (25%) 2	(50%)	0	
PHOTOSENSITIVITY REACTION	≤63 Days (All)	238	1	(<1%)	1.0000	1	1	(100%)		0	0		0	
	s49 Days (Group 1)	81	0			0	0			0	0		0	
	50-56 Days (Group 2)	89	1	(1%)		1	1	(100%)		0	0		0	
	57-63 Days (Group 3)	68	Ó			0	0			0	0		0	
PRURITUS GENITAL	≰63 Days (All)	238	1	(<1%)	0.2857	1	1	(100%)		0	0		0	
	≤49 Days (Group 1)	81	0			0	0			0	0		0	
1	50-56 Days (Group 2)	89	0			0	0		1	0	0		0	
	57-63 Days (Group 3)	68	1	(1%)		1	1	(100%)	İ	0	0		0	
RASH	≤63 Days (All)	238	1	(<1%)	0.2857	1	0			1 (100) 0		0	
$ec{m{\epsilon}}$	≰49 Days (Group 1)	81	0		į	0	0	•	•	0	0		0	
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	50-56 Days (Group 2)	89	0		į	• 0	0	j		0	0		0	
	57-63 Days (Group 3)	68	1	(1%)		1		r ì		1 (100) 0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's			•	•	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
SKIN AND APPÉNDAGES DISORDERS (cont.)				The second secon					-
SWEATING INCREASED	≤63 Days (All)	238	5 (2%)	1.0000	6	0	3 (50%)	3 (50%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	2 (2%)		3	0	2 (67%)	1 (33%)	0
	57-63 Days (Group 3)	68 .	1 (1%)		1	0	0	1 (100%)	0
URTICARIA	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	0	1 (100%)	0
i	≤49 Days (Group 1)	81	0		0	0	0	O ;	0
	50-56 Days (Group 2)	89	0		0	0	О ,	o'	0
	57-63 Days (Group 3)	68	1 (1%)		, 1	0	0	1 (100%)	0
USCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	5 (2%)	0.3849	6	2 (33%)	2 (33%)	2 (33%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	68	3 (4%)		3	1 (33%)	2 (67%)	0	0
ARTHRALGIA	≤63 Days (All)	238	3 (1%)	0.1954	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
r · · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
ARTHRITIS	≤63 Days (All)	238	1 (<1%)	1.0000	2	1 (50%)	0	1 (50%)	0
$\hat{\boldsymbol{\epsilon}}$	≤49 Days (Group 1)	81	0		0	0 .	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		. 2	1 (50%)	0	1 (50%)	0
•	57-63 Days (Group 3)	68	0		0	o .	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number	- -		.	Seve	ity		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
USCULO-SKELETAL SYSTEM DISORDERS (cont.)													
SKELETAL PAIN	≰63 Days (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68 -	1	(1%)		1	0		1	(100%)	0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≰63 Days (All)	238	89	(37%)	0.7435	163	51	(31%)	89	(55%)	23	(14%)	0
	≤49 Days (Group 1)	81	33	(41%)		53	18	(34%)	31	(581)	4 '	(89)	0
	50-56 Days (Group 2)	89	32	(36%)		.62	22	(35%)	29	(47%)	11	(18%)	0
	57-63 Days (Group 3)	68	24	(35%)		48	11	(23%)	29	(60%)	8	(17%)	0
DIZZINESS	s63 Days (All)	238	21	(9%)	0.4057	25	10	(40%)	10	(40%)	5	(20%)	0
	≰49 Days (Group 1)	81	9	(11%)		11	4	(36%)	5	(45%)	2	(18%)	0
	50-56 Days (Group 2)	89	5	(6%)		5	3	(60%)	0		2	(40%)	0
	57-63 Days (Group 3)	68	7	(10%)		9	3	(33%)	5	(56%)	1	(11%)	0
HEADACHE	s63 Days (All)	238	77	(32%)	0.8668	131	40	(31%)	74	(56%)	17	(13%)	0
	≤49 Days (Group 1)	81	28	(35%)		42	14	(33%)	26	(62%)	2	(5%)	0
e · · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	89	27	(30%):		51	18	(35%)	25	(49%)	8	(16%)	0
	57-63 Days (Group 3)	68	22	(32%)		38	8	(21%)	23	(61%)	7	(18%)	0
HYPERTONIA	≤'63 Days (All)	238	3	(1%)	0.5061	4	1	(25%)	3	(75%)	р		0
₹. , , , ,	≰49 Days (Group 1)	81	0			0	0	.,•	0	4.	þ		0
	50-56 Days (Group 2)	89	2	(2%)		. 3	1	(33%)	<u> </u>	(671)	ò		0
	57-63 Days (Group 3)	68	1	(1%)		1	0	'r !	1	(100%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

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FINAL

^[2] NOS = Not otherwise specified

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p·value	Number of Events	Mild	Moderate	Severe	Unknown
ENTR & PERSON NERVOUS SYSTEM DISC	ORDERS (cont.)				·				
MIGRAINE	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	Ö
	≤49 Days (Group 1)	81	0 .		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TREMOR	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	2 (100%)	a	0
	s49 Days (Group 1)	81	0		0	0	0	0	0
·	50-56 Days (Group 2)	89	2 (2%)		2	D	2 (100°)	0	0
	57-63 Days (Group 3)	68	0		. 0	0	0	0	0
EARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.3345	2 ·	0	0	2 (100%)	0
	≰49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2 '	0	0	2 (100%)	0
	57-63 Days (Group 3)	68	0		υ	0	0	0	0
EAR ACHE	≤63 Days (All)	238	1 (<1\$)	1.0000	1	Ó	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	. 0	1 (100%)	0
•	57-63 Days (Group 3)	68	0		0	0	0	0	0
TINNITUS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0 .	1 (100%)	0
,	≤49 Days (Group 1)	81	0		0	0	. , 0	0	0
٠,	50-56 Days (Group 2)	89	1 (1%)		1	o ;	0	1 (100%)	0
e v • • • · · · · · · · · · · · · · · · ·	57 63 Days (Group 3)	68	0		0	0	0,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational ;	Total Number	Number of Pts	Fisher's					
Body System/Event [2]	Group [3]	of Pts	w/Event	exact p value	Number of Events	Mild	Moderate	ity Severe	Unknown
PECIAL SENSES OTHER, DISORDERS								-	
ANY EVENT	≤63 Days (All)	238	1 (<1%	0.6261	. 1	1 (100%)	•	_	_
	≤49 Days (Group 1)	81	1 (1%		,		0	0	0
	50-56 Days (Group 2)	89	0	•	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
	or to bays (Group 37	00			0	0	0	0	0
TASTE PERVERSION	≤63 Days (All)	238	1 (<1%	0.6261	1	1 (100%)	0	_	_
1	≤49 Days (Group 1)	81	1 (19		1	1 (100%)	-	0	0
	50-56 Days (Group 2)	89	0 (1		0	0	0 ,	0	0
	57-63 Days (Group 3)	68	0		0	0	0 .	0	0
			Ū		. 0	U	U	0	0
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	238	16 (7%	0.4621	21	5 (24%)	10 (400)		
	≰49 Days (Group 1)	81	4 (5%		7	0	10 (48%)	6 (29%)	0
	50-56 Days (Group 2)	89	5 (6%		7	-	3 (43%)	4 (57%)	0
	57-63 Days (Group 3)	68	7 (10%		7	,	4 (57%)	1 (14%)	0
	=	00	, (104		,	3 (43%)	3 (43%)	1 (14%)	0
ANOREXIA	≤63 Days (All)	238	2 (<1%	1.0000	2	0	1 (200)		_
	≤49 Days (Group 1)	81	1 (1%)		î	0	1 (50%)	1 (50%)	0
· ·	50-56 Days (Group 2)	89	1 (1%)		•	_	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	1 (100%)	0
	5 51 12js (515ap 3)	00	Ū		U	U	0	0	0
ANXIETY	≤63 Days (All)	238	3 (1%)	0.2868	3	1 (33%)	2 (67%)		_
.	≤49 Days (Group 1)	81	0	0.2000	0		* I	0	0
	50-56 Days (Group 2)	89	1 (1%)		. 1	0 1 (100%)		0	0
•	57-63 Days (Group 3)	68	2 (3%)		. • 1	0	0	0	0
			~ (30)		4	· · ·	2 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)				· · · · · · · · · · · · · · · · · · ·					
APPETITE INCREASED	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	£49 Days (Group 1)	81	0		0	0	0	0	0
	50 56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
1	s49 Days (Group 1)	81	1 (1%)		<u>p</u>	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		ò	0	0	0 '	0
	57-63 Days (Group 3)	68	0		. 0	o	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	6 (3%)	0.5880	6	1 (17%)	4 (67%)	1 (17%)	a
	≤49 Days (Group 1)	81	3 (4%)		3	0	2 (67%)	1 (33%)	0
i	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
1	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
HALLUCINATION	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
·	≰49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
INSOMNIA	£63 Days (All)	238	6 (3%)	1.0000	7	2 (29%)	2 (29%)	3 (43%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	0	2 (100%)	0
→ , , , , , , , , , , , , , , , , , , ,	50-56 Days (Group 2)	89	2 (2%)		3	1 (33%),-	. 2 (67%)	0	0
o e o o o o o o o o o o o o o o o o o o	57-63 Days (Group 3)	68	2 (3%)		. 2	1 (50%)	(O · · ·	1 (50%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total		mber	Fisher's								
Body System/Event {2}	Age Group [3]	Number of Pts		Pts Event	exact p·value	Number of Events		1 d		·Sever erate	-	/ere	Unknown
AASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	238	178	(75%)	0.0688	503	201	(40%)	192	(38%)	110	(221)	
•	#49 Days (Group 1)	81	53	(65%)	0.0000	134	59	(44%)	46	(34%)	29	(224)	0
	50-56 Days (Group 2)	89	71	(80%)		217	95	(44%)	78	(36%)	44	(20%)	0
	57-63 Days (Group 3)	68	54			152	47	(31%)	68	(45%)	37	(24%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	6	(3%)	1.0000	7	1	(14%)		(57%)	•	(202)	
4	. s49 Days (Group 1)	81	2	(2%)	1.0000	2	0	(144)	4	(5/4)		(29%)	0
	50-56 Days (Group 2)	89	2	(2%)		2	1	(50%)	,	(505)		(100%)	0
	57-63 Days (Group 3)	68	2	(3%)		3	0	(304)	3	(50%) (100%)	0		0
CONSTIPATION	≤63 Days (All)	238	2	(<1%)	0.0808	2	0		1	(50%)		(F0b)	
	≤49 Days (Group 1)	81	0	()	0.0000	^	0			(50%)	1	(50♦)	0
	50-56 Days (Group 2)	89	0			0	^		0		U		0
	57-63 Days (Group 3)	68	2	(3%)		2	0		1	(50%)	1	(50%)	0
DIARRHEA	≤63 Days (All)	238	61	(26%)	0.6832	80	44	(55%)	28	(35%)		(10%)	•
•	≤49 Days (Group 1)	81	22	(27%)	0.0032	25	16	(64%)	6	(24%)	3		0
	50-56 Days (Group 2)	89	20	(22%)		32	18	(56%)	13	(41%)	,	(3%)	0
	57-63 Days (Group 3)	68	19	(28%)		23	10	(43%)	9	(39%)	4		0 0
DYSPEPSIA	≤63 Days (All)	238	10	(4%)	0.4327	13	6	(46%)	i 6	(461)	1	(8%)	
	≤49 Days (Group 1)	81	4	(5%)	,	4	2	(508)	_	(50%)	0	(94)	0
	50-56 Days (Group 2)	89	5	(6%)		Ä	4	(50%)	. , 2	(38%)	1	(13%)	Ü
• • • • • • • • • • • • • • • • • • •	57-63 Days (Group 3)	68	1	(1%)	ļ	. 1	ō	,,	, ,	(1q0*)	0	(134)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total Number	Numb of P		Fisher's	Number				Sauce	4		
Body System/Event [2]	Age Group [3]	of Pts	w/Ev		exact p-value	of Events	Mi	1d	Mode	Sever	Sev	ere	Unknow
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)	······································									· · · · · · · · · · · · · · · · · · ·			····
FLATULENCE	≤63 Days (All)	238	4	(2%)	0.2625	5	0		3	(60%)	2	(40%)	0
	£49 Days (Group 1)	81	3	(4%)		3	0		2	(67%)	1	(33%)	0
	50-56 Days (Group 2)	89	1	(1%)		2	0		1	(50%)	1	(50%)	0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
HAEMATEMESIS	≤63 Days (All)	238	1	(<1%)	1.0000	1	1	(100%)	0	1	0		0
1	≤49 Days (Group 1)	81	0			0	0	1	0	. 1	Q		0
·	50-56 Days (Group 2)	89	1	(1%)		1	1	(100%)	0		ø		0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
HAEMORRHOIDS	≰63 Days (All)	238	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	68	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	238	154	(65%)	0.0088	270	107	(40%)	94	(35%)	69	(26%)	0
·	≰49 Days (Group 1)	81	42	(52%)		70	29	(41%)	23	(33%)	18	(26%)	0
	50-56 Days (Group 2)	89	66	(74%)		117	51	(44%)	39	(33%)	27	(23%)	0
1	57-63 Days (Group 3)	68	46	(68%)		83	27	(33%)	32	(39%)	24	(29%)	0
TOOTH ACHE	≤63 Days (All)	238	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
4.	50-56 Days (Group 2)	89	1	(1%)		1	0	•	, 1	(100%)	0		0
e e 🎉 - Å	57-63 Days (Group 3)	68	0			, o	0	,;	0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Severi	tv		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	11d	Mode	erate	-	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (CONt.)													
VOMITING	≤63 Days (All)	238	85	(36%)	0.1411	123	42	(34%)	54	(44%)	27	(221)	0
	≤49 Days (Group 1)	81	22	(27%)		30	12	(40%)	13		5	(17%)	0
	50-56 Days (Group 2)	89	36	(40%)		53	20	(38%)	19	(36%)	14	(26%)	0
	57-63 Days (Group 3)	68	27	(40%)		40	10	(25%)	22		8		0
METABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	238	3	(1%)	0.3861	4	1	(25%)	2	(50%)	1	(25%)	0
	≤49 Days (Group 1)	81	2	(28)	0.3001	2	ī	(50%)	0	(30)	1	(501)	0
	50-56 Days (Group 2)	89	0	,		0	0	(300)	ő		ō	(304)	ň
	57-63 Days (Group 3)	68	1	(1%)		2	0		2	(100 %)	ō		ō
DEHYDRATION	≤63 Days (All)	238	1	(<1%)	0.6261	1	0		0		,	(100%)	0
	≤49 Days (Group 1)	81	1	(1%)	******	1	ō		ň			(100%)	0
	50-56 Days (Group 2)	89	0	,,,		ō	0		ő			(1000)	0
	57-63 Days (Group 3)	69	0			0	0		o		0		0
THIRST	≤63 Days (All)	238	1	(<1%)	0.6261	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	81	1	(1%)	******	i		(100%)	o		0		0
•	50-56 Days (Group 2)	89	ō	, ,		0	0	(1000)	Ö		0		0
	57-63 Days (Group 3)	68	ō	1		ō	ō		Ö		0		0
WEIGHT DECREASE	≤63 Days (All)	238	1	(<1%)	0.2857	2	0		,	(100%)	;		0
- .	≤49 Days (Group 1)	81	Ô	, /	0.203,	0	Ö		0	(1004)	Ä		0
	50-56 Days (Group 2)	89	0			. 0	ō		∜ 0	4	, l		0
•	57-63 Days (Group 3)	68	1	(1%)		2	0	y y		(1001)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's	M. mh a m				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
ARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	Ō
	50.56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68 .	0		0	0	0	0	0
HYPOTENSION	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
1	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50 56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	o
	57-63 Days (Group 3)	68	0		. 0	0	0	0	0
BART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TACHYCARDIA	s63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	s49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	Ö	ō
	50-56 Days (Group 2)	89	0		0	0	0	0	o
	57-63 Days (Group 3)	68	0		0	0	0	0	0
ESPIRATORY SYSTEM DISORDERS	•								
ANY EVENT	≤63 Days (All)	238	18 (8%)	0.1493	30	14 (478),	12 (401)	4 (13%)	0
and the second second	≤49 Days (Group 1)	81	10 (12%)		.17	10 (59%)	5 (291)	2 (12%)	Ō
	50-56 Days (Group 2)	89	4 (4%)		7	3 (43%)	3 (43%)	1 (14%)	0
	57-63 Days (Group 3)	68	4 (6%)		6	1 (17≸)	4 (67%)	1 (17%)	0
*						i	1		

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's					
nada Garatan (mara) (n)	Age	Number	of Pts	exact			· · · · · · · Severi	•	-
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
COUGHING	≤63 Days (All)	238	3 (11)	0.0610	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	81	3 (4%)		4	1 (25%)	2 (50%)	1 (25%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	Ô
	57-63 Days (Group 3)	68	0		0	0	0	o	o
DYSPNOEA	s63 Days (All)	238	1 (<1%)	1.0000	2	2 (100%)	0	0	0
ı	≤49 Days (Group 1)	81	0		0	0	0	0	o
	50-56 Days (Group 2)	89	1 (14)		2	2 (100%)	o '	0 .	o
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMOPTYSIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	238	4 (2%)	0.0190	4	3 (75%)	1 (25%)	0	0
•	≰49 Days (Group 1)	81	4 (5%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
ϵ	57-63 Days (Group 3)	68	0		0	o	0	0	0
PLEURAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
•	≤49 Days (Group 1)	81	0		0	0	0	0	0
τ.	50-56 Days (Group 2)	89	0		0	0	0 - 1	0	0
	57-63 Days (Group 3)	68	1 (1%)		. 1	0	1 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number				····Severi	tv		
Body System/Event [2]	Group [3]	of Pts	w/Ever	nt	p-value	of Events	Mi			erate		ere	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)													·
PULMONARY CONGESTION	≤63 Days (All)	238	2 (<	<14)	0.1957	2	2	(100%)	0		^		0
	≤49 Days (Group 1)	81		(21)	0.1557	2		(100%)	0		,		0
	50-56 Days (Group 2)	89	0	,		0	0	(1004)	0		0		0
	57-63 Days (Group 3)	68	ō			o	ō		0		0		0
RHINITIS	≰63 Days (All)	238	5 ((2%)	0.3257	: 7	3	(43%)	4	(57%)	0		^
1	≤49 Days (Group 1)	81		(4%)		1	2	(67%)	,	(33%)	Ö		0
	50-56 Days (Group 2)	89		(2%)		4	1	(25%)	3		o ·		0
	57 63 Days (Group 3)	68	0	, ,		ō	ō	(134)	0	(/3•/	0		0
SINUSITIS	≤63 Days (All)	238	7 ((3%)	0.0673	9	3	(33%)	4	(44%)	2	(22%)	0
	≤49 Days (Group 1)	81		(5%)		á	2	(50%)	,	(25%)	1	(25%)	-0
1	50-56 Days (Group 2)	89	o `	/		0	0	(300)	ō	(234)	•	(234)	0
!	57-63 Days (Group 3)	68	3 ((4%)		5	1	(20%)	3	(60%)	1	(20%)	0
ED BLOOD CELL DISORDERS		!											
ANY EVENT	≤63 Days (All)	238	3 ((1%)	0.5061	3	1	(33%)	2	(671)	0		0
	≤49 Days (Group 1)	81	0	•		0	0	(,	0	(0,0)	0		Ô
,	50-56 Days (Group 2)	89	2 ((2%)		2	0		-	(100%)	ŏ		0
	57-63 Days (Group 3)	68	1 ((1%)		1	1	(100%)	0		ō		Ö
ANAEMIA	≤63 Days (All)	238	3 ((1%)	0.5061	3	1	(33%)	2	(67%)	0		0
.	≤49 Days (Group 1)	81	0			0	0	,	0.		ő		Õ
r e 🐞 .	50-56 Days (Group 2)	89	2 ((2%)		. 2	ō			(100%)	0		ñ
	57-63 Days (Group 3)	68	1 ((1%)		1		(100%)	0,		ō		ō

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total Number	Number of Pts	Fisher's	Marin and		0	t &	
Body System/Event {2}	Age Group (3)	of Pts	w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
HITE CELL AND RES DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	. 0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68 .	0		0	0	0	0	0
LYMPHADENOPATHY	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	o	0
ı	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0 '	0	0
	57-63 Days (Group 3)	68	0 ,		. 0	0	0	0	0
LATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.7444	2	1 (50%)	1 (50%)	0	0
	s49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
EPISTAXIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	i o	0	0
PURPURA	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
Ť ,	<pre>s49 Days (Group 1)</pre>	81	0	İ	0	ο.	. 0	0	0
	50-56 Days (Group 2)	89	0	,	<u>;</u> 0	0 ;	0	0	0
•	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: HASKELL (#2)

Body System/Event [2]	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	tv	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RIMARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.6361	3	1 (225)			
	≤49 Days (Group 1)	81	2 (2%)	0.0301	3	1 (33%)	1 (33%)	1 (33%)	0
	50 56 Days (Group 2)	89	1 (1%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	1 (100%)	0	0
	, , , , , , , , , , , , , , , , , , , ,	•	v		U	0	0	0	0
MICTURITION FREQUENCY	≤63 Days (All)	238	1 (<1%)	0.6261	,	1 (100%)		_	
1	. ≤49 Days (Group 1)	81	1 (1%)	0.0201	1	1 (100%)	0 1	o -	0
	50-56 Days (Group 2)	89	0			0	0 ,	Q	0
	57-63 Days (Group 3)	68	Ō		- 0	0	0 .	0	0
	• • • •	•••	ū		U	U	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	238	2 (<1%)	1.0000	2	0			
	≤49 Days (Group 1)	81	1 (1%)	1.0000	,	•	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1%)		,	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0 (10)			0	1 (100%)	0	0
	,		Ū		U	U	0	0	0
PRODUCTIVE DISORDERS, PEMALE									
ANY EVENT	≤63 Days (All)	238	81 (34%)	0.6484	101	16 (16%)			
	≤49 Days (Group 1)	81	25 (31%)	0.0101	32		33 (33%)	52 (51%)	0
•	50-56 Days (Group 2)	89	30 (34%)		34	3 (9%)	. 15 (47%)	14 (44%)	0
	57-63 Days (Group 3)	68	26 (38%)		35	10 (29%) 3 (9%)	6 (18%)	18 (53%)	0
			(300)		33	3 (9€)	12 (34%)	20 (57%)	0
CERVICITIS	≤63 Days (All)	238	1 (<1%)	0.2857	1	0			
-7 . , , , , , , , , , , , , , , , , , , ,	≤49 Days (Group 1)	81	0	5.2051			1 (100%)	0	0
and a second second second second second second second second second second second second second second second	50-56 Days (Group 2)	89	Ö		. 0	0	0 4.1	0	0
	57-63 Days (Group 3)	68	1 (1%)			=	1 0	0	0
	, 1- (p 3)		* (14)		1	0 _r	1 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

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^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Savari	lty	
Body System/Event {2}	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)									
LEUKORRHOEA	≰63 Days (All)	238	3 (1%)	0.7790	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MENSTRUAL DISORDER	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
T.	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0 '	0 ·	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
OVARIAN DISORDER	s63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PREMENSTRUAL TENSION	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
•	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
•	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
UTERINE DISORDER NOS	≤63 Days (All)	238	2 (<1%)	0.5298	2	0	2 (100%)	0	0
**************************************	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	φ	0
1 .	50-56 Days (Group 2)	89	0		0	ο.	0 1	þ	0
	57-63 Days (Group 3)	68	1 (1%)		; 1	0	1 (1001)	þ	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluablé Patients]

Center: HASKELL (#2)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Ca	4			
Body System/Event [2]	Group [3]	of Pts		Event	p value	of Events		.1d		rate	•	ere	Unk	nown
REPRODUCTIVE DISORDERS, FEMALE (cont.)														-
UTERINE HAEMORRHAGE	≤63 Days (All)	238	54	(23%)	0.8212	63	2	(3%)	9	(14%)	52	(83%)	0	
	s49 Days (Group 1)	81	17	(211)		20	1	(5%)	5	(25%)	14	(70%)	0	
	50-56 Dayв (Group 2)	89	20	(21)		21	1	(5%)	2	(10%)	18	(86%)	0	
	57-63 Days (Group 3)	68	. 17	(25%)		22	0		2	(9%)	20	(91%)	0	
VAGINITIS	≤63 Days (All)	238	27	(11%)	0.8149	29	11	(38%)	18	(62%)	0		0	
1	≤49 Days (Group 1)	81	8	(10%)		10	2	(20%)	8	(80%)	0		0	
	50-56 Days (Group 2)	89	10	(11%)		10	7	(70%)	3	(30%)	0		0	
	57-63 Days (Group 3)	68	9	(13%)		. 9	2	(22%)	7	(78%)	0		0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	238	237	(>99%)	1.0000	1024	356	(35%)	370	(36%)	297	(29 %)	1	(<1%)
	≤49 Days (Group 1)	81	81	(100%)		336	131	(39%)	122	(36%)	82	(24%)	1	(<1%)
	50-56 Days (Group 2)	89	68	(99%)		345	115	(33%)	118	(34%)	112	(32%)	0	
	57-63 Days (Group 3)	68	68	(100%)		343	110	(32%)	130	(38%)	103	(30%)	0	
ABDOMINAL PAIN	≤63 Days (All)	238	236	(>99%)	1.0000	932	322	(35%)	332	(36%)	277	(30%)	1	(<1%)
	≤49 Days (Group 1)	81	80	(991)		301	115	(38%)	111	(37%)	74	(25%)	1	(<1%)
r - 1	50-56 Days (Group 2)	89	88	(99%)		323	106	(33%)	110	(34%)	107	(33%)	0	
	57-63 Days (Group 3)	68	68	(100%)		308	101	(33%)	111	(36%)	96	(31%)	0	
ALLERGY	≰63 Days (All)	238	5	(Ž%)	0 0354	6	1	(17%)	5	(83%)	0		0	
7.	≤49 Days (Group 1)	81	0			. 0	0	.•	, 0	1.	0		0	
	50-56 Days (Group 2)	89	1	(1%)		• 1	1	(100%)	. 0		0		0	
•	57-63 Days (Group 3)	68	4	(6%)		5	0		5	(4004)	0		0	
									i					

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total Number	Number of Pts	Fisher's	Number		Severi		
Body System/Event [2]	Age Group [3]	of Pts	w/Event	exact p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHÔLE - GENERAL DISORDERS (cont.))								
ASTHENIA	≤63 Days (All)	238	2 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≰49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68 .	, 0		0	0	0	0	0
BACK PAIN	s63 Days (All)	238	19 (8%)	0.6919	24	8 (33%)	11 (46%)	5 (21%)	0
•	≤49 Days (Group 1)	81	8 (10%)		12	4 (33%)	5 (42%)	3 (25%)	0
·	50-56 Days (Group 2)	89	7 (8)		7	1 (14%)	5 (71\$)	1 (14%)	0
	57-63 Days (Group 3)	68	4 (61)		5	3 (60%)	1 (20%)	1 (20%)	0
CHEST PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	#49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
FATIGUE	≤63 Days (All)	238	16 (7%)	0.8504	20	12 (60%)	5 (25%)	3 (15%)	0
	≰49 Days (Group 1)	81	6 (7%)		9	5 (56%)	1 (11%)	3 (33%)	0
	50-56 Days (Group 2)	89	5 (6%)		5	4 (80%)	1 (20%)	0	0
	57-63 Days (Group 3)	68	5 (7%)		6	3 (50%)	3 (50%)	0	0
FEVER	≤63 Days (All)	238	9 (4%)	0.0215	10	4 (40%)	5 (50%)	1 (10%)	0
	≰49 Days (Group 1)	81	4 (5%)		5	2 (40%)	3 (60%)	0	0
-i ,	50-56 Days (Group 2)	89	0		0	0	. 0	0	0
	57-63 Days (Group 3)	68	5 (7%)		, , 5	2 (40%)	2 (40%)	1 (20%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Sever	1+v	
Body System/Event (2)	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISOR	DERS (cont.)								
HOT FLUSHES	≤63 Days (All)	238	2 (<1%)	1.0000	3	3 (100%)	0	0	0
	≰49 Days (Group 1)	81	1 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68 ·	0		0	0	0	0	0
HYPOVOLAEMIA	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
1	≰49 Days (Group 1)	81	0		þ	0	Ο .	0	0
	50 56 Days (Group 2)	89	1 (1%)		1	0	0 .	1 (100%)	0
	57 63 Days (Group 3)	68	0 .		. 0	0	0	0	0
LEG PAIN	≤63 Days (All)	238	4 (2%)	1.0000	5	1 (20%)	2 (40%)	2 (40%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
;	50-56 Days (Group 2)	89	2 (2%)		3	1 (33%)	0	2 (67%)	0
1	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
MALAISE .	≤63 Days (All)	238	2 (<1%)	0.5298	2	1 (50%)	1 (50%)	0	0
,	£49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
,	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
OEDEMA	≤63 Days (All)	238	2 (<1%)	0.0808	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
4 ,	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		• 2	o ,i	2 (100%)	0	0
						•	•		

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	l bar	
Body System/Event [2]	Group {3}	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A WHÔLE - GENERAL DISORDERS (cont.)							,	 -
PAIN	≤63 Days (All)	238	3 (1%	0.1954	4	2 (50%)	0	2 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (31)	3	1 (33%)	0	2 (67%)	0
RIGORS	≤63 Days (All)	238	7 (3%	0.2989	7	1 (14%)	4 (57%)	2 (29%)	0
	≰49 Days (Group 1)	81	1 (1%)	1	0	1 (100%)	0	0
	50-56 Dayв (Group 2)	89	2 (2%)	2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	68	4 (6%)	. 4	0	2 (50%)	2 (50%)	0
SYNCOPE	≤63 Days (All)	238	5 (2%	0.7401	5	0	1 (20%)	4 (80%)	0
	≰49 Days (Group 1)	81	2 (2%)	2	0	0	2 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	2 (31)	2	0	1 (50%)	1 (50%)	0
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≰63 Days (All)	238	14 (6%	1.0000	17	2 (12%)	15 (88%)	0	0
	≤49 Days (Group 1)	81	5 (6))	6	1 (17%)	5 (83%)	0	0
	50-56 Days (Group 2)	89	5 (6))	6	1 (17%)	5 (83%)	0	0
	57-63 Days (Group 3)	68	4 (61)	5	0	5 (100%)	0	0
HERPES SIMPLEX	≤63 Days (All)	238	1 (<1%	1.0000	1	0	1 (100%)	o	0
≠ .	<pre>s49 Days (Group 1)</pre>	81	0	Ì	. 0	0	• • • •	O	0
	50-56 Days (Group 2)	89	1 (1)	• 1	o 🤞	1 (1d0%)	0	0
	57 63 Days (Group 3)	68	0		0	О,	0 +	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: HASKELL (#2)

	Gestational	Total	Numbe of Pt		Fisher's	Number -		Sever	l true	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Eve		exact p-value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS (cont.)		-, <u></u> ,								
INFECTION BACTERIAL	≤63 Days (All)	238	4	(2%)	0.6841	6	1 (17%)	5 (83%)	0	0
	£49 Days (Group 1)	81	1	(14)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1	(1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	2	(3%)		3	0	3 (100%)	0	0
INFECTION VIRAL	≤63 Days (All)	238	10	(4%)	0.6091	10	1 (10%)	9 (90%)	0	0
1	≤49 Days (Group 1)	81	5	(6%)		5	o '	5 (100 %)	Q,	0
	50-56 Days (Group 2)	89	3	(3%)		3	1 (33%)	2 (67%)	ď	0
	57 63 Days (Group 3)	68	2	(3%)		. 2	0	2 (100%)	0	0
SECONDARY TERMS										
ANY EVENT	≤63 Days (All)	238	2 ((<1%)	1.0000	5	0	2 (40%)	3 (60%)	0
	≤49 Days (Group 1)	81	1	(1%)		3	0	1 (33%)	2 (67%)	0
	50-56 Days (Group 2)	89	1	(1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
INFLICTED INJURY	≤63 Days (All)	238	2 ((<1%)	1.0000	4	0	2 (50%)	2 (50%)	0
	s49 Days (Group 1)	81	1	(1%)		2	0	1 (50%)	1 (50%)	0
e e e e e e e e e e e e e e e e e e e	50-56 Days (Group 2)	89	1	(1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
POST OPERATIVE PAIN	≤63 Days (All)	238	1 ((<1%)	0.6261	1	0	0	1 (100%)	0
→	s49 Days (Group 1)	81	1	(1%)		. 1	•	0	1 (100%)	0
	50-56 Days (Group 2)	89	0			• 0	o .i	, 0	0	0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	68	0			0	0	0 ,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Sever	itv			
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events		.ld		rate	-	ere	Unk	known
		- 8 -											
ANY EVENT	≤63 Days (All)	164	164 (100%)		1326	428	(32%)	517	(39%)	372	(28%)	9	(<1 \$
	≤49 Days (Group 1)	65	65 (100%)		482	163	(34%)	196	(41%)	118	(24%)	5	(19)
	50-56 Days (Group 2)	65	65 (100%)		527	171	(32%)	200	(38%)	154	(29%)	-	
	57-63 Days (Group 3)	34 .	34 (100%)		317	94	(30%)	121	(38%)	100	(32%)		(<1%) (<1%)
KIN AND APPENDAGES DISORDERS													
ANY EVENT	. ≤63 Days (All)	164	5 (3%)	0.8418	7	3	(43%)	2	(29%)	2	(29%)	0	
	≤49 Days (Group 1)	65	1 (2%)		1	ō		0	(= 2,07		(100%)	0	
	50-56 Days (Group 2)	65	3 (5%)		5	3	(60%)	2	(40%)	0	(1004)	0	
	57-63 Days (Group 3)	34	1 (3%)		1	0	,,,,	0	(100)	_	(100%)	0	
RASH MACULO-PAPULAR	≤63 Days (All)	164	1 (<1%)	1.0000	2	1	(50%)	1	(50%)	0		•	
	≤49 Days (Group 1)	65	0		0	ô	(300)	0	(304)	0		0	
	50-56 Days (Group 2)	65	1 (2%)		2	ı	(50%)	1	(50%)	0			
	57-63 Days (Group 3)	34	0		ō	ō	(300)	ō	(300)	0		0	
SWEATING INCREASED	≰63 Days (All)	164	4 (2%)	1.0000	4	1	(25%)	1	(251)		(505)	_	
	s49 Days (Group 1)	65	1 (2%)	1.0000	•	0	(238)		(254)		(50%) (100%)	0	
r ·	50 56 Days (Group 2)	65	2 (3%)		2	1	(50%)	1	(50%)	0	(1004)	0	
	57-63 Days (Group 3)	34	1 (31)		i	0	(304)	0	(504)	•	(1008)	0	
			. (34)		*	v		U		1	(100%)	0	
VERRUCA	≤63 Days (All)	164	1 (<1%)	1.0000	1	1	(100%)	0		0		0	
4 .	<pre>\$49 Days (Group 1)</pre>	65	0		0	0	"•	, 0	• •	6		ō	
) - A	50-56 Days (Group 2)	65	1 (2%)		. 1	1	(100%)		4.	Į		0	
•	57-63 Days (Group 3)	34	0		0	0	ŗ	1 0	•	0		ō	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number	. .			Severi	ty			• · • ·
Body System/Event (2)	Group [3]	of Pts	w/Eve		p·value	of Events		ld		rate	Sev		Unkn	10WN
USCULO-SKELETAL SYSTEM DISORDERS									*************************************					
ANY EVENT	≰63 Days (All)	164	7	(4%)	1.0000	10	3	(30¥)	5	(50%)	2	(20%)	0	
	\$49 Days (Group 1)	65	3	(5%)		5	3	(60%)	1	(20%)	1	(20%)	0	
	50-56 Days (Group 2)	65	3	(5%)		4	0		3	(75%)	1	(25%)	0	
	57-63 Days (Group 3)	34 .	1	(3%)		1	0		1	(100%)	0		0	
ARTHRALGIA	s63 Days (All)	164	1 ((<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	65	1	(2%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	65	0			0	0		0		0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
MYALGIA	≤63 Days (All)	164	4	(2%)	1.0000	6	2	(33%)	2	(33%)	2	(33%)	0	
	s49 Days (Group 1)	65	2	(3%)		4.)	2	(50%)	1	(25%)	1	(25%)	0	
	50-56 Days (Group 2)	65	1	(2%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0	
SKELETAL PAIN	≤63 Days (All)	164	2	(1%)	0.3532	3	ó		3	(100%)	0		0	
·	s49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	2	(3%)		3	0		3	(100%)	0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
INTR & PERIPH NERVOUS SYSTEM DISORDERS						÷								
ANY EVENT	≤63 Days (All)	164	79	(48%)	0.7743	116	37	(32%)	54	(47%)	21	(18%)	4	C
4.	≤49 Days (Group 1)	65	33	(51%)		46	17	(37%).	, 22	(484)	5	(11%)	2	(
	50-56 Days (Group 2)	65	29 ((45%)		•41	15	(37%)	15		11	(27%)	0	
•	57-63 Days (Group 3)	34	17	(50%)		29	5	(17%)	17	(59%)	5		2	(

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
{Safety Evaluable Patients}

Center: POPPEMA (#3)

	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number				Severi				 .
Body System/Event [2]	Group [3]	of Pts	w/Eve		p value	of Events	Mi	1d	Mode	rate	Sev	ere	Unkı	10 W 11
ENTR & PERIPH NERVOUS SYSTEM DISORD	ERS (cont.)													
DIZZINESS	≤63 Days (All)	164	22 (13%)	0.6377	25	9	(36%)	10	(40%)	6	(24%)	0	
	≤49 Days (Group 1)	65	7 (11%)		8	3	(38%)	3	(38%)	2	(25%)	0	
	50-56 Days (Group 2)	65	9 (14%)		9	5	(56%)	2	(22%)	2	(22%)	0	
	57 63 Days (Group 3)	34	6 (18%)		8	1	(13%)	5	(63%)	2	(25%)	0	
HEADACHE	≤63 Days (All)	164	62 (38%)	0.7295	82	28	(34%)	40	(49%)	11	(13%)	3	(4%)
	≤49 Days (Group 1)	65	26 (40%)		37	14	(38%)	19	(51%)	2	(5%)	2	(5%)
	50-56 Days (Group 2)	65	22 (34%)		28	10	(36%)	12	(43%)	6	(21%)	0	
	57 63 Days (Group 3)	34	14 (414)		17	4	(24%)	9	(53%)	3	(184)	1	(6%)
HYPOAESTHES I A	≤63 Days (All)	164	1 (<11)	0.2073	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	0			0	0		0		0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0		0	
MIGRAINE	≤63 Days (All)	164	1 (<11)	1.0000	1	0		0		1	(100%)	0	
•	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(2%)		1	0		0		1	(100%)	0	
•	57-63 Days (Group 3)	34	0			0	0		. 0		0		0	
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	, 164	1 (<11)	0.2073	1	0		1	(100%)	0		0	
	s49 Days (Group 1)	[!] 65	0			0	0		0		0		0	
Ť	50-56 Days (Group 2)	65	0			0	0	.•		41	0		0	
	57-63 Days (Group 3)	34	1	(3%)		. 1	0	,} "	` v 1	(1001)	0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Severi Moderate	Severe	Unknown
body by been, by been (2)	Group (3)	01 708	w/Evenc	p-varue	Or Evenies	MIIU	Moderate		Unknown
CENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)								
NEURALGIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	<pre>s49 Days (Group 1)</pre>	65	0		0	0	0	0	0
	50 56 Days (Group 2)	65	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	34 .	0		0	0	0	0	0
PARAESTHESIA	≤63 Days (All)	164	2 (1%)	0.6839	2	0	1 (50%)	1 (50%)	0
ı	. ≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50 56 Days (Group 2)	65	0		0	0	0	0	0
	57 63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
STUPOR	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	0	o	1 (100
	≤49 Days (Group 1)	65	0		0	0	0	0	0
,	50-56 Days (Group 2)	65	0		0	0	0	0	0
;	57-63 Days (Group 3)	34	1 (3%)		1	0	l 0	0	1 (100
TREMOR	≤63 Days (All)	164	2 (1%)	0.3532	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
VISION DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
4 .	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		. 0	0 ;	0	0	0
•	57 63 Days (Group 3)	34	0		0	0	0,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total	Number	Fisher's	•				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	severe	Unknown
VISION DISORDERS (cont.)						· · · · · · · · · · · · · · · · · · ·			
EYE PAIN	≤63 Days (All)	164	1 (<1%)	1.0000	•	•	1 . /10081	•	_
DID FAIR	s49 Days (Group 1)	65		1.0000	1	0	1 (100%)	0	0
					1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	-	0
	57-63 Days (Group 3)	34 .	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	. s63 Days (All)	164	9 (5%)	1.0000	10	3 (30%)	6 (60%)	1 (10%)	0
	≤49 Days (Group 1)	65	4 (6%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	65	3 (5%)		. 3	1 (33%)	2 (67%)	0	o
	57-63 Days (Group 3)	34	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
ANXIETY	≤63 Days (All)	164	2 (1%)	0.6839	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	Ô
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		2	1 (50%)	1 (50%)	0	0
						_ (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			•
APPETITE INCREASED	≰63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
<i>i</i>	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	164	4 (2%)	0.6835	4	1 (25%)	3 (75%)	0	0
÷,	\$49 Days (Group 1)	65	2 (3%)		2	0	e i	0	0
•	50 56 Days (Group 2)	65	2 (3%)	\	. 2	1 (50%)	1 (50%)	Ö	ő
1	57-63 Days (Group 3)	34	0		0	0	0	ō	Ö
	2: 22 22/5 (Stoup 3/	- ·	·		-	r		ū	•

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational ;	Total Number	Numi of		Fisher's exact	Number				Sever	l+v		
Body System/Event [2]	Group [3]	of Pts		vent	p value	of Events	Mi	1d	Mode	rate		Severe 1 (100%) 0 0 1 (100%) 0 0 0 0 1 (100%) 0 0 0 116 (31%) 29 (24%) 50 (33%) 37 (36%) 2 (17%) 0 0 2 (29%) 1 (25%) 1 (33%) 0 0	Unknown
SYCHIATRIC DISORDERS (cont.)													
EMOTIONAL LABILITY	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34 .	1	(3%)		1	. 0		0		1	(100%)	0
INSOMNIA	≤63 Days (All)	164	1	(<1%)	1.0000	1	0		1	(100%) j	0		0
ı	≤49 Days (Group 1)	65	1	(21)		1	0	,		(100%)	0:		0
	50-56 Days (Group 2)	65	0			0	0		0		o	•	0
	57-63 Days (Group 3)	34	0			0	0		0		0		0
STRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	164	135	(82%)	0.1372	374	109	(29%)	149	(40%)	116	(31%)	0
	≤49 Days (Group 1)	65	49	(75%)		121	37	(31%)	55	(45%)	29	(24%)	0
	50-56 Days (Group 2)	65	55	(85%)		150	40	(27%)	60	(40%)	50	(33%)	0
	57-63 Days (Group 3)	34	31	(91%)		103	32	(31%)	34	(33%)	37	(36%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	6	(4%)	0.7492	12	6	(50%)	4	(334)	2	(17%)	0
	≤49 Days (Group 1)	65	2	(3%)		3	1	(33%)	2	(67%)	0		o
	50-56 Days (Group 2)	65	2	(3%)		2	1	(50%)	· 1	(50%)	0		0
	57-63 Days (Group 3)	34	2	(6%)		7	4	(57%)	1	(14%)	2	(29%)	0
CONSTIPATION	s63 Days (All)	164	3	(2%)	0.8010	4	2	(50%)	1	(25%)	1	(25%)	0
à.	≤49 Days (Group 1)	65	2	(3%)		3	2	(67%).	, 0		1		0
	50-56 Days (Group 2)	65	1	(2%)		• 1	0	;		(100%)	0		0
	57-63 Days (Group 3)	34	0			0	0	, !	0	•	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Ptr		Fisher's exact	Number				Sava	ritv		
Body System/Event [2]	Group (3)	of Pts	w/Eve		p value	of Events		ld		erate	•	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)											··		
DIARRHEA	≤63 Days (All)	164	37 (23%)	0.9129	44	15	(34%)	23	(52%)	6	(14%)	0
	≰49 Days (Group 1)	65	14 (221)		18	6	(33%)	10	(56%)	2	(11%)	0
	50-56 Days (Group 2)	65	16 (251)		17	7	(41%)	7	(41%)	3	(18%)	0
	57 63 Days (Group 3)	34	7 (21%)		9	2	(22%)	6	(67%)	1	(11%)	0
DYSPEPSIA	≤63 Days (All)	164	6	(4%)	0.4439	7	4	(57%)	3	(43%)	0		0
	≰49 Days (Group 1)	65	1	(2%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	65	4	(6%)		4	2	(50%)	2	(50%)	0	•	0
	57-63 Days (Group 3)	34	1	(3%)		2	1	(50%)	1	(50%)	0		0
FLATULENCE	≤63 Days (All)	164	3	(2%)	0.2304	3	0		2	(67%)	1	(33%)	0
	≤49 Days (Group 1)	65	3	(5%)		3	0		2	(67%)	1	(33%)	0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	0			0	0		0		0		0
MELAENA	≰63 Days (All)	164	1 (<1%)	1.0000	1	0		1	(100%)	0		0
ı	s49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	34	0	ı		0	0		0		. 0		0
NAUSEA	≤63 Days (All)	164		73%) '	0.1269	221	73	(33%)	76	(34%)	72	(33%)	0
	≤49 Days (Group 1)	65		651)		73	25	(34%)	30		18	(25%)	0
4 .	50-56 Days (Group 2)	65	50 (77%)		90	27	(30%)	, 31	(348)	32	(36%)	0
	57-63 Days (Group 3)	34	28 (82%)		.58	21	(36%)	15	(26%)	22	(384)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
TOOTH ACHE	≤63 Days (All)	164	1 (<11) 1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (21) [']	1	0	1 (100%)	0	0
	57 63 Days (Group 3)	34 .	0		0	0	0	0	0
VOMITING	£63 Days (A11)	164	61 (37)) 0.0147	81	9 (11%)	38 (47%)	34 (42%)	0
ı ,	≤49 Days (Group 1)	65	17 (261)	20	2 (10%)	11 (55%)	7 (35%)	0
	50-56 Days (Group 2)	65	25 (381)	34	3 (9%)	16 (47%)	15 (44%)	0
	57-63 Days (Group 3)	34	19 (561)	27	4 (15%)	11 (41%)	12 (44%)	0
ETABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	2 (1) 1.0000	2 +	0	2 (100%)	0	0
	≤49 Days (Group 1)	65	1 (21)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	1 (2))	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	164	1 (<11) 1.0000	1	ó	1 (100%)	0	0
	£49 Days (Group 1)	65	1 (21		1	0	1 (100%)	Ô	Ö
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	65	0		0	0	0	o o	o o
	57-63 Days (Group 3)	34	0		0	0	0	0	0
THIRST	≤63 Days (All)	164	1 (<14) 1.0000	1	0	1 (100%)	0	0
i	≤49 Days (Group 1)	65	0		0	0	0	Ō	0
	50-56 Days (Group 2)	65	1 (21)	, 1	0 ;	1 (100%)	0	0
4	57-63 Days (Group 3)	34	0		0	0 '	0 ,	0	0
							1		

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total	Number	Fisher's				***	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULÂR DISORDERS, GENERAL			······································						
ANY EVENT	≤63 Days (All)	164	2 (1%)	0.6839	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34 -	1 (3%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
4	s49 Days (Group 1)	65	0 1		0	0	О,	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (34)		. 1	0	1 (100%)	0	0
HYPOTENSION POSTURAL	≰63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
EART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
TACHYCARDIA	≤63 Days (All)	Į 164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%).*	. 0 .	0	0
	50-56 Days (Group 2)	65	0		• 0	0 .	0	0	0
•	57-63 Days (Group 3)	34	0		0	0 '	0 ,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severi		
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY BYSTEM DISORDERS	· · · · · · · · · · · · · · · · · · ·					·····			
ANY EVENT	≤63 Days (All)	164	8 (5	0.9019	12	4 (33%)	6 (50%)	2 (17%)	0
	≤49 Days (Group 1)	65	3 (5	b)	3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	65	4 (6	b)	8	2 (25%)	5 (63%)	1 (13%)	0
	57-63 Days (Group 3)	34	1 (3	b)	1	1 (100%)	0	0	0
COUGHING	≤63 Days (All)	164	2 (1	0.3532	5	2 (40%)	2 (40%)	1 (20%)	0
ı	s49 Days (Group 1)	65	0		,O	0	0	0	0
	50-56 Days (Group 2)	65	2 (3)	5	2 (40%)	2 (40%)	1 (20%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PHARYNGITIS	s63 Days (All)	164	2 (1	1.0000	2	O	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	65	1 (2	b)	1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	1 (2	t)	1	0	1 (100%)	0	0
en en en en en en en en en en en en en e	57-63 Days (Group 3)	34	0		0	0	l o	0	0
PULMONARY CONGESTION	≤63 Days (All)	164	1 (<1	1.0000	1	0	1 (100%)	0	0
•	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2	b)	1	0	1 (100%)	0	0
4	57-63 Days (Group 3)	34	0		0	0	. 0	o	0
SINUSITIS	≤63 Days (All)	164	4 (2	1.0000	4	2 (50%)	2 (50%)	o	0
	≤49 Days (Group 1)	65	2 (3	b)	2	1 (50%)	1 (50%)	0	0
i .	50-56 Days (Group 2)	65	1 (2	b)	1	ο.	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3	t)	; 1	1 (100)	0 "	0	0

^[1] Includem all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Savari	tv	
Body System/Event (2)	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	(57%) 0 (50%) 0 (75%) 0 (57%) 0 (57%) 0 (50%) 0 (75%) 0	Unknown
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	164	6 (4%)	0.2081	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	-	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	-	-	0
	57-63 Days (Group 3)	34	3 (91)		4	1 (251)	3 (75%)	-	0
ANAEMI A	≤63 Days (All)	164	6 (4%)	0.2081	7	3 (43%)	4 (57%)	•	•
1	≤49 Days (Group 1)	65	1 (2%)	0.2001	í	1 (100%)			0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	=		0
	57-63 Days (Group 3)	34	3 (9%)		- 4	1 (25%)	3 (75%)	•	0 0
HITE CELL AND RES DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	•	1 (100%
	s49 Days (Group 1)	65	1 (2%)	1.0000	ī	0	0	=	1 (100%
	50 56 Days (Group 2)	65	0		ō	Ö	0	-	0
	57-63 Days (Group 3)	34	Ó		o	ō	0	-	0
LYMPHADENOPATHY	≤63 Days (All)	164	1 (<1%)	1.0000	,	0	0	•	
	s49 Days (Group 1)	65	1 (2%)	1.0000	•	0	•	-	1 (100%
t in the second of the second	50-56 Days (Group 2)	65	0		0	0	1 0	-	1 (100%
	57 63 Days (Group 3)	34	0		0	0	0	•	0
LATELET, BLEEDING & CLOTTING DISORDERS				1					
ANY EVENT	≰63 Days (All)	164	1 (<1%)	0.2073	. 1			. (_
	≤49 Days (Group 1)	65	0	0.2073	• 0	0	` U 4. !		0
	50-56 Days (Group 2)	65	0		0	•	, 0	-	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0 1	-	0
•	- os bajo (oroup s)	,,,	1 (30)			,	į U	1 (100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling. Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknow
PLATELET, BLEEDING & CLOTTING DISOR	DERS (cont.)						· · · · · · · · · · · · · · · · · · ·		
EPISTAXIS	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	Ô
	50-56 Days (Group 2)	65	0		0	0	0	Ô	Ô
	57 63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	ō
JRINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
·	s49 Days (Group 1)	65	0		0	0	0	ď	Ô
	50-56 Days (Group 2)	65	0		0	0	o ·	Ô	Ô
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
MICTURITION FREQUENCY	≰63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	o
	50-56 Days (Group 2)	65	0		0	0	0	0	Ō
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
EPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	164	38 (23%)	0.7020	64	22 (34%)	33 (52%)	9 (14%)	0
,	≤49 Days (Group 1)	65	13 (20%)		23	9 (39%)	12 (52%)	2 (9%)	0
	50-56 Days (Group 2)	65	17 (26%)		27	9 (33%)	13 (48%)	5 (194)	0
	57-63 Days (Group 3)	34	8 (24%)		14	4 (29%)	8 (57%)	2 (14%)	Ö
	•								
BREAST ENGORGEMENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	1 (100%).	0	0	0
	≤49 Days (Group 1)	65	0		. 0	o ; "	0	0	0
• • • • • • • • • • • • • • • • • • • •	50-56 Days (Group 2)	65	0		, o	0	10.	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0 '	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number				Severi	ty	• • • • • • • • •
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p value	of Events	Mi	1d	Mod	lerate	Severe 0 0 0 0 0 1 (25%) 1 (25%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)												
BREAST ENLARGEMENT	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0	0
	\$49 Days (Group 1)	65	0			0	0		0)	0	0
	50 56 Days (Group 2)	65	0			0	0		0)	0	0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100%)	0	0
BREAST PAIN FEMALE	≤63 Days (All)	164	2	(11)	0.3532	4	2	(50%)	1	(25%)	1 (254)	0
I ,	≤49 Days (Group 1)	65	2	(3%)		4	2	(50%)	1	(25%)	1 (25%)	0
	50-56 Days (Group 2)	65	0			0	0		0	,	0	0
	57 63 Days (Group 3)	34	0			. 0	0		0)	0	0
ENDOMETRITIS	≤63 Days (All)	164	11	(7%)	0.8471	11	5	(45%)	6	(55%)	0	0
	<pre>s49 Days (Group 1)</pre>	65	4	(6%)		4	2	(50%)	2	(50%)	0	0
	50-56 Days (Group 2)	65	4	(6%)		4	2	(50%)	2	(50%)	0	0
	57-63 Days (Group 3)	34	3	(9%)		3	1	(33%)	2	(67%)	0	0
LEUKORRHOEA	≤63 Days (All)	164	14	(9%)	0.3440	14	8	(57%)	6	(43%)	0	0
	≤49 Days (Group 1)	65	5	(8%)		5	3	(60%)	2	(40%)	0	0
	50-56 Days (Group 2)	65	8	(12%)		8	5	(63%)	3	(38%)	0	0
,	57-63 Days (Group 3)	34	1	(31):	:	1	0		1	(100%)	0	0
OVARIAN DISORDER	≤63 Days (All)	164	2	(1%)	0.3532	2	1	(50%)	1	(50%)	, O	0
	≤49 Days (Group 1)	65	2	(3%)		2	1	(50%)	1	(50%)	q i	0
-1 ,	50-56 Days (Group 2)	65	0			0	0	,,•)	ď	0
***	57-63 Days (Group 3)	34	0			• 0	0	i	0	• • •	ď	0

^[1] Includes'all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total	Numb		Fisher's					.			
Body System/Event [2]	Age Group [3]	Number of Pts	of F w/Ev		exact p·value	Number of Events		.1d		Severi erate		ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)													·
SALPINGITIS	≤63 Days (All)	164	2	(1%)	0.3532	2	1	(50%)	1	(50%)	0		0
	#49 Days (Group 1)	65	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	65	0			0	0		0		0		0
	57-63 Days (Group 3)	34	. 0			Ó	0		0		0		0
UTERINE DISORDER NOS	≤63 Days (All)	164	1	(<1%)	0.2073	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	65	0			0	0		0		0		0
·	50-56 Days (Group 2)	65	0			0	0		0	•	0		0
	57-63 Days (Group 3)	34	1	(3%)		1	0		1	(100 \$)	0		0
UTERINE HAEMORRHAGE	≤63 Days (All)	164	15	(9%)	0.2023	16	1	(6%)	7	(44%)	8	(50%)	0
	#49 Days (Group 1)	65	3	(5%)		3 +	0		2	(67%)	1	(33%)	0
	50-56 Days (Group 2)	65	7	(11%)		7	0		2	(29%)	5	(71%)	0
	57-63 Days (Group 3)	34	5	(15%)		6	1	(17%)	3	(50%)	2	(334)	0
VAGINAL DISCOMFORT	≤63 Days (All)	1.64	2	(1%)	0.3532	4	1'	(25%)	3	(75%)	0		0
•	≰49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	2	(3%)		4	1	(25%)	3	(75%)	0		0
r · · · · · ·	57-63 Days (Group 3)	34	0			0	0		0		0		0
VAGINITIS	≤63 Days (All)	164	7	(4%)	1.0000	8	2	(25%)	6	(75%)	0		0
	≤49 Days (Group 1)	65	3	(5%)		3	0			(100%)	0		0
	50-56 Days (Group 2)	65	3	(5%)		4	1	(25%)	, 3	(75%)	0		0
	57-63 Days (Group 3)	34	1	(3%)		, 1	1	(100%)	` :	1	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational /	Total Number		mber Pts	Fisher's exact	Number								
Body System/Event [2]	Group (3)	of Pts		erts	p value	of Events		1 d		Sever erate	•	ere	Unk	cnown
TEOPLASH		·												
ANY EVENT	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	£49 Days (Group 1)	65	0	,		0	0		0		ō		o	
	50-56 Days (Group 2)	65	1	(21)		1	1	(100%)	0		o		0	
	57-63 Days (Group 3)	34	; 0			0	0	,	0		0		0	
OVARIAN CYST	s63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
i	≤49 Days (Group 1)	65	0	1		0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(28)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	34	0	1		0	0		0		0		0	
BODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	164	162	(99%)	1.0000	702	237	(34%)	243	(35%)	218	(31%)	4	(<1%)
	≤49 Days (Group 1)	65	64	(98%)		268	91	(34%)	96	(36%)	79	(29%)		(<1%)
	50-56 Days (Group 2)	65	64	(98%)		278	96	(35%)	94	(34%)	86	(31%)		(<1%)
	57-63 Days (Group 3)	34	34	(100%)		156	50	(32%)	53		53		0	
ABDOMINAL PAIN	s63 Days (All)	164	162	(991)	1.0000	571	202	(35%)	183	(32%)	183	(32%)	3	(<1%)
	≤49 Days (Group 1)	65	64	(981)		218	74	(34%)	. 77	(35%)	66	(30%)	1	
· ·	50-56 Days (Group 2)	65	64	(98%)		230	81	(35%)	72	(31%)	75	(33%)	2	
	57-63 Days (Group 3)	34	34	(100%)		123	47	(38%)	34		42		0	, ,
ALLERGY	≤63 Days (All)	164	2	(1%)	1.0000	2	0		,	(EQA)	,	(50%)		
ALDERGI 1.	\$49 Days (Group 1)	65	1	(2%)	1.0000	1	0			(50%) (100%)		(504)	0	
, ,	50-56 Days (Group 2)	65	_	(2%)		• 1	0	; "	7	(1004)	0	(1008)	0	
4 · · · • · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	34	1	(24)		, • 1	0	•	0	,		(100%)	0	
	37.03 Days (Group 3)	31	U			J	U	;	0	•	0		О	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total Number	Numb of P		Fisher's exact	Number				Severi	ltv		
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events	Mi	1 đ	Mod	erate	Sev	ere	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)					·							
ASTHENIA	≤63 Days (All)	164	9	(5%)	0.1575	12	2	(17%)	3	(25%)	7	(58%)	0
	≰49 Days (Group 1)	65	5	(8%)		8	1	(13%)	2	(25%)	5	(63%)	0
	50-56 Days (Group 2)	65	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	34 ,	3	(9%)		3	. 0		1	(33%)	2	(67%)	0
BACK PAIN	s63 Days (All)	164	20	(12%)	0.2630	26	7	(27%)	13	(50%)	5	(19%)	1 (4%
1	≤49 Days (Group 1)	65	5	(8%)		7	2	(291)	2	(29%)	2	(29%)	1 (14%
	50-56 Days (Group 2)	65	11	(17%)		14	5	(36%)	8	(574)	1	(7%)	0
	57-63 Days (Group 3)	34	4	(12%)		5	0		3	(604)	2	(40%)	0
FATIGUE	≤63 Days (All)	164	26	(16%)	0.5747	33	9	(27%)	15	(45%)	9	(27%)	0
	≰49 Days (Group 1)	65	13	(20%)		16	6	(38%)	8	(50%)	2	(13%)	0
ļ.	50-56 Days (Group 2)	65	9	(14%)		9	3	(33%)	3	(33%)	3	(33%)	0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	34	4	(12%)		8	0		1 4	(50%)	4	(50%)	0
FEVER .	≤63 Days (All)	164	12	(7%)	0.4021	15	5	(33%)	7	(47%)	3	(20%)	0
	≤49 Days (Group 1)	65	5	(8%)		6	3	(50%)	2	(33%)	1	(17%)	0
	50-56 Days (Group 2)	65	3	(5%)		4	1	(25%)	2	(50%)	1	(25%)	0
** *** *** *** *** *** *** *** *** ***	57-63 Days (Group 3)	34	4	(12%)		5	1	(20%)	. 3	(60%)	1	(20%)	0
HOT FLUSHES	≤63 Days (All)	164	6	(4%)	0.5732	6	1	(17%)	3	(Ś0 %)	2	(33%)	0
	≤49 Days (Group 1)	65	1	(2%)	•	1	0		0		1	(100%)	0
,	50-56 Days (Group 2)	65	3	(5%)		3	1	(33%)	. 1	· (33%)	1	(33%)	0
	57-63 Days (Group 3)	34	2	(61)		, 2	0	į	` ; 2 	(100%)	0		0

^[1] Includes, all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
(Safety Evaluable Patients)

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont	.)								
LEG PAIN	≰63 Days (All)	164	3 (2%)	0.1093	3	0	3 (100%)	0	0
	s49 Days (Group 1)	65	0		0	0	! o	0	Ó
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34 -	2 (6%)		2	0	2 (100%)	0	0
MALAISE	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
'	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0 .	0
	50-56 Days (Group 2)	65	0		0	0	0 '	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	164	2 (1%)	0.6839	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0	0	0
PAIN	≤63 Days (All)	164	6 (4%)	1.0000	9	3 (33%)	5 (56%)	1 (11%)	0
	≰49 Days (Group 1)	65	3 (5%)		5	3 (60%)	1 (20%)	1 (20%)	0
,	50-56 Days (Group 2)	65	2 (3%)		3	0	3 (100%)	0	0
,	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
RIGORS	≤63 Days (All)	164	15 (9\$)	0.5693	15	4 (27%)	8 (53%)	3 (20%)	0
<u>.</u>	s49 Days (Group 1)	65	4 (6%)	ļ	4	2 (50%)	2 (50%)	0	0
4.	50-56 Days (Group 2)	65	7 (11%)	1	. 7	1 (14%)	and the second s	2 (29%)	0
• • •	57-63 Days (Group 3)	34	4 (12%)		٠ 4	1 (25∜)	2 (50%)	1 (25%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe 3 (60%) 0 2 (67%) 1 (50%) 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont	.)								
SYNCOPE	≰63 Days (All)	164	5 (3%)	0.1536	5	1 (20%)	1 (20%)	3 (60%)	•
	≤49 Days (Group 1)	65	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ő	0	0		0
	50-56 Days (Group 2)	65	3 (5%)		3	1 (33%)	Ö	•	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	1 (50%)		0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	164	2 (1%)	1.0000	2	1 (50%)			_
ı	≤49 Days (Group 1)	65	1 (2%)	1.0000	1	0 (504)	0		0
·	50-56 Days (Group 2)	65	1 (2%)		,	1 (100%)	0 , '	1 (100%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PPLICATION SITE DISORDERS [4]									
ANY EVENT	s63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	65	0		0	0	0	=	0
	50-56 Days (Group 2)	65	0		0	0	Ō	-	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	_	0
INJECTION SITE PAIN	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)		
	≤49 Days (Group 1)	65	0	0.20.3	0	0	1 (1004)		0
r · · · · · · ·	50-56 Days (Group 2)	65	0		ň	Ö	. 0	-	0
	57 63 Days (Group 3)	34	1 (3%)		1	ő	1 (100%)	•	0
ESISTANCE MECHANISM DISORDERS	,								
ANY EVENT	≤63 Days (All)	164	11 (7%)	0.5200	13	5 (38%)	8 (62%)	0	0
	≤49 Days (Group 1)	65	6 (91)		. 6	2 (33%)	4 (67%)	-	o o
* · · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	65	4 (6%)		6	3 (50%)	3 (50%)		0
· ·	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)		ó

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	itv	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ESISTANCE MÉCHANISM DISORDERS (cont.)									
HERPES SIMPLEX	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	o	1 (100%)	Ö	Ŏ
	50-56 Days (Group 2)	65	0		0	0	0	0	ŏ
	57-63 Days (Group 3)	34 .	0		0	0	Ō	ō	Ŏ
INFECTION FUNGAL	≤63 Days (All)	164	3 (2%)	0.8010	3	1 (33%)	2 (67%)	0	^
1	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	Ö	0
	50 56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	o '	0
	57-63 Days (Group 3)	34	0		0	0	0	ō	Ö
INFECTION VIRAL	≤63 Daye (All)	164	9 (5%)	0.8246	9	4 (44%)	5 (56%)	0	0
	s49 Days (Group 1)	65	4 (6%)		4	2 (50%)	2 (50%)	ő	Ö
	50-56 Days (Group 2)	65	4 (6%)		4	2 (50%)	2 (50%)	Ö	Ô
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	Ö	Ö

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				_	4.		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events		1 d		Sever erate	-	ere	Unknow
*												· · · · · · · · · · · · · · · · · · ·
ANY EVENT	s63 Days (All)	102	102 (100%)		673	267	(40%)	271	(41%)	133	(20%)	0
	≰49 Days (Group 1)	68	68 (100%)		465	191	(41%)	187	(40%)	87	(19%)	Ö
	50-56 Days (Group 2)	25	25 (100%)		171	64	(37%)	73		34	(20%)	0
	57 63 Days (Group 3)	9.	9 (100%)		37	12	(321)		(35%)		(32%)	Ö
CIN AND APPENDAGES DISORDERS												
ANY EVENT	. s63 Days (All)	102	4 (4%)	1.0000	4	0		4	(100%)	0		0
	≤49 Days (Group 1)	68	3 (4%)		3	o			(1001)	0		
	50-56 Days (Group 2)	25	1 (4%)		í	o			(100%)	0		0
	57-63 Days (Group 3)	. 9	0		ō	ō		Ô	(1001)	0		0
RASH .	≰63 Days (All)	102	2 (2%)	1.0000	2	0		9	(100%)	0		0
	≰49 Days (Group 1)	68	2 (3%)		2	0			(100%)	o		0
	50-56 Days (Group 2)	25	0		<u>-</u> 1	ň		0	(1004)	0		0
	57-63 Days (Group 3)	9	0		ō	ō		0		0		0
SWEATING INCREASED	≤63 Days (All)	102	2 (2%)	0.5578	2	á		,	(100%)	0		•
	≤49 Days (Group 1)	68	1 (1%)		1	0			(100%)	0		0
The state of the s	50-56 Days (Group 2)	25	1 (4%)		1	Ď			(100%)	0		0
	57-63 Days (Group 3)	9	0		ō	. 0		0	(100%)	0		0
SCULO-SKELETAL SYSTEM DISORDERS	•											
ANY EVENT	≤63 Days (All)	102	4 (4%)	0.5135	5	1	(20%).	. 1	(60%)	1	(20%)	0
,	≤49 Days (Group 1)	68	2 (3%)		2	1	(50%)		*(40.0)	1	(50%)	0
	50-56 Days (Group 2)	25	2 (8%)		3	Ô			(100%)	0	(304)	0
	57-63 Days (Group 3)	9	0		0	ō	i	0	p.2000,	ő		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number				Severi	tv		
Body System/Event (2)	Group [3]	of Pts	w/Event		p value	of Events	Mi	1d	Mode	rate	-	ere	Unknown
USCULO-SKELTAL SYSTEM DISORDERS (cont.)				·····									
MYALGIA	≤63 Days (All)	102	2	(2%)	0.5578	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	25	1	(4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9 .	0			0	. 0		0		0		0
SKELETAL PAIN	≤63 Days (All)	102	2	(2%)	0.5578	3	1	(33%)	2	(67%)	0		0
	£49 Days (Group 1)	68	1	(1%)		1	1	(1001)	0		0		0
	50-56 Days (Group 2)	25	1	(48)		2	0		2	(100%)	0		0
	57 63 Days (Group 3)	9	0			. 0	0		0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	44	(43%)	0.1052	76	21	(28%)	48	(63%)	7	(91)	0
	≤49 Days (Group 1)	68	33	(491)		57	16	(28%)	34	(60%)	7	(12%)	Ô
	50-56 Days (Group 2)	25	10	(40%)		18	5	(28%)	13	-	0	(2,	Ô
	57-63 Days (Group 3)	9	1	(11%)		1	0	,,		(100%)	ō		o
DIZZINESS	≤63 Days (All)	102	12	(12%)	0.3219	16	8	(50%)	7	(44%)	1	(61)	0
	≰49 Days (Group 1)	68	6	(9%)		6	3	(50%)	2	•	1	(17%)	Ö
1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	50-56 Days (Group 2)	25	5	(20%)		9	5	(56%)		(44%)	ō	(2,-,	ñ
	57-63 Days (Group 3)	9		(11%)		1	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(100%)	0		ō
HEADACHE	≤63 Days (All)	102	37	(36%)	0.0144	55	11	(20%)	40	(73%)	4	(7%)	0
÷.	≤49 Days (Group 1)	68	30	(44%)		46	11	(24%).		(671)	4	(91)	Ö
	50-56 Days (Group 2)	25	7	(28%)		• 9	0	1		(100%)	0		0
	57-63 Days (Group 3)	9	0	.=,		0	0	•	O	• -	ō		o

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	M				
Body System/Event [2]	Group [3]	of Pts	w/Event	exact p-value	Number of Events	Mild	Moderate	2 (100%) 2 (100%) 0 0 0 0 0 0 1 (50%) 1 (50%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Unknown
ENTR & PERPPH NERVOUS SYSTEM DISORDES	RS (cont.)								
MIGRAINE	≤63 Days (All)	102	2 (2%)	1.0000	2	0	0	2 (100%)	0
	£49 Day 1 Trong 11	68	2 (3%)		2	Ō	Ō		0
	50-56 Days (Group 2)	25	0		0	0	0	0	ő
	57-63 Days (Group 3)	9 .	0		0	0	0	ō	ō
TREMOR	≤63 Days (All)	102	3 (3%)	0.6683	3	2 (67%)	1 (33%)	0	0
i .	≤49 Days (Group 1)	6B	3 (4%)		i3	2 (67%)	1 (33%)	-	0
	50-56 Days (Group 2)	25	0		O	0	0 (55,0)		Ŏ
	57 63 Days (Group 3)	9	0		0	0	0	=	Ö
ISION DISORDERS									
ANY EVENT	≰63 Days (All)	102	2 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	1 (50%)		0
i ·	50-56 Days (Group 2)	25	0		0	0 (0	0	Ô
:	57-63 Days (Group 3)	9	0,		0	o	0	Ō	Ö
CONJUNCTIVITIS	≤63 Days (All)	102	2 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
	#49 Days (Group 1)	68	2 (3%)		2	0	1 (50%)		0
,	50-56 Days (Group 2)	25	0		0	0	0	•	0
	57-63 Days (Group 3)	9	0		0	ō	ō	-	0
BARING AND VESTIBULAR DISORDERS	,								
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	68	1 (1%)		. 1	0	1 (100%)		0
•	50-56 Days (Group 2)	25	0		0	o ,	1 0	Ö	0
	57-63 Days (Group 3)	9	0		0	0 'r	0 '	Ö	0
•	•	•				i	1	ŭ	•

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

⁽²⁾ NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational	Total	Number	Fisher's	**b				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS (cont.)						·			
EAR ACHE	≤63 Days (All)	102	1 (<14)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9.	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.2788	7	3 (43%)	4 (57%)	0	0
	s49 Days (Group 1)	68	6 (9%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0
ANXIETY	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	102	1 (<1%)	0.0882	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
A contract of the contract of	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	i o	0	0
INSOMNIA	≤63 Days (All)	102	5 (5%)	0.4397	5	2 (40%)	3 (60%)	0	0
Ť	≤49 Days (Group 1)	68	5 (7%)	ì	5	2 (40%).	3 (60%)	0	0
	50-56 Days (Group 2)	25	0	ţ	• 0	0 ;	0	0	0
•	57-63 Days (Group 3)	9	0		0	0	0,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable, Patients]

Center: TYSON (#4)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number		••••	·	Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/E	vent .	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	77	(75%)	0.3778	181	78	(43%)	63	(35%)	40	(22%)	0
	≤49 Days (Group 1)	68	53	(78%)		122	55	(45%)	40	(33%)	27	(22%)	0
	50-56 Days (Group 2)	25	19	(76%)		50	20	(40%)	20	(40%)	10	(20%)	0
	57-63 Days (Group 3)	9	. 5	(56%)		9	3	(33%)	3	(33%)	3	(33%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	3	(3%)	1.0000	3	0	:	0	1	3	(100%)	0
ı	≤49 Days (Group 1)	68	2	(3%)		2	0	1	0	1	2	(100%)	0
	50-56 Days (Group 2)	25	1	(4%)		1	0		0	•	1	(100%)	0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
CONSTIPATION	≤63 Days (All)	102	3	(3%)	1.0000	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	25	1	(4%)		1	1	(100%)	0		0		. 0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
DIARRHEA .	≤63 Days (All)	102	24	(24%)	1.0000	28	18	(64%)	5	(18%)	5	(18%)	0
	≤49 Days (Group 1)	68	16	(24%)		19	14	(74%)	2	(11%)	3	(16%)	0
	50-56 Days (Group 2)	25	6	(24%)		7	3	(43%)	3	(43%)	1	(14%)	0
r .	57-63 Days (Group 3)	9	2	(22%)		2	1	(50%)	0		1	(50%)	0
DYSPEPSIA	≤63 Days (All)	102	3	(3%)	1.0000	5	1	(20%)	1	(20%)	3	(60%)	0
	≰49 Days (Group 1)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0
4 ,	50-56 Days (Group 2)	25	1	(4%)		3	0	,,•	, 0	* <u> </u>	3	(100%)	0
	57-63 Days (Group 3)	9	0			. 0	0	,i "	0	•	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p value	of Events	Mi	1d	Mode	rate	Sev	/ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)			*										
FLATULENCE	≤63 Days (All)	102	2	(2%)	1.0000	4	2	(50%)	2	(50%)	0		0
	≤49 Days (Group 1)	68	2	(3%)		4	2	(50%)	2	(50%)	0		0
	50-56 Days (Group 2)	25	0	1307		0	0	(300)	0	(304)	0		0
	57-63 Days (Group 3)	9	0			Ö	ŏ		ō		0		0
NAUSEA	≤63 Days (All)	102	67	(66%)	0.4063	93	46	(49%)	28	(30%)	19	(20%)	0
1	≤49 Days (Group 1)	68	46	(68%)		65	32	(49%)	18	(28%)	15	(23%)	0
	50-56 Days (Group 2)	25	17	(68%)		24	12	(50%)	9	(38%)	3		0
	57-63 Days (Group 3)	9	4	(44%)		4	2	(50%)	1		1		0
VOMITING	≤63 Days (All)	102	31	(30%)	0.8906	45	9	(20%)	26	(58%)	10	(22%)	0
	≤49 Days (Group 1)	68	21	(31%)		28	5	(18%)	16	(57%)	7	(25%)	0
	50-56 Days (Group 2)	25	8	(32%)		14	4	(29%)	8	(57%)	2		0
	57-63 Days (Group 3)	9	2	(221)		3	ō	(230)	2			(33%)	0
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	102	2	(2%)	0.5578	2	0		0		2	(100%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0			(100%)	ō
	50 56 Days (Group 2)	25	1	(4%)		1	0		0			(100%)	0
	57-63 Days (Group 3)	9	0	,		0	0		0		0	(1000)	Ō
DEHYDRATION	≤63 Days (All)	102	2	(2%)	0.5578	2	0		0		2	(100%)	0
τ.	≰49 Days (Group 1)	68	1	(1%)		1	0		. 0	• !	1	(100%)	ō
$r = \mathbf{e}^{\frac{1}{2}r} \cdot \mathbf{e}^{\frac{1}{2}r}$	50-56 Days (Group 2)	25	1	(4%)		• 1	Ö	j	1.5	7.	Ţ	(100%)	ō
	57-63 Days (Group 3)	9	0			o	0	· •	0		0		Ö

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a' (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational	Total	Number	Fisher's					
Budio Good of the Australia	Age	Number	of Pts	exact	Number		Sever	lty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.8307	8	4 (50%)	3 (38%)	1 (13%)	0
	≤49 Days (Group 1)	68	6 (9%)		7	3 (43%)	3 (43%)	1 (14%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9 .	0		0	0	Ō	Ö	ō
BRONCHITIS	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	•
	≤49 Days (Group 1)	68	1 (11)	1.0000	i	1 (100%)	0	0	0
•	50-56 Days (Group 2)	25	0		n	0	0 '	0	0
	57-63 Days (Group 3)	9	0		Ö	o	0	0	0
DYSPNOEA	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	•	
	≤49 Days (Group 1)	68	0	0.3333	•	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		o	0	0	0	0
PHARYNGITIS	≤63 Days (All)	102	3 (3%)	0.6683	2	ı1 (33 %)	2 (67%)		
•	≰49 Days (Group 1)	68	3 (4%)	0.0003	,	1 (33%)	2 (67%)	0	U
	50-56 Days (Group 2)	25	0		0	1 (334)	2 (6/4)	0	0
	57-63 Days (Group 3)	9	0		0	ō	0	0	0
SINUSITIS	≤63 Days (All)	102	3 (3%)	0.6683	3	1 (33%)	1 (33%)	1 (225)	•
	s49 Days (Group 1)	68	3 (4%)	2.000	3	1 (33%)	1 (334)	1 (33%) 1 (33%)	0
و	50-56 Days (Group 2)	25	0		ó	0	0 (334)	1 (334)	0
•	57-63 Days (Group 3)	9	ŏ		, 0	•	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational,	Total	Num		Fisher's			_	•	
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p value	Number - of Events	Mild	Moderate	Severe	Unknown
MINARY SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	102	1	(<1%)	1.0000	. 1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1	(1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0			0	0	0	0	0
	57 63 Days (Group 3)	9 -,	0			0 .	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	102	1	(<1%)	1.0000	1	1 (100%)	0	0	0
ı	≤49 Days (Group 1)	68	1	(,1 %)		1	1 (100%)	0 '	0	0
	50-56 Days (Group 2)	25	0			0	0	0 .	0	0
	57-63 Days (Group 3)	9	0	1		0	0	0	O	0
EPRODUCTIVE DISORDERS, FEMALE										
ANY EVENT	≤63 Days (All)	102	14	(14%)	0.2954	15	3 (20%)	5 (33%)	7 (47%)	0
	s49 Days (Group 1)	68	7	(10%)		7	2 (29%)	3 (43%)	2 (29%)	0
	50-56 Days (Group 2)	25	5	(20%)		6	1 (17%)	1 (17%)	4 (67%)	0
	57-63 Days (Group 3)	9	2	(22%)		2	0	1 (50%)	1 (50%)	0
BREAST ENLARGEMENT	≤63 Days (All)	102	1	(<1%)	1.0000	1	0	1 (100%)	0	n
	≤49 Days (Group 1)	68	1	(1%)	2.000	1	0	1 (100%)	0	n
•	50-56 Days (Group 2)	25	0			0	0	0	Ô	Ô
	57-63 Days (Group 3)	9	0			0	0	0	o	o
BREAST PAIN FEMALE	≤63 Days (All)	102	1	(<1%)	1.0000	1	1 (100%)	0	0	0
1 . , , ,	≤49 Days (Group 1)	68	1	(1%)		. 1	1 (100%)	0 1	0	Ō
y de la companya de	50-56 Days (Group 2)	25	0			. • 0	0	0	0	Ō
	57-63 Days (Group 3)	9	ō			o	0	0,	0	ō

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational	Total	Number	Fisher's					
	Age	Number	of Pts	exact	Number		·Sever	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
ENDOMETRITIS	≰63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9 ,	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	102	1 (<1%)	1.0000	1	o	1 (100%)	0	0
T .	≤49 Days (Group 1)	68	1 (1%)		į 1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		O	0	o '	0.	0
	57-63 Days (Group 3)	9	0		. 0	0	0	0	0
OVARIAN DISORDER	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
; . !	57-63 Days (Group 3)	9	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	102	8 (8%)	0.0209	, 8	0	1 (13%)	7 (88%)	0
•	s49 Days (Group 1)	68	2 (3%)		2	0	0	2 (100%)	0
	50 56 Days (Group 2)	25	5 (20%)		5	0	1 (20%)	4 (80%)	0
	57 63 Days (Group 3)	9	1 (11%)		1	0	0	1 (100%)	0
VAGINAL DISCOMFORT	s63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
Ť	50-56 Days (Group 2)	25	0		0	0 , ,	0	0	0
	57-63 Days (Group 3)	9	0		. 0	0 ;	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number				·Sever:	ity		-
Body System/Event [2]	Group [3]	of Pts	w/Ev	vent	p value	of Events	Mi	1 d	Mod	erate	Sev	ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)							*						
VAGINITIS	s63 Days (All)	102	1	(<1%)	0.0882	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	68	0			0	0		. 0		0		0
	50.56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9 -	1	(11%)		1	0		1	(100%)	0		0
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	102	102	(100%)		362	151	(42%)	138	(38%)	73	(20%)	0
	≤49 Days (Group 1)	68		(100%)		250	109	(44%)	95		46	(18%)	Ô
	50-56 Days (Group 2)	25		(100%)		90	36	(40%)	35		19	(21%)	0
	57-63 Days (Group 3)	9		(100%)		22	6	(27%)	8		8	(36%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	101 ((>99%)	1.0000	313	129	(41%)	116	(37%)	68	(22%)	0
	s49 Days (Group 1)	68		(991)		211	91	(43%)		(37%)	41	(19%)	Ô
	50-56 Days (Group 2)	25		(100%)		80	32	(40%)	29		19	(24%)	Ō
	57-63 Days (Group 3)	9		(100%)		22	6	(27%)	8		8	(36%)	Ō
ALLERGY	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	68	1	(1%)		1	0			(100%)	0		0
1	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	. 0		i o		0		0
ASTHENIA	≤63 Days (All)	102	6	(61)	0.3885	6	3	(50%)	2	(33 %)	1	(17%)	0
- . ,	≤49 Days (Group 1)	68	3	(4%)	1	. 3	1	(334)		*(33%)	1		ō
	50-56 Days (Group 2)	25	3	(12%)	į	3	2	(67%)	C.	(331)	ō		0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	9	0	,		0	0	7	i	1	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational	Total	Numbe		Fisher's								
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt		exact p value	Number of Events				·Severi erate	•	vere	Unknown
200, 0,000,,000,000	Group (3)	Of PCs	W/EV6		p value	Of Evencs	М.	110	Mode	tate		vere	Unknown
ODY AS A WMOLE - GENERAL DISORDERS (cont.	•												
BACK PAIN	≤63 Days (All)	102	12	(12%)	0.5534	14	3	(21%)	10	(71%)	1	(7%)	0
	≰49 Days (Group 1)	68	10	(15%)		12	3	(25%)	8	(67%)	1	(8%)	0
	50-56 Days (Group 2)	25	2	(8%)		2	0		2	(100%)	0		0
	57-63 Days (Group 3)	9 .	0			0	0		0		0		0
CHEST PAIN	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		0		1	(100%)	0
1	≤49 Days (Group 1)	68	1	(1%)		1	0	1	0	1	1	(100%)	0
•	50-56 Days (Group 2)	25	0			0	0		0	!	Ď	•	0
	57-63 Days (Group 3)	9	0			0	0		0		Ö		0
FATIGUE	≤63 Days (All)	102	7	(7%)	0.8307	. 8	3	(38%)	3	(38%)	2	(25%)	0
	≤49 Days (Group 1)	68	6	(9%)		7	3	(43%)	2	(29%)	2	(291)	0
	50-56 Days (Group 2)	25	1	(4%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
FEVER	≤63 Days (All)	102	2	(2%)	1.0000	2	1	(50%)	1	(50%)	0		0
•	≤49 Days (Group 1)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
LEG PAIN	≤63 Days (All)	102	2	(2%)	1.0000	3	3	(100%)	0		0		0
	≰49 Days (Group 1)	68	2	(3%)		3	3	(100%)	0		0		0
ي	50-56 Days (Group 2)	25	0			0	0		0		0		0
	57-63 Days (Group 3)	9	0			• 0	0		, oʻ	*. !	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont.)								
MALAISE	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	68	0		0	ō	0	n	0
	50 56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	Ö	0
	57 63 Days (Group 3)	9 ·	0		0	, 0	0	ō	0
PAIN	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	•	
	≤49 Days (Group 1)	68	1 (1%)	1.0000	i	1 (100%)	0 .	0	0
	50-56 Days (Group 2)	25	0 (10)		ń	0	0 .	0.	0
	57-63 Days (Group 3)	9	0		. 0	0	0	0	0
RIGORS	≤63 Days (All)	102	9 (9%)	0.7440	10	6 (603)	4 (400)	_	
	≤49 Days (Group 1)	68	6 (9%)	0.7440	10	6 (60%)	4 (40%)	0	0
	50-56 Days (Group 2)	25	3 (12%)		7	4 (57%)	3 (43%)	0	0
	57-63 Days (Group 3)	25 9	0 (124)		,	2 (67%)	1 (33%)	0	0
	37-63 Days (Group 3)	9	U		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≰49 Days (Group 1)	68	2 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
·	57-63 Days (Group 3)	9	0 :		0	0	0	0	0
ESISTANCE MECHANISM DISORDERS			,					1	
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.6825	8	4 (50%)	3 (38%)	1 (13%)	0
7	≤49 Days (Group 1)	68	5 (7%)		6	2 (33%)	3 (50%)	1 (174)	Ö
€ A · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	25	1 (4%)		• 1	1 (100%)	0	0 , , ,	Ô
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0,	o	0
•						i	i		

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: TYSON (#4)

	Gestational	Total Number	Num of		Fisher's exact	Number -			Severi	•••	
Body System/Event [2]	Age Group [3]	of Pts		vent	p-value	of Events	Mild		rate	Severe	Unknown
RESISTANCE RECHANISH DISORDERS (cont.)											
INFECTION BACTERIAL	≤63 Days (All)	102	1	(<1 %)	0.0882	1	1 (100%)	0		0	0
	s49 Days (Group 1)	68	0			0	0	0		0	0
	50-56 Days (Group 2)	25	0	,		0	0	0		0	0
	57-63 Days (Group 3)	9 .	1	(11%)		1	1 (100%)	0		0	0
INFECTION VIRAL	≤63 Days (All)	102	6	(6%)	1.0000	7	3 (43%)	3	(43%)	1 (14%)	0
ı	s49 Days (Group 1)	68	5	(7%)		6	2 (33%)	3	(50%)	1 (17%)	0
	50+56 Days (Group 2)	25	1	(4%)		1	1 (100%)	0	•	0.	0
	57-63 Days (Group 3)	9	0			0	0	0		0	0
SECONDARY TERMS											
ANY EVENT	≰63 Days (All)	102	1	(<1%)	0.0882	1	1 (100%)	0		0	0
	≤49 Days (Group 1)	68	0			0	0 .	0		0	0
	50-56 Days (Group 2)	25	0			o [']	0	0		0	0
	57-63 Days (Group 3)	9	1	(11%)		1	1 (100%)	0		0	0
POST-OPERATIVE PAIN	≤63 Days (All)	102	1	(<1%)	0.0882	1	1 (100%)	0		0	0
	\$49 Days (Group 1)	68	0			0	0	0		0	0
e ·	50-56 Days (Group 2)	25	0			0	0	. 0		0	0
	57-63 Days (Group 3)	9	1	(11%)		1	1 (100%)	0		0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

 $\begin{tabular}{ll} $J:\USA\166A\SASPGMS\apdxd\final\ade1.SAS & 24NOV98:16:20 \\ \begin{tabular}{ll} $USA\SASPGMS\apdxd\final\ade1.SAS & 24NOV98:16:20 \\ \begin{tabular}{ll} $USA\SASPGMS\apdxd\final\ade1.SAS & 24NOV98:16:20 \\ \begin{tabular}{ll} $USA\SASPGMS\apdxd\final\ade1.SAS & 24NOV98:16:20 \\ \begin{tabular}{ll} $USA\SASPGMS\apdxd\Apdx$

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational	Total	Number	Fisher's								
Body Guston (Burnt 10)	Age	Number	of Pts	exact					Sever	•		
Body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events	M	.1 d	Mode	rate	Sev	ere	Unknow
•						•						
ANY EVENT	s63 Days (All)	44	44 (100%)		270	128	(47%)	110	(41%)	32	(12%)	0
	≤49 Days (Group 1)	13	13 (100%)		77	35	(45%)	35	(45%)	7	(9%)	0
	50-56 Days (Group 2)	23	23 (100%)		149	67	(45%)	59	(40%)	23	(15%)	0
	57-63 Days (Group 3)	B .	B (100%)		44	26	(59%)	16	(36%)	2	(5%)	0
IN AND APPENDAGES DISORDERS												
ANY EVENT	• ≤63 Days (All)	44	2 (5%)	0.4165	2	2	(100%)	0	,	0.		0
	≤49 Days (Group 1)	13	0		0	0		0	4	0		0
	50-56 Days (Group 2)	23	1. (44)		1	1	(100%)	0		0		Ô
	57-63 Days (Group 3)	8	1 (13%)		1		(100%)	0		0		0
FOLLICULITIS	≤63 Daye (All)	44	1 (2%)	0.1818	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	13	0		0	0		0		0		0
	50-56 Days (Group 2)	23	0		0	0		0		0		0
	57-63 Days (Group 3)	8	1 (13%)		1	1	(100%)	0		0		0
PRURITUS GENITAL	≰63 Days (All)	44	1 (2%)	1.0000	1	1	(100%)	0		0		0
	≰49 Days (Group 1)	13	0		0	0		0		0		0
· '	50-56 Days (Group 2)	23	1 (4%)		1	1	(100%)	. 0		0		o
	57-63 Days (Group 3)	8	0		0	0		0		0		0
SCULO-SKELETAL SYSTEM DISORDERS	•	t										
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.4773	. 1	1	(100%) ,	0'		0		0
s a 🐞 🖟 🧎	≤49 Days (Group 1)	13	1 (8%)		• 1		(100%)		1. !	Ō		ō
•	50-56 Days (Group 2)	23	0		O	0		0,	•	0		0
	57-63 Days (Group 3)	8	0		0	0	·r	0,1		Ō		Ô

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational Age	Total	Numb		Fisher's								
Body System/Event [2]	Group [3]	Number of Pts	of i		exact p-value	Number - of Events				Severi		/ere	Unknown
					•						361		Unknown
USCULO-SEELETAL SYSTEM DISORDERS (cont.) ARTHRALGIA													
ARTHRALGIA	≤63 Days (A11)	44	1	(2%)	0.4773	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	13	1	(8%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	23	0			0	0		0		0		0
	57-63 Days (Group 3)	8 .	0			0	0		0		0		0
ENTR & PERIPH HERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	44	11	(25%)	0.8068	.20	4	(20%)	12	(60%)	4	(20%)	•
•	≤49 Days (Group 1)	13	4	(31%)		7	i	(14%)	5	(71%)	1	(14%)	0
	50-56 Days (Group 2)	23		(26%)		12	2	(17%)	7	(58%)	_		0
	57-63 Days (Group 3)	8		(13%)		1		(100%)	0	(504)	3	(25%)	0
DIZZINESS	≤63 Days (All)	44		(0.5)	0.6366		_						-
	*49 Days (Group 1)	44 13	4	(9%)	0.6366	4	1	(25%)	2		1	,	0
i e e e			2	(15%)		2	0		1	(50%)	1	(50¥)	0
!	50-56 Days (Group 2)	23	2	(91)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	8	0			0	0	'	0		0		0
HEADACHE	≤63 Days (All)	1 44	10	(23%)	0.7095	16	3	(19%)	10	(63%)	3	(19%)	0
	≰49 Days (Group 1)	13	4	(31%)		5	1	(20%)	4	(80%)	0		0
· ·	50-56 Days (Group 2)	23	5	(22%)		10	1	(10%)	6	(60%)	3	(30%)	ō
	57-63 Days (Group 3)	8	1	(13%)		1	1	(100%)	0	, . ,	0	,,,,,	ō
SYCHIATRIC DISORDERS										•			
ANY EVENT	≤63 Days (All)	44	1	(2%)	1.0000	1	1	(100%)	0 /	*	0		0
	s49 Days (Group 1)	13	0			0	0		0 1	. !	0		0
•	50-56 Days (Group 2)	23	1	(4%)		1	_	(1001)	. .	•	0		•
	57-63 Days (Group 3)	8	ō			0	ò	(1000)	ď		0		0
	•	-	-			•	·	, i			U		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number					Severi	ty		.
Body System/Event [2]	Group [3]	of Pts	w/Ev	ent	p-value	of Events	Mi	14	M	lode	rate	Sev	ere	Unknown
PSYCHIATRIC DISORDERS (cont.)														
DEPRESSION	s63 Days (All)	44	1	(2%)	1.0000	1	1	(100%)	1	0		0		0
	≤49 Days (Group 1)	13	0			0	0		!	0		0		0
	50-56 Days (Group 2)	23	1	(48)		1	1	(100%)		0		0		0
	57-63 Days (Group 3)	8	0	,		0	0			0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS														
ANY EVENT	- ≤63 Days (All)	44	36	(82%)	0.5781	98	46	(47%)		38	(39%)	14	(14%)	0
	≤49 Days (Group 1)	13	12	(92%)		32	15	(47%)		13	(41%)	4	(13%)	0
	50-56 Days (Group 2)	23	18	(78%)		51	20	(39%)		22	(43%)	9	(18%)	0
	57-63 Days (Group 3)	. 8	6	(75%)		15	11	(73%)		3	(20%)	1	(7%)	0
DIARRHEA	≤63 Days (All)	44	7	(16%)	0.8558	10	3	(30%)		4	(40%)	ż	(30%)	0
	≤49 Days (Group 1)	13	3	(23%)		3	1	(33%)		1	(33%)	1	(33%)	0
1	50-56 Days (Group 2)	23	3	(13%)		6	1	(17%)		3	(50%)	2	(33%)	0
	57-63 Days (Group 3)	8	.1	(13%)		1	1	(100%)		0		0		0
FLATULENCE	s63 Days (All)	44	1	(21)	1.0000	3	0			2	(67%)	1	(33%)	0
	≤49 Days (Group 1)	13	0			0	0			0		0		0
1 '	50-56 Days (Group 2)	23	1	(4%)		3	0		- }	2	(67%)	1	(33%)	0
	57-63 Days (Group 3)	8	0			0	. 0		İ	0		0		0
NAUSEA	≤63 Days (All)	44	34	(77%)	0.3097	60	35	(58%)		19,	(32%)	6	(10%)	0
* ·	≰49 Days (Group 1)	13	12	(92%)		, 21	11	(52,41	• y	8	(98%)	2	(10%)	0
a e 🙀 - A	50-56 Days (Group 2)	23	17	(74%)	;	* 31	17	(55%)	ì	10	(32%)	4	(13%)	0
•	57 63 Days (Group 3)	8	5	(63%)		8	7	(88)		1 1	(13%)	0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational	Total Number	Number of Pts	Fisher's	Number		0	l b	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	exact p·value	of Events	Mild	Moderate	Severe	Unknown
MASTRO-INTESTINAL SYSTEM DISORDERS (cont.)	/// // / / / / / / / / / / / / / / / /	· · · · · · · · · · · · · · · · · · ·	*						
VOMITING	≤63 Days (All)	44	16 (36%)	1.0000	25	8 (32%)	13 (52%)	4 (16%)	0
	≤49 Days (Group 1)	13	5 (38%)		8	3 (38%)	4 (50%)	1 (13%)	0
	50-56 Days (Group 2)	23	8 (35%)		11	2 (18%)	7 (64%)	2 (18%)	0
	57-63 Days (Group 3)	8 .	3 (38%)		6	3 (50%)	2 (33%)	1 (17%)	0
RESPIRATORY SYSTEM DISORDERS							1		
ANY EVENT	≰63 Days (All)	44	2 (5%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	b ·	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	44	2 (5%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0 .	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	O	0	0
URIMARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
i · · · · · · ·	≰49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0
URINARY TRACT INFECTION	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
• • • · · · · · · · · · · · · · · · · ·	≤49 Days (Group 1)	13	0		. 0	0 ;	0 °;	0	0
	50-56 Days (Group 2)	23	0		0	0 '	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0 !	1 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational	Total	Number	Fisher's			•		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknow
EPRODUCTIVE DISORDERS, PENALE			 						
ANY EVENT	≤63 Days (All)	44	4 (9%)	1.0000	6	3 (50%)	3 (50%)	0	0
	s49 Days (Group 1)	13	1 (8%)		i	1 (100%)	0	Ō	Ö
	50-56 Days (Group 2)	23	2 (9%)		4	1 (25%)	3 (75%)	0	ō
	57-63 Days (Group 3)	8 .	1 (13%)		1	1 (100%)	0	0	ō
BREAST ENGORGEMENT	≤63 Days (All)	44	1 (2%)	1.0000	2	0	2 (100%)	0	0
1	≤49 Days (Group 1)	13	0		0	0	ο,	0	0
	50-56 Days (Group 2)	23	1 (4%)		2	0	2 (100%)	o ·	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	44	2 (5%)	0.4165	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
LEUKORRHOEA	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	13	0		0	0	0	0	0
,	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
,	57-63 Days (Group 3)	8	0		0	0	0	· 0	0
VAGINITIS	≤63 Days (All)	44	1 (2%)	0.4773	1	1 (100%)	0	0	0
<u>.</u>	≰49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	, o	0
σ .	50-56 Days (Group 2)	23	0		. 0	۰ ب ن	0	o	0
e e • • • · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	8	0		• 0	0	0	'o	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center (Safety Evaluable Patients)

Center: BLUMENTHAL (#5)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknow
ODY AS A WHOLE - GENERAL DISORDERS										• •	(****	•
ANY EVENT	≰63 Days (All)	44	44 (100%)		137	70	(51%)	53		14	(10%) (6%)	0
	<pre>s49 Days (Group 1)</pre>	13	13 (100%)		34	17	(50%)	15	(44%)	2 11	(14%)	0
	50-56 Days (Group 2)	23	23 (100%)		79	41	(52%)	27		1	(4%)	0
	57-63 Days (Group 3)	8 -	8 (100%)		24	12	(50%)	11	(46%)	1	(44)	U
ABDOMINAL PAIN	≤63 Days (All)	44	43 (98%)	0.1818	126	68	(54%)	45	(36%)	13		0
Appointment than	≤49 Days (Group 1)	13	13 (100%)		29	17	(59%)	10	(34%)	2	(7%)	0
•	50 56 Days (Group 2)	23	23 (100%)		75	40	(53%)	25	(33%)	10		0
	57 63 Days (Group 3)	8	7. (88%)		22	11	(50%)	10	(45%)	1	(5%)	0
FATIGUE	s63 Days (All)	44	3 (7%)	0.4182	3	1	(33%)	2	(67%)	0		0
PATIGOE	≤49 Days (Group 1)	13	2 (15%)		2	0		2	(100%)	0		0
	50-56 Days (Group 2)	23	1 (4%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	8	0		o ˈ	0		0		0		0
			. (25)	1.0000	1	0		1	(100%)	0	-	0
FEVER	s63 Days (All)	44	1 (2%)	1.0000	•	0		ò	(1000)	ō		0
	≤49 Days (Group 1)	13	0 1 (4%)		1	ŏ		1	(100%)	0		0
	50-56 Days (Group 2)	23	1 (4%)		Ô	0		ō		0		0
•	57-63 Days (Group 3)	В	U		Ū	v		·		_		
LEG PAIN	≤63 Days (All)	44	3 (7%)	0.0533	3	1	(33%)		(67%)	0		0
550 1	≰49 Days (Group 1)	13	1 (8%)		1	0			(100%)	0		0
 ,	50 56 Days (Group 2)	23	0		0	0		0	4. 4.	0		0
v v 🔥 🖟	57-63 Days (Group 3)	8	2 (25%)		. 2	1	(50%)	1. 	(50%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational	Total	Number	Fisher	_				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Even	exact p-valu	Number e of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont	.)				····				
MALAISE	s63 Days (All)	44	1 (*) 0.4773	2	0	2 (100%)	0	o
	s49 Days (Group 1)	13		(%)	2	0	2 (100%)	o	Ď
	50-56 Days (Group 2)	23	0		0	0	0	0	Ô
	57-63 Days (Group 3)	8 1,	0		0	0	ō	ō	0
OEDEMA	≤63 Days (All)	44	1 (1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	13	0		0	0	О,	0	0
	50-56 Days (Group 2)	23	1 (₹)	1	0	0	1 (100%)	ō
	57-63 Days (Group 3)	8	0		. 0	0	0	0	ō
PAIN	≤63 Days (All)	44	1 (%) 1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	Ö	n
	50-56 Days (Group 2)	23	1 (%)	1	0	1 (100%)	0	Ô
	57-63 Days (Group 3)	8	0		0	0	0	0	ō
PPLICATION SITE DISORDERS [4]									
ANY EVENT	≤63 Days (All)	44	1 (:	%) 0.4773	1	o	1 (100%)	0	0
	≤49 Days (Group 1)	13	1 (*)	1	0	1 (100%)	Ö	o
f ·	50-56 Days (Group 2)	23	0		0	0	0	Ö	Ď
	57-63 Days (Group 3)	8	0		0	0	0	0	ō
INJECTION SITE PAIN	≤63 Days (All)	44	1 (:	%) 0.4773	1	0	1 (100%)	0	0
→ ,	≰49 Days (Group 1)	13	1 (*)	1	0 -	1 (100%)	0	o
v v 🔥 🕹	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0 · _r	0 1	0	ō
,						į.	į		

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severi	•••	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISH DISORDERS					***···	·			
ANY EVENT	s63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	13	0		0	0	0	o	0
	50-56 Days (Group 2)	23	0		. 0	0	0	Ō	0
	57-63 Days (Group 3)	8 -	1 (13%)		1	O	1 (100%)	0	0
INFECTION VIRAL	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	13	0		! O	0	0	0	0
	50-56 Days (Group 2)	23	0		· 0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severi	t v		.,
Body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events		ld		erate	Sev	ere	Unknown
•								-				
ANY EVENT	≤63 Days (All)	64	63 (98%)	0.4375	405	166	(41%)	159	(39%)	80	(20%)	0
	≤49 Days (Group 1)	36	36 (100%)		222	95	(43%)	79	(36%)	48	(22%)	0
	50-56 Days (Group 2)	16	15 (94%)		102	44	(43%)	35	(34%)	23	(23%)	0
	57-63 Days (Group 3)	12 .	12 (100%)		81	. 27	(33%)	45	(56%)	9	(11%)	0
KIN AND APPENDAGES DISORDERS												
ANY EVENT	. ≤63 Days (All)	64	1 (2%)	1.0000	1	0			(10p%)	0		0
	≤49 Days (Group 1)	36	1 (3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0		0	0		0		0		0
	57-63 Days (Group 3)	12	0		0	0		0		0		0
RASH	≤63 Days (All)	64	1 (2%)	1.0000	1	0			(100%)	0		0
	≰49 Days (Group 1)	36	1 (3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0		0	0		0		. 0		0
	57-63 Days (Group 3)	12	0		0	0		0		0		0
RUSCULO-SKELETAL SYSTEM DISORDERS			,									
ANY EVENT	≤63 Days (All)	64	2 (3%)	0.4018	2	Q			(100%)	0		0
r	≤49 Days (Group 1)	36	1 (3%)		1	0			(100%)	0		0
	50-56 Days (Group 2)	16	0		0	0		0		0		0
	57-63 Days (Group 3)	12	1 (8%)		1	0		1	(100%)	0		0
ARTHRALGIA *	≤63 Days (All)	64	2 (3%)	0.4018	2	0	.•		(100%)	0		0
* · · ·	≤49 Days (Group 1)	36	1 (3%)	1	• 1	0	j	1	(100%)	0		0
P P S S S S S S S S S S S S S S S S S S	50-56 Days (Group 2)	16	0		0	0	•	0		0		0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1	1	(100%)	0		0
,	2: 22 23/2 (6002)						i	ı				

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number				Severi			
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events		.1d	Mode	rate	Sev		Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	≰63 Days (All)	64	21 (33%)	0.2961	40	16	(40%)	17	(43%)	7	(18%)	0
	≰49 Days (Group 1)	36	9 (25%)		13	4	(31%)	7	(54%)	2	(15%)	0
	50-56 Days (Group 2)	16	7 (44%)		19	9	(47%)	5	(26%)	5	(26%)	0
	57-63 Days (Group 3)	12	5 (42%)		8	3	(38%)	5	(63%)	0		0
DIZZINESS	≤63 Days (All)	64	5 (8%)	1.0000	5	4	: (80 %)	1	(20%)	0		0
1	≰49 Days (Group 1)	36	3 (8%)		3	2	(67%)	1	(339)	0		0
·	50-56 Days (Group 2)	16	1 (6%)		1	1	(100%)	0		þ.		0
	57-63 Days (Group 3)	12	1 (8%)		1	1	(100%)	0		0		0
HEADACHE	≤63 Days (All)	64	16 (25%)	0.1827	33	11	(33%)	15	(45%)	7	(21%)	0
	≤49 Days (Group 1)	36	6 (17%)		8	1	(13%)	5	(63%)	2	(25%)	0
i i	50-56 Days (Group 2)	16	6 (38%)		18	8	(44%)	5	(28%)	5	(28%)	0
	57-63 Days (Group 3)	12	4 (33%)		7	2	(29%)	5	(71%)	0		0
PARAESTHESIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0			(100%)	0		0
,	≤49 Days (Group 1)	36	1 (3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0		0	0		0		0		0
•	57-63 Days (Group 3)	12	0		0	0		0		0		0
TREMOR	≤63 Days (All)	64	1 (2%)	1.0000	1		(100%)	0		0		0
	≰49 Days (Group 1)	36	1 (3%)		1	1	(100%)	0		0		0
à .	50-56 Days (Group 2)	16	0		0	0	.•	, 0	- 1	0		0
e e 🔹	57-63 Days (Group 3)	12	0		. 0	0	, , ,) (0 	4. 7	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Seve r	itv	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	64	5 (8%)	0.2235	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	36	5 (14%)		5	2 (40%)	3 (60%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12 ·	0		0	0	0	0	0
ANOREXIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (10,0%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		. 0	0	0	0	0
ANXIETY	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	O	0	0
DEPRESSION	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	o	0	0
	s49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	12	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	64	2 (31)	1.0000	2	1 (50%)	1 (50%)	o	0
	≰49 Days (Group 1)	36	2 (6%)		2	1 (50%)	1 (50%)	, O	0
4. γ	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		• 0	0 .	0	'ο	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic exemination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational Age	Total Number	Numb of 1		Fisher's exact	Number			-	Severi	.tv		-
Body System/Event [2]	Group [3]	of Pts	w/E		p-value	of Events		1 d		rate	Sev		Unknown
GASTRO-INTEŠTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	64	45	(70%)	0.3651	122	47	(39%)	44	(36%)	31	(25%)	0
	≰49 Days (Group 1)	36	27	(75%)		77	28	(36%)	26	(34%)	23	(30%)	0
	50 56 Days (Group 2)	16	9	(56%)		25	12	(48%)	7	(28%)	6	(24%)	0
	57-63 Days (Group 3)	12 .	9	(75₹)		20	7	(35%)	11	(55%)	2	(10%)	0
DIARRHEA	≤63 Days (All)	64	13	(20%)	0.5833	15	7	(47%)	6	(40%)	2	(13%)	0
ı	≤49 Days (Group 1)	36	8	(22%)		9	4	(44%)	3	(33%)	2	(22%)	0
	50-56 Days (Group 2)	16	4	(25%)		4	2	(50%)	2	(50%)	0		0
	57-63 Days (Group 3)	12	1	(8%)		2	1	(50%)	1	(50%)	0		0
DYSPEPSIA	≤63 Days (All)	64	2	(3%)	0.4018	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	36	1	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	0			d	0		0		0		0
	57-63 Days (Group 3).	12	1	(8%)		1	0		1	(100%)	0		0
FLATULENCE	≤63 Days (All)	64	1	(2%)	0.1875	1	0		0		1	(100%)	0
·	≰49 Days (Group 1)	36	0			0	0		0		0	!	0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
1	57-63 Days (Group 3)	12	1	(8%)		1	0		. 0		1	(100%)	0
NAUSEA	≤63 Days (All)	64	39	(614)	0.6108	76	31	(41%)	26	(34%)	19	(25%)	0
	≥49 Days (Group 1)	36	23	(64%)		46	17	(37%)		(33%)	14	(30%)	0
₹ ,	50-56 Days (Group 2)	16	8	(50 %)		17	8	(47%)		(29%)	4	(24%)	0
1 × 1	57-63 Days (Group 3)	12	8	(67%)		, 13	6	(46%)	Į	* (46 %)	1	(8%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.))	·····							
VOMITING	≤63 Days (All)	64	19 (30%)	0.4601	28	9 (32%)	10 (36%)	9 (32%)	0
	≤49 Days (Group 1)	36	13 (36%)		21	7 (33%)	7 (33%)	7 (33%)	o
	50.56 Days (Group 2)	16	3 (19%)		4	2 (50%)	0	2 (50%)	0
	57-63 Days (Group 3)	12	3 (25%)		3	0	3 (100%)	0	ō
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	2 (3%)	0.6875	2	1 (50%)	0 ,	1 (50%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	o '	0	0
	50-56 Days (Group 2)	16	1 (61)		, <u>1</u>	0	Ö	1 (100%)	0
	57-63 Days (Group 3)	12	0		0	0	o	0	ŏ
COUGHING	≤63 Days (All)	64	1 (2%)	0.4375	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	0		ō	ō	Ö	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	Ö	0	1 (100%)	0
	57-63 Days (Group 3)	12	0		ō	0	0	0	0
SINUSITIS	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	36	1 (3%)		1	1 (100%)	Ö	o o	0
	50-56 Days (Group 2)	16	0		0	0	. 0	0	0
	57-63 Days (Group 3)	12	0		0	o	o	ō	0
ED BLOOD CELL DISORDERS	•								
ANY EVENT	≤63 Days (All)	64	2 (3%)	1.0000	2	2 (100%)	0 .	0	0
r r 📲 - A	s49 Days (Group 1)	36	2 (6%)	2:2000	2	2 (100%)	0	0	0
•	50 56 Days (Group 2)	16	0		0	0	0,	0	0
	57-63 Days (Group 3)	12	Ō		ō	o '	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Sever	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)			····						
ANAEMIA	≰63 Days (All)	64	2 (3%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12 .	0		0	. 0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	64	12 (19%)	0.9061	14	4 (29%)	9 (64%)	1 (7%)	0
	≤49 Days (Group 1)	36	(17%)		7	2 (29%)	4 (57%)	1 (14%)	0
	50-56 Days (Group 2)	16	3 (19%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	12	3 (25%)		4	0	4 (100%)	0	0
CERVICITIS	≤63 Days (All)	64	3 (5%)	0.0441	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	, 16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	2 (100%)	0	0
LEUKORRHOEA .	≰63 Days (All)	64	1 (2%)	1.0000	' 1	(100%)	0	o	0
	≰49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	16	0		0	0	. 0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0 -	1 (100%)	0
å ,	≤49 Days (Group 1)	36	1 (3%)		1	0	0-1	1 (100%)	0
, s	50-56 Days (Group 2)	16	0		<u>;</u> 0	0	0 1	0	0
• • • • • • • • • • • • • • • • • • •	57 63 Days (Group 3)	12	0		• 0	o '	0,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINAL DISCOMFORT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12 ·	0		0	0	0	0	0
VAGINITIS	≤63 Days (All)	64	7 (11%)	0.6468	8	2 (25%)	6 (75%)	0	0
· ·	≤49 Days (Group 1)	36	3 (8%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	16	2 (13%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	2 (100%)	0	0
DY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	64	60 (94%)	0.8096	212	90 (42%)	82 (39%)	40 (19%)	0
	≰49 Days (Group 1)	36	33 (92%)		113	54 (48%)	37 (33%)	22 (19%)	0
i i	50-56 Days (Group 2)	16	15 (94%)		52	20 (38%)	21 (40%)	11 (21%)	0
	57-63 Days (Group 3)	12	12 (100%)		47	16 (34%)	24 (51%)	7 (15%)	0
ABDOMINAL PAIN	≤63 Days (All)	64	59 (92%)	0.8202	173	75 (43%)	65 (38%)	33 (19%)	0
	≤49 Days (Group 1)	36	32 (891)		91	45 (49%)	28 (31%)	18 (20%)	ō
· · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	16	15 (941)		41	15 (37%)	17 (41%)	9 (22%)	o
	57-63 Days (Group 3)	12	12 (100%)		41	15 (37%)	20 (49%)	6 (15%)	0
BACK PAIN	≤63 Days (All)	64	5 (8%)	1.0000	9	4 (44%)	3 (33%)	2 (22%)	o
÷ ;	≤49 Days (Group 1)	36	3 (8%)	ì	6	2 (33%)	2 (33*)	2 (33%)	0
1 4 6 A	50-56 Days (Group 2)	16	1 (6%)	ł	. 2	2 (100%)	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1,(100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number -		Severi	F-10	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (CON-	t.)					····			
FATIGUE	s63 Days (All)	64	13 (20%)	0.9149	17	3 (18%)	11 (65%)	3 (18%)	0
	≤49 Days (Group 1)	36	7 (19%)		8	0	7 (88%)	1 (13%)	0
	50-56 Days (Group 2)	16	3 (19%)		6	2 (33%)	3 (50%)	1 (17%)	0
	57-63 Days (Group 3)	12 .	3 (25%)		3	1 (33%)	1 (33%)	1 (33%)	0
FEVER	≤63 Days (All)	64	2 (3%)	0.6875	2	2 (100%)	0 1	0	0
1	£49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	; O	0
·	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		. 0	0	0	0	0
HOT FLUSHES	≰63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	1 (50%)	0	0
	s49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
1	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
LEG PAIN	≤63 Days (All)	64	2 (3%)	0.6875	2	1 (50%)	0	1 (50%)	0
·	≰49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	0	1 (100%)	0
•	57-63 Days (Group 3)	12	0		0	0	. 0	0	0
MALAISE	≰63 Days (All)	64	3 (5%)	1.0000	4	3 (75%)	1 (25%)	0	0
	±49 Days (Group 1)	36	2 (6%)		3	3 (100%)	0	0	0
$\vec{\sigma}_i$	50-56 Days (Group 2)	16	1 (6%)		1	0 . ,	1 (100%)	0	0
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	57-63 Days (Group 3)	12	0		. 0	0 ,	0 1.	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

⁽²⁾ NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	· · · • • • • · · · · · · · · · · · · ·	Sever:	itv	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
DY AS A WROLE - GENERAL DISORDERS (cont	.)		· · · · · · · · · · · · · · · · · · ·						
RIGORS	≤63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	Ô	Ô
	50-56 Days (Group 2)	16	0		0	0	0	Ô	o o
	57-63 Days (Group 3)	12 .	1 (8%)		1	0	1 (100%)	ō	0
SYNCOPE	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	
1	≤49 Days (Group 1)	36	1 (3%)	2.000	1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0			0	•	1 (1004)	0
	57 63 Days (Group 3)	12	0		. 0	ō	o	0	0
SISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	64	5 (8%)	0.6966	5	4 (80%)	1 (20%)	0	•
	s49 Days (Group 1)	36	2 (6%)	0.0300	2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	2 (13%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0
INFECTION	≤63 Days (All)		1 (28)	1 0000			_		
	#49 Days (Group 1)	64 36	1 (2%)	1.0000	1	1 (100%)	0	0	0
,	50-56 Days (Group 2)	16	1 (3%) 0		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12			0	0	0	. 0	0
	57-03 Days (Group 3)	12	0	•	0	0	0	. 0	0
INFECTION BACTERIAL	≰63 Days (All)	64	2 (3%)	0.4018	2	2 (100%)	0	0	0
*	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%) ,	0	↓o	0
	50-56 Days (Group 2)	16	0		• 0	0 j	0	o	o
·	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0,	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	_		Severi	lty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
ESISTANCE MECHANISM DISORDERS (cont.)									
INFECTION FUNGAL	≤63 Days (All)	64	1 (2)	0.4375	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	0	1	0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	64	1 (2	0.4375	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	36	0		0	0	ο .	O.	0
•	50 156 Days (Group 2)	16	1 (6	:)	1	0	1 (100%)	0	0
	57163 Days (Group 3)	12	0		. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational Age	Total Number	Number of Pts	Fisher's								
Body System/Event [2]	Group [3]	of Pts	w/Event	exact p value	Number of Events		.1d		Severi rate	•	ere	Unknown
•									· · · · · · · · · · · · · · · · · · ·			
ANY EVENT	≤63 Days (All)	52	52 (100%)		389	147	(38%)	151	(39%)	91	(23%)	•
	≤49 Days (Group 1)	19	19 (100%)		127	50	(39%)	47	(37%)	30	(24%)	0
	50-56 Days (Group 2)	11	11 (100%)		77	37	(48%)	28	(36%)	12	(16%)	0
	57-63 Days (Group 3)	22	22 (100%)		185	. 60	(32%)	76	(41%)	49	(26%)	0
USCULO-SKELETAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	52	1 (2%)	0.5769	2	0		0		2	(100%)	•
	≤49 Days (Group 1)	19	1 (5%)		2	Õ		0	1		(100%)	0
	50-56 Days (Group 2)	11	0 (7)		. 0	ň		0		0	(1004)	0
	57-63 Days (Group 3)	22	0		0	0		ő		o		0
ARTHRALGIA	≤63 Days (All)	52	1 (2%)	0.5769	1	0		0			(100%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	Ō		0			(100%)	
	50-56 Days (Group 2)	11	0		o o	ň		0		0	(1004)	0
	57-63 Days (Group 3)	22	0		o	o		0		0		0
MYALGIA	≤63 Days (All)	52	1 (2%)	0.5769	1	0		0		,	(100%)	0
	≰49 Days (Group 1)	19	1 (5%)		ī	ŏ		Ô			(100%)	0
I '	50-56 Days (Group 2)	11	0		0	ō		. 0		ō	(1004)	0
	57-63 Days (Group 3)	22	0		o	ō		ŏ		o		0
INTR & PERIPE NERVOUS SYSTEM DISORDERS	•			•								
ANY EVENT	≤63 Days (All)	52	22 (42%)	0.7140	43	15	(35%}	22	(51%)	6	(14%)	0
F F Mark 199	≰49 Days (Group 1)	19	7 (37%)		. 9	3	(33≹)		(67%)	0		0
•	50-56 Days (Group 2)	11	4 (36%)		. 8	7	(88%)	0.		1	(13%)	Ō
•	57-63 Days (Group 3)	22	11 (50%)		26	5	(19%)	16	(62%)	5	(19%)	ō

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISC	PRES (cont.)								····
DIZZINESS	≤63 Days (All)	52	9 (17%)	1.0000	12	6 (50%)	5 (42%)	1 (8%)	0
	≤49 Days (Group 1)	19	3 (16%)		3	1 (33%)	2 (67%)	0 (00)	n
	50-56 Days (Group 2)	11	2 (18%)		2	2 (100%)	0	0	Ô
	57-63 Days (Group 3)	22	4 (18%)		7	3 (43%)	3 (43%)	1 (14%)	o
HEADACHE	≤63 Days (All)	52	17 (33%)	0.7440	31	9 (29%)	17 (55%)	5 (16%)	0
1	≤49 Days (Group 1)	19	5 (26%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	11	4 (36%)		6	5 (83%)	0	1 (17%)	0
	57 63 Days (Group 3)	22	8 (36%)		· 19	2 (11%)	13 (68%)	4 (21%)	Ō
EARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	, 19	0		Q	0 1	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57 63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
TINNITUS	≤63 Days (All)	52	1 (2%)	1.0000		1 (100%)	•	•	•
1100	≤49 Days (Group 1)	19	0	1.0000		1 (1004)	0	0	0
i '	50-56 Days (Group 2)	11	0		0	0	0	0	•
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
YCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	52	4 (8%)	0.8217	5	2 (40%)	3 (60%)	0	0
* * * * * * * * * * * * * * * * * * *	≤49 Days (Group 1)	19	2 (11%)		. 3	0 .	3 (100%)	0	n
•	50-56 Days (Group 2)	11	1 (9%)		í	1 (100%)	0,	0	0
	57-63 Days (Group 3)	22 .	1 (5%)		ī	1 (100%)	0	n	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Numbe		Fisher's								
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt		exact p value	Number of Events		ild		Severi erate	•	ere	Unknown
SYCHIATRIC, DISORDERS (cont.)			· · · · ·				_			····			
INSOMNIA	≤63 Days (All)	52	4	(8%)	0.8217	5	,	(40%)	! 3	(60%)	0		0
	≤49 Days (Group 1)	19		(11%)	0.0217	3	0	(404)		(100%)	ő		0
	50-56 Days (Group 2)	11	1	(98)		1	-	(100%)	, 0	(1000)	ō		0
	57-63 Days (Group 3)	22	1	(5%)		1		(100%)	0		o		0
ASTRO-INTESTINAL SYSTEM DISORDERS		•			i.								
ANY EVENT	≤63 Days (All)	52	40	(77%)	1.0000	118	44	(37%)	37	(31%)	37	(31%)	0
•	≤49 Days (Group 1)	19		(79%)		37	16		11		10	(27%)	Ö
	50-56 Days (Group 2)	11		(73%)		24	11		10	(42%)	3	(13%)	0
,	57-63 Days (Group 3)	22		(77%)		- 57	17		16		24		o
CONSTIPATION	≤63 Days (All)	52	2	(4%)	0.5023	2	0		0		2	(100%)	0
	≤49 Days (Group 1)	19	0			0	Ô		0			(2001)	Ô
	50-56 Days (Group 2)	11	0			0	o		ō		0		ň
	57-63 Days (Group 3)	22	2	(9%)		2	0		ō		2	(100%)	0
DIARRHEA	≤63 Days (All)	52	12 ((23%)	0.4046	13	7	(54%)	3	(23%)	3	(23%)	0
	≤49 Days (Group 1)	19	6	(32%)		6	4		2	(33%)	ō	,	0
	50-56 Days (Group 2)	11	1	(9%)		1	1	(100%)	. 0	,,	0		ō
	57-63 Days (Group 3)	22	5 ((23%)		6	2	(33%)	1	(17%)	3	(50%)	0
DYSPEPSIA	#63 Days (All)	, 52	1	(21)	0.5769	1	0		0		1	(100%)	0
;	≤49 Days (Group 1)	19	1	(5%)	ļ	1	0		0			(100%)	0
***	50-56 Days (Group 2)	11	0		\	; O	0		0	1.	0		0
s a septimination of the sep	57-63 Days (Group 3)	22	0			• 0	0	ji.	. 0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Numb		Fisher's	Wb							
Body System/Event [2]	Age Group [3]	Number of Pts			exact p value	Number of Events		1d		Severi erate	Sev		Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)			···	,									
FLATULENCE	≤63 Days (All)	52	2	(4%)	0.3281	2	0		2	(100%)	0		0
	≰49 Days (Group 1)	-19	1	(5%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	11	1	(9%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	22	0			9	0		0		0		0
NAUSEA	s63 Days (All)	52	37	(71%)	0.7318	70	27	: (39%)	22	(31%)	21	(30%)	0
	s49 Days (Group 1)	19	13	(68%)		23	10	(43%)	5	(221)	8	(35%)	0
	50-56 Days (Group 2)	11	7	(64%)		13	6	(46%)	6	(46%)	1	(8%)	0
	57-63 Days (Group 3)	22	17	(77%)		. 34	11	(32%)	11	(32%)	12	(35%)	0
VOMITING	≤63 Days (All)	52	17	(33%)	0.7440	30	10	(33%)	10	(33%)	10	(33%)	0
	≤49 Days (Group 1)	19	5	(26%)		6	2	(33%)	3	(50%)	1	(17%)	0
;	50-56 Days (Group 2)	11	4	(36%)		9	4	(44%)	3	(33%)	2	(22%)	0
	57-63 Days (Group 3)	22	8	(36%)		15	4	(27%)	4	(27%)	7	(47%)	0
ENDOCRINE DISORDERS													
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	19	0			0	0		0		0		0
· '	50-56 Days (Group 2)	11	0			0	0		. 0		0		0
	57-63 Days (Group 3)	22	1	(5%)		1	1	(100%)	0		0		0
ENDOCRINE DISORDER NOS	≤63 Days (All)	52	1	(2%)	1.0000	1	1	(100%)	0		0		0
- ,	≤49 Days (Group 1)	19	0			0	0		0	4. (0		O
4 4 A	50-56 Days (Group 2)	11	0			• 0	0	,	0		0		0
•	57-63 Days (Group 3)	22	1	(5%)		1	1	(100%)	0	•	0		0
								í	i				

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Sever	itv	• • • • • • • • • • • • • • • • • • •
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
HEART RATE AND RHYTHM DISORDERS				······································	- 1 - 3 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 				
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50 56 Days (Group 2)	11	0		0	0	0	0	o
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	ō
TACHYCARDIA	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	٥
4	≤49 Days (Group 1)	19	0		0	0	Ŏ	Ô	0
	50-56 Days (Group 2)	11	0		0	o o	o '	Ô	0
	57 63 Days (Group 3)	22	1 (5%)		1	1 (100%)	Ö	ō	ō
ESPIRATORY SYSTEM DISORDERS		•							
ANY EVENT	≤63 Days (All)	52	2 (4%)	1.0000	2	0	2 (100%)	0	0
	≰49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	ō	Ô
	50-56 Days (Group 2)	11	0		0	ō	0	0	Ô
	57-63 Days (Group 3)	22	1 (5%)		1	ō	1 (100%)	ō	0
PHARYNGITIS	≤63 Days (All)	52	1 (2%)	0.5769	1	0	1 (100%)	0	•
	≤49 Days (Group 1)	19	1 (5%)		,	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0 (30)		•	0	. 0	0	0
	57-63 Days (Group 3)	22	n	I .	0 .	0	. 0	: 0	0
	3, 03 bays (Group 3)		v	1	•	v	U	· ·	U
PULMONARY CONGESTION	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)		0
4.	≤49 Days (Group 1)	19	0		0	0	0	o	0
	50-56 Days (Group 2)	11	0		: 0	0 .* 1	0 * !	6	Ó
•	57-63 Days (Group 3)	22	1 (5%)		1	0 ,	1 (100%)	0	ō

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

CJ.

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational Age	Total Number	Number of Pts	Fisher's	M		_		
Body System/Event [2]	Group [3]	of Pts	w/Event	exact p value	Number of Events	Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0	0
	s49 Days (Group 1)	19	0	*******	ō	0	0	o o	n
	50-56 Days (Group 2)	11	2 (18%)		2	1 (50%)	1 (50%)	Ô	o o
	57 63 Days (Group 3)	22 .	0		0	. 0	0	ō	0
ANAEMIA	≰63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0	0
ı	. ≤49 Days (Group 1)	19	0		0	0	0 .	Ō	0
	50 56 Days (Group 2)	11	2 (18%)		2	1 (50%)	1 (50%)	o ·	Ô
	57-63 Days (Group 3)	22	0		. 0	0	0	ō	0
JRINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	2 (4%)	0.6848	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	19	0		ol	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	Ô	Ô
	57-63 Days (Group 3)	2.2	1 (5%)		2	1 (50%)	0	1 (50%)	0
MICTURITION FREQUENCY	≤63 Days (All)	52	1 (2%)	0.2115	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	Ô	Ô
t '	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	Ô	Ŏ
	57-63 Days (Group 3)	22	0		0	0	0	ō	Ō
URINARY TRACT INFECTION	≤63 Days (All)	52	1 (2%)	1.0000	2	1 (50%)	0	1 (50%)	0
$\hat{\boldsymbol{\tau}}_{i}$.	≰49 Days (Group 1)	19	0		0	0	0	0	n
8 4 6 €	50 56 Days (Group 2)	11	0		• 0	0	0	Ŏ	0
•	57-63 Days (Group 3)	22	1 (5%)		2	1 (50%)	0,	1 (50%)	Ö

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A 1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Severi Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE				· · · · · · · · · · · · · · · · · · ·					
ANY EVENT	≤63 Days (All)	52	11 (21%)	0.5082	11	5 (45%)	5 (45%)	1 (9%)	0
	≤49 Days (Group 1)	19	5 (26%)		5	2 (40%)	2 (40%)	1 (20%)	Ö
	50-56 Days (Group 2)	11	3 (27%)		3	1 (33%)	2 (67%)	0	Õ
	57-63 Days (Group 3)	22	3 (14%)		3	2 (67%)	1 (33%)	0	0
BREAST PAIN FEMALE	≰63 Days (All)	52	1 (2%)	0.2115	1	1 (100%)	0	0	0
t	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50 56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0 '	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
CERVICITIS	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
LEUKORRHOEA	≤63 Days (All)	52	1 (2%)	0.5769	1	0	0	1 (100%)	0
•	≤49 Days (Group 1)	19	1 (5%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	22	0		0	0 .	0	0	0
VAGINITIS	≤63 Days (All)	52	8 (15%)	0.5428	8	4 (50%)	4 (50%)	0	0
	#49 Days (Group 1)	19	4 (21%)		4	2 (50%)	2 (50%)	0	0
ά.	50-56 Days (Group 2)	11	2 (18%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	2 (100)	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Number	Fisher's	11b				Severi	• • • • • •		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events				erate	Sev	еге	Unknown
ODY AS A WHOLE - GENERAL DISORDERS				· · · · · · · · · · · · · · · · · · ·								
ANY EVENT	≤63 Days (All)	52	51 (98%)	1.0000	197	76	(39%)	78	(40%)	43	(22%)	0
	≰49 Days (Group 1)	19	19 (100%)		67	29	(43%)	22	(33%)	16	(24%)	0
	50-56 Days (Group 2)	11	11 (100%)		38	16	(42%)	14	(37%)	8	(21%)	0
	57-63 Days (Group 3)	22	21 (95%)		92	31	(34%)	42	(46%)	19	(21%)	0
ABDOMINAL PAIN	≤63 Days (All)	52	50 (96%)	0.5023	167	68	(41%)	59	(35%)	40	(24%)	0
1	s49 Days (Group 1)	19	19 (100%)		61	27	(44%)	18	(30%)	16	(26%)	0
	50-56 Days (Group 2)	11	11 (100%)		34	14	(41%)	13	(38%)	7	(21%)	0
	57-63 Daye (Group 3)	22	20 (91%)		72	27	(38%)	28	(39%)	17	(24%)	0
ALLERGY	s63 Days (All)	52	4 (8%)	0.5229	4	0		4	(100%)	0		0
	≤49 Days (Group 1)	19	1 (5%)		1	0		1	(100%)	0		0
	50 56 Days (Group 2)	11	0		0	0		, 0		0		0
	57 63 Days (Group 3)	22	3 (14%)		3	0		3	(100%)	0		0
ASTHENIA	≤63 Days (All)	52	3 (6%)	0.7919	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	19	1 (5%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	11	0		0	0		0		0		0
· '	57-63 Days (Group 3)	22	2 (9%)		2	1	(50%)	1	(50%)	0		0
BACK PAIN	≤63 Days (All)	52	7 (13%)	0.0838	8	2	(25%)	6	(75%)	0		0
	≤49 Days (Group 1)	19	0		0	0		0	. 1	0		0
•	50-56 Days (Group 2)	11	2 (18%)		. 2	1	(50%)	1.7	(50%)	0		0
1 (1 1 1 1 1 1	57-63 Days (Group 3)	22	5 (23%)		• 6	1	(174)	1	· (83%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		·Sever	ity	· · · • • • • · · · · · · · · · · · · ·
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont	.)								
FATIGUE	≤63 Days (All)	52	5 (10%)	0.8328	5	1 (20%)	3 (60%)	1 (20%)	0
	≰49 Days (Group 1)	.19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	3 (14%)		3	0	2 (67%)	1 (33%)	0
FEVER	≤63 Days (All)	52	3 (6%)	0.7919	3	1 (33%)	2 (67%)	0	0
4	≤49 Days (Group 1)	19	1 (5%)		1	1 (100%)	ο , '	;O	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	0	2 (100%)	0	0
HOT FLUSHES	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
LEG PAIN	≤63 Days (All)	52	2 (4%)	1.0000	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
•	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
RIGORS	s63 Days (All)	, 52	2 (4%)	0.6848	2	1 (50%)	0	1 (50%)	0
	≰49 Days (Group 1)	19	0		0	0	0	0	0
ě .	50-56 Days (Group 2)	11	1 (9%)		1	0	0-	1 (100%)	0
r r 💕	57-63 Days (Group 3)	22	1 (5%)		. 1	1 (100%)	0 1	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS * Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational Age	Total Number	Numb		Fisher's exact	Number -						
Body System/Event [2]	Group [3]	of Pts	of Pts w/Event		p value	of Events	Mild		Severi derate	Severe		nown
BODY AS A WROLE - GENERAL DISORDERS (CONT	E.)											
SYNCOPE	≤63 Days (All)	52	1	(2%)	1.0000	1	0		0	1 (10	0 (
	≤49 Days (Group 1)	19	0			0	0		0	0	0	
	50-56 Days (Group 2)	11	0			0	0		- D	o	0	
	57-63 Days (Group 3)	22 .	1	(5%)		1	0	ı	0	1 (10	01) 0	
RESISTANCE MECHANISM DISORDERS												
ANY EVENT	≤63 Days (All)	52	2	(4%)	0.1704	3	0	:	2 (67%)	1 (3	31) 0	
	≤49 Days (Group 1)	19	2	(11%)		3	0		2 (67%)		3%) 0	
	50-56 Days (Group 2)	11	0			0	Ō		0	0	0	
	57-63 Days (Group 3)	22	0			0	0		0	Ō	0	
INFECTION BACTERIAL	≤63 Days (All)	52	,	(2%)	0.5769	1	0		1 (100%)	0	n	
1	≤49 Days (Group 1)	19	1	(5%)		1	o		1 (100%)	Ö	n	
i i	50-56 Days (Group 2)	11	0			ō	0		0	Ď	0	
:	57-63 Days (Group 3)	22	0			0	0	·	, D	ő	0	
INFECTION PARASITIC	≤63 Days (All)	52	1	(2%)	0.5769	1	0		1 (100%)	0	•	
	≤49 Days (Group 1)	19	1	(5%)	0.3,05	1	Ô		1 (100%)	Ô	0	
· ·	50-56 Days (Group 2)	11	ō	(30)		Ô	ň		1 (1001)	Š	0	
	57-63 Days (Group 3)	22	o	!,		0 .	ō	Ì	Ď	į	0	
INFECTION VIRAL	≤63 Days (All)	52	1	(2%)	0.5769	1	0	()	1 (10	o t) o	
♣ ,	#49 Days (Group 1)	19	1	(5%)		1	0 .		D- j	1 (10		
	50-56 Days (Group 2)	11	0			. 0	0	* y (D ** :	6	0	
	57-63 Days (Group 3)	22	0			0	0	,	ָר. •	0	0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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FINAL

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: ROTHENBERG (#8)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	1 d	Mode	rate	Sev	ere	Unknown
•												_
ANY EVENT	s63 Days (All)	21	21 (100%)		98	38	(39%)	37		23		0
	≰49 Days (Group 1)	13	13 (100%)		48	25	(52%)	17	(35%)	6	1/	0
	50-56 Days (Group 2)	5	5 (100%)		31	7	(23%)		(52%)	8	(26%)	0
	57-63 Days (Group 3)	3 .	3 (100%)		19	. 6	(32*)	4	(21%)	9	(47%)	0
ENTR & PERIPH MERVOUS SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	21	9 (43%)	0.3870	16	0		13	(81%)	3	(19%)	0
•	≤49 Days (Group 1)	13	4 (31%)		8	0		7	(88%)	1	(13%)	0
	50-56 Days (Group 2)	5	3 (60%)		6	0		5	(83%)	1	(17%)	0
	57 63 Days (Group 3)	3	2 (67%)		2	0		1	(50%)	1	(50%)	0
DIZZINESS	≤63 Days (All)	21	1 (5%)	1.0000	2	0		2	(100%)	0		0
	s49 Days (Group 1)	13	1 (8%)		2	0		2	(100%)	0		0
	50-56 Days (Group 2)	5	0		o'	0		0		0		0
	57-63 Days (Group 3)	3	0		0	0		0		0		0
HEADACHE	s63 Days (All)	21	9 (43%)	0.3870	14	0		11	(79%)	3	(21%)	0
	s49 Days (Group 1)	13	4 (31%)		6	0		5	(83%)	1	(17%)	0
, ,	50-56 Days (Group 2)	5	3 (60%)		6	0		. 5	(03%)	1	(17%)	0
	57-63 Days (Group 3)	3	2 (67%)		2	0		1	(50%)	1	(50%)	0
STRO-INTESTINAL SYSTEM DISORDERS	•											
ANY EVENT	≤63 Days (All)	21	16 (76%)	0.7892	37	19	(51%)	10	(27%)	8	(22%)	0
	≤49 Days (Group 1)	13	9 (69%)		18	12	(674)	g 3 1	1 (178)	3	(17%)	0
N → N N N N N N N N N N N N N N N N N N	50-56 Days (Group 2)	5	4 (80%)		12	3	(251)	6	(50%)	3	(25%)	0
	57-63 Days (Group 3)	3	3 (100%)		7	4	(57%)	11	(14%)	2	(29%)	0
g•							i	1				

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: ROTHENBERG (#8)

	Gestational	Total	Number	Fisher's					
- 1 · · · · · · · · · · · · · · · ·	Age	Number	of Pts	exact		• • • • • • • • • • • • • • • • • • • •	00.0110	y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	. eyere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)	,								
CONSTIPATION	≰63 Days (All)	21	1 (5%)	0.3810	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	21	5 (24%)	0.7892	7	5 (71%)	2 (29%)	0	0
· ·	≰49 Days (Group 1)	13	4 (31%)		5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	5	1 (20%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	3	0		. 0	0	0	0	0
FLATULENCE	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	21	11 (52%)	0.0383	18	10 (56%)	4 (22%)	4 (22%)	0
,	≤49 Days (Group 1)	13	4 (31%)		8	5 (63%)	1 (13%)	2 (25%)	0
	50-56 Days (Group 2)	5	4 (80%)		6	1 (17%)	3 (50%)	2 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		4	4 (100%)	0	0	0
VOMITING	≤63 Days (All)	21	7 (33%)	0.4466	10	3 (30%)	3 (30%)	4 (40%)	0
·	k49 Days (Group 1)	13	3 (23%)		4	3 (75%)	0.	1 (25%)	0
\vec{r}_{i} .	50-56 Days (Group 2)	5	2 (40%)		3	0	2; (67%)	1 (33%)	0
	57-63 Days (Group 3)	3	2 (67%)		3	• • •	1 (334)	2 (67%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: ROTHENBERG (#8)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severi	l trace	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unki: %n
RESPIRATORY SYSTEM DISORDERS			····		· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·			
ANY EVENT	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3 .	0		0	0	0	O	0
SINUSITIS	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
1	≰49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0 ,	0	0
	50-56 Days (Group 2)	5	0		0	0	0	O T	0
	57 63 Days (Group 3)	3	0.		. 0	0	0	0	0
ODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	21	20 (95%)	1.0000	44	18 (41%)	14 (32%)	12 (27%)	0
	≤49 Days (Group 1)	13	12 (92%)		21	12 (57%)	7 (33%)	2 (10%)	0
	50-56 Days (Group 2)	1 5	5 (100%)		13	4 (31%)	5 (38%)	4 (31%)	0
	57-63 Days (Group 3)	3	3 (100%)		10	2 (20%)	2 (20%)	6 (60%)	0
ABDOMINAL PAIN	≤63 Days (All)	21	20 (95%)	1.0000	38	17 (45%)	12 (32%)	9 (24%)	0
	≤49 Days (Group 1)	13	12 (92%)		19	11 (58%)	6 (32%)	2 (11%)	0
C .	50-56 Days (Group 2)	5	5 (100%)		12	4 (33%)	4 (33%)	4 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		7	2 (29%)	2 (29%)	3 (43%)	0
BACK PAIN	≰63 Days (All)	21	3 (14%)	0.3158	5	0	2 (40%)	3 (60%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
r e 🐞 - A	50-56 Days (Group 2)	5	1 (20%)		1	0 ji	1 (100%)	0	0
	57-63 Days (Group 3)	3	1 (33%)		3	0	0,	3 (100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: ROTHENBERG (#8)

	Gestational Age	Total Number	Numbe of Pt	_	Fisher's exact			Sever	itv	
Body System/Event [2]	Group [3]	of Pts	w/Eve	nt	p value	of Events	Mild	Moderate	Severe	Unknown
ody as a whole - general disorder	S (cont.)					=				
LEG PAIN	≤63 Days (All)	21	1	(5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	- 13	1	(8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0			0	0	0	0	o o
	57-63 Days (Group 3)		0			_	n	0		,

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5b Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: MISHELL (#1)

Body System/Frent [2]		Gestational Age	Total Number	Num of		Fisher's exact	Number	-			Sever	itv		
#49 Days (Group 1) 145 99 (688) 199 74 (378) 78 (398) 47 (248) 0 50-56 Days (Group 2) 40 35 (888) 57 17 (308) 25 (448) 15 (268) 0 57-63 Days (Group 3) 19 12 (638) 23 8 (358) 7 (308) 8 (358) 0 ### ANY EVENT #63 Days (Group 1) 145 1 (<18) 1.0000 1 0 1 (1008) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Body System/Event [2]	Group [3]	of Pts									-	ere	Unknown
#49 Days (Group 1) 145 99 (688) 199 74 (378) 78 (398) 47 (248) 0 50-56 Days (Group 2) 40 35 (888) 57 17 (308) 25 (448) 15 (268) 0 57-63 Days (Group 3) 19 12 (638) 23 8 (358) 7 (308) 8 (358) 0 ### ANY EVENT #63 Days (Group 1) 145 1 (<18) 1.0000 1 0 1 (1008) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	•													
Second Second	ANY EVENT		204			0.0301	279	99	(35%)	110	(39%)	70	(25%)	0
57-63 Days (Group 3)			145	99	(681)		199	74	(37%)	78	(39%)	47	(24%)	0
KIN AND APPENDAGES DISORDERS ANY EVENT \$63 Days (All) 204 1 (<1\$) 1.0000 1 0 1 (100\$) 0 0 \$49 Days (Group 1) 145 1 (<1\$) 1.0000 1 0 1 (100\$) 0 0 50-56 Days (Group 2) 40 0 0 0 0 0 0 0 0 57-63 Days (Group 3) 19 0 0 0 0 0 0 0 0 SWEATING INCREASED \$63 Days (All) 204 1 (<1\$) 1.0000 1 0 1 (100\$) 0 0 \$49 Days (Group 1) 145 1 (<1\$) 1.0000 1 0 1 (100\$) 0 0 \$49 Days (Group 1) 145 1 (<1\$) 1 0 0 0 1 (100\$) 0 0 \$50-56 Days (Group 2) 40 0 0 0 0 0 0 0 0 0 57-63 Days (Group 3) 19 0 0 0 0 0 0 0 0 ENTR 4 PERIPH MERVOUS SYSTEM DISORDERS ANY EVENT \$63 Days (All) 204 18 (9\$) 0.6062 19 9 (47\$) 7 (37\$) 3 (16\$) 0 \$49 Days (Group 1) 145 15 (10\$) 16 7 (44\$) 6 (38\$) 3 (19\$) 0 50-56 Days (Group 2) 40 2 (5\$\$) 2 1 (50\$) 1 (50\$) 0		• •	40	35	(88%)		57	17	(30%)	25	(44%)	15	(26%)	0
ANY EVENT		57-63 Days (Group 3)	19	12	(63%)		23	8	(35%)	7	(30%)	8	(35%)	0
SWEATING INCREASED \$63 Days (Group 1) 145 1 (<1\cdot) 1 0000 1 (100\cdot) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	KIN AND APPENDAGES DISORDERS													
#49 Days (Group 1) 145 1 (<1%) 1 0 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	ANY EVENT	≤63 Days (All)	204	1	(<1%)	1.0000	1	0		1	(100%)	0		0
SWEATING INCREASED \$63 Days (Group 3) 19 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		#49 Days (Group 1)	145	1	(<1%)		1	0			•	7.4		_
SWEATING INCREASED \$63 Days (All) \$49 Days (Group 1) \$145		50-56 Days (Group 2)	40	0			0	0		ō	(2021)	0		Ô
#49 Days (Group 1) 145 1 (<1%) 1 0 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		57-63 Days (Group 3)	19	0			0	0		ō		ō		Ö
#49 Days (Group 1) 145 1 (<1%) 1 0 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	SWEATING INCREASED	≤63 Davs (All)	204	1	(<1 %)	1.0000	1	0		,	(100%)			•
50-56 Days (Group 2) 40 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	;	-				1.000	i	_						
57-63 Days (Group 3) 19 0 0 0 0 0 0 0 0 ENTR 4 PERIPH NERVOUS SYSTEM DISORDERS ANY EVENT 63 Days (All) 204 18 (9%) 0.6062 19 9 (47%) 7 (37%) 3 (16%) 0 549 Days (Group 1) 145 15 (10%) 16 7 (44%) 6 (38%) 3 (19%) 0 50-56 Days (Group 2) 40 2 (5%) 2 1 (50%) 1 (50%) 0 0				_	,		n	-		•	(1004)	0		0
ANY EVENT #63 Days (All) 204 18 (9%) 0.6062 19 9 (47%) 7 (37%) 3 (16%) 0 #49 Days (Group 1) 145 15 (10%) 16 7 (44%) 6 (38%) 3 (19%) 0 50-56 Days (Group 2) 40 2 (5%) 2 1 (50%) 1 (50%) 0 0	:						0	_		0		0		0
ANY EVENT s63 Days (All) 204 18 (9%) 0.6062 19 9 (47%) 7 (37%) 3 (16%) 0 s49 Days (Group 1) 145 15 (10%) 16 7 (44%) 6 (38%) 3 (19%) 0 50-56 Days (Group 2) 40 2 (5%) 2 1 (50%) 1 (50%) 0 0	ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
\$49 Days (Group 1) 145 15 (10%) 16 7 (44%) 6 (38%) 3 (19%) 0 50-56 Days (Group 2) 40 2 (5%) 2 1 (50%) 1 (50%) 0		≤63 Days (All)	204	18	(9%)	0.6062	19	9	(47%)	7	(379)	2	(168)	
50-56 Days (Group 2) 40 2 (5%) 2 1 (50%) 1 (50%) 0	· ·	-										_		
								1		1		-	(174)	0
1 1 (1004)				- 1			1	,			(304)			0
			**	-	,		-	•	(1000)	٠.		U		U

^[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Appendix A.1, Table 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center {Safety Evaluable Patients}

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -	• • · • • • • • • • • • • •	Severity					
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown			
ENTR & PERIPH MERVOUS SYSTEM DISC	ORDERS (cont.)											
DIZZINESS	≤63 Days (All)	204	7 (3%)	0.4317	8	4 (50%)	2 (25%)	2 (25%)	0			
	≤49 Days (Group 1)	145	7 (5%)		8	4 (50%)	2 (25%)	2 (25%)	0			
	50-56 Days (Group 2)	40	0		0	0	0	0	0			
	57-63 Days (Group 3)	19	0		0	0	0	0	0			
HEADACHE	≤63 Days (All)	204	11 (5%)	1.0000	11	5 (45%)	5 (45%)	1 (9%)	0			
	≤49 Days (Group 1)	145	8 (6%)		8	3 (38%)	4 (50%)	1 (13%)	0			
	50 56 Days (Group 2)	40	2 (5%)		2	1 (50%)	1 (50%)	0	0			
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0			
SYCHIATRIC DISORDERS												
ANY EVENT	s63 Days (All)	204	2 (<1%)	1.0000	3	1 (33%)	2 (67%)	0	0			
	#49 Days (Group 1)	145	2 (1%)		3	1 (33%)	2 (67%)	0	0			
	50-56 Days (Group 2)	40	0		0	0	0	0	0			
	57-63 Days (Group 3)	19	0		0	0	0	0	0			
ANXIETY	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0			
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0			
,	50-56 Days (Group 2)	40	0		0	0	0	0	0			
	57-63 Days (Group 3)	19	0		0	0	0	0	0			
DEPRESSION	≰63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0			
4 .	≰49 Days (Group 1)	145	1 (<1%)		1	0 . ,	1 (100%)	0	0			
or each of	50-56 Days (Group 2)	40	0		. 0	0 j	0	0	0			
	57-63 Days (Group 3)	19	0		0	o .	0,	0	0			

^[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Appendix A.1, Table 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: MISHELL (#1)

Body System/Event [2]	Gestational	Total	Number	Fisher's								
	Age Group [3]	Number	of Pts	exact				ty	Unknown			
		of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe				
PSYCHIATRIC DISORDERS	(cont.)											
INSOMNIA	≰63 Days (All)	204	1 (<1%)	1.0000	. 1	0	1 (100%)	0	0			
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0			
	50-56 Days (Group 2)	40	0		0	0	0	0	0			
	57-63 Days (Group 3)	19	0		o	0	0	0	0			
ASTRO-INTESTINAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	204	84 (41%)	0.2197	127	34 (27%)	42 (33%)	51 (40%)	0			
	s49 Days (Group 1)	145	57 (39%)		86	25 (29%)	27 (31%)	34 (40%)	0			
	50-56 Days (Group 2)	40	21 (53%)		32	8 (25%)	12 (38%)	12 (38%)	0			
	57-63 Days (Group 3)	19	6 (32%)		9	1 (11%)	3 (33%)	5 (56%)	0			
ABDOMINAL PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0			
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0			
	50-56 Days (Group 2)	40	0		0	0	0	0	0			
	57-63 Days (Group 3)	19	0		0	0	0	0	0			
DIARRHEA	≤63 Days (All)	204	2 (<1%)	0.0450	3	1 (33%)	1 (33%)	1 (33%)	0			
	s49 Days (Group 1)	145	0		0	0	0	0	0			
, ,	50-56 Days (Group 2)	40	1 (3%)		2	1 (50%)	1 (50%)	0	0			
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0			
DYSPEPSIA	≤63 Days (All)	204	2 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0			
	≤49 Days (Group 1)	145	2 (1%)		2	1 (50%)	1 (50%)	0	0			
	50-56 Days (Group 2)	40	0		• 0	0 , '	e o ***	0	0			
	57-63 Days (Group 3)	19	0		0	o ''	0,	0	0			

^[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Appendix A.1, Table 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography

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Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center (Safety Evaluable Patients)

Center: MISHELL (#1)

	Gestational Age Group (3)	Total Number	Number of Pts	Fisher's exact	Number				Severi	i +							
Body System/Event [2]		of Pts	w/Event	p-value	of Events	Mild		Moderate		Severe		Unknown					
JASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)																
FLATULENCE	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0		0		0					
	≰49 Days (Group 1)	145	1 (<1%)		1		100%)	ō		ō		Ö					
	50-56 Days (Group 2)	40	0		0	0		Ō		0		Ö					
	57-63 Days (Group 3)	19	0		0	0		0		0		o					
NAUSEA	≤63 Days (All)	204	79 (39%)	0.0539	89	25	(28%)	23	(26%)	41	(46%)	0					
ı	≤49 Days (Group 1)	145	54 (37%)		62		(32%)	14	(234)	28	(45%)	Ö					
	50-56 Days (Group 2)	40	21 (53%)		23		(22%)	8	(351)	10	(43%)	ő					
	57-63 Days (Group 3)	19	4 (21%)		4	0	,,	1	(25%)	3		Ö					
VOMITING	s63 Days (All)	204	27 (13%)	0.2676	31	5	(16%)	17	(55%)	9	(29%)	0					
	≤49 Days (Group 1)	145	16 (11%)		20		(10%)	12	(60%)	6	(30%)	0					
	50-56 Days (Group 2)	40	7 (18%)		7		(29%)	3	(43%)	2	(29%)	0					
	57-63 Days (Group 3)	19	4 (21%)		4		(25%)	2	(50%)	1	(25%)	ō					
ESPIRATORY SYSTEM DISORDERS		İ															
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0		1	(100%)	0		0					
	≤49 Days (Group 1)	145	1 (<1%)		1	0			(100%)	0		ō					
t · · · · · · · · · · · · · · · · · · ·	50-56 Days (Group 2)	40	0		0	0		0		0		o					
	57-63 Days (Group 3)	19	0		0	0		0		0		0					
RHINITIS	≰63 Days (All)	204	1 (<1%)	1.0000	1	0		1	(100%)	0		0					
4 .	≤49 Days (Group 1)	145	1 (<1%)		1	0	_		(100%)	Ō		o					
	50-56 Days (Group 2)	40	0		. 0	0		٠ .	9. 1	0		Ō					
	57-63 Days (Group 3)	19	0		0	0	i. Tr	0,	• 1	0		0					

^[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Appendix A.1, Table 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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Appendix D, Table 5b (Continued) Adverse Events Possibly or Probably Related to Mifepristone [1] By Center [Safety Evaluable Patients]

Center: MISHELL (#1)

	Gestational Age Group [3]	Total			Fisher's									
Body System/Event [2]		Number of Pts			exact p-value	Number of Events	Mild		Moderate		Severe	Unknown		
REPRODUCTIVÉ DISORDERS, FEMALE														
ANY EVENT	≤63 Days (All)	204	3	(1%)	0.3435	3	1	(33%)	1	(33%)	1 (33%)	0		
	≰49 Days (Group 1)	145	2	(1%)		2	1	(50%)	1	(50%)	0	0		
	50-56 Days (Group 2)	40	Ð			0	0		Ò		0	0		
	57-63 Days (Group 3)	19 -	1	(5%)		1	0		0		1 (100%)	0		
LEUKORRHOEA	≤63 Days (All)	204	1 ((<1%)	1.0000	1	1	(100%)	0		0	0		
ſ	. ≤49 Days (Group 1)	145	1 ((<1%)		1	1	(100%)	0		0	0		
	50-56 Days (Group 2)	40	0			0	0		0		0	0		
	57 63 Days (Group 3)	19	0			0	0		0		0	0		
UTERINE HAEMORRHAGE	≤63 Days (All)	204	1 ((<1%)	0.0931	1	0		0		1 (100%)	0		
	≤49 Days (Group 1)	145	0			0	0		0		Ó	0		
	50-56 Days (Group 2)	40	0			U	0		0		0	0		
:	57-63 Days (Group 3)	19	1	(5%)		1	0		0		1 (100%)	0		
VAGINITIS	≤63 Days (All)	204	.1 ((<1%)	1.0000	1	'o		1	(100%)	0	0		
	s49 Days (Group 1)	145	1 ((<11)		1	0		1	(100%)	0	0		
	50-56 Days (Group 2)	40	0			0	0		0		0	0		
	57-63 Days (Group 3)	19	0			0	0		0		0	0		
ODY AS A WHOLE - GENERAL DISORDERS							1		'					
ANY EVENT	≰63 Days (All)	204		(52%)	0.8520	125	54	(43%)		(45%)	15 (12%)	0		
···	≤49 Days (Group 1)	145		(52%)		90	40	(44%).		(448)	10 (11%)	0		
or an orași de la companii de la com	50-56 Days (Group 2)	40	22 ((55%)	1	• 23	8	(35.)		(52%)	3 (13%)	0		
	57-63 Days (Group 3)	19	9 ((47%)		12	6	(50 <u>%</u>)	4	, (33 %)	2 (17%)	0		

^[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.

Appendix A.1, Table 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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