Center: MISHELL (#1)

	Gestational Age	Total Number	Num of	ber Pts	Fisher's exact	Number				Sever	ity		
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknow
ANY EVENT	≤63 Days (All)	204	198	(97%)	0.4929	1131	405	(36%)	386	(34%)	340	(30%)	0
	≤49 Days (Group 1)	145	139	(96%)		766	296	(39%)	257	(34%)	213	(28%)	0
	50-56 Days (Group 2)	40	40	(100%)		255	75	(29%)	93	(36%)	87	(34%)	0
	57-63 Days (Group 3)	19	19	(100%)		110	34	(31%)	36	(33%)	40	(36%)	0
KIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	204	8	(4%)	0.7173	8	6	(751)	2	(25%)	0		0
ı	≤49 Days (Group 1)	145	6	(4%)		6	5	(83%)	1	(17%)	0		0
	50-56 Days (Group 2)	40	1	(3%)		` 1	1	(100%)	0		0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0		1	(100%)	0		0
ACNE	≤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
PRURITUS	≤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
PRURITUS GENITAL	≤6,3 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		0
	57-63 Days (Group 3)	19	0			• 0	0		0	l	0		0

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

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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: MISHELL (#1)

	Gestational	Total Number		ber Pts	Fisher's	M				Caucai	•		
Body System/Event [2]	Age Group (3)	of Pts		vent	exact p-value	Number of Events		.1d		Severi erate	-	ere	Unknown
KIN AND APPENDAGES DISORDERS (cont.)				· · · · · · · · · · · · · · · · · · ·									
SWEATING INCREASED	≤63 Days (All)	204	4	(2%)	0.2125	4	2	(50%)	2	(50%)	0		0
	≤49 Days (Group 1)	145	2	(1%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	40	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	19	1	(5%)		1	0		1	(100%)	0		0
TUSCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	s63 Days (All)	204	4	(2%)	0.7159	4	2	(50%)	2	(50%)	0		0
	≤49 Days (Group 1)	145	4	(3%)		4	2	(50%)	2	(50%)	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
MYALGIA	≤63 Days (All)	204	3	(1%)	1.0000	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	145	3	(2%)		3	2	(67%)	1	(33%)	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
SKELETAL PAIN	≤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
ENTR & PERIPH NERVOUS SYSTEM DISORDERS	1												
ANY EVENT	≤63 Days (All)	204	59	(29%)	0.9684	.90	42	(47%)	33	(37%)	15	(17%)	0
	≤49 Days (Group 1)	145	43	(30%)		67	31	(46%)	26	(39%)	10	(15%)	0
	50-56 Days (Group 2)	40	11	(28%)		15	6	(40%)	5	(33%)	4	(27%)	0
	57-63 Days (Group 3)	19	5	(26%)		8	5	(63%)	2	(25%)	1	(13%)	0

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

Appendix A.1, Tables 16 and 25

^[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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Center: MISHELL (#1)

	Gestational Age	Total Number	Numbe of Pt	-	Fisher's	Mumbau				C'			
Body System/Event [2]	Group [3]	of Pts	w/Eve		exact p-value	Number of Events	Mi	1d	Mode	Severi rate	-	ere	Unknow
ENTR & PERIPH MERVOUS SYSTEM DIS	ORDERS (cont.)									·····			
DIZZINESS	≤63 Days (All)	204	25 (12%)	0.5331	32	16	(50%)	7	(22%)	9	(28%)	0
	≤49 Days (Group 1)	145		13%)		23	12	(52%)	5	(22%)	6	(26%)	0
	50-56 Days (Group 2)	40	3	(8%)		5	2	(40%)	1	(20%)	2	(40%)	0
	57-63 Days (Group 3)	19	3 (16%)		4	2	(50%)	1	(25%)	1		0
HEADACHE	s63 Days (All)	204	39 (191)	1.0000	56	25	(45%)	26	(46%)	5	(9%)	0
	≤49 Days (Group 1)	145		19%)		42	18	(43%)	21	(50%)	3	(7%)	0
ı	50-56 Days (Group 2)	40		20%)		10	4	(40%)	4	(40%)	2	(20%)	ō
	57-63 Days (Group 3)	19		161)	•	4	3	(75%)	1	(25%)	0	(201)	ō
MIGRAINE	≤63 Days (All)	204	1 (<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	145		<1%)		1	Ö		0			(100%)	ō
	50-56 Days (Group 2)	40	0 `	,		0	ō		ō		ō	(1000)	0
	57-63 Days (Group 3)	19	0			0	ō		ō		0		0
NEURALGIA	≤63 Days (All)	204	1 (<1%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	145		<1%)		1		(100%)	0		0		0
	50-56 Days (Group 2)	40	o .	,		0	ō	(2007)	ō		0		Ö
	57-63 Days (Group 3)	19	0			ō	0		o		ō		0
ISION DISORDERS													
ANY EVENT	≤63 Days (All)	204		(1%)	1.0000	3	2	(67%)	0		1	(33%)	0
	≤49 Days (Group 1)	145	3	(2%)		3	2	(67%)	0		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	l.	0		0

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

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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.

Center: MISHELL (#1)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severi	ty	<i></i>
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
/ISION DISORDERS (cont.)									
EYE INFECTION	≤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
EYE PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
I	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	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
VISION ABNORMAL	≤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	Ö	0	o
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	204	7 (3%)	0.4317	9	2 (22%)	7 (78%)	0	0
	≤49 Days (Group 1)	145	7 (5%)		9	2 (22%)	7 (78%)	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	5 (2%)	0.7478	6	1 (17%)	5 (83%)	o	0
	≤49 Days (Group 1)	145	5 (3%)		6	1 (17%)	5 (83%)	0 ,	0
	50-56 Days (Group 2)	40	0		• 0	0	0 ,	0	0
	57-63 Days (Group 3)	19	0		0	0	o 14	0	0

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

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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.

Center: MISHELL (#1)

	Gestational Age	Total	Numbe:		Fisher's								
Body System/Event [2]	Group [3]	Number of Pts	of Pt: w/Eve		exact p value	Number of Events		ild		Sever	•	rere	Unknown
PSYCHIATRIC DISORDERS (cont.)													
DEPRESSION	≤63 Days (All)	204	1 (<1%)	1.0000	1	0		1	(100%)	0		0
	s49 Days (Group 1)	145	1 (-	<1%)		1	0			(100%)	0		0
	50-56 Days (Group 2)	40	0			0	0		0		0		ó
	57-63 Days (Group 3)	19	0			0	0		ō		ō		o
INSOMNIA	≤63 Days (All)	204	2 (-	<1%)	1.0000	2	1	(50%)	1	(50%)	0		0
:	≤49 Days (Group 1)	145		(1%)		2	1	(50%)	1	(50%)	0		Ô
	50-56 Days (Group 2)	40	0	, ,		0	0	100-7	0	,	0		Ô
	57-63 Days (Group 3)	19	0		•	0	o		ō		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	204	140 (6	59%)	0.8832	349	121	(35%)	90	(26%)	138	(40%)	0
	≤49 Days (Group 1)	145		58%)		224	86	(38%)	51	(23%)	87	(39%)	0
	50-56 Days (Group 2)	40		73%)		87	23	(26%)	27	(31%)	37	(43%)	0
	57-63 Days (Group 3)	19		68%)		38	12	(32%)	12	(32%)	14		0
ABDOMINAL PAIN	≤63 Days (All)	204	2 (<1%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	145		(1%)		2		(100%)	ō		0		0
	50-56 Days (Group 2)	40	0			0	0	(2000)	0		0		ō
	57-63 Days (Group 3)	19	0			0	ō		ō		ō		0
CONSTIPATION	≤63 Days (All)	204	2 (<	(1%)	1.0000	2	2	(100%)	0		0		o
	≤49 Days (Group 1)	145	-	(1%)		2		(100%)	ō		0		Ö
	50-56 Days (Group 2)	40	0	/		: 0	0	, /	ő		0		0
	57-63 Days (Group 3)	19	0 '			• 0	0		0	L.	0		0

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

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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.

Center: MISHELL (#1)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Carrows			
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events		.ld		Severi rate	•	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													···
DIARRHEA	≤63 Days (All)	204	28	(14%)	0.0780	32	21	(66%)	7	(22%)	4	(13%)	0
	≤49 Days (Group 1)	145	18	(12%)		19	13	(68%)	3	(16%)	3		0
	50-56 Days (Group 2)	40	4	(10%)		6	4	(67%)	2	(33%)	0	,,	0
	57-63 Days (Group 3)	19	6	(32%)		7	4	(57%)	2		1	(14%)	0
DYSPEPSIA	≤63 Days (All)	204	6	(3*)	0.4929	8	3	(38%)	4	(50%)	1	(13%)	0
I	≤49 Days (Group 1)	145	6	(4%)		8	3	(38%)		(50%)		(13%)	ō
	50-56 Days (Group 2)	40	ō	,		ñ	0	(300)	0	(300)	0	(124)	0
	57-63 Days (Group 3)	19	0			o	ŏ		0		0		0
FLATULENCE	≤63 Days (All)	204	2	(< 1%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	145	2	(1%)		2		(100%)	ō		0		ō
	50-56 Days (Group 2)	40	0	,		0	0	(2007)	0		0		ō
	57-63 Days (Group 3)	19	0			0	ō		0		ŏ		ō
GASTRIC ULCER	s63 Days (All)	204	1	(<1%)	0.2892	2	0		2	(100%)	0		0
	≰49 Days (Group 1)	145	0	,		0	ō		0	(/	o		0
	50-56 Days (Group 2)	40	1	(3%)		2	0		2	(100%)	0		o
	57-63 Days (Group 3)	19	0			0	0		0		0		0
HAEMORRHOIDS	≤63 Days (All)	204	1	(<1%)	1.0000	1	1	(100%)	0		0		0
	s49 Days (Group 1)	145	1	(<1%)		1		(100%)	0		0		0
	50-56 Days (Group 2)	40	0			0	0	,	0		0	1	0
	57-63 Days (Group 3)	19	0			• 0	0		o	l.	ō	•	ō

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

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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.

Center: MISHELL (#1)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)					•								
NAUSEA	≤63 Days (All)	204	127	(62%)	0.5180	233	73	(31%)	49	(21%)	111	(48%)	0
	≤49 Days (Group 1)	145	87	(60%)		152	55	(36%)	28	(18%)	69	(45%)	0
	50-56 Days (Group 2)	40	28	(70%)		61	14	(23%)	16	(26%)	31	(51%)	0
	57-63 Days (Group 3)	19	12	(63%)		20	4	(20%)	5	(25%)	11	(55%)	0
VOMITING	≤63 Days (All)	204	46	(23%)	0.3365	67	17	(25%)	28	(42%)	22	(33%)	0
1	s49 Days (Group 1)	145	29	(20%)		38	8	(21%)	16	(42%)	14	(37%)	0
	50-56 Days (Group 2)	40	11	(28%)		. 18	5	(28%)	7	(39%)	6	(33%)	0
	57-63 Days (Group 3)	19	6	(32%)		11	4	(36%)	5	(45%)	2	(18%)	0
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	204	4	(2%)	1.0000	4	1	(25%)	1	(25%)	2	(50%)	0
	≤49 Days (Group 1)	145	3	(2%)		3	1	(33%)	1	(33%)	1	(33%)	0
	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
DEHYDRATION	≤63 Days (All)	204	3	(1%)	0.6431	3	1	(33%)	0		2	(67%)	0
	s49 Days (Group 1)	145	2	(1%)		2	1	(50%)	0		1	(50%)	0
	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
HYPOGLYCAEMIA	≤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			į 0	0		0		0		0
	57-63 Days (Group 3)	19	0			• 0	0		0	ţ.	0		0

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

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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.

Center: MISHELL (#1)

	Gestational	Total	Number of Pts	Fisher's	M			••	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event	exact p·value	Number of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL	· · · · · · · · · · · · · · · · · · ·	-							
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	ō
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
1	≤49 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	0	0	0	0
HEART 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		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
TACHYCARDIA	≤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		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
ASCULAR (EXTRACARDIAC) DISORDERS	•								
ANY EVENT	≤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	o l	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.

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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: MISHELL (#1)

	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	Unknow
VASCULAR (EXTRACARDIAC) DISORDERS (cont.)									
FLUSHING	≤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	۰ .	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
	s49 Days (Group 1)	145	2 (1%		2	2 (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	o	0	0
RHINITIS	±63 Days (All)	204	2 (<1%	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	145	2 (1%	1	2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0		0	0	ο,	0 '	0
	57-63 Days (Group 3)	19	o		0	0	۰ ،	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.

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

Center: MISHELL (#1)

	Gestational	Total	Number	Fisher's	M. contracts		Carrani	i #	
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.)									
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
	50-56 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
ANAEMI A	≤63 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
PLATELET, BLEEDING & CLOTTING DISORDERS	•								
ANY EVENT	≰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 1	0 '	0
	50-56 Days (Group 2)	40	o o		0	0	O 4	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.

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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.

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			0	£ 6	
Padri Overban / Priamb (2)	Age	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
Body System/Event [2]	Group [3]	OI PLS	w/Event	p-varue	Of Evenes	71110			
PLATELET, BLEEDING & CLOTTING DISORDER	S (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 (1%)	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%)	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 TRACT INFECTION	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	o	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		n	0	0	0	0
URINE ABNORMAL	≰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%)	O ·	0
	50-56 Days (Group 2)	40	0		. 0	0	0 ,	0	0
	57-63 Days (Group 3)	19	o T		0	0	o 'i	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.

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

Center: MISHELL (#1)

	Gestational	Total	Numi		Fisher's	Number				Severi	tv		
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E		exact p value	of Events	Mi	1d	Mode		Sev	ere	Unknow
EPRODUCTIVE DISORDERS, FEMALE							10	(30%)	۰	(24%)	15	(45%)	0
ANY EVENT	≤63 Days (All)	204	29	(14%)	0.0012	33	10	(31%)		(38%)	5	(31%)	Ö
	≤49 Days (Group 1)	145	14	(10%)		16	5	(50%)	,	(13%)	3		0
	50-56 Days (Group 2)	40	7	(18%)		8	4		1	(11%)		(78%)	0
	57-63 Days (Group 3)	19	8	(42%)		9	1	(11%)	1	(114)	•	(/04/	v
BREAST PAIN FEMALE	≤63 Days (All)	204	2	(<1%)	0.4958	2	1	(50%)	1	(50%)	0		0
BREASI PAIN FEMALE	≤49 Days (Group 1)	145	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
CERVICAL DISPLASIA	≤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
mmounds to 10	≤63 Days (All)	204	3	(1%)	1.0000	3	1	(33%)	1	(33%)	1	(33%)	0
ENDOMETRITIS	≤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
	≤63 Days (All)	204	3	(1%)	1.0000	3	2	(67%)	1	(33%)	0		0
LEUKORRHOEA	\$49 Days (Group 1)	145	3	(2%)	2.2.2	3	2	(67%)	1	(33%)	0		0
	50-56 Days (Group 2)	40	0	()		0	0		0		0		0
	57-63 Days (Group 3)	19	o,			. 0	0		0	l.	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.

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

Center: MISHELL (#1)

	Gestational	Total	Numb		Fisher's			Severi	tv	
Body System/Event [2]	Age Group [3]	Number of Pts	of i		exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)		204	1	(<1%)	0.2892	1	0	1 (100%)	0	0
OVARIAN DISORDER	≤63 Days (All)	204	0	(<1.4)	0.2072	0	0	0	0	0
	≤49 Days (Group 1)	145	1	(3%)		1	Ö	1 (100%)	0	0
	50-56 Days (Group 2)	40	_	(34)		0	0	0	0	0
	57-63 Days (Group 3)	19	0			U	· ·	U	Ū	•
SEXUAL FUNCTION ABNORMAL	≤63 Days (All)	204	1	(<1%)	0.2892	1	1 (100%)	0	0	0
SEXUAL FUNCTION ABNORMAL	s49 Days (Group 1)	145	0	•		0	0	0	0	0
ŀ	50-56 Days (Group 2)	40	1	(3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0	(2,		0	0	0	0	0
							•	1 (7%)	13 (93%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	14	(7%)	0.0004	14	0	1 (20%)	4 (80%)	0
	≤49 Days (Group 1)	145	5	(3%)		5	0		3 (100%)	0
	50-56 Days (Group 2)	40	3	(8%)		3	0	0	6 (100%)	0
	57-63 Days (Group 3)	19	6	(32%)		6	0	0	6 (1004)	U
	≤63 Days (All)	204	8	(4%)	0.0213	8	5 (63%)	2 (25%)	1 (13%)	0
VAGINITIS	≤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
1	≤49 Days (Group 1)	145	3	(2%)		3	1 (33%)	1 (33%)	1 , (33%)	0
	50-56 Days (Group 2)	40	2	(5%)		2	0	2 (100%)	ο.	0
	57-63 Days (Group 3)	19	0			0	0	0 t	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.

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

Center: MISHELL (#1)

	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	Unknow
EOPLASM (cont.)													_
CERVICAL SMEAR TEST POSITIVE	≤63 Days (All)	204	4	(2%)	0.3287	4	0		3	(75%)	1		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			(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		0		0
1	≤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
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 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	(38%)	18	(34%)	0
ABDOMINAL PAIN	≤63 Days (All)	204	195	(96%)	0.2077	527	171	(32%)	206	(39%)	150	(28%)	0
ADDOMINAD TATA	≤49 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	≤63 Days (All)	204	5	(2%)	0.4316	5	1	(20%)	2	(40%)	2	(40%)	0
	≤49 Days (Group 1)	145	3	(2%)		3	1	(33%)	2	(67%)	0		0
	50-56 Days (Group 2)	40	1	(3%)		• 1	0		0	l.	1	(100%)	0
	57-63 Days (Group 3)	19	1	(5%)		1	0		0	ч	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

^[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	Numb of I		Fisher's exact	Number -		Severi	ity	
Body System/Event [2]	Group [3]	of Pts	w/E		p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont.)								5 (221)	•
BACK PAIN	≤63 Days (All)	204	14	(7%)	0.9015	22	7 (32%)	10 (45%)	5 (23%)	0
	≰49 Days (Group 1)	145	11	(8%)		19	6 (32%)	9 (47%)	4 (21%)	0
	50-56 Days (Group 2)	40	2	(5%)		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	(2%)	1.0000	6	3 (50%)	2 (33%)	1 (17%)	0
CHEST PAIN	≤49 Days (Group 1)	145	4	(3%)		5	2 (40%)	2 (40%)	1 (20%)	0
i	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
DAMAGUE	≤63 Days (All)	204	12	(6%)	0.7890	12	9 (75%)	2 (17%)	1 (8%)	0
FATIGUE	≤49 Days (Group 1)	145	10	(7%)		10	7 (70%)	2 (20%)	1 (10%)	0
	50-56 Days (Group 2)	40	2	(5%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	19	0	(2-7		0	0	0	0	0
001100	≤63 Days (All)	204	6	(3%)	1.0000	7	3 (43%)	3 (43%)	1 (14%)	0
FEVER	≤49 Days (Group 1)	145	5	(3%)		6	3 (50%)	2 (33%)	1 (17%)	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
HOT FLUSHES	≰63 Days (All)	204	1	(<1%)	0.2892	1	0	1 (100%)	0	0
HUT FLUSHES	s49 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	1= :/		. 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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^[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	Number		Severi	ity	
Body System/Event [2]	Age Group (3)	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
SODY AS A WHOLE - GENERAL DISORDERS (C	cont.)							•	•
LEG PAIN	≤63 Days (All)	204	2 (<1%		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	0
	57-63 Days (Group 3)	19	0		0	0	0	0	U
MALAISE	≤63 Days (All)	204	1 (<1%	0.0931	1	1 (100%)	0	0	0
PALATOE	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)	1	1 (100%)	0	0	0
	≤63 Days (All)	204	3 (1%) 0.0411	3	1 (33%)	2 (67%)	0	0
PAIN	≤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
:	≤63 Days (All)	204	4 (21) 0.7159	5	3 (60%)	1 (20%)	1 (20%)	0
RIGORS	s49 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
0.11.00.00	≤63 Days (All)	204	4 (21) 1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
SYNCOPE	49 Days (Group 1)	145	3 (21	•	3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	40	1 (31		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0	•	. 0	0	ο,	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.

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

Center: MISHELL (#1)

	Gestational	Total	Numbe		Fisher's	M		Severi	tv	- : - : - : - : - : - :
Body System/Event [2]	Age Group [3]	Number of Pts	of P		exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
2007 07200, 200										
SODY AS A WHOLE - GENERAL DISORDERS (cont.			_			•		1 (100%)	0	0
TEMPERATURE CHANGED SENSATION	≰63 Days (All)	204		(<1%)	1.0000	1	0	1 (100%)	Ö	Ö
	≤49 Days (Group 1)	145		(<1%)		1	0	0	0	0
	50-56 Days (Group 2)	40	0			0	0	0	0	0
	57-63 Days (Group 3)	19	0			0	0	U	U	U
RESISTANCE MECHANISH DISORDERS									_	_
ANY EVENT	≤63 Days (All)	204	5	(2%)	1.0000	5	5 (100%)	0	0	0
1	≤49 Days (Group 1)	145	4	(3%)		4	4 (100%)	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
INFECTION BACTERIAL	≤63 Days (All)	204	1	(<1%)	1.0000	1	1 (100%)	0	o	0
INFECTION BACTERIAL	≤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
THE POST OF THE PARTY OF THE PA	≤63 Days (All)	204	4	(2%)	1.0000	4	4 (100%)	0	0	0
INFECTION VIRAL	≤49 Days (Group 1)	145	3	(2%)		3	3 (100%)	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
SECONDARY TERMS										
ANY EVENT	≤63 Days (All)	204	2	(<1%)	1.0000	2	0	2 (100%)	ο,	0
WHI EAGHI	≤49 Days (Group 1)	145	2	(1%)		2	0	2 (100%)	Ο .	0
	50-56 Days (Group 2)	40	0.	,/		• 0	0	0 h	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.

^[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: 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
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		0	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.

^[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		ber Pts	Fisher's exact	Number				Sever	i rv			. .
Body System/Event [2]	Group (3)	of Pts		vent	p.value	of Events	Mi	1d	Mode	rate	•	ere	Unk	tnown
ANY EVENT	s63 Days (All)	238	237	(>99%)	1.0000	1899	655	(34%)	737	(391)	506	(27%)	1	(<1%
	≤49 Days (Group 1)	81		(100%)		598	226	(38%)	230	(38%)	141	(24%)	1	(<1%
	50-56 Days (Group 2)	89		(99%)		694	251	(36%)	250	(36%)	193	(28%)	0	
	57-63 Days (Group 3)	68		(100%)		607	178	(29%)	257	(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	
	≤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		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	
	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	
RASH	≤63 Days (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	81	0	•		0	0		0		0	1	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	

^[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.

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

Center: HASKELL (#2)

	Gestational	Total	Number of Pts	Fisher's exact	Number		Sever:	itv	
Body System/Event [2]	Age Group (3)	Number of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
SKIN AND APPENDAGES DISORDERS (cont.)									
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	s49 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	0	1 (100%)	0
MUSCULO-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
						1			
ARTHRALGI A	≤63 Days (All)	238	3 (1%)	0.1954	3	1 (33%)	1 (33%)	1 (33%)	0
Attinoisotti	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	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
	≤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	o ·		0	0	o t	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)

	Gestational	Total	Num		Fisher's	No make a se				Severi	+ 1		
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p-value	Number of Events	Mi		Mode		Sev	ere	Unknow
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)													
SKELETAL PAIN	≤63 Days (All)	238	1	(<1%)	0.2857	1	0		1	(100%)	0		0
	≤4'9 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%)	O
	s49 Days (Group 1)	81	33	(41%)	,	53	18	(34%)	31	(58%)	4	(8%)	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	≤63 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	≤63 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
	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%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0		0
	50-56 Days (Group 2)	89	2	(2%)		. 3	1	(33%)	2	(67%)	0		0
	57-63 Days (Group 3)	68	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.

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	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)								
MIGRAINE	≰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
TREMOR	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	2 (100%)	0	0
1	≰49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	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		0	0	0	0	0
EAR ACHE	≤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
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
	50-56 Days (Group 2)	89	1 (1%)		. 1	0	0 1	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	o '	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.

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

Center: HASKELL (#2)

	Gestational	Total	Number		Fisher's	Maria de la com		Severi	***	
n 1 n 1 n 1 n 1 n 1 n 1 n 1 n 1 n 1 n 1	Age Group [3]	Number of Pts	of Pts w/Even		exact p value	Number - of Events	Mild	Moderate	Severe	Unknown
Body System/Event [2]	Group [3]		w/Even		p varue	Or Evenes				
PECIAL SENSES OTHER, 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	O
	50-56 Days (Group 2)	89	0			0	0	0	0	0
	57-63 Days (Group 3)	68	0			0	0	0	0	0
TASTE PERVERSION	≤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	O
SYCHIATRIC DISORDERS										
ANY EVENT	s63 Days (All)	238	16 (7%)	0.4621	21	5 (24%)	10 (48%)	6 (29%)	0
	≤49 Days (Group 1)	81	4 (5%)		7	0	3 (43%)	4 (57%)	0
	50-56 Days (Group 2)	89	5 (6%)		7	2 (29%)	4 (57%)	1 (14%)	0
	57-63 Days (Group 3)	68	7 (1	0%)		7	3 (43%)	3 (43%)	1 (14%)	0
ANOREXIA	≤63 Days (All)	238	2 (<	11)	1.0000	2	0	1 (50%)	1 (50%)	o
RIVIDATA	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	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
ANXIETY	≤63 Days (All)	238	3 (1%)	0.2868	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0			0	0	0	Ο,	O
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	٥ ,	O ·	0
	57-63 Days (Group 3)	68	2	3%)		• 2	0	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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^[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: HASKELL (#2)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severi	i rv	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
SYCHIATRIC 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	≤49 Days (Group 1)	81	1 (1%		1	0	0	1 (100%)	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
EMOTIONAL LABILITY	≤63 Days (All)	238	6 (3%	0.5880	6	1 (17%)	4 (67%)	1 (17%)	0
	≤49 Days (Group 1)	81	3 (4%		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	89	1 (1%		1	0	1 (100%)	0	0
	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%	ı	1	1 (100%)	0	0	0
INSOMNIA	≤63 Days (All)	238	6 (3%	1.0000	7	2 (29%)	2 (29%)	3 (43%)	0
**************************************	s49 Days (Group 1)	81	2 (2%	+	2	0	0	2 (100%)	0
	50-56 Days (Group 2)	89	2 (2%	1	3	1 (33%)	2 (67%)	0)	0
	57-63 Days (Group 3)	68	2 (3%)	• 2	1 (50%)	٥١	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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^[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: HASKELL (#2)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Sever	ity		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknowr
ASTRO-INTESTINAL SYSTEM DISORDERS													_
ANY EVENT	≤63 Days (All)	238	178	(75%)	0.0688	503	201	(40%)	192	(38%)	110	(22%)	0
	≤49 Days (Group 1)	81	53	(65%)		134	59	(44%)	46	(34%)	29	(22%)	0
	50-56 Days (Group 2)	89	71	(80%)		217	95	(44%)	78	(36%)	44	(20%)	0
	57-63 Days (Group 3)	68	54	(79%)		152	47	(31%)	68	(45%)	37	(24%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	6	(3%)	1.0000	7	1	(14%)	4	(57%)	2	(29%)	0
1	≤49 Days (Group 1)	81	2	(2%)		2	0		0		2	(100%)	0
'	50-56 Days (Group 2)	89	2	(2%)		. 2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	68	2	(3%)		3	0		3	(100%)	0		0
CONSTIPATION	≤63 Days (All)	238	2	(<1%)	0.0808	2	0		1	(50%)	1	(50%)	0
CONSTITUTION	≤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	2	(3%)		2	0		1	(50%)	1	(50%)	0
DIARRHEA	≤63 Days (All)	238	61	(26%)	0.6832	80	44	(55%)	28	(35%)	8	(10%)	0
DIRKHIDA	≤49 Days (Group 1)	81	22	(27%)		25	16	(64%)	6	(24%)	3	(12%)	0
	50-56 Days (Group 2)	89	20	(22%)		32	18	(56%)	13	(41%)	1	(3%)	0
	57-63 Days (Group 3)	68	19	(28%)		23	10	(43%)	9	(39%)	4	(17%)	0
DYSPEPSIA	≤63 Days (All)	238	10	(4%)	0.4327	13	6	(46%)	6	(46%)	1	(8%)	0
	s49 Days (Group 1)	81	4	(5%)		4	2	(50%)	2	(50%)	0		0
	50-56 Days (Group 2)	89	5	(6%)		8	4	(50%)	3	(38%)	1	. (13%)	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)

	Gestational	Total	Numl of	-	Fisher's exact	Number			Severi	tv		
Body System/Event [2]	Age Group [3]	Number of Pts	-	vent	p-value	of Events	Mild		rate	Sev	ere	Unknow
ASTRO-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%)	o		0		0
1	≤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	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
	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
	50-56 Days (Group 2)	89	1	(1%)		1	0	1	(100%)	0 -		0
	57-63 Days (Group 3)	68	0,			. 0	0	0	Į,	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.

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

Center: HASKELL (#2)

	Gestational	Total Number	Num of		Fisher's exact	Number				Severi	tv		.
Body System/Event [2]	Age Group [3]	of Pts		vent	p-value	of Events	Mi			rate		ere	Unknown
MASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
VOMITING	≤63 Days (All)	238	85	(36%)	0.1411	123	42	(34%)	54	(44%)	27	(22%)	0
	≤49 Days (Group 1)	81	22	(27%)		30	12	(40%)	13	(43%)	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	(55%)	8	(20%)	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	(2%)		2	1	(50%)	0		1	(50%)	0
	50-56 Days (Group 2)	89	0			0	0		0		0		0
	57-63 Days (Group 3)	68	1	(1%)		2	0		2	(100%)	0		0
DEHYDRATION	≤63 Days (All)	238	1	(<1%)	0.6261	1	0		0		1	(100%)	0
	£49 Days (Group 1)	81	1	(1%)		1	0		0		1	(100%)	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
THIRST	≤63 Days (All)	238	1	(<1%)	0.6261	1	1	(100%)	0		0		0
IIIIKO I	s49 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
WEIGHT DECREASE	≤63 Days (All)	238	1	(<1%)	0.2857	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	81	0			0	0		0		0	1	0
	50-56 Days (Group 2)	89	0			; o	0		0	1	0		0
	57-63 Days (Group 3)	68	1	(1%)		2	0		2	(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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^[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: HASKELL (#2)

	Gestational	Total	Number	Fisher's	AT		·Sever:	i to a	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknow
CARDIOVASCULAR 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	0
	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%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
BEART 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	≤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
RESPIRATORY SYSTEM DISORDERS	1								
ANY EVENT	≤63 Days (All)	238	18 (8%	0.1493	30	14 (47%)	12 (40%)	4, (13%)	0
	≰49 Days (Group 1)	81	10 (12%)	17	10 (59%)	5 (29%)	2 (12%)	0
	50-56 Days (Group 2)	8 9	4 (4%)	7	3 (43%)	3 1 (43%)	1 (14%)	0
	57-63 Days (Group 3)	68	4 (6%)	6	1 (17%)	4 (67%)	1 (17%)	0

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

^[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 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	Unknow
RESPIRATORY SYSTEM DISORDERS (cont.)									_
COUGHING	≤63 Days (All)	238	3 (1%)	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	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	238	1 (<1%)	1.0000	2	2 (100%)	0	0	0
1	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		2	2 (100%)	0	0	0
	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
INDIOF 11010	≤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
1.1211.11101.110	≤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
	57-63 Days (Group 3)	68	0		, o	0	0	0	0
PLEURAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	249 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	O .	0
	57-63 Days (Group 3)	68	1 (14)		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.

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

Center: HASKELL (#2)

	Gestational	Total	Number	Fisher's	M		0-		
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>			· · · · · · · · · · · · · · · · · · ·				
PULMONARY CONGESTION	≤63 Days (All)	238	2 (<1%)	0.1957	2	2 (100%)	0	0	0
	s49 Days (Group 1)	81	2 (2%)		2	2 (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
RHINITIS	≤63 Days (All)	238	5 (2%)	0.3257	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	81	3 (4%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	238	7 (3%)	0.0673	9	3 (33%)	4 (44%)	2 (22%)	0
	≰49 Days (Group 1)	81	4 (5%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	3 (4%)		5	1 (20%)	3 (60%)	1 (20%)	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
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	0 '	0
	50-56 Days (Group 2)	89	2 (2%)		• 2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	ο "	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)

	Gestational	Total	Number	Fisher's exact	Number -		Severi	i tv	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
THITE 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
	≤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	o	0
LATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	£63 Days (All)	238	2 (<1%)	0.7444	2	1 (50%)	1 (50%)	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	1 (1%)		1	0	1 (100%)	0	0
EPISTAXIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	o	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	0	0	0
PURPURA	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	81	0		0	0	0	Ο,	0
	50-56 Days (Group 2)	89	0		: 0	0	ο .	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.

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		Sever:	ity	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknowr
JRINARY SYSTEM DISORDERS									
ANY EVENT	≰63 Days (All)	238	3 (1		3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	81	2 (2		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1	1)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MICTURITION FREQUENCY	≤63 Days (All)	238	1 (<1	0.6261	1	1 (100%)	0	0	0
1	≤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
URINARY TRACT INFECTION	≤63 Days (All)	238	2 (<1	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1	;)	1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1	1)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
EPRODUCTIVE DISORDERS, FEMALE						1			
ANY EVENT	≤63 Days (All)	238	81 (34	0.6484	101	16 (16%)	33 (33%)	52 (51%)	0
	≤49 Days (Group 1)	81	25 (31	1)	32	3 (9%)	15 (47%)	14 (44%)	0
	50-56 Days (Group 2)	89	30 (34	:)	34	10 (29%)	6 (18%)	18 (53%)	0
	57-63 Days (Group 3)	68	26 (38	1)	35	3 (9%)	12 (34%)	20 (57%)	0
CERVICITIS	≟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	٥,	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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^[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: HASKELL (#2)

	Gestational	Total Number	Number of Pts		Fisher's exact	Number -		Seve	ritv	
Body System/Event [2]	Age Group [3]	of Pts	w/Even		p-value		Mild	Moderate	Severe	Unknow
EPRODUCTIVE DISORDERS, PENALE (cont.)										
LEUKORRHOEA	≤63 Days (All)	238	3 (11)	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 (21)		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 (<	11)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0			0	0	0	0	0
ı	50-56 Days (Group 2)	89	0			0	0	0	0	0
	57-63 Days (Group 3)	68	1 (11)	•	1	1 (100%)	0	0	0
OVARIAN DISORDER	≤63 Days (All)	238	1 (<	11)	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 (14)		1	0	1 (100%)	0	0
UTERINE DISORDER NOS	≤63 Days (All)	238	2 (<	11)	0.5298	2	0	2 (100%)	o	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0			0	0	0	ο,	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.

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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 exact	Number				Cavar	itv			
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events		.1d		rate		ere		cnown
REPRODUCTIVE DISORDERS, FEMALE (cont.)				· · ·									
UTERINE HAEMORRHAGE	≤63 Days (All)	238	54 (23%)	0.8212	63	2	(3%)	9	(14%)	52	(83%)	0	
	≤49 Days (Group 1)	81	17 (21%)		20	1	(5%)	5	(25%)	14	(70%)	0	
	50-56 Days (Group 2)	89	20 (22%)		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	s49 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	
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	≤63 Days (All)	238	237 (>99%)	1.0000	1024	356	(35%)	370	(36%)	297	(29%)	1	(<14
	≤49 Days (Group 1)	81	81 (100%)		336	131	(39%)	122	(36%)	82	(24%)	1	(<11
!	50-56 Days (Group 2)	89	88 (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 (99%)		301	115	(38%)	111	(37%)	74	(25%)	1	(<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 (2%)	0.0354	6	1	(17%)	5	(83%)	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	t	0		0	
	57-63 Days (Group 3)	68	4 (6%)		5	0		5	(100%)	0		0	

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

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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.

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

Center: HASKELL (#2)

	Gestational	Total	Numbe:		Fisher's	Number				Severi	tv		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt: w/Eve		exact p value	of Events	Mi			rate	•	ere	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)												
ASTHENIA	≤63 Days (All)	238	2 (<1%)	1.0000	2	1	(50%)	1	(50%)	0		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	≤63 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
ı	50-56 Days (Group 2)	89		(8%)		7	1	(14%)	5	(71%)	1	(14%)	0
	57-63 Days (Group 3)	68	4	(6%)	•	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	(#0%)	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
	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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^[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: HASKELL (#2)

	Gestational	Total	Numbe		Fisher's			Severi	F.v.	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pi		exact p-value	Number - of Events	Mild	Moderate	Severe	Unknow
DDY AS A WHOLE - GENERAL DISORDERS (CO	ont.)		1							
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
	10 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
HIPOVOLINEPIN	≤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
LEG PAIN	≤63 Days (All)	238	4	(2%)	1.0000	5	1 (20%)	2 (40%)	2 (40%)	0
LEG PAIN	≤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
	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
PADAISE	≤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
ODDMEN	≤49 Days (Group 1)	81	0			0	0	0	0	0
	50-56 Days (Group 2)	89	0			Ø	0	0	0 '	0
	57-63 Days (Group 3)	68	2	(3%)		. 2	0	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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^[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	Numb of F		Fisher's exact	Number -				Severi	t V		
Body System/Event [2]	Group [3]	of Pts	w/Ev		p·value	of Events		ld		rate	•	ere	Unknow
SODY AS A WHOLE - 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	(3%)		3	1	(33%)	0		2	(67%)	0
RIGORS	≤63 Days (All)	238	7	(3%)	0.2989	7	1	(14%)	4	(57%)	2	(29%)	0
. 1	≤49 Days (Group 1)	81	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (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	(3%)		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	(6%)		5	0		5	(100%)	0		0
HERPES SIMPLEX	≰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	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

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^[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: HASKELL (#2)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number -			 -	Severi	.tv	<i></i>	
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events	Mild			rate	Sev	ere	Unknow
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	(1%)		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	0		5	(100%)	0		0
	50-56 Days (Group 2)	89	3	(3%)	•	3	1	(33%)	2	(67%)	0		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		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
	≤49 Days (Group 1)	81	1	(1%)		2	0		1	(50%)	1	(50%)	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
POST-OPERATIVE PAIN	≤63 Days (All)	238	1	(<1%)	0.6261	1	0		0			(100%)	0
	≤49 Days (Group 1)	81	1	(1%)		, 1	0		0		1	(100%)	0
	50-56 Days (Group 2)	89	0.			• 0	0		0	L	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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^[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	Total Number	Num of		Fisher's exact	Number				Sever	itv			
Body System/Event [2]	Age Group [3]	of Pts		vent	p-value	of Events	Mi			rate	-	ere	Unk	nown
ANY EVENT	≤63 Days (All)	164	164	(100%)		1326	428	(32%)	517	(39%)	372	(28%)	9	(<1%
ANI EVENI	≤49 Days (Group 1)	65		(100%)		482	163	(34%)	196	(41%)	118	(24%)	5	(1%
	50-56 Days (Group 2)	65		(100%)		527	171	(32%)	200	(38%)	154	(29%)	2	
	57-63 Days (Group 3)	34		(100%)		317	94	(30%)	121	(38%)	100	(321)	2	(<1%
KIN AND APPENDAGES DISORDERS														
ANY EVENT	≰63 Days (All)	164	5	(3%)	0.8418	7	3	(43%)	2	(29%)		(29%)	0	
,	≤49 Days (Group 1)	65	1	(2%)	,	1	0		0			(100%)	0	
	50-56 Days (Group 2)	65	3	(5%)		5	3	(60%)	2	(40%)	0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		0		1	(100%)	0	
RASH MACULO-PAPULAR	≤63 Days (All)	164	1	(<1%)	1.0000	2	1	(50%)	1	(50%)	0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(2%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
SWEATING INCREASED	≤63 Days (All)	164	4	(2%)	1.0000	4	1	(25%)	1	(25%)	2		0	
	≤49 Days (Group 1)	65	1	(2%)		1	0		0		1	(100%)	0	
	50 56 Days (Group 2)	65	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	34	1	(3%)		1	0		0		1	(100%)	0	
VERRUCA	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(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	0.			• 0	0		0	ę.	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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^[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 P		Fisher's exact	Number -				Severi	ty			
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unkn	nown
USCULO-SKELETAL SYSTEM DISORDERS					-									
ANY EVENT	≰63 Days (All)	164	7	(4%)	1.0000	10	3	(30%)	5			(20%)	0	
	≤49 Days (Group 1)	65	3	(5%)		5	3	(60%)	1	(20%)	1	•	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	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
ACTIONSOLA	≤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	
MINDGIA	≤49 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	0		3	(100%)	0		О	
SKEDEIRD FAIR	≤49 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		4	(
	≤49 Days (Group 1)	65	33	(51%)		46	17	(37%)	22	(48%)	5	(11%)	2	(
	50-56 Days (Group 2)	65	29	(45%)		41	15	(37%)	15	(37%)	11	(27%)	0	
	57-63 Days (Group 3)	34	17	(50%)		29	5	(17%)	17	(59%)	5	(17%)	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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^[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	Num of		Fisher's exact	Number				Severi	ty			
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	1 d	Mode	rate	Sev	ere	Unki	nown
CENTR & PERIPH NERVOUS SYSTEM DISCH	RDERS (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%)
T.	≤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	(41%)		17	4	(24%)	9	(53%)	3	(18%)	1	(6%)
HYPOAESTHESIA	. ≤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	
MIGRAINE	≤63 Days (All)	164	1	(<1%)	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	(<1%)	0.2073	1	0		1	(100%)	0		0	
	<pre>s49 Days (Group 1)</pre>	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	

^[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.

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

Center: POPPEMA (#3)

	Gestational	Total	Number	Fisher's	Mumber		Severi	tv	
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	ORDERS (cont.)								
NEURALGIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	6 5	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
t Aldred Tilboth	≤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	0	1 (100
STUPOR	≤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	0	1 (100
TR THOS	≤63 Days (All)	164	2 (1%)	0.3532	2	0	1 (50%)	1 (50%)	0
TREMOR	≤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
ISION DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
FM14 MTWITA	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0 ,	0
	50-56 Days (Group 2)	65	0		, o	0	0 1	0 .	0
	57-63 Days (Group 3)	34	0		0	0	0 4	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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^[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			0		
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	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
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 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	0
	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	0
	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
	50-56 Days (Group 2)	65	1 (2%	1	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	2 (100%)	O ·	0
	50-56 Days (Group 2)	65	2 (3%)	. 2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	o "	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: POPPEMA (#3)

	Gestational	Total	Num		Fisher's					S			
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p value	Number of Events		.1d		Sever	•	ere	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%)	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
ASTRO-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	(33%)	2	(17%)	0
	s49 Days (Group 1)	65	2	(3%)		3	1	(33%)	2	(67%)	0		0
	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	≤63 Days (All)	164	3	(2%)	0.8010	4	2	(50%)	1	(25%)	1	(25%)	0
	≤49 Days (Group 1)	65	2	(3%)		3	2	(67%)	0		1	(33%)	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	u.	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.

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

Center: POPPEMA (#3)

	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p·value	of Events	Mi	.1d	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
DIARRHEA	≤63 Days (All)	164	37	(23%)	0.9129	44	15	(34%)	23		6	(14%)	0
	≤49 Days (Group 1)	65	14	(22%)		18	6	(33%)	10	(56%)	2	(11%)	0
	50-56 Days (Group 2)	65	16	(25%)		17	7	(41%)	7	,	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
I	≤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
	≤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			Э	0		0		0		0
NAUSEA	≤63 Days (All)	164	120	(73%)	0.1269	221	73	(33%)	76	(34%)	72	(33%)	0
	≰49 Days (Group 1)	65	42	(65%)		73	25	(34%)	30		18	(25%)	0
	50-56 Days (Group 2)	65	50	(77%)		90	27	(30%)	31	(34%)	32	(36%)	0
	57-63 Days (Group 3)	34	28	(82%)		. 58	21	(36%)	15	(26%)	22	(38%)	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.

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 -		····Sever	4 * 4	
Body System/Event [2]	Age Group [3]	of Pts	w/Ever		p-value	of Events	Mild	Moderate	Severe	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)										
TOOTH ACHE	≤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
VOMITING	≤63 Days (All)	164	61 (3	37%)	0.0147	81	9 (11%)	38 (47%)	34 (42%)	0
•	≤49 Days (Group 1)	65	17 (2	26%)		20	2 (10%)	11 (55%)	7 (35%)	0
	50-56 Days (Group 2)	65	25 (3	38%)		34	3 (9%)	16 (47%)	15 (44%)	0
	57-63 Days (Group 3)	34	19 (56%)		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	(2%)		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 (<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
THIRST	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0			0	0	0	O :	0
	50-56 Days (Group 2)	65	1	(2%)		. 1	0	1 (100%)	0 "	0
	57-63 Days (Group 3)	34	0			0	0	o ⁽	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.

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

Center: POPPEMA (#3)

	Gestational	Total	Number	Fisher's	Number		Severi		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
CARDIOVASCULAR 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	O .
	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
ı	≰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
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
HEART 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)	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	o i	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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^[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	Number of Pts	Fisher's exact		- 	Sever	ity	· • • • ·
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)	164	8 (5%		12	4 (33%)	6 (50%)	2 (17%)	0
	≰49 Days (Group 1)	65	3 (5%		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	65	4 (6%		8	2 (25%)	5 (63%)	1 (13%)	0
	57-63 Days (Group 3)	34	1 (3%)	1	1 (100%)	0	0	0
COUGHING	≤63 Days (All)	164	2 (1%	0.3532	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
'	50-56 Days (Group 2)	65	2 (3	}	. 5	2 (401)	2 (40%)	1 (20%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	164	2 (1) 1.0000	2	0	1 (50%)	1 (50%)	0
FIRMINGTALD	≤49 Days (Group 1)	65	1 (2%)	1	0	0	1 (100%)	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
PULMONARY CONGESTION	≤63 Days (All)	164	1 (<1%) 1.0000	1	0	1 (100%)	0	0
to Lational Consideration	≤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
SINUSITIS	≤63 Days (All)	164	4 (2%) 1.0000	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	65	2 (31)	2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	1 (21)	1	0	1 (100%)	Ο,	0
	57-63 Days (Group 3)	34	1 (31)	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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^[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	Total	Number	Fisher's			Sever:	i + v	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe	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	0
	50-56 Days (Group 2)	65	2 (3	;)	2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	3 (9	·)	4	1 (25%)	3 (75%)	0	0
ANAEMIA	≤63 Days (All)	164	6 (4	0.2081	7	3 (43%)	4 (57%)	0	0
l l	≤49 Days (Group 1)	65	1 (2	;)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	2 (3	:)	, 2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	3 (9	1)	4	1 (25%)	3 (75%)	0	0
WHITE CELL AND RES DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1	1.0000	1	0	0	0	1 (100%
	≰49 Days (Group 1)	65	1 (2	;)	1	0	0	0	1 (100%
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
LYMPHADENOPATHY	≤63 Days (All)	164	1 (<1	1.0000	1	0	0	0	1 (100%
	≤49 Days (Group 1)	65	1 (2	i)	1	0	0	0	1 (100%
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PLATELET, BLEEDING & CLOTTING DISORDERS	•								
ANY EVENT	≤63 Days (All)	164	1 (<1	0.2073	, 1	0	0	1 (100%)	0
	≰49 Days (Group 1)	65	0 .		+ 0	0	ه ړ	0	0
	50-56 Days (Group 2)	65	0		0	0	0 "	0	0
	57-63 Days (Group 3)	34	1 (3	k)	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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^[2] NOS = Not otherwise specified

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^[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	Total	Numb		Fisher's	M — b. o. —		Sever:	i F.V	
Body System/Event [2]	Age Group [3]	Number of Pts	of I		exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
LATELET, BLEEDING & CLOTTING DISORDERS	(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	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
JRINARY SYSTEM DISORDERS										
ANY EVENT	≤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
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	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	O
REPRODUCTIVE 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 (19%)	0
	57-63 Days (Group 3)	34	8	(24%)		14	4 (29%)	8 (57%)	2 (14%)	0
BREAST ENGORGEMENT	≤63 Days (All)	164	1	(<1%)	0.2073	1	1 (100%)	0	0 .	0
	≤49 Days (Group 1)	65	0			0	0	0 1	0	0
	50-56 Days (Group 2)	65	0			0	0	0 "	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.

^[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 Fatients)

Center: POPPEMA (#3)

	Gestational	Total	Numb		Fisher's	Number -				Severi	ty	
Body System/Event [2]	Age Group [3]	Number of Pts	of E		exact p value	of Events	Mi			rate	Severe	Unknow
EPRODUCTIVE DISORDERS, FEMALE (cont.)												_
BREAST ENLARGEMENT	≤63 Days (All)	164	1	(<1%)	0.2073	1	0			(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	(1%)	0.3532	4	2	(50%)	1	(25%)	1 (25%)	0
DADAGE FALL FOR THE PROPERTY OF THE PROPERTY O	≤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
ENDONETRITIO	s49 Days (Group 1)	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	s63 Days (All)	164	14	(9%)	0.3440	14	8	(57%)	6	(43%)	0	0
LEGRORRIGEA	≤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	(3%)		1	0		1	(100%)	0	0
OVARIAN DISORDER	s63 Days (All)	164	2	(1%)	0.3532	2	1	(50%)	1	(50%)	0	0
Attacks Asserted	≤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			, 0	0		0	Ł	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.

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

Center: POPPEMA (#3)

	Gestational	Total	Number of Pts	Fisher's exact	Number		Severi	i tv	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)					_	. (504)	1 (50%)	0	0
SALPINGITIS	≤63 Days (All)	164	2 (1%)	0.3532	2	1 (50%) 1 (50%)	1 (50%) 1 (50%)	0	0
	≰49 Days (Group 1)	65	2 (3%)		2		0	0	0
	50-56 Days (Group 2)	65	0		U .	0	0	0	n
	57-63 Days (Group 3)	34	0		0	0	U	Ū	•
process NOS	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
UTERINE DISORDER NOS	\$49 Days (Group 1)	65	0		0	0	0	0	0
F	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
		144	15 (9%)	0.2023	16	1 (6%)	7 (44%)	8 (50%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	164			3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	65	3 (5%)		7	0	2 (29%)	5 (71%)	0
	50-56 Days (Group 2)	65	7 (11%)		6	1 (17%)	3 (50%)	2 (33%)	0
i i	57-63 Days (Group 3)	34	5 (15%)		6	1 (1747	3 (302)	- ,	
VAGINAL DISCOMFORT	≤63 Days (All)	164	2 (1%)	0.3532	4	1 (25%)	3 (75%)	0	0
VAGINAD DISCOMORI	≤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
	57-63 Days (Group 3)	34	0		0	0	0	0	0
	≤63 Days (All)	164	7 (4%	1.0000	8	2 (25%)	6 (75%)	0	0
VAGINITIS	≤63 Days (All)	65	3 (5%		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	65	3 (5%		4	1 (25%)	3 (75%)	O ,	0
	57-63 Days (Group 3)	34	1 (3%		1	1 (100%)	0 ,	0 .	0
	21-63 Days (Group 3)	24	1 (50		• -		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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^[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	Total	Numb of F		Fisher's exact	Number				Sever	itv	 .		
Body System/Event [2]	Age Group [3]	Number of Pts	w/EV		p-value	of Events	Mi		Mode		Sev	ere	Unk	nown
Boplasm				• • •							•			
ANY EVENT	≤63 Days (All)	164	1	(<1%)	1.0000	1		(100%)	0		0		0	
	≤49 Days (Group 1)	65	0			0	0		0		0		0	
	50-56 Days (Group 2)	65	1	(2%)		1	_	(100%)	0		0		0	
	57-63 Days (Group 3)	34	0			0	0		0		0		0	
OVARIAN CYST	≤63 Days (All)	164	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
OVARIAN CISI	≤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	0			0	0		0		0		0	
ODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	164	162	(99%)	1.0000	702	237	(34%)	243	(35%)	218	(31%)	4	
1212 211211	≤49 Days (Group 1)	65	64	(98%)		268	91	(34%)	96	(36%)	79	(29%)	2	(<11
	50-56 Days (Group 2)	65	64	(98%)		278	96	(35%)	94	(34%)	86	(31%)	2	(<1
	57-63 Days (Group 3)	34	34	(100%)		156	50	(32%)	53	(34%)	53	(34%)	0	
ABDOMINAL PAIN	≤63 Days (All)	164	162	(99%)	1.0000	571	202	(35%)	183	(32%)	183	(32%)	3	
ABDOMINAD SAIN	≤49 Days (Group 1)	65	64	(98%)		218	74	(34%)	77	(35%)	66	(30%)	1	(<1
	50-56 Days (Group 2)	65	64	(98%)		230	81	(35%)	72	(31%)	75	(33%)	2	(<1
	57-63 Days (Group 3)	34	34	(100%)		123	47	(38%)	34	(28%)	42	(34%)	0	
ALLERGY	≤63 Days (All)	164	2	(1%)	1.0000	2	0		1	, ,	1		0	
(the section of	≤49 Days (Group 1)	65	1	(2%)		. 1	0		1	(100 %)	0		0	
	50-56 Days (Group 2)	65	1	(2%)		• 1	0		0	l	1	(100%)	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

^[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	Numl of		Fisher's exact	Number -	-			Severi	tv			
Body System/Event [2]	Age Group [3]	of Pts		vent	p-value	of Events	Mi	ld	Mode		Sev	ere	Unk	nown
ODY AS A WHOLE - GENERAL DISORDERS (C	ont.)								_	()	_	(505)	•	
ASTHENIA	≤63 Days (All)	164	9	(5%)	0.1575	12	2		3	(25%)	7	(58%)	0	
	≤49 Days (Group 1)	65	5	(8%)		8	1	,	2	(25%)	5	(63%)	0	
	50-56 Days (Group 2)	65	1	(2%)		1		(100%)	0		0	/c=+\	0	
	57-63 Days (Group 3)	34	3	(9%)		3	0		1	(33%)	2	(67%)	0	
BACK PAIN	≤63 Days (All)	164	20	(12%)	0.2630	26	7	(27%)	13	(50%)	5	(19%)	1	(4%
BACK PAIN	£49 Days (Group 1)	65	5	(8%)		7	2	(29%)	2	(29%)	2	(29%)	1	(14%
ı	50-56 Days (Group 2)	65	11	(17%)		14	5	(36%)	8	(57%)	1	(7%)	0	
	57-63 Days (Group 3)	34	4	(12%)		5	0		3	(60%)	2	(40%)	0	
	≤63 Days (All)	164	26	(16%)	0.5747	33	9	(27%)	15	(45%)	9	(27%)	0	
FATIGUE	≤49 Days (Group 1)	65	13	(20%)		16	6	(38%)	8	(50%)	2	(13%)	0	
	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		4	(50%)	4	(50%)	0	
	≤63 Days (All)	164	12	(7%)	0.4021	15	5	(33%)	7	(47%)	3	(20%)	0	
FEVER	≤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	
	≤63 Days (All)	164	6	(4%)	0.5732	6	1	(17%)	3	(50%)	2	(33%)	0	
HOT FLUSHES	≤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	(6%)		· 2	0		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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^[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	Total Number	Numb of P		Fisher's exact	Number -		Severi	tv	
Body System/Event [2]	Age Group [3]	of Pts	w/Ev		p-value	of Events	Mild	Moderate	Severe	Unknow
DDY AS A WHOLE - GENERAL DISORDERS (cont.)									
LEG PAIN	≤63 Days (All)	164	3	(2%)	0.1093	3	0	3 (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	2	(6%)		2	0	2 (100%)	0	0
MALAISE	≤63 Days (All)	164	1	(<1%)	1.0000	1	0	1 (100%)	0	0
1	≤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
VID 5. 2.	≤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
ENTIN	≤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%)	B (53%)	3 (20%)	0
	≤49 Days (Group 1)	65	4	(6%)		4	2 (50%)	2 (50%)	ο ,	0
	50-56 Days (Group 2)	65	7	(11%)		. 7	1 (14%)	4 (57%)	2 (29%)	0
	57-63 Days (Group 3)	34	4	(12%)		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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^[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 Sa (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POPPEMA (#3)

	Gestational	Total	Numbe		Fisher's					Cavari	+		
Body System/Event [2]	Age Group [3]	Number of Pts	of P		exact p-value	Number - of Events	Mild		Moder		Severe		Unknowr
ODY AS A WHOLE - GENERAL DISORDERS (cont.			~~~		······································								
SYNCOPE CONTRACTOR OF THE SYNCOPE	s63 Days (All)	164	5	(3%)	0.1536	5	1 (20%)	1	(20%)	3 (6)	0%)	0
SINCOPE	≤49 Days (Group 1)	65	0			0	0		0		0		0
	50-56 Days (Group 2)	65	3	(5%)		3	1 (33%)	0		2 (6	71)	0
	57-63 Days (Group 3)	34	2	(6%)		2	0		1	(50%)	1 (5	0%)	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	164	2	(1%)	1.0000	2	1 ((50%)	0		1 (5	0%)	0
TEMPERATURE CIRENCES SERVICES	≤49 Days (Group 1)	65	1	(2%)		1	0		0		1 (10	0%)	0
ı	50-56 Days (Group 2)	65	1	(2%)		1	1 (1	.00%)	0		0		0
	57-63 Days (Group 3)	34	0		•	0	0		0		0		0
APPLICATION SITE DISORDERS [4]													
ANY EVENT	≤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
INJECTION SITE PAIN	≤63 Days (All)	164	1	(<1%)	0.2073	1	Ó		1 (100%)	0		0
1102011011 01111	≰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
RESISTANCE MECHANISM DISORDERS													_
ANY EVENT	≰63 Days (All)	164	11	(7%)	0.5200	13		(38%)		(62%)	0		0
	≤49 Days (Group 1)	65	6	(9%)		6		(33%)		(67%)	0		0
	50-56 Days (Group 2)	65	4 '	(6%)		· 6		(50%)		(50%)	0		0
	57-63 Days (Group 3)	34	1	(3%)		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

^[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	Number of Pts	Fisher's exact	Number		Severi	ty	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ESISTANCE MECHANISM 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	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
INFECTION FUNGAL	≤63 Days (All)	164	3 (2%)	0.8010	3	1 (33%)	2 (67%)	0	0
INFECTION FUNGAL	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
THE PROPERTY OF THE PARTY OF TH	≤63 Days (All)	164	9 (5%)	0.8246	9	4 (44%)	5 (56%)	0	0
INFECTION VIRAL	≤49 Days (Group 1)	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	1 (3%)		1	0 -	1 (100%)	0	0

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

í.

^[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	Numbe of Pt		Fisher'-	Number			- 	Sever	ity		
Body System/Event [2]	Group (3)	of Pts	w/Eve	nt	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknow
ANY EVENT	≤63 Days (All)	102	102 (1	00%)		673	267	(40%)	273	(41%)	133	(20%)	0
	≤49 Days (Group 1)	68	68 (1	00%)		465	191	(41%)	187	(40%)	87	(19%)	0
	50-56 Days (Group 2)	25	25 (1	00%)		171	64	(37%)	73	(43%)	34	(20%)	0
	57-63 Days (Group 3)	9	9 (1	00%)		37	12	(32%)	13	(35%)	12	(32%)	0
KIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	102	4	(4%)	1.0000	4	0			(100%)	0		0
· ·	≤49 Days (Group 1)	68	3	(4%)		3	0			(100%)	0		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
RASH	≤63 Days (All)	102	2	(21)	1.0000	2	0		_	(100%)	0		0
	≤49 Days (Group 1)	68	2	(3%)		2	0		2	(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
SWEATING INCREASED	≰63 Days (All)	102	2	(2%)	0.5578	2	0			(100%)	0		0
	≰49 Days (Group 1)	68	1	(1%)		1	0		_	(100%)	0		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
USCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	4	(4%)	0.5135	5	1	(20%)	3	(60%)		(20%)	0
	≤49 Days (Group 1)	68	2	(3%)		2	1	(50%)	0		1	(50%)	0
	50-56 Days (Group 2)	25	2	(8%)		3	0		-	100%)	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.

^[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	Total Number	Numb of F		Fisher's exact	Number				Severi	tv		
Body System/Event [2]	Age Group [3]	of Pts	w/Ev		p-value	of Events		lđ		rate	Severe	;	Unknow
USCULO-SKELETAL SYSTEM DISORDERS (cont.)													
MYALGIA	≤63 Days (All)	102	2	(2%)	0.5578	2	0		1	(50%)	1 (5	50%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1 (10	00%)	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
1	≤49 Days (Group 1)	68	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	25	1	(4%)		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	(9%)	0
	≤49 Days (Group 1)	68	33	(49%)		57	16	(28%)	34	(60%)	7 (:	12%)	0
	50-56 Days (Group 2)	25	10	(40%)		18	5	(28%)	13	(72%)	0		0
	57-63 Days (Group 3)	9	1	(11%)		1	0		1	(100%)	0		0
DIZZINESS	≤63 Days (All)	102	12	(12%)	0.3219	16	8	(50%)	7	(44%)	1	(6%)	0
	s49 Days (Group 1)	68	6	(9%)		6	3	(50%)	2	(33%)	1 (174)	0
	50-56 Days (Group 2)	25	5	(20%)		9	5	(56%)	4	(44%)	0		0
	57-63 Days (Group 3)	9	1	(11%)		1	0		1	(100%)	0		0
HEADACHE	≤63 Days (All)	102	37	(36%)	0.0144	55	11	(20%)	40	(73%)		(7%)	0
	≤49 Days (Group 1)	68	30	(44%)		46	11	(24%)	31	(67%)	4 '	(9%)	0
	50-56 Days (Group 2)	25	7	(28%)		9	0		9	(froo#)	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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^[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: TYSON (#4)

	Gestational	Total	Numb of I		Fisher's exact	Number			Severi	tv		
Body System/Event [2]	Age Group (3)	Number of Pts	w/E		p-value	of Events	Mild		rate	Sev		Unknown
ENTR & PERIPH MERVOUS SYSTEM DISORDER	RS (cont.)					,						_
MIGRAINE	≤63 Days (All)	102	2	(2%)	1.0000	2	0	0			(100%)	0
	<pre>s49 Days (Group 1)</pre>	68	2	(3%)		2	0	0			(100%)	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
TREMOR	≤63 Days (All)	102	3	(3%)	0.6683	3	2 (67%)	1	(33%)	0		0
TREMOR	≤49 Days (Group 1)	68	3	(4%)		3	2 (67%)	1	(33%)	0		0
ı	50-56 Days (Group 2)	25	0			0	0	0		0		0
	57-63 Days (Group 3)	9	0		,	0	0	0		0		0
VISION DISORDERS												
ANY EVENT	≤63 Days (All)	102	2	(2%)	1.0000	2	0	1	(50%)	1	(50%)	0
ANT EVENT	≤49 Days (Group 1)	68	2	(3%)		2	0	1	(50%)	1	(50%)	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
CONJUNCTIVITIS	≤63 Days (All)	102	2	(2%)	1.0000	2	0	1	(50%)	1	(50%)	0
CONDUNCTIVITIS	s49 Days (Group 1)	68	2	(3%)		2	0	1	(50%)	1	(50%)	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
HEARING AND VESTIBULAR DISORDERS												
ANY EVENT	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		(100%)	0		0
Para Diane	≤49 Days (Group 1)	68	1	(1%)		. 1	0	1	(100%)	0	•	0
	50-56 Days (Group 2)	25	0			• 0	0	0	ł,	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

^[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			Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
EARING AND VESTIBULAR DISORDERS (cont.)		·							
EAR ACHE	≤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
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.2788	7	3 (43%)	4 (57%)	0	0
	≤49 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
	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
INSOMNIA	≤63 Days (All)	102	5 (5%)	0.4397	5	2 (40%)	3 (60%)	0	0
	≰49 Days (Group 1)	68	5 (7%)		. 5	2 (40%)	3 (60%)	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

^[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: TYSON (#4)

	Gestational Age	Total Number	Numb		Fisher's exact	Number	- -		-	Severi	ity		
Body System/Event [2]	Group (3)	of Pts	w/E		p-value	of Events	Mi	ld	Mode	rate	Sev	er e	Unknowr
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	102	77	(75%)	0.3778	181	78	(43%)	63	(35%)	40		0
	<pre>s49 Days (Group 1)</pre>	68	53	(78%)		122	55	(45%)	40	(33%)	27		0
	50-56 Days (Group 2)	25	19	(76%)		50	20	(40%)	20	(40%)	10	-	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			(100%)	0
	≤49 Days (Group 1)	68	2	(3%)		2	0		0		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
CONSTITUTION	≤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
DIAMMEN	≤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
	57-63 Days (Group 3)	9	2	(221)		2	1	(50%)	0		1	(50%)	0
DYSPEPSIA	≤63 Days (All)	102	3	(3%)	1.0000	5	1	(20%)	1	(20%)	3	(60%)	0
51012.0	≤49 Days (Group 1)	68	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	25	1	(4%)		3	0		0		3	(100%)	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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^[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: TYSON (#4)

	Gestational	Total	Num		Fisher's	M. order and				C			
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	vent	exact p value	Number of Events	Mi		Mode	Severi rate	•	vere	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			0	٥		0		0		0
	57-63 Days (Group 3)	9	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	102	67	(66%)	0.4063	93	46	(49%)	28	(30%)	19	(20%)	0
l l	s49 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	(13%)	0
	57-63 Days (Group 3)	9	4	(44%)		4	2	(50%)	1	(25%)	1	(25%)	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	(14%)	0
	57-63 Days (Group 3)	9	2	(22%)		3	0		2	(67%)	1	(33%)	0
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	102	2	(2%)	0.5578	2	0		0		2	(100%)	0
	s49 Days (Group 1)	68	1	(1%)		1	0		0		1	(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
DEHYDRATION	≰63 Days (All)	102	2	(2%)	0.5578	2	0		0			(100%)	0
	≤49 Days (Group 1)	68	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	25	1	(4%)		. 1	0		0	1	1	(100%)	0
	57-63 Days (Group 3)	9	0			0	0		0	Þ	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.

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 -		Severi	.ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS							2 (200)	. (128)	•
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	0	0	0
BRONCHITIS	≤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
DYSPNOEA	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	0	0
DISTROLA	≤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
PHARYNGITIS	≤63 Days (All)	102	3 (3%)	0.6683	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	68	3 (4%)		3	1 (33%)	2 (67%)	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
SINUSITIS	≤63 Days (All)	102	3 (3%)	0.6683	3	1 (33%)	1 (33%)	1 (33%)	0
D111001110	≤49 Days (Group 1)	68	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	25	0		0	0	0	ο,	0
	57-63 Days (Group 3)	9	0		. 0	0	° l	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.

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

Center: TYSON (#4)

	Gestational	Total	Number	Fisher			0		
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Even	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
JRINARY SYSTEM DISORDERS			· · · · · · ·						
ANY EVENT	≤63 Days (All)	102	1 (<	1 .0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	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	o	0	0
URINARY TRACT INFECTION	≤63 Days (All)	102	1 (<	1.0000	1	1 (100%)	0	0	0
. 1	≤49 Days (Group 1)	68	1 (*)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		, О	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
EPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	£63 Days (All)	102	14 (1	1 0.2954	15	3 (20%)	5 (33%)	7 (47%)	0
	≰49 Days (Group 1)	68	7 (1	t)	7	2 (29%)	3 (43%)	2 (29%)	0
	50-56 Days (Group 2)	25	5 (2	%)	6	1 (17%)	1 (17%)	4 (67%)	0
	57-63 Days (Group 3)	9	2 (2	*)	2	0	1 (50%)	1 (50%)	0
BREAST ENLARGEMENT	≤63 Days (All)	102	1 (<	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	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
BREAST PAIN FEMALE	≤63 Days (All)	102	1 (<	*) 1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (%)	. 1	1 (100%)	0	ο '	0
	50-56 Days (Group 2)	25	0 .		• 0	0	o (0	0
	57-63 Days (Group 3)	9	0		0	0	ο "	0	0

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

Appendix A.1, Tables 16 and 25

^[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	Morelland		Severi	P	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, PENALE (cont.)									
ENDOMETRITIS	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 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	0	1 (100%)	o	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
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	ο .	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
	≰49 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	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	o	o	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		; O	0	° Ł	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.

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	ity		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknow
REPRODUCTIVE DISORDERS, FEMALE (cont.)													
VAGINITIS	≰63 Days (All)	102	1	(<1%)	0.0882	1	0			(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	68	(100%)	1	250	109	(44%)	95	(38%)	46	(18%)	0
	50-56 Days (Group 2)	25	25	(100%)		90	36	(40%)	35	(39%)	19	(21%)	0
	57-63 Days (Group 3)	9	9	(100%)		22	6	(27%)	8	(36%)	8	(36%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	101	(>99%)	1.0000	313	129	(41%)	116	(37%)	68	(22%)	0
	≤49 Days (Group 1)	68	67	(99%)		211	91	(43%)	79	(37%)	41	(19%)	0
	50-56 Days (Group 2)	25	25	(100%)		80	32	(40%)	29	(36%)	19	(24%)	0
	57-63 Days (Group 3)	9	9	(100%)		22	6	(27%)	8	(36%)	8	(36%)	0
ALLERGY	≤63 Days (All)	102	1	(<1%)	1.0000	1	0		1	(100%)	0		0
NDDB/G1	≤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
ASTHENIA	≤63 Days (All)	102	6	(6%)	0.3885	6	3	(50%)	2		1		0
	≤49 Days (Group 1)	68	3	(4%)		3	1	(33%)	1	(33%)	1	(33%)	0
	50-56 Days (Group 2)	25	3	(12%)		• 3	2	(67%)	1	į (33%)	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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^[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	Number of Pts	Fisher's exact	Number -		Severi	it v -	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A WHOLE - 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	0	1 (100%)	0
	50-56 Days (Group 2)	25	0	1	0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	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 (29%)	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
	50-56 Days (Group 2)	25	0		0	0	0	O ·	0
	57-63 Days (Group 3)	9	0		O	0	ه ا	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.

> 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 -		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (Co							1 (100%)	0	0
MALAISE	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	0	0	0
	≤49 Days (Group 1)	68	0		0	0	1 (100%)	Ö	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	0	o	0
	57-63 Days (Group 3)	9	0		0	0	U	Ū	•
	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
PAIN	≤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
RIGORS	≤63 Days (All	102	9 (9%)	0.7440	10	6 (60%)	4 (40%)	o	0
RIGORS	≤49 Days (Group 1)	68	6 (9%)		7	4 (57%)	3 (43%)	0	0
	50-56 Days (Group 2)	25	3 (12%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	2 (2%)	1.0000	2	2 (100%)	0	0	0
TEMPERATURE CHANGED DEMORITOR	≤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								. (100)	•
ANY EVENT	≰63 Days (All)	102	7 (7%)	0.6825	8	4 (50%)	. 3 (38%)	1 (13%)	0
	≰49 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	1 (11%)		1	1 (100%)	۰ ۳	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.

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

Center: TYSON (#4)

	Gestational	Total	Numb		Fisher's			Sauce	4 6 9 6	
Body System/Event [2]	Age Group [3]	Number of Pts	of P w/Ev		exact p-value	Number - of Events	Mild	Moderate	Severe	Unknow
RESISTANCE MECHANISM 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
INFECTION VINAD	≤49 Days (Group 1)	68	5	(7%)		6	2 (33%)	3 (50%)	1 (17%)	0
1	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
ECONDARY 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			0	0	0	0	0
l de la companya de	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
toni ormani	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

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

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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	Number				Sever	ity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknow
ANY EVENT	≤63 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)	8	8 (100%)		44	26	(59%)	16	(36%)	2	(5%)	0
KIN AND APPENDAGES DISORDERS												
ANY EVENT	≤63 Days (All)	44	2 (5%)	0.4165	2		(100%)	0		0		0
	≤49 Days (Group 1)	13	0	•	0	0		О		0		0
	50-56 Days (Group 2)	23	1 (4%)		1		(100%)	0		0		0
	57-63 Days (Group 3)	8	1 (13%)		1	1	(100%)	0		0		0
FOLLICULITIS	≤63 Days (All)	44	1 (2%)	0.1818	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		0
	57-63 Days (Group 3)	8	0		0	0		0		0		0
MUSCULO-SKELETAL SYSTEM DISORDERS	•											_
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.4773	. 1		(100%)	0		0	1	0
	≤49 Days (Group 1)	13	1 (8%)		• 1		(100%)	0	Į.	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

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



^[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: BLUMENTHAL (#5)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number -				Severi	ty		
Body System/Event [2]	Group (3)	of Pts	w/Ev		p-value	of Events	M	.1 d	Mode		•	er e	Unknow
WSCULO-SKELETAL SYSTEM DISORDERS (cont.)													
ARTHRALGIA	≤63 Days (All)	44	1	(2%)	0.4773	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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													_
ANY EVENT	≤63 Days (All)	44	11	(25%)	0.8068	20	4	(20%)	12	(60%)		(20%)	0
'	<pre>s49 Days (Group 1)</pre>	13	4	(31%)		7	1	(14%)	5	(71%)	1	• •	0
	50-56 Days (Group 2)	23	6	(26%)		12	2	(17%)	7	(58%)	3	(25%)	0
	57-63 Days (Group 3)	8	1	(13%)		1	1	(100%)	0		0		0
DIZZINESS	≤63 Days (All)	44	4	(9%)	0.6366	4	1	(25%)	2	(50%)		(25%)	0
	≤49 Days (Group 1)	13	2	(15%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	23	2	(9%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
HEADACHE	≤63 Days (All)	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%)	0
	57-63 Days (Group 3)	8	1	(13%)		1	1	(100%)	0		0		0
PSYCHIATRIC DISORDERS	•												
ANY EVENT	≤63 Days (All)	44	1	(2%)	1.0000	1	1	(100%)	0		0,		0
	≤49 Days (Group 1)	13	0			; O	0		0	ı	ο.		0
	50-56 Days (Group 2)	23	1	(4%)		1	1	(100%)	0	<u>,</u>	0		0
	57-63 Days (Group 3)	8	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

^[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 of Pts	Numb of F w/Ev	Pts	Fisher's exact p-value	Number of Events	 Mi		Mode:	Severi rate	ty Seve		Unknown
Body System/Event [2]	Group [3]	OI FCS			p va.ac								
PSYCHIATRIC DISORDERS (cont.)									_		_		
DEPRESSION	≤63 Days (All)	44	1	(2%)	1.0000	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		(100%)	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		38	(39%)	14	(14%)	0
	≤49 Days (Group 1)	13		(92%)	,	32	15	(47%)	13	(41%)	4	(13%)	0
	50-56 Days (Group 2)	23	18	(78%)		51	20	(39%)	22	(43%)	9		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	•	3	• • •	0
DIRECTION	≤49 Days (Group 1)	13	3	(23%)		3	1		1		1	(33%)	0
	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	≤63 Days (All)	44	1	(2%)	1.0000	3	0		2	(67%)	1	(33%)	0
PERTUBNES	≤49 Days (Group 1)	13	0			0	0		0		0		0
	50-56 Days (Group 2)	23	1	(4%)		3	0		2	(67%)	1	(33%)	0
	57-63 Days (Group 3)	8	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	44	34	(77%)	0.3097	60	35	(58%)	19	(32%)	6		0
MOOM	≤49 Days (Group 1)	13	12	(92%)		21	11	(52%)	8	(38%)	2 '		0
	50-56 Days (Group 2)	23	17.	(74%)		• 31	17	(55%)	10	(32%)	4	(13%)	0
	57-63 Days (Group 3)	8	5	(63%)		8	7	(88%)	1	"(13%)	0		0

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

Appendix A.1, Tables 16 and 25

^[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	Num of		Fisher's exact	Number -			Severi	ty		
Body System/Event [2]	Group (3)	of Pts		vent	p-value	of Events	Mild	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)											/1.641	•
VOMITING	≤63 Days (All)	44	16	(36%)	1.0000	25	8 (32%)	13	(52%)		(16%)	0
	≤49 Days (Group 1)	13	5	(38%)		8	3 (38%)	4	(50%)		(13%)	0
	50-56 Days (Group 2)	23	8	(35%)		11	2 (18%)	7	(64%)		(18%)	0
	57-63 Days (Group 3)	8	3	(38%)		6	3 (50%)	2	(33%)	1	(17%)	0
RESPIRATORY SYSTEM DISORDERS						_	, (50%)	1	(50%)	0		0
ANY EVENT	≰63 Days (All)	44	2	(5%)	1.0000	2	1 (50%)	_	(100%)	0		0
	≤49 Days (Group 1)	13	1	(8%)		1	0	-	(1004)	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		U		Ū
PHARYNGITIS	≤63 Days (All)	44	2	(5%)	1.0000	2	1 (50%)		(50%)	0		0
	≤49 Days (Group 1)	13	1	(8%)		1 .	0		(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	0		0		0
URINARY SYSTEM DISORDERS							_	_	(****	•		0
ANY EVENT	≰63 Days (All)	44	1	(2%)	0.1818	1	0		(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		•
	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	-	(100%)	Ο,		0
ONLIMAL INICI IN BOLLOW	s49 Days (Group 1)	13	0			; O	0	0	1	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

^[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 [Safer, Evaluable Patients]

Center: BLUMENTHAL (#5)

	Gestational	Total	Number of Pts	Fisher's exact	Number -		Severi	ity	
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, PENALE					,	3 (50%)	3 (50%)	0	0
ANY EVENT	≰63 Days (All)	44	4 (9%)	1.0000	6	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	23	2 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (1000)	· ·	•	
	(2.25 (2.11)	44	1 (2%)	1.0000	2	0	2 (100%)	0	0
BREAST ENGORGEMENT	≤63 Days (All)		0	1.0000	0	0	0	0	0
1	≤49 Days (Group 1)	13	1 (4%)	,	2	0	2 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	U		•	-			
	≤63 Days (All)	44	2 (5%)	0.4165	2	1 (50%)	1 (50%)	0	0
BREAST PAIN FEMALE	s49 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
	57-63 Days (Group 37	•	1 (13-)						
	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
LEUKORRHOEA	≤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
	5. 55 25,2 Village								_
UNCENTALO	≤63 Days (All)	44	1 (2%)	0.4773	1	1 (100%)	0	0	0
VAGINITIS	s49 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	ο,	o į	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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^[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	Total Number	Number of Pts	Fisher's exact	Number		Severi	ty	
Body System/Event [2]	Age Group (3)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknowr
ODY AS A WHOLE - GENERAL DISORDERS						70 /F181	52 (205)	14 (10%)	0
ANY EVENT	≤63 Days (All)	44	44 (100%)		137	70 (51%)	53 (39%)	2 (6%)	0
	≰49 Days (Group 1)	13	13 (100%)		34	17 (50%)	15 (44%) 27 (34%)	11 (14%)	0
	50-56 Days (Group 2)	23	23 (100%)		79	41 (52%)	- '- '		0
	57-63 Days (Group 3)	8	8 (100%)		24	12 (50%)	11 (46%)	1 (4%)	U
ABDOMINAL PAIN	≤63 Days (All)	44	43 (98%)	0.1818	126	68 (54%)	45 (36%)	13 (10%)	0
ABDOMINAL PAIN	≤49 Days (Group 1)	13	13 (100%)		29	17 (59%)	10 (34%)	2 (7%)	0
ı	50-56 Days (Group 2)	23	23 (100%)		75	40 (53%)	25 (33%)	10 (13%)	0
	57-63 Days (Group 3)	8	7 (88%)		22	11 (50%)	10 (45%)	1 (5%)	0
	≤63 Days (All)	44	3 (7%)	0.4182	3	1 (33%)	2 (67%)	0	0
FATIGUE	s49 Days (Group 1)	13	2 (15%)	0	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		0	0	0	0	0
	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
FEVER	≤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	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	44	3 (7%)	0.0533	3	1 (33%)	2 (67%)	o	0
DEG LUTH	≰49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	Ο,	0
	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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^[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	Numb of F		Fisher's exact	Number -		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Ev		p-value	of Events	Mild	Moderate	Severe	Unknow
BODY AS A WHOLE - GENERAL DISORDERS (cont)						_	5 (1001)	•	0
MALAISE	≰63 Days (All)	44	1	(21)	0.4773	2	0	2 (100%) 2 (100%)	0	0
	≤49 Days (Group 1)	13	1	(8%)		2	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	V	U
	≤63 Days (All)	44	1	(2%)	1.0000	1	0	0	1 (100%)	0
OEDEMA	≤49 Days (Group 1)	13	0	,		0	0	0	0	0
· ·	50-56 Days (Group 2)	23	1	(4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	8	0	, ,		0	0	0	0	0
	-63 Davis (All)	44	1	(2%)	1.0000	1	0	1 (100%)	0	0
PAIN	≤63 Days (All)	13	Ô	(20)		0	0	0	0	0
	≤49 Days (Group 1)	23	1	(4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2) 57-63 Days (Group 3)	8	0	(10)		ō	0	0	0	0
APPLICATION SITE DISORDERS [4]										
ANY EVENT	≰63 Days (All)	44	1	(2%)	0.4773	1	0	1 (100%)	0	0
Wat EARIAT	s49 Days (Group 1)	13	1	(8%)		1	0	1 (100%)	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
THE PARTY OF THE PARTY	≤63 Days (All)	44	1	(2%)	0.4773	1	0	1 (100%)	0	0
INJECTION SITE PAIN	s49 Days (Group 1)	13	1	(8%)		1	0	1 (100%)	O ,	0
	50-56 Days (Group 2)	23	0	•		. 0	0	0 ,	0	0
	57-63 Days (Group 3)	8	ò			0	0	o 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.

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

Center: BLUMENTHAL (#5)

	Gestational	Total	Number	Fisher's	Mumbar		Sever	i tv	
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤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
INFECTION VIRAL	≰63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
INFECTION VINAD	≤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

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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.

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

Center: BORGATTA (#6)

	Gestational	Total	Number		Fisher's exact	Number				Severi	tv		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Even		p-value	of Events	Mi		Mode		Sev		Unknown
2007 1711111													
	s63 Days (All)	64	63 (9	98%)	0.4375	405	166	(41%)	159	(39%)	80	(20%)	0
ANY EVENT	s49 Days (Group 1)	36	36 (10			222	95	(43%)	79	(36%)	48	(22%)	0
	50-56 Days (Group 2)	16	15 (9			102	44	(43%)	35	(34%)	23	(23%)	0
	57-63 Days (Group 3)	12	12 (10			81	27	(33%)	45	(56%)	9	(11%)	0
SKIN AND APPENDAGES DISORDERS						,	0		1	(100%)	0		0
ANY EVENT	≤63 Days (All)	64		(2%)	1.0000	1	0			(100%)	0		0
	≤49 Days (Group 1)	36		(3%)		1	0		0	(1000)	0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	0			U	U		v				•
	≤63 Days (All)	64	1	(2%)	1.0000	1	0		1	(100%)	0		0
RASH	s49 Days (Group 1)	36		(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
MUSCULO-SKELETAL SYSTEM DISORDERS						•	0		2	(100%)	0		0
ANY EVENT	≤63 Days (All)	64		(3%)	0.4018	2	0			(100%)	0		0
	≰49 Days (Group 1)	36		(3%)		1	0		0	(1004)	0		0
	50-56 Days (Group 2)	16	0			U	0			(100%)	0		0
•	57-63 Days (Group 3)	12	1	(8%)		1	U		•	(1000)	·		
	≤63 Days (All)	64	2	(3%)	0.4018	. 2	0		2	(100%)	0	! !	0
ARTHRALGIA	s49 Days (Group 1)	36		(3%)		• 1	0		1	(100%)	0		0
	50-56 Days (Group 2)	16	ō	,		0	0		0	,	0		0
	57-63 Days (Group 3)	12		(8%)		1	0		1	(100%)	0		0

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

^[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 Age	Total Number	Num of		Fisher's exact	Number				Severi	ty	<i></i>	
Body System/Event [2]	Group (3)	of Pts		vent	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISORDERS				(224)	0.2961	40	16	(40%)	17	(43%)	7	(18%)	0
ANY EVENT	≤63 Days (All)	64	21	(33%) (25%)	0.2901	13	4	(31%)	7	(54%)	2	(15%)	0
	s49 Days (Group 1)	36	9			19	9	(47%)	5	(26%)	5	(26%)	0
	50-56 Days (Group 2)	16	7	(44%)		8	3	(38%)	5	(63%)	0		0
	57-63 Days (Group 3)	12	5	(42%)		•	,	(30-7	,	(00-7			
	≤63 Days (All)	64	5	(8%)	1.0000	5	4	(80%)	1	(20%)	0		0
DIZZINESS	≤49 Days (Group 1)	36	3	(8%)		3	2	(67%)	1	(33%)	0		0
1	50-56 Days (Group 2)	16	1	(6%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	12	1	(8%)		1	1	(100%)	0		0		0
	37-03 Days (Group 37			, .							_		_
UPADA CUE	≤63 Days (All)	64	16	(25%)	0.1827	33	11	(33%)		(45%)	7		0
HEADACHE	≤49 Days (Group 1)	36	6	(17%)		8	1	(13%)	5	(63%)	2		0
	50-56 Days (Group 2)	16	6	(38%)		18	8	(44%)	5	•	5	(28%)	0
	57-63 Days (Group 3)	12	4	(33%)		7	2	(29%)	5	(71%)	0		0
			1	(2%)	1.0000	1	0		1	(100%)	0		0
PARAESTHESIA	≤63 Days (All)	64	1	(3%)	1.0000	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	36	0	(34)		n	0		0		0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	U			ū							
	≤63 Days (All)	64	1	(2%)	1.0000	1	1	(100%)	0		0		0
TREMOR	≰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			; 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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^[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	Numb		Fisher's exact	Number -		_ 		Severity	/	
Body System/Event [2]	Age Group [3]	Number of Pts	of P w/Ev		p-value	of Events	Mi	1d	Moderate	e	Severe	Unknowr
PSYCHIATRIC DISORDERS					0.2235	5	2	(40%)	3 (6	01)	0	0
ANY EVENT	≰63 Days (All)	64	5	(8%) (14%)	0.2235	5	2	(40%)	•	0%)	0	0
	s49 Days (Group 1)	36	5	(148)		0	0	(101)	0		0	0
	50 56 Days (Group 2)	16	0			0	0		0		0	0
	57-63 Days (Group 3)	12	0			•	-					
				(2%)	1.0000	1	0		1 (10	0%)	0	0
ANOREXI A	≤63 Days (All)	64	,	(3%)	1.0000	1	0		1 (10	0%)	0	0
1	≤49 Days (Group 1)	36	1	(30)		0	o.		0		0	0
	50-56 Days (Group 2)	16	0			0	0		0		0	0
	. 57-63 Days (Group 3)	12	U			•	-					
			1	(2%)	1.0000	1	0		1 (10	01)	0	0
ANXIETY	≤63 Days (All)	64	1	(3%)	1.0000	1	0		1 (10	01)	0	0
	s49 Days (Group 1)	36	0	(30)		0	0		0		0	0
	50-56 Days (Group 2)	16 12	0			0	0		0		0	0
	57-63 Days (Group 3)	12	v			•						
	(222)	64	1	(2%)	1.0000	1	1	(100%)	0		0	0
DEPRESSION	≤63 Days (All)	36	1	(3%)	2.0000	1	1	(100%)	0		0	0
	≤49 Days (Group 1)	16	ō	(30)		0	0		0		0	0
	50-56 Days (Group 2) 57-63 Days (Group 3)	12	ō			0	0		0		0	0
	57-63 Days (Group 37		•									
	(C) Davis (All)	64	2	(3%)	1.0000	2	1	(50%)	1 (5	50%)	0	0
EMOTIONAL LABILITY	≤63 Days (All) ≤49 Days (Group 1)	36	2	(6%)		2	1	(50%)	1 (5	50%)	0	0
	£49 Days (Group 1) 50-56 Days (Group 2)	16	0	/		0	0		0		0 +	0
	57-63 Days (Group 3)	12	ō			. 0	0		٥,		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.

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

Center: BORGATTA (#6)

	Gestational	Total	Num		Fisher's					Severi	F 17		
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	Pts vent	exact p-value	Number of Events		1d		rate	Sev		Unknow
NASTRO-INTESTINAL SYSTEM DISORDERS			-					(208)		(36%)	31	(25%)	0
ANY EVENT	≰63 Days (All)	64	45	(70%)	0.3651	122	47	(39%) (36%)	44 26	(34%)	23	(30%)	0
	≤49 Days (Group 1)	36	27	(75%)		77	28		7	(28%)	6		Ö
	50-56 Days (Group 2)	16	9	(56%)		,25	12	(48%)	11	(55%)	2		0
	57-63 Days (Group 3)	12	9	(75%)		20	7	(35%)	11	(224)	2	(104)	U
DIARRHEA	≤63 Days (All)	64	13	(20%)	0.5833	15	7	(47%)	6	(40%)	2		0
DIARRIEA	≤49 Days (Group 1)	36	8	(22%)		9	4	(44%)	3	(33%)	2	(22%)	0
1	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
	≤63 Days (All)	64	2	(3%)	0.4018	2	0		2	(100%)	0		0
DYSPEPSIA	≤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	1	(8%)		1	0		1	(100%)	0		0
DI NEW DWGD	≰63 Days (All)	64	1	(2%)	0.1875	1	O		0		1	(100%)	0
FLATULENCE	≤49 Days (Group 1)	36	0			0	0		0		0		0
	50-56 Days (Group 2)	16	0			0	0		0		0		0
	57-63 Days (Group 3)	12	1	(B %)		1	0		0		1	(100%)	0
	≤63 Days (All)	64	39	(61%)	0.6108	76	31	(41%)	26	(34%)	19	(25%)	0
NAUSEA	≰49 Days (Group 1)	36	23	(64%)		46	17	(37%)	15	(33%)	14	(30%)	0
	50-56 Days (Group 2)	16	8	(50%)		17	8	(47%)	5	(29%)	4 -	(24%)	0
	57-63 Days (Group 3)	12	8	(67%)		, 13	6	(46%)	6	(46%)	1	(8%)	0

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

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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.

> 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-val ue	of Events	Mild	Moderate	Severe	Unknow
LASTRO-INTESTINAL SYSTEM DISORDERS (cont.)						. (000)	10 (25%)	9 (32%)	0
VOMITING	≤63 Days (All)	64	19 (30)		28	9 (32%)	10 (36%) 7 (33%)	7 (33%)	0
	≤49 Days (Group 1)	36	13 (36		21	7 (33%)	0 (334)	2 (50%)	0
	50-56 Days (Group 2)	16	3 (191		4	2 (50%)	3 (100%)	0	0
	57-63 Days (Group 3)	12	3 (25))	3	0	3 (1004)	Ū	J
ESPIRATORY SYSTEM DISORDERS					_	. (505)	•	1 (50%)	0
ANY EVENT	≰63 Days (All)	64	2 (3		2	1 (50%) 1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (35	-	1	- •	0	1 (100%)	0
	50-56 Days (Group 2)	16	1 (69)	1	0	0	0	Ô
	57-63 Days (Group 3)	12	0		0	0	U	U	•
COUGHING	≤63 Days (All)	64	1 (2	0.4375	1	0	0	1 (100%)	0
COOGNING	≤49 Days (Group 1)	36	0		0	0	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
SINUSITIS	≤63 Days (All)	64	1 (2) 1.0000	1	1 (100%)	0	0	0
SINOSILIS	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
RED BLOOD CELL DISORDERS		İ							
ANY EVENT	≤63 Days (All)	64	2 (3	1.0000	2	2 (100%)	0	0 (0
WAI PARMI	≤49 Days (Group 1)	36	2 (6	;)	, 2	2 (100%)	٥,	0 '	0
	50-56 Days (Group 2)	16	o ·		0	0	0 %	0	0
	57-63 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.

^[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	Fisher's			Sever:	itv	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknow
RED BLOOD CELL DISORDERS (cont.)							_		•
ANAEMIA	≤63 Days (All)	64	2 (31		2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	2 (61)	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
EPRODUCTIVE DISORDERS, FEMALE							0 (518)	1 (76)	0
ANY EVENT	≤63 Days (All)	64	12 (191		14	4 (29%)	9 (64%)	1 (7%)	0
	≰49 Days (Group 1)	36	6 (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
Cantional	≤49 Days (Group 1)	36	0		0	0	0	0	0
4	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	1 (100%)	0	0	0
DEURORRHOEA	≤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
UIEKINE DISORDER NOS	≤49 Days (Group 1)	36	1 (3	:)	1	0	0	1, (100%)	0
	50-56 Days (Group 2)	16	0		. 0	0	0 ,	0.	0
	57-63 Days (Group 3)	12	Ó		• 0	0	o !	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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^[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			Severi		
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, 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
AVGIVILIE	≤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
ODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	64	60 (94%)	0.8096	212	90 (42%)	82 (39%)	40 (19%)	0
CHI. WYMIT.	≤49 Days (Group 1)	36	33 (92%)		113	54 (48%)	37 (33%)	22 (19%)	0
	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
ADDOMINAL TAXA	≰49 Days (Group 1)	36	32 (89%)		91	45 (49%)	28 (31%)	18 (20%)	0
	50-56 Days (Group 2)	16	15 (94%)		41	15 (37%)	17 (41%)	9 (22%)	0
	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%)	0
DUCK LUIN	≤49 Days (Group 1)	36	3 (8%)		6	2 (33%)	2 (33%)	2 (33%)	0
	50-56 Days (Group 2)	16	1 (6%)		. 2	2 (100%)	0 ,	o '	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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^[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 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	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (C	ont.)								
FATIGUE	≤63 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	0	0
. Dvan	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	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
HOT FLUSHES	≤63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	1 (50%)	0	0
NOT FEOSIES	≤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	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
DDG TATA	≤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
I BILBILO D	≰49 Days (Group 1)	36	2 (6%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0 .	0
	57-63 Days (Group 3)	12	O _,		• 0	0	o ţ	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.

> 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	itv	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
DDY AS A WHOLE - GENERAL DISORDERS (cont.)					_	. (608)	1 (50%)	0	0
RIGORS	≤63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	0 (504)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	•	0	0
	50-56 Days (Group 2)	16	0		0	0	0 (2001)	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	U	U
SYNCOPE	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	0
SINCOPE	49 Days (Group 1)	36	1 (3%)		1	0	0	1 (100%)	0
1	50-56 Days (Group 2)	16	0	,	0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	64	5 (8%)	0.6966	5	4 (80%)	1 (20%)	0	0
	s49 Days (Group 1)	36	2 (6%)		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	s63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
INFECTION	≤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
INFECTION BACTERIAL	'≤63 Days (All)	64	2 (3%)	0.4018	2	2 (100%)	0	0	0
INIBCTION DICTERIAL	≤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	1 (8%)		1	1 (100%)	o ^t	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.

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

Center: BORGATTA (#6)

	Gestational Age	Total Number	Number of P		Fisher's exact	Number		Severi	.ty	
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p-value	of Events	Mild	Moderate	Severe	Unknown
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			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	(21)	0.4375	1	0	1 (100%)	0	0
1	≤49 Days (Group 1)	36	0			0	0	0	0	0
	50-56 Days (Group 2)	16	1	(6%)		1	0	1 (100%)	0	0
	57-63 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.

^[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: MALLOY (#7)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number				Severi	.ty		
Body System/Event [2]	Group [3]	of Pts	w/Event		o-value	of Events	Mi	1d	Mode		•	ere	Unknown
			52 (100	 .		389	147	(38%)	151	(39%)	91	(23%)	0
ANY EVENT	≤63 Days (All)	52	19 (100			127	50	(39%)	47	(37%)	30	(24%)	0
	≰49 Days (Group 1)	19	11 (100			77	37	(481)	28	(36%)	12	(16%)	0
	50-56 Days (Group 2) 57-63 Days (Group 3)	11 22	22 (100			185	60	(321)	76	(41%)	49		0
USCULO-SKELETAL SYSTEM DISORDERS									_		_	(1005)	0
ANY EVENT	≤63 Days (All)	52			0.5769	2	0		0			(100%) (100%)	0
	≰49 Days (Group 1)	19		54)		2	0		0			(1004)	0
	50-56 Days (Group 2)	11	0			0	0		0		0		0
	57-63 Days (Group 3)	22	0			0	0		0		U		U
ARTHRALGIA	≤63 Days (All)	52	1 (3	24)	0.5769	1	0		0			(100%)	0
ARTIMO 27	≤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
MYALGIA	≤63 Days (All)	52	1 (:	2%)	0.5769	1	0		0			(100%)	0
ninaoin	≤49 Days (Group 1)	19	1 (51)		1	0		0		_	(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
ENTR & PERIPH MERVOUS SYSTEM DISORDERS		İ									_		•
ANY EVENT	≤63 Days (All)	52	22 (4	21)	0.7140	43	15	(35%)	22		6	ı	0
	≤49 Days (Group 1)	19	7 (3	7%)		9	3	(33%)	6	(67%)	0		0
	50-56 Days (Group 2)	11	4 (3	61)		8	7	(88%)	0	**	1	(13%)	0
	57-63 Days (Group 3)	22	11 (5	0%)		26	5	(19 1)	16	(62%)	5	(19%)	0

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

^[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 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	Unknow
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (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	0
	50-56 Days (Group 2)	11	2 (18%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	22	4 (18%)		7	3 (43%)	3 (43%)	1 (14%)	0
HEADACHE	s63 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%)	0
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		0	0	0	0	0
1	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	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
SYCHIATRIC 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 '	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	o "	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0

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

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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.

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	Numb of 1		Fisher's exact	Number				Severi	tv		 .
Body System/Event [2]	Age Group [3]	Number of Pts		vent	p-value	of Events	Mi	.1d	Mode		•	ere	Unknown
SYCHIATRIC DISORDERS (cont.)													
INSOMNIA	≤63 Days (All)	52	4	(8%)	0.8217	5	2	(40%)		(60%)	0		0
	≤49 Days (Group 1)	19	2	(11%)		3	0			(100%)	0		.0
	50-56 Days (Group 2)	11	1	(9%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	22	1	(5%)		1	1	(100%)	0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	52	40	(77%)	1.0000	118	44		37	(31%)	37	(31%)	0
	≤49 Days (Group 1)	19	15	(79%)		37	16	(43%)	11	(30%)	10	(27%)	0
	50-56 Days (Group 2)	11	8	(73%)		24	11	(46%)	10	(42%)	3	(13%)	0
	57-63 Days (Group 3)	22	17	(77%)		57	17	(30%)	16	(28%)	24	(42%)	0
CONSTIPATION	s63 Days (All)	52	2	(4%)	0.5023	2	0		0		2	(100%)	0
CONDITION	≤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	2	(9%)		2	0		0		2	(100%)	0
DIARRHEA	≤63 Days (All)	52	12	(23%)	0.4046	13	7	(54%)	3	(23₹)	3	(23%)	0
DIARRIEA	≤49 Days (Group 1)	19	6	(32%)		6	4	(67%)	2	(33%)	0		0
	50-56 Days (Group 2)	11	1	(9%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	22	5	(23%)		6	2	(33%)	1	(17%)	3	(50%)	0
DYSPEPSIA	≰63 Days (All)	52	1	(2%)	0.5769	1	0		0		1	(100%)	0
DIGIBIOIN	≤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	o'			• 0	0		0	L.	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 Fraluable Patients]

Center: MALLOY (#7)

	Gestational	Total Number	Numb of 1		Fisher's exact	Number				Severi	i + v		
Body System/Event [2]	Age Group [3]	of Pts		vent	p-value	of Events		.1d	Mode		-	ere	Unknow
ASTRO-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			0	0		0		0		0
NAUSEA	≤63 Days (All)	52	37	(71%)	0.7318	70	27	(39%)	22	(31%)	21	(30%)	0
1	≤49 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
INDOCRINE DISORDERS													
ANY EVENT	≤63 Days (All)	52	1	(2%)	1.0000	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	19	O			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	s'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	1	0	•	0
	57-63 Days (Group 3)	22	1	(5%)		1	1	(100%)	0	b.	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	Total	Number		Fisher's	Number -		Sever	tv	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Ever		exact p-value	of Events	Mild	Moderate	Severe	Unknow
EART RATE AND RHYTHM 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
TACHYCARDIA	≤63 Days (All)	52	1	(2%)	1.0000	1	1 (100%)	0	0	0
The state of the s	≤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
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%)	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
PHARYNGITIS	≤63 Days (All)	52	1	(2%)	0.5769	1	0	1 (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	0			c	0	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	52	1	(2%)	1.0000	1	0	1 (100%)	0	0
1 OM OFFICE COMMON LAND	≤49 Days (Group 1)	19	0			0	0	0	O ·	0
	50-56 Days (Group 2)	11	0			. 0	0	0 1	0 '	0
	57-63 Days (Group 3)	22	1	(5%)		1	0	1 (100%)	0	0

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

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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.

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	Unknow
RED BLOOD CELL DISORDERS					_	. (=**)	. (505)	•	0
ANY EVENT	≰63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0 0	0
	≤49 Days (Group 1)	19	0		0	0 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	11	2 (18%)		. 2	1 (50%)	· · · · · · · · · · · · · · · · · · ·	-	0
	57-63 Days (Group 3)	22	0		0	0	0	0	U
ANAEMIA	≤63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0	0
, i	≤49 Days (Group 1)	19	0		0	0	0	0	0
· ·	50-56 Days (Group 2)	11	2 (18%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
TRINARY 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		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	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
MICIONITION INDEPENCE	≰49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
URINARY TRACT INFECTION	≰63 Days (All)	52	1 (2%)	1.0000	2	1 (50%)	0	1 (50%)	0
ORIHARI IRACI INFECTION	≤49 Days (Group 1)	19	0		0	0	0	Ο,	0
	50-56 Days (Group 2)	11	0		; o	0	0 ,	0	0
	57-63 Days (Group 3)	22	1 (5%)		' 2	1 (50%)	o i	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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^[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:	it v -	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
EPRODUCTIVE 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%)	0
	50-56 Days (Group 2)	11	3 (27%)		3	1 (33%)	2 (67%)	0	0
	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
1	≤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
	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

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Appendix A.1, Tables 16 and 25

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^[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: MALLOY (#7)

	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	ld	Mode	rate	Sev	ere	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
ABDOMINAD FAIN	≤49 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 Days (Group 3)	22	20 (91%)		72	27	(38%)	28	(39%)	17	(24%)	0
ALLERGY	≰63 Days (All)	52	4 (8%)	0.5229	4	0		4	(100%)	0		0
ALLERGI	s49 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
ASIRENIA	≤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
BACK PAIN	\$49 Days (Group 1)	19	0		0	0		0		0		0
	50-56 Days (Group 2)	11	2 (18%)		2	1	(50%)	1	(50%)	Ο,		0
	57-63 Days (Group 3)	22	5 (23%)		6	1	(17%)	5	(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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