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

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact   p-value	Number of Events				···-Severity			
			, 5	<del></del>			. 1 <b>u</b>	HOUE	race	sev	ere	Unknown
ANY EVENT	≤63 Days (All)	71	71 (100%)		150		(400)					
	≤49 Days (Group 1)	28	28 (100%)		357 112	151		160		46		0
	50-56 Days (Group 2)	26	26 (100%)			50	(45%)	57	(51%)	5	(4%)	0
	57-63 Days (Group 3)	17	17 (100%)		128	52	(41%)	52	• •	24		0
	s. os baya (Group s)	1,	17 (1004)		117	49	(42%)	51	(44%)	17	(15%)	0
KIN AND APPENDAGES DISORDERS		•										
ANY EVENT	≤63 Days (All)	71	1 (1%)	0.2394	1	0		1	(100%)	0		•
	≰49 Days (Group 1)	28	0		0	0		0	(1000)	o		0
	50-56 Days (Group 2)	26	0		0	ō		Ô		0		0
	57-63 Days (Group 3)	17	1 (6%)		1	ō		•	(100%)	0		0
									,,	·		v
SWEATING INCREASED	≰63 Days (All)	71	1 (1%)	0.2394	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28	0		0	0		0	, - , - , ,	0		0
	50-56 Days (Group 2)	26	0		0	0		0		n		^
	57-63 Days (Group 3)	17	1 (6%)		1	0		1	(100%)	ō		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	-61 Davis (811)	<b></b>	20 (200)									
	s63 Days (All)	71	28 (39%)	0.0057	42	15	(36%)	19		8	(19%)	0
	≤49 Days (Group 1)	28	15 (54%)		16	7	(44%)	7	,	2	(13%)	0
·	50 56 Days (Group 2)	26	4 (15%)		7	1	(14%)	3	(43%)	3	(43%)	0
	57-63 Days (Group 3)	17	9 (53%)		19	7	(37%)	9	(47%)	3	(16%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Ever	3	Fisher's exact p-value	Number of Events		,	Mođe	- Severity	Sev	ere	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)	<del></del>			<del></del>			·····	<del></del>	<del> </del>			
DIZZINESŠ	s63 Days (All)	71	3 (	(4%)	0.0119	4	1	(25%)	2	(50%)	1	(25%)	0
	≤49 Days (Group 1)	28	0	•		0	0	,,	0	(201)	'n	(230)	0
	50-56 Days (Group 2)	26	0			0	ō		n		n		0
	57-63 Days (Group 3)	17	3 (1	18%)		4	1	(25%)	2	(50%)	1	(25%)	Ö
HEADACHE	≤63 Days (All)	71	26 (3	37%)	0.0145	36	14	(39%)	16	(44%)	6	(178)	0
	≤49 Days (Group 1)	28	14 (9	50%)		15	7	(47%)		(47%)	1	(7%)	0
	50-56 Days (Group 2)	26	4 (1	15%)		7	1	(14%)		(43%)	3		Ö
	57-63 Days (Group 3)	17		17%)		14	6	(43%)		(43%)	-	(14%)	o
MIGRAINE	≤63 Days (All)	71	2 (	(3%)	0.7070	. 2	0		1	(50%)	1	(50%)	0
•	≰49 Days (Group 1)	28		(4%)		1	0		. 0	, ,		(100%)	0
	50-56 Days (Group 2)	26	0			0	Ó		Ô		0	(2000)	Ō
	57 63 Days (Group 3)	17	1 (	(6%)		1	0		1	(100%)	0		0
PSYCHIATRIC DISORDERS													
ANY EVENT	≰63 Days (All)	71	5 (	(7%)	0.7284	10	6	(60%)	3	(30%)	1	(10%)	0
•	≤49 Days (Group 1)	28	2 (	(7%)		3	2	(67%)	1	(33%)	0	(,	0
	50-56 Days (Group 2)	26	1 (	(41)		4		(100%)	0	(001,	Ô		Ď
	57-63 Days (Group 3)	17	2 (1	21)		3	0		2	(671)	1	(33%)	0
ANXIETY	≤63 Days (All)	71	3 (	(4%)	1.0000	6	5	(83%)	1	(17%)	0		0
	≤49 Days (Group 1)	28	1 (	4%)		1		(100%)	0	,	ō		0
,	50-56 Days (Group 2)	26		(4%)		4		(100%)	0 !		0		0
4. 1 1	57-63 Days (Group 3)	17		(6%)		1	0		. i	(1001)	0		0

<sup>[1]</sup> Includes all adverse event's reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number		· · · · · · · · · · · · · · · · · · ·	•	Severi	t <b>y</b>		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p value	of Events	Mi	1 <b>d</b>	Mode	rate	Sev	ere	Unknown
PSYCHIATRIC DISORDERS (cont.)													
INSOMNIA	≤63 Days (All)	71	3	(4%)	0.4523	4	1	(25%)	2	(50%)	1	(25%)	0
	≤49 Days (Group 1)	28	2	(7%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	1	(6%)		2	0		1	(50%)	1	(50%)	0
FASTRO-INTESTINAL SYSTEM DISORDERS		-											
ANY EVENT	≤63 Days (All)	71	52	(73%)	0.1254	123	51	(41%)	53	(43%)	19	(15%)	0
	≤49 Days (Group 1)	28	17	(61%)		30	14	(47%)	14	(47%)	2	(7%)	0
	50-56 Days (Group 2)	26	20	(77%)		50	18	(36%)	21	(42%)	11	(221)	0
	57-63 Days (Group 3)	17	15	(88\$)		43	19	(44%)	18	(42%)	6	(14%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	71	2	(3%)	1.0000	2	1	(50%)	. 0		1	(50%)	0
	≤49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0	,	0		0
	50-56 Days (Group 2)	26	1	(4%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	17	0			0	0		0		0		0
DIARRHEA	≤63 Days (All)	71	8	(111)	0.6427	10	6	(60%)	3	(30%)	1	(10%)	0
•	≤49 Days (Group 1)	28	2	(7%)		3	2	(67%)	0		1	(33%)	0
	50-56 Days (Group 2)	26	4	(15%)		5	3	(60%)	2	(40%)	0		0
	57-63 Days (Group 3)	17	2	(12%)		2	1	(50%)	1	(50%)	0		0
DYSPEPSIA	≤63 Days (All)	71	2	(3%)	0.5155	2	1	(50%)	0	j	1	(50%)	0
	≰49 Days (Group 1)	28	0			0	0		0		. 0		0
5	50-56 Days (Group 2)	26	1	(4%)		1	0		-0	*	1	(100%)	0
	57-63 Days (Group 3)	17	1	(6%)		1	1	(1001)	( <b>0</b> (	.!	' 0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				-Severit	γ		
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknown
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)												
FLATULENCE	≤63 Days (All)	71	3 (4%)	0.6115	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	28	1 (4%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	26	2 (8%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	17	0		0	0		0		0		0
NAUSEA	≤63 Days (All)	71	42 (59%)	0.3779	67	27	(40%)	30	(45%)	10	(15%)	0
	≤49 Days (Group 1)	28	14 (50%)		17	7	(41%)	9	(53 %)	1	(6%)	0
	50-56 Days (Group 2)	26	16 (62%)		24	9	(38%)	10	)	: 5	(21%)	Ö
	57-63 Days (Group 3)	17	12 (71%)		26	11	(42%)	11			(15%)	0
VOMITING	≤63 Days (All)	71	25 (35%)	0.1310	39	14	(36%)	19	(49%)	6	(15%)	0
•	≤49 Days (Group 1)	28	6 (21%)		8	3	(38%)	5		0	(13-)	Ö
	50-56 Days (Group 2)	26	11 (42%)		17	5	(29%)	8	(47%)	4	(24%)	Ö
	57-63 Days (Group 3)	17	8 (47%)		14	6	(43%)	6			(14%)	ō
ASCULAR (EXTRACARDIAC) DISORDERS												
ANY EVENT .	s63 Days (All)	71	1 (1%)	0.6056	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	28	0		0	0		0		0		0
	50-56 Days (Group 2)	26	1 (4%)		1	0		. 1	(100%)	0		0
·	57-63 Days (Group 3)	17	0		0	0		0		0		0
FLUSHING	≤63 Days (All)	71	1 (1%)	0.6056	1	0		1	(100%)	0		0
•	≤49 Days (Group 1)	28	0		0	0		0,	-	0		0
·	50-56 Days (Group 2)	26	1 (4%)		1	0	٠. ٠		(100%)	0		0
	57-63 Days (Group 3)	17	0		0	0		0	•	0		o

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	,	Severit	<b>y</b>	
Body System/Event (2)	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS						· · · · · · · · · · · · · · · · · · ·			
ANY EVENT	s63 Days (All)	71	5 (7	0.2784	8	6 (75%)	2 (25%)	0	0
	≤49 Days (Group 1)	28	4 (14)	:)	4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	26	1 (4	:)	4	4 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	71	1 (1	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	1 (4)	:)	1	1 (100%)	0	0	Ô
	50 56 Days (Group 2)	26	0		0	0	0	0	Ô
	57-63 Days (Group 3)	17	0		0	0	0	0	ō
PULMONARY CONGESTION	≤63 Days (All)	71	1 (1	1.0000	1	0	1 (100%)	0	0
T.	≤49 Days (Group 1)	28	1 (4)	)	1	0	· 1 (10Q%)	0	n
	50-56 Days (Group 2)	26	0		0	0	0	o	0
	57 63 Days (Group 3)	17	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	71	3 (41	) 0.7835	6	5 (83%)	1 (17%)	0	0
	≤49 Days (Group 1)	28	2 (79	.)	2	1 (50%)	1 (50%)	0	0
•	50-56 Days (Group 2)	26	1 (4)	)	4	4 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
LATELET, BLEEDING & CLOTTING DISORDERS			!						
ANY EVENT	≰63 Days (All)	71	1 (19	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4)	)	1	0	1 (100%)	Ō	0
<del>1</del> .	50-56 Days (Group 2)	26	0		0	0	.0	1 0	ō
	57-63 Days (Group 3)	17	0		0	0	<b>o</b> ;	0	ō

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

	Gestational	Total	Numbe		Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt w/Eve		exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
PLATELET, ALBEDING & CLOTTING DISOR	DERS (cont.)									
EPISTAXIS	≤63 Days (All)	71	1	(1%)	1.0000	1	0 .	1 (100%)	0	0
	≤49 Days (Group 1)	28	1	(4%)		1 .	0	1 (100%)	0	0
	50 56 Days (Group 2)	26	0	1		0	0	0	0	0
	57 63 Days (Group 3)	17	0			0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE										
ANY EVENT	≤63 Days (All)	71	4	(6%)	0.8280	4	2 (50%)	1 (25%)	1 (25%)	0
	≰49 Days (Group 1)	28	1	(4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	2	(8%)		2	1 (50%)	0	1 (50%)	0
	57 63 Days (Group 3)	17	- 1	(6%)		1	1 (100%)	0	0	0
LEUKORRHOEA	≤63 Days (All)	71	1	(1%)	0.6056	. 1	1 (100%)	. o '	0	0
	≤49 Days (Group 1)	28	0			O	0	0	0	0
	50 56 Days (Group 2)	26	1	(4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0			0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	71	1	(1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1	(4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0			0	0	0	0	0
( )	57-63 Days (Group 3)	17	0			0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	71	1	(1%)	0.6056	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	28	0			0	0	, <b>Q</b>	0	0
<del>*</del> .	50-56 Days (Group 2)	26	1	(4%)		1	0 * 1	<b>6</b> . :	1 (100%)	0
	57-63 Days (Group 3)	17	0			0	0	o ·	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Mild	Severity Moderate	Severe	Unknown
PRODUCTURE DISCORDERS PRINTE (cont.)				<del></del>			······································		
EPRODUCTIVE DISORDERS, PEMALE (cont.) VAGINITIS	≤63 Days (All)	71	1 (1%)	0.2394	1	1 (100%)	0	0	0
VAGINIIIS	s49 Days (Group 1)	28	0 (10,	0.2374	•	0	Ō	ō	ň
	50-56 Days (Group 2)	26	0		0	0	0	0	n
	57-63 Days (Group 3)	17	1 (6%)		1	1 (100%)	0	o	0
	-	•							
ODY AS A WHOLE - GENERAL DISORDERS						()	4		_
ANY EVENT	≤63 Days (All)	71	69 (97%)	1.0000	165	69 (42%)	79 (48%)	17 (10%)	0
	≤49 Days (Group 1)	28	27 (96%)		57	25 (44%)	31 (54%)	1 (2%)	0
	50-56 Days (Group 2)	26	25 (96%)		5 <b>8</b>	22 (38%)	27 (47%)	9 (16%)	0
	57-63 Days (Group 3)	17	17 (100%)		50	22 (44%)	21 (42%)	7 (14%)	0
ABDOMINAL PAIN	≤63 Days (All)	71	65 (92%)	0.8736	147	60 (41%)	75 (51%)	12 (8%)	0
	≤49 Days (Group 1)	28	26 (93%)		52	22 (42%)	29 (56%)	1 (2%)	0
	50-56 Days (Group 2)	26	24 (92%)		53	21 (40%)	25 (47%)	7 (13%)	0
	57-63 Days (Group 3)	17	15 (88%)		42	17 (40%)	21 (50%)	4 (10%)	0
ALLERGY	≤63 Days (All)	71	1 (1%)	0.2394	1	1 (100%)	0	0	0
ABBBROT	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	0		0	0	0	0	0
r · · · · · ·	57-63 Days (Group 3)	17	1 (6%)		1	1 (100%)	0	0	0
ASTHENIA	s63 Days (All)	71	2 (3%)	0.0547	2	2 (100%)	0	0	0
ADIDENIA	≤49 Days (Group 1)	28	0	3.03	0	0	0 .	0	0
i.	50-56 Days (Group 2)	26	0		0	0	d,	n	0
	57-63 Days (Group 3)	26 17	2 (12%)		2	2 (100%)	0.	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	t <b>v</b>	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (	cont.)								
BACK PAIN	≰63 Days (All)	71	7 (10%)	0.6817	7	4 (57%)	2 (29%)	1 (14%)	0
	≤49 Days (Group 1)	28	4 (14%)		4	3 (75%)	1 (25%)	0	ň
	50-56 Days (Group 2)	26	2 (8%)		2	1 (50%)	1 (50%)	o	ŏ
	57-63 Days (Group 3)	17	1 (6%)		1	0	0	1 (100%)	ō
FATIGUE	≤63 Days (All)	71	1 (1%)	0.2394	2	2 (100%)	0	0	j 0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	0		O	0	0	0	n
	57-63 Days (Group 3)	17	1 (6%)		2	2 (100%)	0	0	Ö
FEVER	≤63 Days (All)	71	1 (1%)	0.6056	1	0	1 (100%)	0	n
	≤49 Days (Group 1)	28	0		0	0 .	0 '	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
LEG PAIN	≰63 Days (All)	71	1 (1%)	0.2394	1	0	0	1 (100%)	0
•	≤49 Days (Group 1)	28	0		0	0	0	0	ō
	50-56 Days (Group 2)	26	0		0	0	0	0	ŏ
,	57 63 Days (Group 3)	17	1 (6%)		1	0	0	1 (100%)	ō
PAIN	≤63 Days (All)	71	1 (1%)	0.6056	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	28	0		0	0	0	0	0
÷	50-56 Days (Group 2)	26	1 (4%)		1	0	<b>o</b> ,	1 (100%)	0
	57-63 Days (Group 3)	17	0		0	•	0.	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number -	Mild	Severity Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont.)									
RIGORS 4	≤63 Days (All)	71	2 (31	1.0000	2	0	1 (50%)	1 (50%)	0
n.como	≤49 Days (Group 1)	28	1 (4%	-	1	o ,	1 (100%)	0	o o
	50-56 Days (Group 2)	26	1 (41		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	0	,	0	0	0	0	Ō
SYNCOPE	≤63 Days (All)	71	1 (11	) 0.2394	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50 56 Days (Group 2)	26	0		0	0	0	0	0
	57-63 Days (Group 3)	17	1 (61	)	1	0	0	1 (100%)	0
PPLICATION SITE DISORDERS [4]									
ANY EVENT	≤63 Days (All)	71	1 (19	0.6056	1	1 (100%)	. 0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (41	)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
INJECTION SITE BRUISING	≤63 Days (All)	71	. 1 (19	0.6056	1	1 (100%)	0	<b>o</b> ,	0
•	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (41	)	1	1 (100%)	0	0	0
r ·	57-63 Days (Group 3)	17	0		0	0	. 0	0	0
ESISTANCE MECHANISM DISORDERS						,			
ANY EVENT	≤63 Days (All)	71	1 (19	0:6056	1	1 (100%)	0	0	0
<b>T</b>	≤49 Days (Group 1)	28	0		0	0,	ď	0	0
* * *	50-56 Days (Group 2)	26	1 (41	<u> </u>	1	1 (190%)	ī <b>d</b> ,	0	0
	57-63 Days (Group 3)	17	0		0	0 .	P	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

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

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Mild	Severity Moderate	Severe	Unknown
SISTANCE MECHANISM DISORDERS (cont.)								-	
INFECTION PARASITIC	≰63 Days (All)	71	1 (1%)	0.6056	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	Ö	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		1		Severi	t <b>v</b>		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events		1d '		erate	•	ere	Unknow
ANY EVENT	≤63 Days (All)	151	150 (>99%)	0.2517	841	291	(35%)	361	(43%)	189	(22%)	0
	≰49 Days (Group 1)	70	70 (100%)	1	347	121	(35%)	164	(47%)	62	(18%)	0
	50-56 Days (Group 2)	43	43 (100%)	)	268	93	(35%)	110	(41%)	65	(24%)	0
	57-63 Days (Group 3)	38	37 (97%)	)	226	77	(34%)	87	(38%)	62	(27%)	0
KIN AND APPENDAGES DISORDERS												
ANY EVENT	≤63 Days (All)	151	3 (2%)	0.7966	3	2	(67%)	1	(33%)	0		0
	s49 Days (Group 1)	70	2 (3%)	)	2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	43	1 (2%)	1	1	1	(100%)	0		0		0
	57-63 Days (Group 3)	38	.0		0	0		0		0		0
RASH	≰63 Days (All)	151	2 (14)	1.0000	2	2	(100%)	. 0		0		0
	≤49 Days (Group 1)	70	1 (1%)	1	1	1	(100%)	0	•	0		0
	50-56 Days (Group 2)	43	1 (2%)	)	1	1	(100%)	0		0		0
	57-63 Days (Group 3)	38	0		0	0		0		0		0
URTICARIA	≰63 Days (All)	151	1 (<1%)	1.0000	1	0		1	(100%)	0		0
•	≰49 Days (Group 1)	70	1 (1*)	1	1	0		1	(100%)	0		0
	50-56 Days (Group 2)	43	0		0	0		0		0		0
	57 63 Days (Group 3)	38	0		0	0		0		0		0
JSCULO-SKELETAL SYSTEM DISORDERS			,						į			
ANY EVENT	≰63 Days (All)	151	2 (1%)	0.2861	2	0		2	(100%)	0		0
<b>.</b>	s49 Days (Group 1)	70	0		0	0		0	1	0		0
	50-56 Days (Group 2)	43	1 (2%)		1	0			(100%)	1 0		0
•	57-63 Days (Group 3)	38	1 (3%	1	1	0	•	1	(100%)	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: 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: VARGAS (#22)

Body System/Event [2]	Gestational Age Group {3}	Total Number of Pts	Number of Pi w/Eve	ts	Fisher's exact p-value	Number of Events	 Mi			Severit			Unknown
	0.00p (5)					OF EVENCS			Houe		- OE 1	·	UIIXIIOWII
USCULO-SKELETAL SYSTEM DISORDERS (cont.)													
ARTHRALGIA	≤63 Days (All)	151	1	(<1,8)	0.5364	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	- 43	1	(21)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
MYALGIA	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	4.3	0			0	0		0		0		0
	57 63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	151	65	(43%)	0.7381	97	36	(37%)	51	(53%)	10	(10%)	0
	≤49 Days (Group 1)	70	28	(40%)		41	16	(39%)	21		4		0
	50-56 Days (Group 2)	43	19	(44%)		29	13	(451)	15	(52%)	1	-	Ô
	57-63 Days (Group 3)	38	18	(47%)		27	7	(26%)	15		5		0
DIZZINESS	≤63 Days (All)	151	22	(15%)	0.7975	27	10	(37%)	16	(59%)	1	(4%)	0
	s49 Days (Group 1)	70		(16%)		13	6	(46%)	7		0	, ,	n
	50-56 Days (Group 2)	43	7	(16%)		8	3	(38%)		(631)	0		o
,	57-63 Days (Group 3)	38		(11%)		6	1	(17%)	4		1	(174)	o
HEADACHE	≤63 Days (All)	151	54	(36%)	0.4003	68	25	(37%)	35	(51%)	8	(12%)	0
	≤49 Days (Group 1)	70		(31%)		26	9	(35%)		(54%)	3		0
$\hat{\boldsymbol{q}}_{i}$	50 56 Days (Group 2)	43		(35%)		21	10	(481)		· (48%)	1		Õ
e e e e	57-63 Days (Group 3)	38		(45%)		21	6	(29%)		(521)	4		0
						- •	_	, =	1	,	•	,	Ū

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

- 1 - 1 - 1 - 1 - 1	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severity		-
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISORD	ERS (cont.)								
HYPOAESTHESIA	≤63 Days (All)	151	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
MIGRAINE	≤63 Days (All)	151	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	70	1 (1%)	1.0000	i	0	0	1 (100%)	0
	50.56 Days (Group 2)	43	0			0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
ISION DISORDERS			,						
ANY EVENT	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	. 0	0	0
	≤49 Days (Group 1)	70	0		0	0	о '	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57.63 Days (Group 3)	38	0		0	o	0	0	0
VISION ABNORMAL	s63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	O
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50 56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
r ,	57-63 Days (Group 3)	38	0		0	0	0	0	Ō
ARING AND VESTIBULAR DISORDERS					•				
ANY EVENT	≤63 Days (All)	151	1 (<1%)	0.2517	1	0	1 (100%)	0	0
$\vec{\sigma}_{i}$ , $i$	≤49 Days (Group 1)	70	0		0	0	0!	0	0
4 1 6 A	50-56 Days (Group 2)	43	0		0	0; **	o" ,	0	0
•	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	0
			1			r	•		

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number	Number of Pt	t.s	Fisher's exact	Number				- Severity		
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p-value	of Events	Mi	1 d	Mode	erate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS (cont.)												
TINNITUS	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0	0
	≰49 Days (Group 1)	70	0			0	0		0		0	0
	50-56 Days (Group 2)	43	0			0	0		0		0	0
	57-63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	0	0
PSYCHIATRIC DISORDERS		•									<u>;</u>	i
ANY EVENT	≤63 Days (All)	151	9	(6%)	0.6789	9	2	(22%)	5	(56%)	2 (22%)	\
	≤49 Days (Group 1)	70	5	(7%)		5	2	(40%)	3	(60%)	0	0
	50-56 Days (Group 2)	43	3	(7%)		3	0		2	(67%)	1 (33%)	0
	57-63 Days (Group 3)	38	1	(3%)		. 1	0		0		1 (100%)	0
ANOREXIA	≤63 Days (All)	151	2	(1%)	0.2861	2	0		· 1	(50%)	1 (50%)	0
	≤49 Days (Group 1)	70	0			0	0		0		0	0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0	0
	57-63 Days (Group 3)	38	1	(3%)		1	0	I	o		1 (100%)	0
DEPRESSION ,	s63 Days (All)	151	1	(<1%)	1.0000	• 1	1	(100%)	0		0	0
	≤49 Days (Group 1)	70	1	(1%)		1	1	(100%)	0		0	0
	50-56 Days (Group 2)	43	0			0	0		0		0	0
· ′	57-63 Days (Group 3)	38	0			0	0		0		0	0
EMOTIONAL LABILITY	≰63 Days (All)	151	2	(1%)	1.0000	2	1	(50%)	0		1 (50%)	0
	≤49 Days (Group 1)	70	1	(1%)		1	1	(100%)	0		0	0
नं. ,	50-56 Days (Group 2)	43	1	(2%)		1	0	<i>₽</i> •	ď	ş. <b>4</b> . •	1 (100%)	0
	57-63 Days (Group 3)	38	0			0	0	, <b>i</b>	0	•	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number							
Body System/Event [2]	Group [3]	of Pts		event	p-value	of Events		.1d		Severi erate	Sev	ere	Unknowr
PSYCHIATRIC DISORDERS (cont.)									*				
INSOMNIA	≤63 Days (All)	151	4	(3%)	0.6950	4	0		4	(100%)	0		0
	≰49 Days (Group 1)	70	3	(4%)		3	0	•		(100%)	0		Ō
	50-56 Days (Group 2)	43	1	(2%)		1	0		)	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
ASTRO-INTESTINAL SYSTEM DISORDERS		•											
ANY EVENT	≰63 Days (All)	151	119	(79%)	0.1176	316	125	(40%)	134	(42%)	57	(18%)	0
	\$49 Days (Group 1)	70	50	(71%)		119	43	(36%)	59		17	(14%)	Ô
	50-56 Days (Group 2)	43	36	(84%)		105	41	(39%)	41		23	(22%)	0
	57-63 Days (Group 3)	38	33	(87%)		92	41	(45%)	34		17	(18%)	0
CONSTIPATION	≤63 Days (All)	151	1	(<1%)	0.5364	1	0		. 1	(100,)	0		0
	≤49 Days (Group 1)	70	0			0	0		0	•	0		0
	50-56 Days (Group 2)	43	1	(21)		1	0		•	(100%)	0		0
T.	57-63 Days (Group 3)	38	0	,		ō	ō		0	-	o		0
DIARRHEA .	≤63 Days (A11)	151	`50	(33%)	0.1287	68	34	(50%)	25	(37%)	۰	(13%)	0
	≰49 Days (Group 1)	70	18	(26%)		24	11	(46%)	10			(13%)	0
	50-56 Days (Group 2)	43	19	(44%)		24	11	(46%)	10			(13%)	0
	57-63 Days (Group 3)	38	13	(34%)		20	12	(60%)		(25%)		(15%)	0
DYSPEPSIA	≤63 Days (All)	151	2	(1%)	0.4993	2	. 0	1	1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	70	2	(3%)		2	ō		1	(50%)	î	(50%)	0
<i>₹.</i> , ,	50-56 Days (Group 2)	43	0		!	0	0		0.		ō	, , , , ,	0
and the second s	57-63 Days (Group 3)	38	0		į	0	ō	ji	. 0		0		0
•	•						-				J		U

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number	of	mber Pts	Fisher's exact					Severit	y		
Body System/Event [2]	Group [3] c		w/E	Event	p-value	of Events	Mi	.1 <b>d</b>	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)			-										
NAUSEA	≤63 Days (All)	151	104	(69%)	0.3257	166	71	(43%)	67	(40%)	28	(17%)	0
	≤49 Days (Group 1)	70	44	(63%)		65	27	(42%)	29	(45%)	9	(14%)	0
	50-56 Days (Group 2)	43	31	(72%)		53	21	(40%)	22	(421)	10	(19%)	0
	57-63 Days (Group 3)	30	29	(76%)		48	23	(48%)	16	(33%)	9		0
TOOTH ACHE	≤63 Days (All)	151	2	(1%)	0.7342	2	0.		2	(100%)	0		o
	≤49 Days (Group 1)	70	1	(1%)		1	0 -		1	(1001)	0		0
	50-56 Days (Group 2)	43	0			0	0		0		10		0
	57 63 Days (Group 3)	38	1	(3%)		1	0		1	(100%)	O		0
VOMITING	≰63 Days (All)	151	51	(34%)	0.1493	77	20	(26%)	38	(49%)	19	(25%)	0
,	s49 Days (Group 1)	70	18	(26%)		27	5	(19%)	18	(67%)	4	(15%)	0
	50-56 Days (Group 2)	43	18	(42%)		27	9	(33%)	8	(30%)	10	(37%)	0
	57-63 Days (Group 3)	38	15	(39%)		23	6	(26%)	12	(52%)	5	(22%)	0
TABOLIC AND MUTRITIONAL DISORDERS								•					
ANY EVENT	≤63 Days (All)	151	2	(1%)	0.2861	2	1	(50%)	1	(50%)	0		0
	≰49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0		0
	57 63 Days (Group 3)	38	1	(3%)		1	1	(100%)	0		0		0
DEHYDRATION	s63 Days (All)	151	1	(<1%)	0.2517	1	1	(100%)	0		0		0
4.	≤49 Days (Group 1)	70	0			0	0		Ο,		0		0
	50 56 Days (Group 2)	43	0			0	0		0 4	· !	0		0
•	57-63 Days (Group 3)	38	1	(31)		1	1	(1001)	0	•	0		0

<sup>[1]</sup> Includes all adverse event# reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>|2|</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational	Total	Number	Fisher's		į.			
Body System/Event [2]	Age Group [3]	Number of Pts of Pts w/Event		exact p-value	Number of Events	Mild	Severity Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS	(cont.)		- W. M. M.						<del></del>
THIRST +	≤63 Days (All)	151	1 (<1%)	0.5364	1	n	1 (100%)	0	
	≤49 Days (Group 1)	70	0		0	n	0	0	0
	50 56 Days (Group 2)	43	1 (2%)		ĭ	ň	1 (100%)	0	0
	57-63 Days (Group 3)	38	0		0	ō	0	0	0
ESPIRATORY SYSTEM DISORDERS		•							
ANY EVENT	≤63 Days (All)	151	3 (2%)	0.7966	6	4 (67%)	1 (17%)	1 (17%)	0
	≰49 Days (Group 1)	70	2 (3%)		5	4 (80%)	0	1 (20%)	0
	50-56 Days (Group 2)	43	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	30	0		0	0	0	o	0
BRONCHITIS	≤63 Days (All)	151	1 (<1%)	1.0000	3	2 (67%)	. 0 ,	1 (33%)	0
	≤49 Days (Group 1)	70	1 (1%)		3	2 (67%)	o '	1 (33%)	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	o	Ö	0
PHARYNGITIS	≤63 Days (All)	151	1 (<1%)	1.0000	1	1 (100%)	0	o	•
•	s49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	43	0		0	0	0	n	0
,	57-63 Days (Group 3)	38	0		0	0	. 0	0	Ô
			t					_	Ū
SINUSITIS	≰63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	O
•	≤49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	Ô
r.	50-56 Days (Group 2)	43	1 (2%)		1	0	1:(100%)	10	n
	57-63 Days (Group 3)	38	O		0	0	0 1 1	o	ō

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Mild	Severity Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDERS	<u>, , , , , , , , , , , , , , , , , , , </u>								
ANY EVENT	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0
The state of the s	≤49 Days (Group 1)	70	1 (11)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	43	1 (21)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	30	0		0	0	0	0	0
EPISTAXIS	s63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≰49 Days (Group 1)	70	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	507-63 Days (Group 3)	38	0		0	0	0	0	0
RINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	2 (1%)	1.0000	,3	1 (33%)	2 (67%)	0	0
	≰49 Days (Group 1)	70	1 (1%)		2	0	2 (100%)	0	o
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
DYSURIA	s63 Days (All)	151	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
•	57-63 Days (Group 3)	38	0		0	0	0	0	0
MICTURITION DISORDER	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
4.	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	α,	0	0
	57-63 Days (Group 3)	38	0		0	0 ;	0 <sup>-1</sup>	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			····Severit	<b>y</b> .	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
URINARY SYŞTEM DISORDERS (cont.)									
MICTURITION FREQUENCY	≰63 Days (All)	151	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, PEMALE		• •							
ANY EVENT	≰63 Days (All)	151	9 (6%)	1.0000	9	2 (22%)	3 (33%)	4 (44%)	0
	≤49 Days (Group 1)	70	4 (6%)		4	1 (25%)	2 (50%)	1 (25%)	0
	50-56 Days (Group 2)	43	3 (7%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	38	2 (5%)		. 2	0	0	2 (100%)	0
BREAST PAIN FEMALE	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	· 0 i	o	0
	≰49 Days (Group 1)	70	0		0	0	Ó	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
LEUKORRHOEA	≰63 Days (All)	151	2 (1%)	0.4993	2	1 (50%)	1 (50%)	o	0
	≤49 Days (Group 1)	70	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
r '	57-63 Days (Group 3)	38	0		0	0	0	O	0
UTERINE HAEMORRHAGE	≰63 Days (All)	151	5 (3%)	0.7184	5	0	1 (20%)	4 (80%)	0
	≤49 Days (Group 1)	70	2 (3%)		2	0	1 (50%)	1 (50%)	0
$\hat{m{r}}_{i}$ . $\hat{m{r}}_{i}$	50-56 Days (Group 2)	43	1 (2%)		1	0	<b>o</b> ,	1 (100%)	0
i i 🎳 - A	57-63 Days (Group 3)	38	2 (5%)		2	0 ,	0	2 (100%)	0

<sup>[1]</sup> Includes all adverse event's reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number	Numb of F		Fisher's exact	Number				Severi	tv		
Body System/Event [2]	Group [3]			vent	p-value	of Events		11 <b>d</b>		rate	Sev		Unknow
REPRODUCTIVE DISORDERS, FEMALE (cont.)													
vaginitiš	≤63 Days (All)	151	1	(<1%)	0.5364	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	Ô		0
	57-63 Days (Group 3)	38	0			0	0		0		0	1	0
BODY AS A WHOLE - GENERAL DISORDERS		•											i
ANY EVENT	≤63 Days (All)	151	150 (	(>99%)	0.2517	382	114	(30%)	156	(41%)	112	(29%)	, o
	≤49 Days (Group 1)	70		(100%)		164	53	(321)	73	(45%)	30	(23%)	Õ
	50-56 Days (Group 2)	43	43 (	(100%)		118	33	(28%)	47	(40%)	30	(32%)	0
	57-63 Days (Group 3)	38	37	(971)		100	28	(28%)	36		36	(36%)	0
ABDOMINAL PAIN	≤63 Days (All)	151	150 (	(>99%)	0.2517	337	88	(26%)	137	(41%)	112	(33%)	0
	≤49 Days (Group 1)	70		(100%)		146	42	(29%)	66	(45%)	38	(26%)	Ö
	50-56 Days (Group 2)	43	43 (	(100%)		101	24	(24%)	39	(39%)	38	(38%)	0
	57-63 Days (Group 3)	38	37	(97%)		90	22	(24%)	32	(36%)	36	(40%)	0
ALLERGY	≤63 Days (All)	151	2	(1%)	0.0621	2	2	(100%)	0		0		0
	≰49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	0			0	0		0		0		0
	57-63 Days (Group 3)	38	2	(5%)		2	2	(100%)	0		0		0
BACK PAIN	≤63 Days (All)	151	15	(10%)	0.6078	18	11	(61%)	7	(391)	0		0
	≰49 Days (Group 1)	70	6	(9%)		7	5	(71%)	2	(29%)	0		0
<del>-</del>	50-56 Days (Group 2)	43	6	(14%)		8	5	(63)	3 5	(381)	0		0
	57-63 Days (Group 3)	38	3	(8♥)		3	1	(331)	2.	(67%)	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numbe of Pt w/Eve	9	Fisher's exact p value	Number of Events		1d		Severity- oderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont.	,											
FATIGUE *	≤63 Days (All)	151	8	(5%)	0.8096	9	2	(221)		7 (78%)	0	0
	≤49 Days (Group 1)	70	4	(6%)		4	2	(50%)	İ	2 (50%)	0	0
	50-56 Days (Group 2)	43	3	(7%)		4	0		ļ	4 (100%)	0	0
	57-63 Days (Group 3)	38	1	(3%)		1	0			1 (100%)	0	0
FEVER	≤63 Days (All)	151	4	(31)	0.8104	4	4	(100%)		0	0	0
	≤49 Days (Group 1)	70	1	(1%)		1	1	(100%)		0	0	0
	50-56 Days (Group 2)	43	2	(5%)		2	2	(100%)		0	0	0
	57-63 Days (Group 3)	38	1	(3%)		1	1	(100%)		0	0	0
HOT FLUSHES	≰63 Days (All)	151	3	(21)	0.6120	3	2	(67%)		1 (33%)	0	0
· ·	≤49 Days (Group 1)	70	2	(3%)		2	1	(50%)		1 (50%)	0	0
	50-56 Days (Group 2)	43	0			0	0			0	0	0
	57-63 Days (Group 3)	38	1	(3%)		1	1	(100%)		0	0	0
LEG PAIN	≤63 Days (All)	151	1 (	<1%)	0.2517	1	0			1 (100%)	0	0
	≤49 Days (Group 1)	70	. 0			0	0			0	0	0
•	50-56 Days (Group 2)	43	0			0	0			0	0	0
	57-63 Days (Group 3)	38	1	(3%)		1	0			1 (100%)	0	. 0
RIGORS	s63 Days (All)	151	6	(4%)	1.0000	6	, 4	(67%)	!	2 (33%)	0	0
	≤49 Days (Group 1)	70	3	(4%)		3	2	(67%)		1 (33%)	0	0
	50-56 Days (Group 2)	43	2	(5%)	1	2	1	(50%)		1 (50%)	0	0
	57-63 Days (Group 3)	38	1	(3%)	ļ	1	1	(100 <b>%)</b>	• <u>\</u>	0 1.	0	0

<sup>(1)</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		···Severit	; <b>v</b>	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.	)								
SYNCOPE *	≤63 Days (All)	151	2 (1%	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	70	1 (1%	)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	1 (2%	)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	151	7 (5%	0.8873	8	2 (25%)	4 (50N)	2 (25%)	0
	≤49 Days (Group 1)	70	4 (6%	)	4	1 (25%)	3 (75%)	; <b>0</b>	0
	50-56 Days (Group 2)	43	2 (5%	)	3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	38	1 (31	)	. 1	0	0	1 (100%)	0
HERPES SIMPLEX	≤63 Days (All)	151	1 (<1%	0.5364	2	1 (50%)	. 0	1 (50%)	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	1 (2%	)	2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	38	0		0	O	0	. 0	0
INFECTION .	≤63 Days (All)	151	1 (<1%	1.0000	1	o	1 (100%)	0	0
	≤49 Days (Group 1)	70	1 (1%	)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
1	57-63 Days (Group 3)	38	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	151	5 (3%	1.0000	5	1 (20%)	3 (60%)	1 (20%)	0
	≰49 Days (Group 1)	70	3 (4%	)	3	1 (33%)	2 (67%)	0	0
<del>4</del> .	50-56 Days (Group 2)	43	1 (2%	)	1	0	4 (100%)	0	0
1	57-63 Days (Group 3)	38	1 (3%	)	1	0	. <b>o</b> '. , '	i (100%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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]

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		· ,		Severi	tv			
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi]		Mode		Sev			nown
ANY EVENT	≤63 Days (All)	89	89 (100 <b>%</b> )		770	307	(40%)	303	(39%)	157	(20%)	3	(<1 <b>%</b>
	≤49 Days (Group 1)	35	35 (100%)		288	123	(43%)	105	(36%)	59	(20%)		
	50-56 Days (Group 2)	34	34 (100%)		304	107	(35%)	133	(44%)	64	(21%)	0	•
	57-63 Days (Group 3)	20	20 (100%)		178	77	(43%)	65	(37%)	34	(19%)	2	(1%
KIN AND APPENDAGES DISORDERS		•											
ANY EVENT	≤63 Days (All)	89	3 (3%)	0.7904	3	1	(33%)	1	(33%)	1	(33%)	0	
	≤49 Days (Group 1)	35	2 (6%)		2	1	(50%)	0		1	(50%)	0	
	50-56 Days (Group 2)	34	1 (3%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	20	0		. 0	0		0		0		0	
SKIN DISORDER	≤63 Days (All)	89	1 (1%)	0.6067	1	0		. 1	(100%)	0		0	
	s49 Days (Group 1)	35	0		0	0		0		0		0	
	50-56 Days (Group 2)	34	1 (3%)		1	0		1	(100%)	0		. 0	
	57-63 Days (Group 3)	20	0		0	0		0		0		0	
SWEATING INCREASED	≤63 Days (All)	89	1 (1%)	1.0000	1	0		0		1	(100%)	0	
·	≤49 Days (Group 1)	35	1 (3%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	34	0		0	0		0		0		0	
, ,	57-63 Days (Group 3)	20	0		0	0		0		0		0	
VERRUCA	≤63 Days (All)	89	1 (1%)	1.0000	1	1	(100%)	0	Ì	0		0	
	<pre>\$49 Days (Group 1)</pre>	35	1 (3%)		1	1	(100%)	0		, 0		0	
<del>.</del> , , , , , , , , , , , , , , , , , , ,	50-56 Days (Group 2)	34	0		0	0		0		0		0	
	57-63 Days (Group 3)	20	0		0	0		o. '	:	່ າ		0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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SKELETAL PAIN

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

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Num of w/E		Fisher's exact p value	Number of Events	Mild	Severi	•	
					p total	OI EVENCE	MIIG	Moderace	Severe	Unknown
USCULO-SKELETAL SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	89	2	(2%)	0.5174	4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	35	0	1		0	0	0	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1	(5%)		3	3 (100%)	0	0	0
ARTHRALGIA	≰63 Days (All)	89	1	(1%)	0.2247	1 .	1 (100%)	0	_	_
	≤49 Days (Group 1)	35	ō	12-7	0.2247	0	1 (1004)	0	0	0
	50-56 Days (Group 2)	34	0			Ů	0	0	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	1 (100%)	0	0	0
MYALGIA	≤63 Days (All)	89	1	(1%)	0.6067	1	0	0	1 (100%)	•
•	≰49 Days (Group 1)	35	0			0	0	. 0 .	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	o '	1 (100%)	0
	57-63 Days (Group 3)	20	0			o	0	n	0	0

	50-56 Days (Group 2)	34	0			0	0		0	n		ň
	57 63 Days (Group 3)	20	1	(5%)		2	2 (	(100%)	0	ň		^
,	· · · · · · · · · · · · · · · · · · ·					_		,	·	·		U
CENTR 4 PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	89	51	(57%)	0.5776	101	34	(34%)	48 (48%)	19	(19%)	٥
	≰49 Days (Group 1)	35	22	(63%)		36	16	(44%)	15 (42%)		(14%)	0
<i>₹.</i> ,	50-56 Days (Group 2)	34	17	(50%)		35	10	(29,1)	18 (51%)	7	(20%)	ň
and the state of t	57-63 Days (Group 3)	20	12	(60%)		30		(278) L	15 (501)	7	(23%)	ō
•								- C			•	•

0

(1%)

0.2247

2 (100%)

89

35

≤63 Days (All)

≤49 Days (Group 1)

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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

•	Gestational	Total	Number	_	Fisher's exact	Number				Severit	y		
	Age	Number	of Pts		p value	of Events	Mi		Mode		Seve		Unknow
Body System/Event [2]	Group [3]	of Pts	w/Ever		p varue								
ENTR & PERIPH NERVOUS SYSTEM DISORDERS	(cont.)			2041	0.1305	29	13	(45%)	8	(28%)	8	(28%)	0
DIZZINESS	≤63 Days (All)	89		,	0.1305	17	9	(53%)	4	(24%)	4	(24%)	0
	≰49 Days (Group 1)	35		31%)		7	2	(29%)	4	(57%)	1	(14%)	0
	50 56 Days (Group 2)	34		12%)		5	2	(40%)	0		3	(60%)	0
	57-63 Days (Group 3)	20	3 (	15%)		,	·	(404)	•				
		20.1	38 (	43%)	0.3337	72	21	(291)	40	(56%)	11	(15%)	0
HEADACHE	≤63 Days (All)	89	-	34%)	0.333,	19	7	(37%)	11	(58%)	1	(5%)	0
	≤49 Daye (Group 1)	35		44%)		28	8	(29%)	14	(50%)	6	(21%)	0
	50 56 Days (Group 2)	34		55%)		25	6	(24%)	15	(60%)	4	(16%)	0
	57-63 Days (Group 3)	20		750,									
ISION DISORDERS	62 Davis (811)	89	1	(1%)	0.6067	1	0		. 1	(100%)	0		0
ANY EVENT	s63 Days (All)	35	0	, = - ,		0	0		0		0		0
	s49 Days (Group 1)	34	-	(3%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2) 57-63 Days (Group 3)	20	ō	(3-,		0	0		0		0		0
	,			(1%)	0.6067	1	0		1	(100%)	0		0
BLEPHARITIS	≤63 Days (All)	89	_	(14)	0.0007	ō	o		0		0		0
,	<pre>s49 Days (Group 1)</pre>	35	0	(30)		1	0		1	(100%)	0		0
	50 56 Days (Group 2)	34		(3%)		0	0		. 0	, ,	0		0
· ·	57-63 Days (Group 3)	20	0			V	·		·				
EARING AND VESTIBULAR DISORDERS			2	(2%)	0.3437	3	1	(33%)	1	(33%)	1	(331)	0
ANY EVENT	≤63 Days (All)	89		(6%)	0.3131	3	1	(33%)	1	(33%)	1	(33%)	0
<b>4</b> .	s49 Days (Group 1)	35	2	(01)		o	0		. 0	4 - 1	0		0
	50 56 Days (Group 2)	34	0			, 0	0	,i	. 0	* 1	0		0
	57-63 Days (Group 3)	20	0			•	·		1				

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: 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:

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		···-Severit		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS (cont.)									
EAR ACHE	≤63 Days (All)	89	2 (2%)	0.3437	3	1 (33%)	1 (33%)	1 (33%)	0
	≰49 Days (Group 1)	35	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
SYCHIATRIC DISORDERS		-						i ,	i
ANY EVENT	≤63 Days (All)	89	7 (8%)	0.6869	11	5 (45%)	3 (27%)	3 (27%)	' O
	≤49 Days (Group 1)	35	4 (11%)		<b>7</b>	3 (43%)	2 (29%)	2 (29%)	0
	50 56 Days (Group 2)	34	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
•	57-63 Days (Group 3)	20	1 (5%)		. 1	1 (100%)	0	0	0
ANOREXIA	≤63 Days (All)	89	4 (4%)	0.2672	5	4 (80%)	. 1 (20%)	0	0
	≰49 Days (Group 1)	35	3 (91)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
DEPRESSION	≤63 Days (All)	89	4 (4%)	0.6735	5	1 (20%)	2 (40%)	2 (40%)	0
•	≤49 Days (Group 1)	35	2 (6%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	34	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
e · · · · ·	57-63 Days (Group 3)	20	0		0	0	0	0	0
INSOMNIA	≤63 Days (All)	89	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	35	1 (3%)		1	0	0	1 (100%)	0
د	50-56 Days (Group 2)	34	0		0	0	0:	0	0
	57-63 Days (Group 3)	20	0		0	0 , 1	o" ,'	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Center: -

DIARRHEA

DYSPEPSIA

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

	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Severit	; <b>y</b>			
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	M	1d	Mode	erate	Sev	ere	Unk	nown
BASTRO-INTESTINAL SYSTEM DISORDERS					·····									
ANY EVENT	≤63 Days (All)	89	69	(78¥)	0.3563	212	86	(41%)	99	(47%)	26	(12%)	1	(<1%)
	≤49 Days (Group 1)	35	28	(80%)		69	27	(39%)	28	(41%)	14	(20%)	0	
	50-56 Days (Group 2)	34	28	(82%)		94	34	(36%)	52	(55%)	8	(9%)	0	
	57-63 Days (Group 3)	20	13	(65%)		49	25	(51%)	19	(39%)	4	(8%)	1	(21)
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	89	2	(21)	0.5174	2	1	(50%)	0		1	(50%)	0	
	≤49 Days (Group 1)	35	0			0	0		0		0		0	
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	20	1	(5\$)		1	0		0		1	(100%)	0	
CONSTIPATION	≤63 Days (All)	89	1	(1%)	0.2247	1	0		0		0		1	(100%)
ı	≤49 Days (Group 1)	35	0			0	0		. 0	t .	0		0	
	50-56 Days (Group 2)	34	0			0	0		0		0		0	1
	57-63 Days (Group 3)	20	1	(5%)		1	0		0		0		1	(100%)

27 (30%)

11 (321)

(31%)

(25%)

(3%)

(3%)

(3%)

(5%)

1.0000

33

13

14

1

(45%)

(62%)

(43%)

1 (17%)

2 (40%)

1 (100%)

1 (33%)

14 (42%)

7 (50%)

3 (50%)

3 (60%)

1 (100%)

(67%)

(31%)

4 (12%)

(8%)

(33%)

(7%)

≤63 Days (All)

≤63 Days (All)

≤49 Days (Group 1)

**s49** Days (Group 1) 50-56 Days (Group 2)

57-63 Days (Group 3)

50-56 Days (Group 2)

57-63 Days (Group 3)

89

35

34

20

89

35

34

20

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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:	-
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	Gestational Age	Total Number	Number of Pts	Fisher's exact					Severit	.v	••••	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events		14		rate	Sev		Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)												
FLATULENCE	≰63 Days (All)	89	3 (3	0.1772	3	1	(33%)	0		2	(67%)	0
	s49 Days (Group 1)	35	3 (9	1)	3	1	(33%)	0		2	(67%)	0
	50-56 Days (Group 2)	34	0		0	0		0		0		0
	57-63 Days (Group 3)	20	0		0	0		0		0		0
NAUSEA	≤63 Days (All)	89	61 (69	0.4707	117	52	(44%)	51	(44%)	14	(12%)	0
	≤49 Days (Group 1)	35	22 (63	1)	37	13,	(35%)	16	(43%)	8	(22%)	0
	50-56 Days (Group 2)	34	26 (76	<b>i</b> )	53	22	(42%)	26	(49%)	<sub>1</sub> 5	(9%)	0
	57-63 Days (Group 3)	20	13 (65	k)	27	17	(63%)	9	(334)	1	(4%)	0
SALIVA INCREASED	≤63 Days (All)	89	1 (1	0.2247	1	0		1	(100%)	0		0
•	≤49 Days (Group 1)	35	0		0	0		. 0	r	0		0
	50-56 Days (Group 2)	34	0		0	0		0		0		0
	57-63 Days (Group 3)	20	1 (5	<b>k</b> )	. 1	0		1	(100%)	0		0
VOMITING	≤63 Days (All)	89	33 (37	0.2789	50	15	(30%)	30	(60%)	5	(10%)	0
,	≤49 Days (Group 1)	35	10 (29	<b>)</b>	15	5	(33%)	7	(47%)	3	(20%)	0
	50-56 Days (Group 2)	34	16 (47	<b>h</b> )	25	4	(16%)	19	(76%)	2	(8%)	0
,	57-63 Days (Group 3)	20	7 (35	i)	10	6	(60%)	4	(40%)	0		0
ARDIOVASCULAR DISORDERS, GENERAL												
ANY EVENT	≤63 Days (All)	89	2 (2	0.5174	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	35	0		0	0		0	,	0		0
$oldsymbol{\hat{oldsymbol{\epsilon}}}_{i}$	50-56 Days (Group 2)	34	1 (3	1)	1	0		٥,		1	(100%)	0
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	57-63 Days (Group 3)	20	1 (5	<b>i</b> )	1	0		1	(100%)	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS \* Not otherwise specified

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

<sup>[4]</sup> 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: -

	Gestational Age	Total Number	Number of P		Fisher's exact	Number -		; 		-Severit	y	
Body System/Event [2]	Group (3)	of Pts	w/Ev		p-value	of Events	Mil	<b>d</b> '	Modes		Severe	Unknow
ARDIOVASCULAR DISORDERS, GENERAL (cont.)											_	
HYPOTENS FON	≤63 Days (All)	89	2	(2%)	0.5174	2	0		1	(50%)	1 (50%)	0
	≤49 Days (Group 1)	35	0			0	0		0		0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0		0		1 (100%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0	0
ART RATE AND RHYTHM DISORDERS												
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.2247	1	0		0		1 (100%)	a
	≰49 Days (Group 1)	35	0			0	0		0		0	0
	50-56 Days (Group 2)	34	0			0	0		0		0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0		0		1 (100%)	0
PALPITATION	≤63 Days (All)	89	1	(1%)	0.2247	1	0		. 0		1 (100%)	0
	≤49 Days (Group 1)	35	0			0	0		0		0	0
	50-56 Days (Group 2)	34	0			0	0		0		0	0
	57-63 Days (Group 3)	20	1	(51)		1	0		0		1 (100%)	0
SPIRATORY SYSTEM DISORDERS												
ANY EVENT	≰63 Days (All)	89	6	(7%)	0.6419	11	5	(45%)	5	(45%)	1 (9%)	0
	≰49 Days (Group 1)	35	3	(9%)		5	2	(40%)	3	(60%)	0	0
,	50 56 Days (Group 2)	34	1	(3%)		1	0		. 0		1 (100%)	0
•	57-63 Days (Group 3)	20	2	(10%)		5	3	(60%)	2	(40%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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:

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number			*		y	
Body System/Event [2]	Group [3]	of Pts	W/EV		p-value	of Events		14		erate	Severe	Unknown
SSPIRATORY SYSTEM DISORDERS (cont.)												
COUGHING <sup>4</sup>	≤63 Days (All)	89	1	(1%)	0.6067	1	0		0	)	1 (100%)	0
	≰49 Days (Group 1)	35	0	,		0	0		0	)	0	0
	50-56 Days (Group 2)	34	1	(3/%)		1	0		0	)	1 (100%)	0
	57-63 Days (Group 3)	20	0			0	0		0	·	0	0
PHARYNGITIS	s63 Days (All)	89	3	(3%)	0.4394	3	2	(67%)	1	(33%)	0	0
	≤49 Days (Group 1)	35	2	(61)		2	1	(50%)	1	(50%)	0	0
	50 56 Days (Group 2)	34	0			0	0		0	)	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	1	(100%)	o	)	0	0
PULMONARY CONGESTION	s63 Days (All)	89	2	(2%)	0.6961	2	1	(50%)	1	(50%)	0	0
•	≰49 Days (Group 1)	35	1	(3%)		1	1	(100%)	0	,	0	0
	50-56 Days (Group 2)	34	0			0	0		0	)	0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0	0
RHINITIS	s63 Days (All)	89	1	(1%)	0.2247	3	2	(67%)	1	(33%)	0	0
•	≤49 Days (Group 1)	35	0			0	0		0	)	0	0
	50-56 Days (Group 2)	34	0			0	0		0		0	0
	57-63 Days (Group 3)	20	1	(5%)		3	2	(671)	1	(331)	0	0
SINUSITIS	s63 Days (All)	89	1	(1%)	1.0000	2	0		2	(100%)	0	0
	≤49 Days (Group 1)	35	1	(3%)		2	0		2	(100%)	0	0
	50 56 Days (Group 2)	34	0			0	0		0	<b>1</b> ,	0	0
	57-63 Days (Group 3)	20	0			0	O		t	)! 4. !	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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:

	Gestational	Total	Numbe of Pt		Fisher's	<b>A.S.b</b>				
Body System/Event [2]	Age Group [3]	Number of Pts	w/Eve		exact p-value	Number of Events	Mild '	Moderate	Severe	Unknow
RINARY SYŞTEM DISORDERS										
ANY EVENT	≤63 Days (All)	89	2	(2%)	1.0000	4	3 (75%)	0	1 (25%)	0
	s49 Days (Group 1)	35	1	(3%)		2	2 (100%)	0	0	Ô
	50-56 Days (Group 2)	34	1	(3%)		2	1 (50%)	0	1 (50%)	n
	57-63 Days (Group 3)	20	0			0	0	0	0	o
MICTURITION FREQUENCY	≤63 Days (All)	89	1	(1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0	i		0	0	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
MICTURITION URGENCY	≤63 Days (All)	89	1	(1%)	0.6067	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	35	0			0	0	· 0 ,	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	1 (100%)	σ	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
URINARY RETENTION	≤63 Days (All)	89	1	(1%)	1.0000	1	1 (100%)	o	0	0
	≤49 Days (Group 1)	35	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
URINARY TRACT INFECTION	≰63 Days (All)	89	1	(1%)	0.6067	1	0	0	1 (100%)	0
4	≰49 Days (Group 1)	35	0			0	0	0	0	0
,	50-56 Days (Group 2)	34	1	(3%)		1	0	ø	1 (100%)	0
	57-63 Days (Group 3)	20	0			0	0 ,	<b>b</b> ! , ,	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Center:

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

	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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≰63 Days (All)	89	14 (16%)	0.1194	17	6 (35%)	0	11 (65%)	0
·	≤49 Days (Group 1)	35	3 (9%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	34	9 (26%)		12	3 (25%)	0	9 (75%)	0
	57-63 Days (Group 3)	20	2 (10%)		2	1 (50%)	0	1 (50%)	0
BREAST DISCHARGE	≤63 Days (All)	89 -	1 (1%)	1.0000	1	1 (100%)	0	o :	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	` o
	50-56 Days (Group 2)	34	0		, <b>0</b>	0	0	0	0
	57-63 Days (Group 3)	20	0		' 0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	89	3 (3%)	1.0000	3	1 (33%)	0	2 (67%)	0
1	s49 Days (Group 1)	35	1 (3%)		1	0	. 0	1 (100%)	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	о `	1 (100%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
LEUKORRHOEA	≤63 Days (All)	89	2 (2%)	0.1918	2	2 (100%)	0	0	0

0

2

0

(6%)

(1%)

(3%)

1.0000

0

2 (100%)

1 (100%)

1 (100%)

0

≤49 Days (Group 1)

≤63 Days (All)

50-56 Days (Group 2)

57-63 Days (Group 3)

≤49 Days (Group 1)

50-56 Days (Group 2)

57-63 Days (Group 3)

OVARIAN DISÓRDER

35

34

89

35

34

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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]

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		g-v-mt	•	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, PENALE (cont.)									
UTERINE HAEMORRHAGE	≰63 Days (All)	89	7 (8%)	0.0113	10	1 (10%)	0	9 (90%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	6 (18%)		9	1 (11%)	0	8 (89%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
ROPLASM									
ANY EVENT	≤63 Days (All)	89	2 (2%)	0.6961	2	1 (50%)	0	0	1 (50)
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	0	1 (100
CERVICAL SMEAR TEST POSITIVE	≤63 Days (All)	89	1 (1%)	0.2247	1	0	. 0 ,	0	1 (100
	≰49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
·	57-63 Days (Group 3)	20	1 (5%)		1	0	0	0	1 (1001
OVARIAN CYST	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57 63 Days (Group 3)	20	0		0	0	0	0	0
ODY AS A WHOLE - GENERAL DISORDERS						s			
ANY EVENT	≤63 Days (All)	89	88 (99%)	0.606,7	392	161 (41%)	142 .(36%)	88 (22%)	1 (<11
$ec{m{r}}_{i}$ , $ec{m{r}}_{i}$	<pre>s49 Days (Group 1)</pre>	35	35 (100%)	Ì	158	68 (434),	5 <b>5</b> , (35 <b>%</b> )	34 (22%)	1 (<11
e a 🎳 - B	50-56 Days (Group 2)	34	33 (97%)	1	149	57 (38%)	59 (401)	33 (221)	0
•	57 63 Days (Group 3)	20	20 (100%)		85	36 (42%)	28 (33%)	21 (25%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: 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:

	Gestational	Total	Number	Fisher's					<b>.</b>				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events		ld '		Severit erate	Sev			nown
ODY AS A WHOLE - GENERAL DISORDERS (COM	it.)												
ABDOMINAL PAIN	≰63 Days (All)	89	88 (99%)	0.6067	333	138	(41%)	118	(35%)	76	(23%)	1	(<1%)
	≤49 Days (Group 1)	35	35 (100%)		130	57	(44%)	41	(32%)	31	(24%)	1	(<14)
	50-56 Days (Group 2)	34	33 (97%)		128	48	(38%)	54	(42%)	26	(20%)	0	
	57-63 Days (Group 3)	20	20 (100%)		75	33	(44%)	23	(31%)	19	(25%)	0	
ALLERGY	≰63 Days (All)	89	1 (1%)	0.2247	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	35	0		0	O,		0	ţ	0		0	
	50-56 Days (Group 2)	34	0		0	0		0	!	<sub>i</sub> 0		0	
	57-63 Days (Group 3)	20	1 (5%)		1	0		1	(100%)	! O		0	
ASTHENIA	≤63 Days (All)	89	3 (3%)	0.6123	5	1	(20%)	2	(40%)	2	(40%)	0	
ı	≰49 Days (Group 1)	35	1 (3%)		2	1	(50%)	. 1	(50%)	0		0	
	50-56 Days (Group 2)	34	2 (6%)		3	0		1	(334)	2	(67%)	0	
	57-63 Days (Group 3)	20	0		0	0		0		0		0	
BACK PAIN	≤63 Days (All)	89	10 (11%)	0.5711	12	4	(33%)	4	(33%)	4	(33%)	0	
	≰49 Days (Group 1)	35	4 (11%)		5	1	(20%)	3	(60%)	1	(20%)	0	
	50-56 Days (Group 2)	34	5 (15%)		6	3	(50%)	1	(17%)	2	(33%)	0	
	57-63 Days (Group 3)	20	1 (5%)		1	0		0		1	(100%)	0	
CHEST PAIN	≤63 Days (All)	89	1 (13)	0.6067	2	1	(50%)	1	(50%)	0		0	
	≰49 Days (Group 1)	35	0		0	0		0		0		0	
	50-56 Days (Group 2)	34	1 (3%)		2	1	(50%)	1	(50%)	0		0	
	57-63 Days (Group 3)	20	0		0	0	,i **		i 1. <u>†</u>	0		0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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]

	Gestational Age	Total Number	Numb of I		Fisher's exact	Number -				- Severity	<b>y</b>		
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p value	of Events	М	1đ	Mode	rate	Sev	vere	Unknow
DDY AS A WHOLE - GENERAL DISORDERS (cont	.)			-									
FATIGUE *	≤63 Days (All)	89	20	(22%)	0.3933	25	9	(36%)	11	(44%)	5	(20%)	0
	≤49 Days (Group 1)	35	9	(26%)		12	4	(33%)	6	(50%)	2	(17%)	0
	50-56 Days (Group 2)	34	5	(15%)		6	3	(50%)	1	(17%)	2	(33%)	0
	57-63 Days (Group 3)	20	6	(30%)		7	2	(29%)	4	(57%)	1	(14%)	0
FEVER	≤63 Days (All)	89	6	(7%)	1.0000	6	5	(83%)	1	(17%)	0		0
	≰49 Days (Group 1)	35	3	(9%)		3	3	(100%)	0		0		0
	50-56 Days (Group 2)	34	2	(6%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	20	1	(51)		1	1	(100%)	0		0		0
LEG PAIN	≤63 Days (All)	89	1	(1%)	1.0000	3	0		3	(100%)	0		0
*	≰49 Days (Group 1)	35	1	(3%)		3	0	•	3	(100%)	0		0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
PAIN	≤63 Days (All)	89	1	(14)	0.6067	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
•	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
RIGORS	≤63 Days (All)	89	3	(3%)	0.7904	3	2	(67%)	0		1	(33%)	0
	≤49 Days (Group 1)	35	2	(6%)		2	2	(100%)	0	i	0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		0		1 1	(100%)	0
<del>4</del> . ,	57 63 Days (Group 3)	20	0			0	0		<b>'y</b>	!	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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]

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number -		Severit	<b>v</b>	
Body System/Event [2]	Group [3]	of Pts	w/Even	nt	p value	of Events	Mild '	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
SYNCOPE .	£63 Days (All)	89	1 (	(1%)	1.0000	1	0	1 (100%)	0	0
-	≰49 Days (Group 1)	35	1 (	(3%)		1	0 .	1 (100%)	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	0	;		0	0	0	0	0
ESISTANCE MECHANISM DISORDERS										
NY EVENT	≤63 Days (All)	89	4 (	(4%)	0.6735	6	1 (17%)	2 (33%)	3 (50%)	0
	≤49 Days (Group 1)	35	2 (	(6%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	34	2 (	(6%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
HERPES SIMPLEX	s63 Days (All)	89	1 (	(1%)	1.0000	1	0	. 0 .	1 (100%)	0
	≰49 Days (Group 1)	35	1 (	(3%)		, 1	0	о '	1 (100%)	0
	50-56 Days (Group 2)	34	0			0	0	0	0	0
	57-63 Days (Group 3)	20	0			0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	89	3 (	(3%)	0.6123	5	1 (20%)	2 (40%)	2 (40%)	0
•	#49 Days (Group 1)	35	1 (	(3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	34	2 (	(6%)		4	1 (25%)	1 (25%)	2 (50%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

57-63 Days (Group 3)

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		,		Severi	tγ···			
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events		1d `		rate	Sev			nown
•													
ANY EVENT	≤63 Days (All)	175	171 (98%)	0.6779	983	433	(44%)	401			(15%)	2	(<1%)
	≰49 Days (Group 1)	71	69 (97%)		359	147	(41%)	152		60	(17%)	0	
	50-56 Days (Group 2)	72	71 (99%)		398	199	(50%)	152	(38%)	46	(12%)	1	
	57-63 Days (Group 3)	32	31 (97%)		226	87	(38%)	97	(43%)	41	(18%)	1	(<1%
SKIN AND APPENDAGES DISORDERS		*,											
ANY EVENT	≤63 Days (All)	175	6 (3%)	0.7426	7	4	(57%)	3	(43%)	0		0	
	≤49 Days (Group 1)	71	3 (4%)		4	3	(75%)	1	(25%)	0		0	
	50-56 Days (Group 2)	72	3 (4%)		3	1	(33%)	2	(67%)	0		0	
	57-63 Days (Group 3)	32	0		. 0	0		0		0		0	
ACNE	≤63 Days (All)	175	1 (<1%)	1.0000	1	1	(100%)	. 0	t	0		0	
	s49 Days (Group 1)	71	0		0	0		0		0		0	
	50-56 Days (Group 2)	72	1 (1%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	32	0		0	0		0		0		0	
PRURITUS .	s63 Days (All)	175	1 (<1%)	0.5886	2	2	(100%)	0		0		0	
	≤49 Days (Group 1)	71	1 (1%)		2	2	(100%)	0		0		0	
	50-56 Days (Group 2)	72	0		0	0		0		0		0	
	57-63 Days (Group 3)	32	0		0	0		0		0		0	
RASH .	s63 Days (All)	175	2 (1%)	1.0000	2	0		2	(100%)	0		0	
	≰49 Days (Group 1)	71	1 (1%)		1	0			(100%)	0		0	
<del>4</del> .	50-56 Days (Group 2)	72	1 (1%)		1	0		1,	(1001)	0		0	
1	57-63 Days (Group 3)	32	o		, о	0		0.		0		0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -	· · · · · · · · · · · · · · · · · · ·	Severity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
KIN AND APPENDAGES DISORDERS (cont.)									
SWEATING INCREASED	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	0 .	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
VERRUCA	≤63 Days (All)	175	1 (<1%)	0.5886	1	1 (100%)	0	ο .	0
	≤49 Days (Group 1)	71	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
:	57-63 Days (Group 3)	32	0		O	0	0	0	0
USCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≰63 Days (All)	175	3 (2%)	0.7933	3	1 (33%)	. 2 (67%)	0	0
	≤49 Days (Group 1)	71	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	175	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
1	s49 Days (Group 1)	71	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
i e e e e e e e e e e e e e e e e e e e	57-63 Days (Group 3)	32	0		0	0	0	0	0
SKELETAL PAIN	≤63 Days (All)	175	1 (<1%)	0.5886	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	1 (100%)	0	0
÷	50-56 Days (Group 2)	72	0		0	0	0!	0	0
	57-63 Days (Group 3)	32	0		0	0 ;	<b>0</b>	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number		ber Pts	Fisher's	W. amb. c								
Body System/Event [2]	Group [3]	of Pts		vent	exact p-value	Number of Events		11d			Severit rate	•	ere	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS													<del></del>	
ANY EVENT	≤63 Days (All)	175	64	(37%)	0.2349	110	40	(36%)		49	(45%)	21	(19%)	0
	≰49 Days (Group 1)	71	30	(42%)		48	17	(35%)	1	24	(50%)	7	(15%)	0
	50-56 Days (Group 2)	72	21	(29%)		39	16	(41%)	1	16	(41%)	7	(18%)	0
	57-63 Days (Group 3)	32	13	(41%)		23	7	(30%)		9	(39%)	7	(30%)	0
CONVULSIONS	≤63 Days (All)	175	1	(<1%)	0.5886	1	1	(100%)		0		0		0
	≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)		0		0		0
	50-56 Days (Group 2)	72	0			0	0			0		0		0
	57-63 Days (Group 3)	32	0			0	0			0		0		0
DIZZINESS	s63 Days (All)	175	16	(9%)	0.7410	25	10	(40%)		9	(36%)	6	(24%)	0
•	≤49 Days (Group 1)	71	6	(8%)		8	2	(25%)		5	(63.1)	1		0
	50-56 Days (Group 2)	72	6	(8%)		10	5	(50%)		3	(30%)	2	(20%)	0
	57-63 Days (Group 3)	32	4	(13%)		7	3	(43%)		1			(43%)	ō
HEADACHE	≤63 Days (All)	175	58	(33%)	0.2714	84	29	(35%)		40	(48%)	15	(18%)	0
	≤49 Days (Group 1)	71	27	(38%)		39	14	(36%)		19	(49%)	6	(15%)	0
•	50-56 Days (Group 2)	72	19	(26%)		29	11	(38%)		13	(45%)	5	(17%)	Ō
	57-63 Days (Group 3)	32	12	(38%)		16	4	(25%)		8	(50%)	4	(25%)	0
SYCHIATRIC DISORDERS														
ANY EVENT	≤63 Days (All)	175	18	(10%)	0.2758	26	8	(31%)		13	(50%)	5	(19%)	0
	s49 Days (Group 1)	71	10	(14%)	1	17	6	(35%)		9	(53%)		(12%)	0
7.	50 56 Days (Group 2)	72	7	(10%)		7	2	(29,4)		4.,	(57%)	1	(14%)	0
	57-63 Days (Group 3)	32	1	(3%)	1	2	0	į,	1	0.	•		(100%)	0
•								,	1	1				

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational	Total	Number	Fisher's	1				
	Age	Number	of Pts	exact	Number		Severi	ty	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknow
SYCHIATRIC DISORDERS (cont.)									
ANOREX I A.	≤63 Days (All)	175	2 (19	0.6642	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	Ô
	50-56 Days (Group 2)	72	2 (31	)	2	0	2 (100%)	Ō	Ô
	57-63 Days (Group 3)	32	0		0	0	0	0	ō
ANXIETY	≤63 Days (All)	175	6 (31	) 0.0462	8	3 (38%)	2 (25%)	3 (38%)	0
	≤49 Days (Group 1)	71	5 (79	)	6	3 (50%)	2 (33%)	1 (17%)	ō
	50-56 Days (Group 2)	72	0		0	0	0	0	Ö
	57-63 Days (Group 3)	32	1 (31	)	2	0	0	2 (100%)	ō
DEPRESSION	≤63 Days (All)	175	3 (21	) 0.7933	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	71	2 (31	)	2	1 (50%)	1 (50%)	0	ŏ
	50-56 Days (Group 2)	72	1 (19	)	1	0	0 ' '	1 (100%)	o
	57 63 Days (Group 3)	32	0		O	0	0	0	ō
DYSPAREUNIA	≤63 Days (All)	175	1 (<19	) 1.0000	1	0	1 (100%)	0	n
	≤49 Days (Group 1)	71	0		0	0	0	0	n
•	50-56 Days (Group 2)	72	1 (19	)	1	0	1 (100%)	o	n
	57-63 Days (Group 3)	32	0		3	0	0	0	o
EMOTIONAL LABILITY	≤63 Days (All)	175	2 (11	) 0.4964	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	71	2 (31		4	2 (50%)	2 (50%)	0	Ô
	50 56 Days (Group 2)	72	0		0	0	0	Ö	n
<b>.</b>	57-63 Days (Group 3)	32	0		0	0	0	ō	ō

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Num of		Fisher's exact	Number			<b></b> .	Sever	it <b>y</b>		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p value	of Events		1d		erate	-	vere	Unknown
PSYCHIATRIC DISORDERS (cont.)													
INSOMNIA4	s63 Days (All)	175	7	(4%)	0.4620	7	2	(29%)	4	(57%)	1	(14%)	0
	\$49 Days (Group 1)	71	4	(6%)		4	0		3	(75%)	1	(25%)	0
	50-56 Days (Group 2)	72	3	(4%)		3	2	(67%)	1	(33%)	0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
PSYCHOSIS	≤63 Days (All)	175	1	(<1%)	0.5886	1	0		1	(100%)	o		0
	≤49 Days (Group 1)	71	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
iastro-intestinal system disorders													
ANY EVENT	s63 Days (All)	175	113	(65%)	0.0989	270	129	(48%)	107	(40%)	34	(13%)	0
	≤49 Days (Group 1)	71	39	(55%)		85	30	(35%)	37	(44%)	18	(21%)	0
	50-56 Days (Group 2)	72	51	(71%)		123	69	(56%)	46	(37%)	8	(7%)	0
	57-63 Days (Group 3)	32	23	(72%)		62	30	(48%)	24	(39%)	8	(13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	175	4	(2%)	0.6779	4	1	(25%)	2	(50%)	1	(25%)	0
•	≤49 Days (Group 1)	71	2	(3%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
1	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0
CONSTIPATION	≰63 Days (All)	175	4	(2%)	0.8318	4	3	(75%)	0		1	(25%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	0		0		, 1	(100%)	0
÷.	50-56 Days (Group 2)	72	2	(3%)		2	2	(100%),	o,	1. 1	0		0
	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	0	٠,	' 0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Num of	ber Pts	Fisher's exact	Number	<b>.</b>			Severit	y		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi		Mode		Sev		Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
DIARRHEA	≰63 Days (All)	175	32	(18%)	0.1747	33	19	(58%)	13	(39%)	1	(3%)	0
	≤49 Days (Group 1)	71	9	(131)		9	4	(44%)	4	(44%)	1	(11%)	0
	50-56 Days (Group 2)	72	14	(19%)		14	10	(71%)	4	(29%)	0		0
	57-63 bays (Group 3)	32	9	(28%)		10	5	(50%)	5	(50%)	0		0
DYSPEPSIA	≤63 Days (All)	175	12	(7%)	0.1428	13	6	(46%)	7	(54%)	0		0
	≤49 Days (Group 1)	71	2	(3%)		3	0		3	(100%)	0		0
	50-56 Days (Group 2)	72	6	(8%)		6	4	(67%)	2	(33%)	0		0
	57-63 Days (Group 3)	32	4	(13%)		4	2	(50%)	2	(50%)	0		0
FLATULENCE	≤63 Days (All)	175	3	(2%)	0.5895	5	4	(80%)	1	(20%)	0		0
•	≤49 Days (Group 1)	71	1	(1%)		2	1	(50%)	. 1	(50%)	0		0
	50-56 Days (Group 2)	72	1	(1%)		† <b>1</b>	1	(100%)	0	•	0		0
	57-63 Days (Group 3)	32	1	(3#)		2	2	(100%)	0		0		0
HAEMORRHOIDS	s63 Days (All)	175	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	71	0			0	0		0		0		0
•	50-56 Days (Group 2)	72	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	175	88	(50%)	0.4871	133	60	(45%)	53	(40%)	20	(15%)	0
	≰49 Days (Group 1)	71	33	(46%)		49	20	(41%)	20	(41%)	9	(18%)	0
•	50-56 Days (Group 2)	72	36	(50%)		54	27	(50%)	21	(39%)	6	(11%)	0
	57-63 Days (Group 3)	32	19	(59%)		30	13	(43,4)	1.2		5	(17%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Num of		Fisher's exact:	Number				Severit	v		
Body System/Event [2]	Group [3]	of Pts		vent	p value	of Events		.1 <b>a</b> '		rate		ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
тоотн асне	≤63 Days (All)	175	4	(2%)	0.0103	4	2	(50%)	0		2	(50%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57-63 Days (Group 3)	32	3	(91)		3	1	(33%)	0		2	(67%)	0
VOMITING	s63 Days (All)	175	59	(34%)	0.0066	73	34	(47%)	30	(41%)	9	(12%)	0
	≰49 Days (Group 1)	71	15	(21%)		18	4	(22%)	8	(44%)	6	(33%)	0
	50-56 Days (Group 2)	72	33	(46%)		44	24	(55%)	18	(41%)	2	(5%)	0
	57-63 Days (Group 3)	32	11	(34%)		11	6	(55%)	4	(36%)	1	(9%)	0
ETABOLIC AND NUTRITIONAL DISORDERS				,									
ANY EVENT	≤63 Days (All)	175	2	(1%)	0.3331	2	0		. 2	(100)	0		0
	≤49 Days (Group 1)	71	0			0	0		0		0		0
	50-56 Days (Group 2)	72	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	32	1	(31)		1	0		1	(100%)	0		0
DEHYDRATION	≤63 Days (All)	175	2	(1%)	0.3331	2	0		2	(100%)	0		o
•	≤49 Days (Group 1)	71	0			0	0		0		0		0
	50-56 Days (Group 2)	72	1	(1%)		1	0		1	(100%)	0		0
· '	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0
BART RATE AND RHYTHM DISORDERS													
ANY EVENT	≰63 Days (All)	175	2	(1%)	0.6642	2	1	(50%)	1	(50%)	0		0
<del>4</del> .	s49 Days (Group 1)	71	0			0	0		ď		0		0
	50-56 Days (Group 2)	72	2	(3%)		2	1	(\$0%)	1.	. (50¥)	0		0
• • • • • • • • • • • • • • • • • • •	57-63 Days (Group 3)	32	0	ı	•	o	0		P		0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: 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: WESTHOFF (#24)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number -		Severit	·V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS (cont.)								· · · · · · · · · · · · · · · · · · ·	
PALPITATION	s63 Days (All)	175	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
TACHYCARDIA	s63 Days (All)	175	1 (<1%)	1.0000	1 .	0	1 (100%)	o ;	, 0
	≤49 Days (Group 1)	71	0		0	0	0	0	, o
	50-56 Days (Group 2)	72	1 (1%)		. 1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	0		i o	0	0	O	0
ASCULAR (EXTRACARDIAC) DISORDERS									
ANY EVENT	≤63 Days (All)	175	1 (<1%)	0.1829	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	71	0		0	0	· 0 '	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	1 (100%)	0	0	0
VEIN PAIN	≤63 Days (All)	175	1 (<1%)	0.1829	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		O	0	0	0	0
,	57-63 Days (Group 3)	32	1 (3%)		1	1 (100%)	0	O	0
ESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	10 (6%)	0.0017	11	4 (36%)	6 (55%)	1 (9%)	0
	≰49 Days (Group 1)	71	5 (7%)		5	2 (40%)	2, (40%)	1 (20%)	0
$\hat{\boldsymbol{\sigma}}_{ij}$	50-56 Days (Group 2)	72	0		0	0	0"	0	0
e e 📦 - Ag	57-63 Days (Group 3)	32	5 (16%)		6	2 (33%)	4 (67 <b>%</b> )	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild '	Moderate	Severe	Unknow
BSPIRATORY SYSTEM DISORDERS (cont.)			··· · · · · · · · · · · · · · · · · ·				·········		·
COUGH1NC	s63 Days (All)	175	1 (<1%)	0.5886	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	1 (1%)		1	1 (100%)	. 0	Ô	n
	50 56 Days (Group 2)	72	0		0	0	0	0	o o
	57 63 Days (Group 3)	32	0		0	0	0	o	o
PHARYNGITIS	≤63 Days (All)	175	3 (2%)	0.3100	3	1 (33%)	1 (33%)	1 (33%)	0
	s49 Days (Group 1)	71	2 (3%)		2	0	1 (50%)	1 (50%)	Ô
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	1 (100%)	0	ō	ō
RHINITIS	≤63 Days (All)	175	1 (<1%)	0.5886	1	1 (100%)	0	o	0
ı	s49 Days (Group 1)	71	1 (1%)		1	1 (100%)	. 0 ,	0	Ô
	50-56 Days (Group 2)	72	0		0	0	0 '	Ô	Ô
	57-63 Days (Group 3)	32	0		0	0	0	ō	o
SINUSITIS	≤63 Days (All)	175	5 (3%)	0.0021	6	1 (17%)	5 (83%)	0	0
	≤49 Days (Group 1)	71	. 1 (1%)		1	0	1 (100%)	Ö	Ö
•	50-56 Days (Group 2)	72	0		0	0	0	Ō	Ô
	57-63 Days (Group 3)	32	4 (13%)		5	1 (20%)	4 (80%)	ō	o
D BLOOD CELL DISORDERS						1			
ANY EVENT	≤63 Days (All)	175	3 (2%)	0.7933	3	1 (33%)	0	2 (67%)	0
	≤49 Days (Group 1)	71	2 (3%)		2	1 (50%)	Ŏ	1 (50%)	0
<del>,</del>	50-56 Days (Group 2)	72	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	32	0	V	0	0	ð,	0	0
							•		

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

Body System/Event [2]  ED BLOOD CELL DISORDERS (cont.)	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Even	3	Fisher's exact p-value	Number of Events				Severity erate	Seve		Unknown
ED BLOOD CELL DISORDERS (cont.)						··					•		
ANAEMIA *	s63 Days (All)	175	3 (	(2%)	0.7933	3	1	(33%)	0		2	(67%)	0
	≰49 Days (Group 1)	71	2 (	(3%)		2	1	(50%)	0			(50%)	0
	50-56 Days (Group 2)	72	1 (	(1%)		1	0		0			100%)	0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
RINARY SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	175	4 (	(2%)	0.5263	4	2	(50%)	2	(5Q <b>%</b> )	0		0
	≰49 Days (Group 1)	71		(1%)		1		(100%)	0	12127	0		Ö
	50-56 Days (Group 2)	72	3 (	(4%)		3	1	(33%)	2	(67%)	0		Ô
	57-63 Days (Group 3)	32	0			0	0	, ,	0	,,,,	0		0
DYSURIA	≤63 Days (All)	175	3 (	(2%)	0.2195	3	1	(33%)	. 2	(67%)	0		0
	≤49 Days (Group 1)	71	0			0	0		0		Ö		0
	50 56 Days (Group 2)	72	3 (	(4%)		3	1	(33%)	2	(67%)	ŏ	ı	Ô
	57-63 Days (Group 3)	32	o			0	0		0		0		0
URINARY TRACT INFECTION	≤63 Days (All)	175	1 (<	:1%)	0.5886	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	71	1 (	(1%)		1	1	(100%)	0		0		ō
	50-56 Days (Group 2)	72	0			0	0		0		0		0
,	57 63 Days (Group 3)	32	0			0	0		. 0		0		0
EPRODUCTIVE DISORDERS, FEMALE													
ANY EVENT	≤63 Days (All)	175	21 (1	121)	0.7869	25	11	(44%)	3	(12%)	11	(44%)	0
<del>-i.</del> , , , ,	≤49 Days (Group 1)	71	8 (1	111)		9	3	(33%),	11	(11%)		(56%)	0
	50-56 Days (Group 2)	72	8 (1	111)		9	5	(56%)	Ö	!		(44%)	0
,	57-63 Days (Group 3)	32	5 (1	161)		7	3	(43%)	,2	(29%)		(291)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: 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: WESTHOFF (#24)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Mild	Severity Moderate	Severe	Unknown
EPRODUCTÍVE DISORDERS, FEMALE (cont.)									
BREAST PAIN FEMALE	≤63 Days (All)	175	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
ENDOMETRITIS	≤63 Days (All)	175	1 (<1*)	0.1829	1	0	0	1 (100%)	0
	≰49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		ø	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	0	1 (100%)	0
LEUKORRHOEA	≤63 Days (All)	175	5 (3%)	0.4077	5	5 (100%)	0	0	0
	≤49 Days (Group 1)	71	1 (1%)		1	1 (100%)	0 '	0	0
	50-56 Days (Group 2)	72	2 (3%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	32	2 (6%)		2	2 (100%)	0	0	0
OVARIAN DISORDER	≤63 Days (All)	175	1 (<1%)	0.1829	1	0	1 (100%)	0	0
•	s49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	Ö	0	0	O
r · · · · ·	57 63 Days (Group 3)	32	1 (3%)		1	0	1 (100%)	0	0
PREMENSTRUAL TENSION	s63 Daye (All)	175	1 (<1%)	0.5886	1	1 (100%)	0	0	0
,	≰49 Days (Group 1)	71	1 (1%)		1	1 (100%)	0	0	О
i.	50-56 Days (Group 2)	72	0		0	0	. О Ф. :	0	0
• •	57-63 Days (Group 3)	32	0		0	0	<b>0</b> . :	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vadinal ultrasonography

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Severity	<i>,</i> .			
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	1d '	Mode	rate	Sev	ere	Unk	nown
REPRODUCTIVE DISORDERS, PENALE (cont.)														
UTERINE DISORDER NOS	≤63 Days (All)	175	3	(2%)	0.4032	3	2	(67%)	1	(33%)	0		0	
•	≰49 Days (Group 1)	71	0			0	0		0		0		0	
	50-56 Days (Group 2)	72	2	(34)		2	2	(100%)	0		0		0	
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	175 <sup>.</sup>	9	(5%)	1.0000	10	0		0		10	(100%)	0	
	≤49 Days (Group 1)	71	4	(61)		5	0		0		5	(100%)	0	
	50-56 Days (Group 2)	72	4	(6%)		4	0		0		4	(100%)	0	
	57-63 Days (Group 3)	32	1	(3%)		. 1	0		0		1	(100%)	0	
VAGINITIS	≤63 Days (All)	175	2	(1%)	0.1818	2	2	(100%)	0		0		0	
	≤49 Days (Group 1)	71	1	(1%)		1		(100%)	. 0		0		0	
·	50-56 Days (Group 2)	72	0	,		0	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0	,	0		0	
	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	0		0		ō	
ODY AS A WHOLE - GENERAL DISORDERS														
ANY EVENT	≤63 Days (All)	175	167	(95%)	0.5126	513	229	(45%)	209	(41%)	73	(14%)	2	{<1%
	≤49 Days (Group 1)	71	66	(93%)		182	82	(45%)	74	(41%)	26	(14%)	0	
	50-56 Days (Group 2)	72	70	(97%)		209	103	(49%)	80	(38%)	25	(12%)	1	(<1%
,	57-63 Days (Group 3)	32	31	(97%)		122	44	(36%)	55	(45%)	22	(18%)	1	(<1%
ABDOMINAL PAIN	≤63 Days (All)	175	162	(93%)	0.5159	437	200	(46%)	176	(40%)	59	(14%)	2	(<1%
· ·	≰49 Days (Group 1)	71	64	(90%)		157	72	(46%)	64	(41%)	21	(13%)	0	
	50 56 Days (Group 2)	72	67	(93%)		182	89	(49%)	69,	(38%)	23	(13%)	1	(<1%
	57-63 Days (Group 3)	32	31	(97%)		98	39	(40%) '	43	!(44%)	15	(15%)	1	(1%

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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

Center: WESTHOFF (#24)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numb of P w/Ev	ts	Fisher's exact p-value	Number -		<del>.</del>	Mode	Severity- rate	Sev		Unknow
ODY AS A WHOLE - GENERAL DISORDERS (cont.)													
ALLERGY *	≤63 Days (All)	175	2	(1%)	1.0000	3	1	(33%)	2	(67%)	0		0
	≰49 Days (Group 1)	71	1	(1%)		2	0		2	(100%)	0		0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
ASTHENIA	≤63 Days (All)	175	8	(5%)	0.7986	10	2	(20%)	6	(60%)	2	(20%)	0
	≤49 Days (Group 1)	71	3	(4%)		3	1	(33%)	2	(67%)	0		0
	50-56 Days (Group 2)	72	3	(4%)		3	1	(33%)	2	(67%)	0		O
	57-63 Days (Group 3)	32	2	(6%)		4	0		2	(50∜)	2	(50%)	0
BACK PAIN	≤63 Days (All)	175	18	(10%)	0.8483	26	9	(35%)	12	(46%)	5	(19%)	0
1	<pre>\$49 Days (Group 1)</pre>	71	8	(11%)		9	3	(33%)	• 4	(44%)	2	(22%)	0
	50-56 Days (Group 2)	72	8	(11%)		11	5	(45%)	5	(45%)	1	(9%)	0
	57-63 Days (Group 3)	32	2	(61)		6	1	(17%)	3	(50%)	2	(33%)	0
CHEST PAIN	≤63 Days (All)	175	1	(<1%)	0.5886	1	1	(100%)	0		0		0
,	≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
i '													
FATIGUE	≤63 Days (All)	175	8	(5%)	0.0880	8	5	(63%)	0		3	(38%)	0
	≰49 Days (Group 1)	71	6	(8%)		6	3	(50%)	0		3	(50 <b>%</b> )	0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	1	(3%)		1	1	(1004)	a,	•	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pi w/Eve	ts	Fisher's exact p value	Number of Events		1d	Mode	Severity- rate	Seve		Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.	<u> </u>	<del></del>					,					147.4	
FEVER CONTROL OF THE PROPERTY COME.	, ≤63 Days (All)	175	10	(6%)	0.6252	12	5	(42%)	6	(50%)	1	(8%)	0
15751	≤49 Days (Group 1)	71	3	(4%)		3	2	(67%)	1	(33%)	0		0
	50 56 Days (Group 2)	72	4	(6%)		4	2	(50%)	2		0		o
	57-63 Days (Group 3)	32	3	(9%)		5	1	(20%)	3	(60%)	1	(20%)	0
LEG PAIN	≤63 Days (All)	175	2	(1%)	0.6642	2	2	(100%)	0		0	1	. 0
	≤49 Days (Group 1)	71	0			, 0	0		0		0		0
	50-56 Days (Group 2)	72	2	(3%)		2	2	(100%)	0		0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
MALAISE	≤63 Days (All)	175	5	(3%)	0.0641	5	1	(20%)	4	(80#)	0		0
T.	≤49 Days (Group 1)	71	1	(1%)		1	0		· 1	(100)	0		0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	3	(9%)		3	0	1	3	(100%)	0		0
PALLOR	≤63 Days (All)	175	1	(<1%)	0.1829	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	71	0			0	0		0		0		0
'	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	0		0		0
RIGORS	≰63 Days (All)	175	2	(1%)	0.3331	2	0		1	(50%)	1	(50%)	0
,	≤49 Days (Group 1)	71	0			0	0		.0		0		0
	50-56 Days (Group 2)	72	1	(1%)		1	0			(100%)	0		0
	57-63 Days (Group 3)	32	1	(3♥)		1	0	je k	0.	.1	1	(100%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS \* Not otherwise specified

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

<sup>[4]</sup> 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: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pt		Fisher's exact	Number -				Severit	. <b>v</b>	
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p value	of Events	Mi			derate	Severe	Unknow
ODY AS A WHOLE - GENERAL DISORDERS (	cont.)											1111112
SYNCOPE	≰63 Days (All)	175	3	(2%)	0.0864	3	1	(33%)	1	0	2 (67%)	0
	≤49 Days (Group 1)	71	0			0	0		-	0	0	0
	50-56 Days (Group 2)	72	1	(1%)		1	0		!	0	1 (100%)	0
	57-63 Days (Group 3)	32	2	(6%)		2	1	(50%)		0	1 (50%)	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	175	3	(2%)	0.4032	3	1	(33%)		2 (67%)	0	0
	≰49 Days (Group 1)	71	0			0	0			0	0	0
	50-56 Days (Group 2)	72	2	(3%)		2	1	(50%)		1 (50%)	0	Ō
	57-63 Days (Group 3)	32	1	(3%)		1	0			1 (100%)	0	o
ESISTANCE MECHANISM DISORDERS												
ANY EVENT	≤63 Days (All)	175	6	(3%)	0.0716	6	2	(33%)	•	4 (67%)	0	0
	≤49 Days (Group 1)	71	4	(6%)		4	2	(50%)		2 (50%)	0	Ô
	50-56 Days (Group 2)	72	0			0	0			0	0	o o
	57 63 Days (Group 3)	32	2	(6%)		2	0			2 (100%)	0	ō
INFECTION VIRAL	≤63 Days (All)	175	. 6	(3%)	0.0716	6	2	(33%)		4 (67%)	o :	0
	≤49 Days (Group 1)	71	4	(6%)		4	2	(50%)		2 (50%)	Ö	o
	50-56 Days (Group 2)	72	0			0	0	•		0	0	ō
•	57-63 Days (Group 3)	32	2	(61)		2	0			2 (100%)	o	n

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

<sup>[3]</sup> Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal untrasonography.

<sup>[4]</sup> 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: NICHOLS (#25)

	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	1đ	Mode	rate	Sev	ere	Unkn	iown
ANY EVENT	≤63 Days (All)	178	175	(98%)	0.6319	1506	578	(38%)	550	(37%)	377	(251)	1	(<1%
WAI EACHI	≤49 Days (Group 1)	72		(97%)	******	534	215	(40%)	186	(35%)	133	(25%)	0	
	50-56 Days (Group 2)	54		100%)		494	203	(41%)	179	(36%)	111	(22%)		(<1%
	57-63 Days (Group 3)	52		(98%)		478	160	(33%)	185	(39%)	133	(28%)	0	
SKIN AND APPENDAGES DISORDERS							1							
ANY EVENT	≰63 Days (All)	178	6	(3%)	0.5845	6	1	(17%)	2	(338)	3		0	
	≰49 Days (Group 1)	72	2	(3%)		2	0		1	(50%)	1	,	0	
	50-56 Days (Group 2)	54	1	(2%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	52	3	(6%)		. 3	1	(331)	1	(33%)	1	(33%)	0	
ACNE .	≤63 Days (All)	178	1	(<1%)	0.2921	1	1	(100%)	. О	1	0		0	
	≤49 Days (Group 1)	72	0			0	0		0		0		0	
	50-56 Days (Group 2)	54	0			0	0		0		0		0	
	57-63 Days (Group 3)	52	1	(21)		1	1	(100%)	0		0		0	
SWEATING INCREASED	≤63 Days (All)	178	3	(2%)	1.0000	3	0		0			(100%)	0	
	≤49 Days (Group 1)	72	1	(1%)		1	0		0			(100%)	0	
	50-56 Days (Group 2)	54	1	(2%)		1	0		0		_	(100%)	0	
	57-63 Days (Group 3)	5 <b>2</b>	1	(2%)		1	0		0		1	(100%)	0	
URTICARIA	≤63 Days (All)	178	2	(1%)	0.7532	2	0			(100%)	0		0	
	≤49 Days (Group 1)	72	1	(1%)		1	0		1	(100%)	0		0	
<b>-</b> €	50-56 Days (Group 2)	54	0			0	0	2.3	Ď,		0		0	
	57-63 Days (Group 3)	52	1	(2%)		1	0	.	1	·(100%)	0		0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pt: w/Ever	8	Fisher's exact p value	Number of Events		 1đ	Mode	Severit	ySeve		Unknown
body Gyodem, byene (2)	010up (3)				p varue	Or Evenes		<u> </u>	Hode				UIIKIIOWII
HUSCULO-SKELETAL SYSTEM DISORDERS													
ANY EVENT	s63 Days (All)	178	3	(2%)	0.4881	4	2	(50%)	1	(25%)	1	(25%)	0
	≤49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	2	(4%)		3	1	(33%)	1	(33%)	1	(33%)	0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
ARTHRALGIA	≤63 Days (All)	178	2	(1%)	0.1750	2	1	(50%)	0		1	(50%)	0
	≰49 Days (Group 1)	72	0			0	0		0		0		0
	50-56 Days (Group 2)	54	2	(4%)		2	1	(50%)	0		1	(50%)	0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
SKELETAL PAIN	≤63 Days (All)	178	2	(1%)	1.0000	2	1	(50%)	1	(50%)	0		0
•	s49 Days (Group 1)	72	1	(1%)		1	1	(100%)	. 0	,	0		0
	50-56 Days (Group 2)	54	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	178	73 (	41%)	0.1182	138	52	(38%)	63	(46%)	23	(17%)	0
	≤49 Days (Group 1)	72	24 (	33%)		36	10	(28%)	19	(53%)	7	(19%)	0
	50-56 Days (Group 2)	54	22 (4	41%)		50	23	(46%)	19	(38%)	8	(16%)	0
•	57-63 Days (Group 3)	52	27 (	521)		52	19	(37%)	25	(48%)	8	(15%)	0
DIZZINESS	≤63 Days (All)	178	23 (	13%)	0.3425	33	12	(36%)	9	(27%)	12	(36%)	0
	≰49 Days (Group 1)	72	7 (	10%)		8	2	(25%)	1	(13%)	5	(63%)	0
$\hat{\sigma}$	50-56 Days (Group 2)	54	10 (	19%)		15	6	(40%),	6	(40%)	3	(20%)	0
or of the second second	57-63 Days (Group 3)	52	6 (	12%)		10	4	(40%)	2.	(20%)	4	(40%)	0
·													

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		· ·Severit	γ	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild '	Moderate	Severe	Unknown
NTR & PERIPH NERVOUS SYSTEM DISORDERS	G (cont.)								
HEADACHE	≰63 Days (All)	178	59 (33%)	0.1795	98	35 (36%)	53 (54%)	10 (10%)	0
•	≰49 Days (Group 1)	72	19 (26%)		26	6 (23%)	18 (69%)	2 (8%)	0
	50-56 Days (Group 2)	54	18 (33%)		34	17 (50%)	13 (38%)	4 (12%)	0
	57-63 Days (Group 3)	52	22 (42%)		38	12 (32%)	22 (58%)	4 (11%)	0
HYPOAESTHESIA	≤63 Days (All)	178	1 (<1%)	0.5955	1 .	0	0	1 (100%)	0
	≤49 Days (Group 1)	72	0		D	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
MIGRAINE	≤63 Days (All)	178	1 (<1%)	0.2921	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	72	0		0	0	. 0 ,	0	0
•	50-56 Days (Group 2)	54	0		;o	0	0	0	0
	57-63 Days (Group 3)	52	1 (2%)		1	0	1 (100%)	0	0
NEURALGIA	≤63 Days (All)	178	1 (<1%)	0.2921	2	2 (100%)	o	0	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	1 (2%)		2	2 (100%)	0	0	0
PARAESTHESÍA	≰63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
2	57-63 Days (Group 3)	52	0		0	0	0	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>(4)</sup> 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: NICHOLS (#25)

	Gestational	Total	Number	Fisher's	•				
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknowr
ENTR & PERIPH MERVOUS SYSTEM DISOR	DERS (cont.)								
SPEECH DISORDER	≤63 Days (All)	178	1 (<1%)	0.2921	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	72	0		0	0	0	Ō	n
	50-56 Days (Group 2)	54	0		0	0	0	0	ň
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	ō	o
TREMOR	≤63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	1 (1%)		1	1 (100%)	Ö	Ö	0
	50-56 Days (Group 2)	54	0 .		0	0	Ö	0	0
	57-63 Days (Group 3)	52	0		Ö	ō	o	o	0
PECIAL SENSES OTHER, DISORDERS			!						
ANY EVENT	≤63 Days (All)	178	1 (<1%)	1.0000	1	0	. 0 ,	1 (100%)	0
	≤49 Days (Group 1)	72	1 (11)		1	0	0 '	1 (100%)	0
	50-56 Days (Group 2)	54	0		0	0	0	0	Ö
	57-63 Days (Group 3)	52	0		0	0	ō	Ō	ō
TASTE PERVERSION	s63 Days (All)	178	1 (<1%)	1.0000	1	0	0	1 (100%)	0
•	≤49 Days (Group 1)	72	1 (1%)		1	0	ō	1 (100%)	0
	50-56 Days (Group 2)	54	0		0	0	Ô	0	Ô
•	57-63 Days (Group 3)	52	0		0	o	ō	ō	0
SYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	178	15 (8%)	0.2858	17	5 (29%)	6 (35%)	6 (35%)	0
<b>.</b> ,	≤49 Days (Group 1)	72	4 (6%)		6	2 (33%)	3 (50%)	1 (17%)	0
· · ·	50-56 Days (Group 2)	54	4 (7%)		4	0	2 (50%)	2 (50%)	Ö
• •	57-63 Days (Group 3)	52	7 (13%)	,	7	3 (43%)	1 (14%)	3 (43%)	0
	•		+			r		, ,	•

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	Gestational Age	Total Number		mber Pts	Fisher's exact	Number				Severi	tv.		
Body System/Event [2]	Group [3]	of Pts	w/1	Event	p-value	of Events		ila '		rate	-	/ere	Unknown
PSYCHIATRIC DISORDERS (cont.)						***************************************		·					··· ·· · · · · · · · · · · · · · · · ·
ANOREXIA*	≤63 Days (All)	178	4	(2%)	1.0000	4	2	(50%)	•	(50%)	_		_
	≰49 Days (Group 1)	72	2	(3%)		2	ı	(50%)	1		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	ō	(304)	_	(100%)	0		0
	57-63 Days (Group 3)	52	1	(2%)		1	_	(100%)	0	(1004)	0		0
						-	-	(1000)	Ū		U		0
ANXIETY	≰63 Days (All)	178	6	(3%)	1.0000	6	3	(50%)	,	(33%)	1	(17%)	1 -
	≤49 Days (Group 1)	72	2	(3%)		2	1	(50%)	1	(50%)	0	(1/4)	! O
	50-56 Days (Group 2)	54	2	(4%)		2	Ô	(304)	1	(50%)		(508)	0
	57 63 Days (Group 3)	52	2	(4%)		2	•	(100%)	0	(504)	1	(50%)	0
							-	(1000)	U		U		0
EMOTIONAL LABILITY	≤63 Days (All)	178	2	(1%)	0.5155	2	0		0		,	(100%)	•
•	≰49 Days (Group 1)	72	0			0	0		. 0			(1004)	0
	50-56 Days (Group 2)	54	1	(2%)		ì	Ö		0	•		(100%)	0
	57-63 Days (Group 3)	52	1	(2%)		1	0		0			(100%)	0
									•		•	(1004)	U
INSOMNIA	≤63 Days (All)	178	5	(3%)	0.2297	5	0		2	(40%)	3	(60%)	
	≤49 Days (Group 1)	72	2	(3%)		2	0		ī	(50%)	1	(50%)	0
	50-56 Days (Group 2)	54	0			0	Ö		Ô	(304)	,	(304)	0
	57 63 Days (Group 3)	52	3	(6%)		3	0		i	(33%)	2	(67%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS											_	(0.0)	Ū
ANY EVENT													
MAI EVENI	≤63 Days (All)	178	148	(83%)	0.5143	456	189	(41%)	172	(38%)	95	(21%)	0
	<pre>s49 Days (Group 1)</pre>	72	57	(79%)		155	71	(46%)	49	(32*)	35	(23%)	0
<del>4</del> .	50-56 Days (Group 2)	54	47	(87%)		158	70	(443)	60	(38%)	28	(18%)	0
k   k   4   0	57-63 Days (Group 3)	52	44	(85%)		143	48	(34%)	63	(44%)	32	(22%)	0
and the second s										•		,	v
	· · · · · · · · · · · · · · · · · · ·							12					

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numi of i w/E	-	Fisher's exact p-value	Number of Events		1d		Severity erate	Sev		Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	178	1	(<1%)	0.2921	1	0		, 1	(100%)	0		0
	≰49 Days (Group 1)	72	0			0	0		0	1	0		0
	50-56 Days (Group 2)	54	0			0	0		, c	•	0		0
	57-63 Days (Group 3)	52	1	(21)		1	0		3	(100%)	0		0
CONSTIPATION	≤63 Days (All)	178	2	(1%)	0.5155	2	1	(50%)	c	ı	1	(50%)	0
	≰49 Days (Group 1)	72	Ð			0	0		(	)	0		0
	50-56 Days (Group 2)	54	1	(2%)		1	1	(100%)	(	)	0		0
	57-63 Days (Group 3)	52	1	(21)		1	0		(	)	1	(100%)	0
DIARRHEA	≤63 Days (All)	178	40	(221)	0.6344	46	19	(41%)	22	(48%)	5	(11%)	0
1	≤49 Days (Group 1)	72	14	(19%)		15	7	(47%)		(33,4)	3	(20%)	0
	50-56 Days (Group 2)	54	12	(22%)		17	7	(41%)	9	(53%)	1	(6%)	0
	57-63 Days (Group 3)	52	14	(27%)		14	5	(36%)	6	(57%)	1	(7%)	0
DYSPEPSIA	≤63 Days (All)	178	5	(3%)	0.4526	5	4	(80%)	1	(20%)	0		0
	≤49 Days (Group 1)	72	<b>' 1</b>	(1%)		1	1	(100%)	(	)	0		0
1	50-56 Days (Group 2)	54	1	(2%)		1	1	(100%)	(	)	0		0
	57-63 Days (Group 3)	52	3	(61)		3	2	(67%)	1	. (33%)	0		0
FLATULENCE	≤63 Days (All)	178	2	(11)	0.3373	2	. 1	(50%)	1	(50%)	0		0
	s49 Days (Group 1)	72	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	54	0		1	0	0		(	)	0		0
<del>à</del> .	57-63 Days (Group 3)	52	0			0	0		•	)! q. i	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

- 1 - 1 - 1 - 1 - 1	Gestational Age	Total Number	Numl of i	Pts	Fisher's exact	Number				Severit	•		
Body System/Event [2]	Group [3]	of Pts	W/E	vent	p value	of Events	Mi	10	Mode	rate	Sev	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
IRRITABLE BOWEL SYNDROME	≤63 Days (All)	178	2	(1%)	1.0000	2	2	(100%)	0		0		0
	≰49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
MOUTH DRY	≤63 Days (All)	178	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	≤49 Days (Group 1)	72	1	(1%)		1	0		0	1	1	(100%)	0
	50-56 Days (Group 2)	54	0			O	0		0		0		Ð
	57-63 Days (Group 3)	52	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	178	141	(79%)	0.8440	301	126	(42%)	108	(36%)	67	(22%)	0
	≤49 Days (Group 1)	72	57	(79%)		103	49	(48%)	. 34	(33%)	20	(19%)	0
	50-56 Days (Group 2)	54	44	(81%)		107	49	(46%)	34	(32%)	24	(22%)	0
	57-63 Days (Group 3)	52	40	(77%)		91	28	(31%)	40	(44%)	23	(25%)	0
VOMITING	≤63 Days (All)	178	71	(40%)	0.1756	96	36	(38%)	39	(41%)	21	(22%)	0
	≤49 Days (Group 1)	72	23	(32%)		32	12	(38%)	9	(28%)	11	(34%)	0
·	50-56 Days (Group 2)	54	23	(43%)		31	11	(35%)	17	(55%)	3	(10%)	0
	57 63 Days (Group 3)	52	25	(48%)		33	13	(39%)	13	(391)	7	(21%)	0
METABOLIC AND MUTRITIONAL DISORDERS													
ANY EVENT	s63 Days (All)	178	1	(<1%)	1.0000	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	72	1	(1%)		1	0			(100%)	0		0
<del>1</del> .	50-56 Days (Group 2)	54	0			0	0	٠ - ٠	0		0		0
	57 63 Days (Group 3)	52	0			0	0	į	0.	•	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number	;	Severit	V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS	(cont.)		-1-91		·				
OEDEMA GENERALISED	≤63 Days (All)	178	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	<pre>s49 Days (Group 1)</pre>	72	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	178	4 (2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	1 (50%)	1 (50%)	0	ň
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	Ô
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	. 0	0
TACHYCARDIA	≰63 Days (All)	178	4 (2%)	1.0000	4	2 (50%)	. 1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	o
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	0	ō
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	178	7 (4%)	0.8021	13	5 (38%)	7 (54%)	1 (8%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	0	2 (100%)	0	ň
	50-56 Days (Group 2)	54	2 (4%)		6	3 (50%)	3 (50%)	Ŏ	n
·	57-63 Days (Group 3)	52	3 (6%)		5	2 (40%)	2 (40%)	1 (20%)	Ö

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severit	: <b>v</b>	
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mild '	Moderate	Severe	Unknown
ESPIRATORY SYSTEM DISORDERS (cont.)									
COUGHING	≤63 Days (All)	178	3 (2%)	0.1928	8	4 (50%)	3 (38%)	1 (13%)	0
	<pre>\$49 Days (Group 1)</pre>	72	0 '		0	0	0	0	0
	50 56 Days (Group 2)	54	1 (2%)		5	3 (60%)	2 (40%)	0	Õ
	57-63 Days (Group 3)	52	2 (4%)		3	1 (33%)	1 (33%)	1 (33%)	ō
DYSPNOEA	≤63 Days (All)	178	1 (<1%)	0.5955	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50 56 Days (Group 2)	54	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	0		0	ō	0	0	0
PHARYNGITIS	≤63 Days (All)	178	1 (<1%)	0.2921	1	0	1 (100%)	0	•
ı	s49 Days (Group 1)	72	0		0	Ö	. 0 .	0	0
	50-56 Days (Group 2)	54	0		0	Ô	0 ,	n	0
	57-63 Days (Group 3)	52	1 (2%)		1	o	1 (100%)	ő	o
RHINITIS	≤63 Days (All)	178	1 (<1%)	0.2921	1	1 (100%)	0	0	
	≤49 Days (Group 1)	72	0		0	0	Ö	Ŏ	ŏ
1	50-56 Days (Group 2)	54	0		0	0	Ö	0 :	Ŏ
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	o	ő	0
SINUSITIS	≤63 Days (All)	178	2 (1%)	0.3373	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	72	2 (3%)		2	0	2 (100%)	Ö	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
<del>1</del> .	57-63 Days (Group 3)	52	0		Ö	Ö	- 0	0	0
					•		4.	v	v

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	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
ED BLOOD CELL DISORDERS				<del></del>			<del></del>		
ANY EVENT	≤63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	•
	≤49 Days (Group 1)	72	1 (1%)		1	1 (100%)	ō	Ô	0
	50-56 Days (Group 2)	54	0		0	0	0	n	Ô
	57-63 Days (Group 3)	52	0		0	0	ō	Ō	Ö
ANAEMIA	≤63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	•
	≰49 Days (Group 1)	72	1 (11)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	54	0		n	0	0	0	0
	57-63 Days (Group 3)	52	0		ō	ō	ő	0	0
LATBLET, BLEEDING & CLOTTING DISORDERS			!						
ANY EVENT	≤63 Days (All)	178	1 (<1%)	0.5955	1	1 (100%)	0 .	0	0
	≤49 Days (Group 1)	72	0		0	0	0 '	Ô	n
	50 56 Days (Group 2)	54	1 (2%)		1	1 (100%)	Ŏ	0	0
	57-63 Days (Group 3)	52	0		0	0	0	ō	ō
EPISTAXIS	≤63 Days (All)	178	1 (<1%)	0.5955	1	1 (100%)	0	0	n
•	≰49 Days (Group 1)	72	0		0	0	0	0	Ô
	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	ň
· · · · · · · · · · · · · · · · · · ·	57-63 Days (Group 3)	52	0		0	0	0	0	o
RINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	178	1 (<1%)	0.5955	1	0	1 (100%)	0	n
÷	≰49 Days (Group 1)	72	0		0	0	O <sub>i</sub>	Ō	ő
	50-56 Days (Group 2)	54	1 (2%)		1	0	1" (100%)	0	ň
• a •	57-63 Days (Group 3)	52	0	1	0	o '	0	0	Ŏ
			1				•		

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: 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: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of w/E		Fisher's exact p-value	Number of Events				Severity	Sev		Unknown
URINARY SYSTEM DISORDERS (cont.)									-				
DYSURIA *	≤63 Days (All)	178	1	(<1%)	0.5955	1	0		1	(100%)	0		0
Brookin	≤49 Days (Group 1)	72	0	, - ,		0	0		0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	52	0	,		0	0		0		0	ļ	. 0
REPRODUCTIVE DISORDERS, PENALE													Ì
ANY EVENT	≤63 Days (All)	178	21	(12%)	0.9155	25	8	(32%)	2	(B%)	15	(60%)	0
	≤49 Days (Group 1)	72	8	(11%)		8	4	(50%)	1	(13%)	3	(38%)	0
	50-56 Days (Group 2)	54	6	(11%)		8	3	(38%)	0		5	(63%)	0
	57-63 Days (Group 3)	52	7	(13%)		. 9	1	(11%)	1	(11%)	7	(78%)	0
BREAST PAIN FEMALE	s63 Days (All)	178	2	(1%)	0.7532	2	1	(50%)	. 1	(50%)	0		0
	≰49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	0			0	0		0		0		0
	57-63 Days (Group 3)	52	1	(21)		1	0	l	1	(100%)	0		0
ENDOMETRITIS	≤63 Days (All)	178	2	(1%)	1.0000	. 2	2	(100%)	0		0		0
	\$49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50 56 Days (Group 2)	54	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
PREMENSTRUAL TENSION	≰63 Days (All)	178	1	(<1%)	1.0000	1		(100%)	0		0		0
	≤49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
<b>.</b>	50-56 Days (Group 2)	54	0			0	0	2 (	, ŏ	+	0		0
	57-63 Days (Group 3)	52	0			0	0		ò	•	0		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

		Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severi		
Body System/Event (2)	j. i.	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknow
REPRODUCTIVE DISORDERS, FEMAL	E (cont.)	)				<del></del>				
SALPINGLTIS		≤63 Days (All)	178	1 (<1%)	0.5955	1	1 (100%)	0	Ο,	, 0
		≰49 Days (Group 1)	72	0		0	0	. 0	0	0
		50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
		57-63 Days (Group 3)	52	0		0	0	0	О '	0
UTERINE DISORDER NOS		s63 Days (All)	178	1 (<1%)	0.2921	1	1 (100%)	0	0	0
		≤49 Days (Group 1)	72	0		0	0	0	0	0
		50-56 Days (Group 2)	54	0		0	0	0	0	0
		57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	0	0
UTERINE HAEMORRHAGE		≤63 Days (All)	178	14 (8%)	0.5002	16	0	1 (6%)	15 (94%)	0
	,	≤49 Days (Group 1)	72	4 (6%)		4	0	. 1 (25%)	3 (75%)	0
		50-56 Days (Group 2)	54	4 (7%)		5	0	ο '	5 (100%)	0
		57-63 Days (Group 3)	52	6 (12%)		7	0	0	7 (100%)	0
VAGINITIS		≤63 Days (All)	178	2 (1%)	1.0000	2	2 (100%)	0	0	0
		£49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	0
		50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
		57-63 Days (Group 3)	52	0		0	0	0	0	0
EOPLASH !							!			
ANY EVENT		≤63 Days (All)	178	2 (1%)	1.0000	2	2 (100%)	0	0	0
		≰49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	0
		50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
		57-63 Days (Group 3)	52	0	1	0	0	0	0	0

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Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

i i	, "Gestational	Total	Number	Fisher's				, ,	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	y	Unknow
EOPLASM (gont.)									
OVARIAN CYST	≤63 Days (All)	178	2 (1%)	1.0000	2	2 (100%)	0	0	, ,
	≤49 Days (Group 1)	72	1 (1%)	1.0000	i	1 (100%)		0	0
	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)			0
	57-63 Days (Group 3)	52	0		0	0	0	0 . 0	0
DDY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	178	175 (98%)	0.6319	818	300 (37%)	290 (35%)	228 (28%)	0
	s49 Days (Group 1)	72	70 (97%)		315	121 (38%)		85 (27%)	Ō
	50-56 Days (Group 2)	54	54 (100%)		252	96 (38%)		65 (26%)	0
	57-63 Days (Group 3)	52	51 (98%)		251	83 (33%)		78 (31%)	o
ABDOMINAL PAIN	≤63 Days (All)	178	174 (98%)	0.3085	730	272 (37%)	· 252 (35A)	206 (28%)	0
	≤49 Days (Group 1)	72	69 (96%)		279	109 (39%)	95 (34%)	75 (27%)	0
	50-56 Days (Group 2)	54	54 (100%)		229	87 (38%)	80 (35%)	62 (27%)	0
	57-63 Days (Group 3)	52	51 (98%)		222	76 (34%)	77 (35%)	69 (31%)	0
ALLERGY	≤63 Days (All)	178	1 (<1%)	0.2921	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	Ō
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	0	0
ASTHENIA	≤63 Days (All)	178	5 (3%)	0.5186	8	2 (25%)	5 (63%)	1 (13%)	0
	≰49 Days (Group 1)	72	1 (1%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	54	3 (6%)		4	2 (50%)	1 (25%)	1 (25%)	0
	57-63 Days (Group 3)	52	1 (2%)		1	0	1 (100%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

		Gestational	Total	Numb		Fisher's			1		2 6	i .		
Body System/Event [2]	1 1	' · ' Age Group [3]	Number of Pts	of P w/Ev		exact p value	Number - of Events	Mi	1d '		Severit rate	Sev		Unknown
ODY AS A WHOLE - GENERAL	DISORDERS (	(cont.)												* ****
BACK PAIN		≤63 Days (All)	178	11	(6%)	0.2234	17	7	(41%)	6	(35%)	4	(24%)	+ <b>O</b>
		≤49 Days (Group 1)	72	5	(7%)		8	5	(63%)	1	(13%)	2	(25%)	0
		50-56 Days (Group 2)	54	1	(2%)		1	0		1	(100%)	0		0
		57-63 Days (Group 3)	52	5	(10%)		8	2	(25%)	4	(50%)	2	(25%)	0
CHEST PAIN		≤63 Days (All)	178	2	(1%)	0.1750	2	0		2	(100%)	0		0
		≤49 Days (Group 1)	72	0			0	0		0		0		0
		50-56 Days (Group 2)	54	2	(4%)		2	0		2	(100%)	0		0
		57-63 Days (Group 3)	52	0			0	0		0		0		0
FATIGUE		≤63 Days (All)	178	17	(10%)	0.3777	23	7	(30%)	11	(48%)	5	(22%)	0
		≤49 Days (Group 1)	72	7	(10%)		10	3	(30%)	. 4	(40%)	3	(30%)	0
		50-56 Days (Group 2)	54	3	(6%)		4	2	(50%)	2	(50%)	0		0
		57-63 Days (Group 3)	52	7	(13%)		9	2	(22%)	5	(56%)	2	(22%)	0
FEVER		≰63 Days (All)	178	8	(4%)	0.2389	8	3	(38%)	4	(50%)	1	(13%)	0
		≤49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
		50-56 Days (Group 2)	54	3	(6%)		3	1	(33%)	2	(67%)	0		0
		57-63 Days (Group 3)	52	4	(8%)		4	1	(25%)	2	(50%)	1	(25%)	0
HOT FLUSHES		≤63 Days (All)	178	3	(21)	0.7812	3	0		2	(67%)	1	(33%)	0
		≤49 Days (Group 1)	72	2	(3%)		2	0		2	(100%)	0		0
		50-56 Days (Group 2)	54	1	(2%)		1	0		0		1	(100%)	0
		57-63 Days (Group 3)	52	0			0	0		0		0		0

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Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	1 4	),	Gestational	Total	Numb	er	Fisher's	-				
	' i ·	• •	Age	Number	of P	ts	exact	Number		Severity		
Body System/Event [2]			Group [3]	of Pts	w/Ev	ent	p-value	of Events	Mild	Moderate	Severe	Unknow
DDY AS A WHOLE - GENERAL I	DISORDERS	(cont.)										
LEG PAIN			≤63 Days (All)	178	3	(2%)	0.7812	3	1 (33%)	2 (67%)	0 ,	, o
			≤49 Days (Group 1)	72	2	(3%)		2	0	2 (100%)	0	0
			50-56 Days (Group 2)	54	1	(2%)		1	1 (100%)	0	Ο,	0
			57-63 Days (Group 3)	52	0			0	0	0	0	0
MALAISE			≤63 Days (All)	178	4	(2%)	0.1014	4	1 (25%)	2 (50%)	1 (25%)	0
			≤49 Days (Group 1)	72	0			0	0	0	0	0
			50-56 Days (Group 2)	54	3	(6%)		3	1 (33%)	2 (67%)	0	0
			57-63 Days (Group 3)	52	1	(2%)		1	0	0	1 (100%)	0
OEDEMA			≤63 Days (All)	178	1	(<1%)	1.0000	1	0	1 (100%)	0	0
	•		≤49 Days (Group 1)	72	1	(1%)		1	0	1 (100%)	0	0
			50-56 Days (Group 2)	54	0			, <b>o</b>	0	0	0	0
			57-63 Days (Group 3)	52	0			0	0	0	0	0
PAIN			≤63 Days (All)	178	3	(2%)	0.6319	3	3 (100%)	0	0	0
			≤49 Days (Group 1)	72	2	(3%)		2	2 (100%)	0	0	0
			50-56 Days (Group 2)	54	0			0	0	0	0	0
			57-63 Days (Group 3)	52	1	(2%)		1	1 (100%)	0	0	0
RIGORS			≤63 Days (All)	178	6	(3%)	0.5094	6	1 (17%)	2 (33%)	3 (50%)	0
			<b>£49</b> Days (Group 1)	72	4	(6%)		4	1 (25%)	0	3 (75%)	0
			50-56 Days (Group 2)	54	1	(2%)		1	0	1 (100%)	0	0
			57-63 Days (Group 3)	52	1	(2%)		1	0	1 (100%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: NICHOLS (#25)

	Gestational	Total Number	Number of Pts	Fisher's exact;	Number			•	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (C	ont.)								
SYNCOPE *	≤63 Days (All)	178	6 (3%)	0.3798	6	1 (17%)	0	5 (83%)	, 0
•	≤49 Days (Group 1)	72	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	54	2 (4%)		2	1 (50%)	0	1 (50%)	ō
	57-63 Days (Group 3)	52	3 (6%)		3	0	0	3 (100%)	ō
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	178	3 (2%)	0.7812	3	1 (33%)	1 (33%)	1 (33%)	0
	≰49 Days (Group 1)	72	2 (3%)		2	0	1 (50%)	1 (50%)	Ö
	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	ō
	57 63 Days (Group 3)	52	0		0	0	o	0	0
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	178	15 (8%)	0.2052	17	10 (59%)	4 (24)	3 (18%)	0
	≰49 Days (Group 1)	72	3 (4%)		3	3 (100%)	0	0	0
	50 56 Days (Group 2)	54	6 (11%)		7	5 (71%)	2 (29%)	o	0
	57-63 Days (Group 3)	52	6 (12%)		7	2 (29%)	2 (29%)	3 (43%)	0
INFECTION VIRAL	≤63 Days (All)	178	15 (8%)	0.2052	17	10 (59%)	4 (24%)	3 (18%)	0
	<pre>s49 Days (Group 1)</pre>	72	3 (4%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	54	6 (11%)		7	5 (71%)	2 (29%)	0	0
	57-63 Days (Group 3)	52	6 (12%)		7	2 (29%)	2 (29%)	3 (43%)	0
ECONDARY TERMS									
ANY EVENT	≤63 Days (All)	178	1 (<1%)	0.5955	1	0	0	0	1 (100%
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	o	1 (100%
	57-63 Days (Group 3)	52	0	1	0	0	0	0	0
			1						

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: 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: NICHOLS (#25)

	. 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 FERMS (cont.)									
INFLICTED INJURY	≰63 Days (All)	178	1 (<1%)	0.5955	1	0	0	0	1 (100%)
	<b>≤49 Days</b> (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	ο.	1 (100%)
	57-63 Days (Group 3)	52	0		0	0	0	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: SHEEHAN (#26)

Pody Sustan/Event [2]	1	Gestational Age	Total Number	Num of		Fisher's exact	Number				Severi	tv	•		
Body System/Event [2]	· · ·	Group [3]	of Pts		vent	p value	of Events	Mi	1d '	Mode	rate	•	ěre	Unk	cnown
ANY EVENT		≤63 Days (All)	179	179	(100%)		1294	518	(40%)	579	(45%)	193	(15%)	. 4	(<1
		s49 Days (Group 1)	63	63	(100%)		422	175	(41%)	193	(46%)	52	(12%)	. 2	
		50-56 Days (Group 2)	59	59	(100%)		4 ? 3	164	(38%)	197	(45%)	71	(16%)	1	
		57-63 Days (Group 3)	57	57	(100%)		439	179	(41%)	189	(43%)	70	(16%)	1	
SKIN AND APPENDAGES DISORDERS															
ANY EVENT		≤63 Days (All)	179	5	(3%)	0.0822	5	3	(60%)	1	(20%)	1	(20%)	0	
		≰49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
		50-56 Days (Group 2)	59	4	(7%)		4	3	(75%)	0		1	(25%)	0	
		57-63 Days (Group 3)	57	0			0	0		0		0		0	
PRURITUS		≤63 Days (All)	179	1	(<1%)	0.6480	1	1	(100%)	. 0		0		0	
		s49 Days (Group 1)	63	0			0	0		0	•	0		0	
		50-56 Days (Group 2)	59	1	(2%)		1	1	(100 <b>%</b> )	0		0		0	
İ		57-63 Days (Group 3)	57	0			0	0		0		0		0	
SKIN DISORDER		≤63 Days (All)	179	. 1	(<1%)	0.6480	1	1	(100%)	0		0		0	
		≰49 Days (Group 1)	63	0			0	0		0		0		0	
		50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0		0		0	
·		57-63 Days (Group 3)	57	0			0	0		0		0		0	
SWEATING INCREASED		≤63 Days (All)	179	2	(1%)	1.0000	2	0		1	(50%)	1	(50%)	0	
		s49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
		50-56 Days (Group 2)	59	1	(2%)		1	0		0		1	(100%)	0	
		57-63 Days (Group 3)	57	0		l	0	0		0		0		0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: SHEEHAN (#26)

	, Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severit	V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
SKIN AND APPENDAGES DISORDERS (cont.)									
URTICARIA	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0 '	' O
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0 .	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	2 (1%)	0.7667	2	1. (50%)	1 (50/%)	0	0
	≰49 Days (Group 1)	63	1 (2%)		1	1 (100%)	о '	. 0	0
	50-56 Days (Group 2)	59	0		0	0	0	<sup>'</sup> 0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
MYALGIA	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	. 0 '	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	o	0	0	0
SKELETAL PAIN	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
CENTR & PERIPH MERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	64 (36%)	0.7717	104	27 (26%)	70 (67%)	6 (6%)	1 (<1%)
	≤49 Days (Group 1)	63	23 (37%)		41	12 (29%)	24 (59%)	5 (12%)	0
	50-56 Days (Group 2)	59	19 (32%)		30	7 (23%)	22 (73%)	1 (3%)	0
	57-63 Days (Group 3)	57	22 (39%)		33	8 (24%)	24 (73%)	0	1 (3%)

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

Center: SHEEHAN (#26)

	1 °ь	Gestational Age	Total Number		ber Pts	Fisher's exact	No seeks as as		1			;	•		
Body System/Event [2]	. '	Group [3]	of Pts		vent	p value	Number of Events	Mi	ld	Mode	Severit rate	•	vere	Unk	nown
CENTR & PERIPH MERVOUS SYST	EM DISORDE	RS (cont.)													
DIZZINESS		≤63 Days (All)	179	20	(11%)	0.0534	24	11	(46%)	9	(38%)	4	(17%)	, 0	
		≤49 Days (Group 1)	63	12	(19%)		14	7	(50%)	4	(29%)	3		0	
		50-56 Days (Group 2)	59	5	(8%)		7	2	(29%)	4	(57%)	1	(14%)	0	
		57-63 Days (Group 3)	57	3	(5%)		3	2	(67%)	1	(33%)	0	•	0	
HEADACHE		≤63 Days (All)	179	53	(30%)	0.3635	79	15	(19%)	61	(77%)	2	(3%)	1	(1%)
		≤49 Days (Group 1)	63	17	(27%)		27	5	(19%)	20	(74%)	2		0	,,
		50-56 Days (Group 2)	59	15	(25%)		23	5	(22%)	18	(78%)	0		0	
		57 63 Days (Group 3)	57	21	(37%)		29	5	(17%)	23	(79%)	0		1	(3%)
PARAESTHESIA		≤63 Days (All)	179	1	(<1%)	0.3184	1	1	(100%)	0		0		0	
	1	<pre>s49 Days (Group 1)</pre>	63	0			0	0		. 0		0		0	
		50-56 Days (Group 2)	59	0			0	0		0		0		0	
		57-63 Days (Group 3)	57	1	(2%)		1	1	(100%)	O		0		0	
ISION DISORDERS						•									
ANY EVENT		≤63 Days (All)	179	1	(<1%)	1.0000	1	0		0		1	(100%)	0	
		≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0	
		50-56 Days (Group 2)	59	0			0	0		0		0		0	
		57-63 Days (Group 3)	57	0			0	0		0		0		0	
VISION ABNORMAL		≤63 Days (All)	179	1	(<1%)	1.0000	1	0		0	i	1	(100%)	0	
		s49 Days (Group 1)	63	1	(2%)		1	0		0			(100%)	ō	
		50-56 Days (Group 2)	59	0			0	0		0		0	,	0	
		57-63 Days (Group 3)	57	0			0	a		0		1 0		0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS - Not otherwise specified

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

<sup>[4]</sup> 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: SHEEHAN (#26)

		Gestational	Total	Numb	er	Fisher's				The second second	
	i n	' ." Age	Number	of P	ts	exact	Number		Severi	t <b>y</b>	
Body System/Event [2]	·	Group [3]	of Pts	w/Ev	ent	p value	of Events	Mild	Moderate	Severe	Unknow
SYCHIATRIC DISORDERS											
ANY EVENT		≤63 Days (All)	179	11	(6%)	0.3620	14	5 (36%)	8 (57%)	1 (74)	۰ 0
		≤49 Days (Group 1)	63	6	(10%)		7	2 (291)	4 (57%)	1 (14%)	0
		50-56 Days (Group 2)	59	2	(3%)		3	2 (67%)	1 (33%)	0	0
		57-63 Days (Group 3)	57	3	(5%)		4	1 (25%)	3 (75%)	ο ΄	0
ANOREXIA		s63 Days (All)	179	1	(<1%)	1.0000	1	1 (100%)	o	0	0
		≤49 Days (Group 1)	63	1	(2%)		1	1 (100%)	0	0	0
		50-56 Days (Group 2)	59	0			0	0	0	0	0
		57-63 Days (Group 3)	57	0			0	0	0	0	0
ANXIETY		≤63 Days (All)	179	4	(2%)	1.0000	4	0	4 (100%)	0	0
		≤49 Days (Group 1)	63	2	(3%)		2	0	2 (1001)	0	0
		50-56 Days (Group 2)	59	1	(2%)		1	0	1 (100%)	0	0
		57-63 Days (Group 3)	57	1	(2%)		1	0	1 (100%)	0	0
DEPRESSION		≤63 Days (All)	179	2	(1%)	0.5413	2	1 (50%)	1 (50%)	0	0
		≤49 Days (Group 1)	63	0			0	0	0	0	0
		50-56 Days (Group 2)	59	1	(2%)		1	1 (100%)	0	0	0
		57-63 Days (Group 3)	57	1	(2%)		1	0	1 (100%)	0	0
EMOTIONAL LABILITY		≤63 Days (All)	179	4	(2%)	0.4684	5	2 (40%)	2 (40%)	1 (20%)	0
		≤49 Days (Group 1)	63	2	(3%)		3	1 (33%)	1 (33%)	1 (33%)	0
		50-56 Days (Group 2)	59	0			0	0	0	0	0
		57-63 Days (Group 3)	57	2	(4%)		2	1 (50%)	1 (50%)	0	0

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Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	V : \$ :	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)									
INSOMNIA 4	≤63 Days (Åll)	179	2 (1%)	1.0000	2	1 (50%)	1 (50%)	ο .	, <b>o</b>
	#49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	о .	0
GASTRO-INTESTIMAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	159 (89%)	0.3485	449	212 (47%)	180 (40%)	56 (12%)	1 (<1%
	≤49 Days (Group 1)	63	53 (84%)		138	67 (49%)	59 (43%)	12 (9%)	0
	50-56 Days (Group 2)	59	54 (92%)		163	69 (42%)	70 (43%)	23 (14%)	1 (<1%
	57-63 Days (Group 3)	57	52 (91%)		148	76 (51%)	51 (34%)	21 (14%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≰63 Days (All)	179	3 (2%)	0.6520	4	2 (50%)	. 1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	63	2 (3%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
CONSTIPATION	≤63 Days (All)	179	1 (<1%)	0.3184	1	o	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	o	1 (100%)	0	0
DIARRHEA	≤63 Day8 (All)	179	27 (15%)	0.7017	30	14 (47%)	16 (53%)	0	0
	≤49 Days (Group 1)	63	11 (17%)		12	4 (33%)	8 (67%)	0	0
	50 56 Days (Group 2)	59	7 (12%)		8	4 (50%)	4 (50%)	0	0
	57-63 Days (Group 3)	57	9 (16%)		10	6 (60%)	4 (40%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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		'Gestational - Age	Total Number		nber Pts	Fisher's exact	M. mb a m	'					•		
Body System/Event [2]	. 1.	Group [3]	of Pts		vent	p-value	Number of Events	Mi	1 <b>d</b>		Severi erate	ty Sev		Unk	cnown
ASTRO-INTESTINAL SYSTEM DIS	ORDERS (cont.	)													
DYSPEPSIA		≤63 Days (All)	179	6	(3%)	0.1224	7	3	(43%)	3	(43%)	1	(14%)	, 0	
		≰49 Days (Group 1)	63	2	(3%)		3	2	(67%)	1		0	(144)	0	
		50-56 Days (Group 2)	59	4	(7%)		4	1	(25%)	2	(50%)	1	(25%)	0	
		57.63 Days (Group 3)	57	0			0	0		0	(200)	ō	12.307	0	
MELAENA		≤63 Days (All)	179	1	(<1%)	0.3184	1	1	(100%)	0		0	,	1 0	
		≤49 Days (Group 1)	63	0			0	0		0		0		0	
		50-56 Days (Group 2)	59	0			0	0		0		0		0	
		57-63 Days (Group 3)	57	1	(21)		1	1	(100%)	0		0		0	
NAUSEA	i	≤63 Days (All)	179	149	(83%)	0.3284	319	166	(52%)	111	(35%)	41	(13%)	,	(<11
		≤49 Days (Group 1)	63	49	(78%)		100	56	(56%)	34		10	(10%)	0	/<14
		50-56 Days (Group 2)	59	52	(88%)		118	54	(46%)	47	(40%)	16	(14%)	1	(<11
		57-63 Days (Group 3)	57	48	(84%)		101	56	(55%)	30	(30%)	15	(15%)	0	(
TOOTH ACHE		≤63 Days (All)	179	1	(<1%)	1.0000	1	0	į.	,	(100%)	0		0	
		≰49 Days (Group 1)	63	1	(2%)		1	0			(100%)	0		0	
		50-56 Days (Group 2)	59	0			. 0	0		ō	(1000)	0		0	
		57-63 Days (Group 3)	57	0			0	0		ō		ő		0	
VOMITING		≰63 Days (All)	179	68	(38%)	0.0606	86	26	(30%)	47	(55%)		(154)		
		≤49 Days (Group 1)	63	17	(27%)		19	3	(16%)	14	(74%)	13 2	(15%) (11%)	0	
		50 56 Days (Group 2)	59	24	(41%)		33	10	(30%)	17	(52%)	6	(11%) (18%)	0	
		57-63 Days (Group 3)	57	27	(47%)		34	13	(38%)	16	(47%)	5	(15%)	0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>(2)</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

	; . ; .	'Gestational 'Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	y	
Body System/Event [2]	· ·	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
ETABOLIC AND MUTRITIONAL D	ISORDERS						<del></del>		· · · · · · · · · · · · · · · · · · ·	1
ANY EVENT		≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	O	0 .	, 0
		≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	. 0
		50-56 Days (Group 2)	59	0		0	0	0	Ô	0
		57-63 Days (Group 3)	57	0		0	0	0	o ,	0
DEHYDRATION		≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	•	•	_
		≤49 Days (Group 1)	63	1 (2%)	1.0000	1	1 (100%)	0	0	0
		50-56 Days (Group 2)	59	0		•	0	0	0	0
		57-63 Days (Group 3)	57	0		ō	0	0 0	0	0
ARDIOVASCULAR DISORDERS, G	ENERAL									
ANY EVENT		s63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (1001)		
		≤49 Days (Group 1)	63	0	0.5101	Ô	0	. 1 (100%) 0	0	0
		50-56 Days (Group 2)	59	o		n	0	0	0	0
	1	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0 0
HYPOTENSION		≤63 Days (All)	179	1 (<1%)	0.3184	1	0		_	
		≤49 Days (Group 1)	63	. 0	0.3104	1	-	1 (100%)	0	0
		50-56 Days (Group 2)	59	0		0	0	0	0	0
		57-63 Days (Group 3)	57	1 (2%)		•	0	0	0	0
1		or or buys (Group 3)	3,	1 (24)		1	U	1 (100%)	0	0
EART RATE AND RHYTHM DISOR	DERS									
ANY EVENT		≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
		≰49 Days (Group 1)	63	0	1	0	0	Ŏ	o o	0
		50-56 Days (Group 2)	59	1 (2%)	1	1	1 (100%)	0	o	0
		57-63 Days (Group 3)	57	0	ļ	0	0	0	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

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Center: SHEEHAN (#26)

		1	Gestational Age	Total Number	Numi of		Fisher's exact	Number				Severil	y	.*	
Body System/Event [2]			Group [3]	of Pts	w/E	vent	p value	of Events	Mil	d	Mode	rate	Sev	ere	Unknown
HEART RATE, AND RHYTHM DISO	RDERS (cont	.)													
TACHYCARDIA			≤63 Days (All)	179	1	(<1%)	0.6480	1	1 (	100%)	0		0		, <b>o</b>
			£49 Days (Group 1)	63	0			0	0		0		0		0
			50-56 Days (Group 2)	59	1	(2%)		1	1 (	100%)	0		0		0
			57-63 Days (Group 3)	57	0			0	0		0		0	·	0
VASCULAR (EXTRACARDIAC) DI	SORDERS														
ANY EVENT			≤63 Days (All)	179	1	(<1%)	0.6480	1	1 (	100%)	0		0		0
			≤49 Days (Group 1)	63	0			0	0.		0	1	0		0
			50 56 Days (Group 2)	59	1	(2%)		1	1 (	100%)	0		: 0		0
			57-63 Days (Group 3)	57	0			0	0		0		0		0
VEIN DISORDER			≤63 Days (All)	179	1	(<1%)	0.6480	1	1 (	100%)	. о	1	0		0
			≤49 Days (Group 1)	63	0			0	0		0		0		0
			50-56 Days (Group 2)	59	1	(2%)		1	1 (	100%)	0		0		0
			57-63 Days (Group 3)	57	0		•	0	0		0		0		0
RESPIRATORY SYSTEM DISORDE	RS														
ANY EVENT			≤63 Days (All)	179	9	(5%)	0.6995	10	3	(30%)	4	(40%)	3	(30%)	0
			≤49 Days (Group 1)	63	3	(5%)		3	1	(33%)	2	(67%)	0		0
			50-56 Days (Group 2)	59	2	(3%)		3	0		1	(33%)	2	(67%)	0
			57-63 Days (Group 3)	57	4	(7%)		4	2	(50%)	1	(25%)	1		0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

		U Gestational	Total	Numb	er	Fisher's			1			#		
	. 1.	Age	Number	of F	ts	exact	Number				Sever	ity	#	
Body System/Event [2]		Group [3]	of Pts	w/Ev	ent	p-value	of Events	Mil	d '	Mode	rate	Sev	ere	Unknown
RESPIRATORY SYSTEM DISORDER	s (cont.)													
COUGHING 4		≤63 Days (All)	179	1	(<1%)	0.3184	1	0		0		1	(100%)	, O
		≤49 Days (Group 1)	63	0			0	0		0		0		0
		50-56 Days (Group 2)	59	0			0	0		0		0		0
		57-63 Days (Group 3)	57	1	(2%)		1	0		0		1	(100%)	0
DYSPNOEA		≤63 Days (All)	179	1	(<1%)	1.0000	1	0		1	(100%)	0		0
		s49 Days (Group 1)	63	1	(2%)		1	0			(100%)	0		0
		50-56 Days (Group 2)	59	0			0	0		0	(,	0		o
		57-63 Days (Group 3)	57	0			0	0		0		o		0
PULMONARY CONGESTION		≤63 Days (All)	179	1	(<1%)	0.3184	1	1 (	100%)	0		0		0
	•	s49 Days (Group 1)	63	0			0	0		. 0		0		o
		50-56 Days (Group 2)	59	0			0	0		0		0		0
		57-63 Days (Group 3)	57	1	(2%)		1	1 (	100%)	0		o		0
SINUSITIS		≤63 Days (All)	179	6	(3%)	1.0000	7	2	(291)	3	(43%)	2	(29%)	0
		s49 Days (Group 1)	63	2	(3%)		2		(50%)	1	(50%)	0	(2)()	Ö
		50-56 Days (Group 2)	59	2	(3%)		3	0		1	(33%)	2	(67%)	0
		57-63 Days (Group 3)	57	2	(4%)		2	1	(50%)	1	(50%)	0	,	o
RED BLOOD CELL DISORDERS		¢.			į									
ANY EVENT		≤63 Days (All)	179	26	(15%)	0.0320	26	17	(65%)	7	(27%)	2	(8%)	0
		≰49 Days (Group 1)	63	4	(6%)		4		(75%)	1	(25%)	0	/	0
		50-56 Days (Group 2)	59	9	(15%)		9	6	(67%)	2	(22%)	; 1	(11%)	0
		57-63 Days (Group 3)	57	13	(23%)		13		(621)	4		1	(8%)	o

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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:	SHEEHAN	(#26
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	i	Gestational Age	Total Number	Numb of P		Fisher's exact	Number				Severity-	1		
Body System/Event [2]	•	Group [3]	of Pts	w/Ev	ent	p value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknow
ED BLOOD CELL DISORDERS (CO	nt.)									_	(224)		(0.0.)	
ANAEMIA		≤63 Days (All)	179		(14%)	0.0345	25	16	(64%)	7	(28%)	2	(8⅓)	, 0 0
		≤49 Days (Group 1)	63	4	(6%)		4	3	(75%)	1	(25%)	0	(134)	•
		50-56 Days (Group 2)	59		(14%)		8	5	(63%)	2	(25%)	1	(13%) '(8%)	0
		57-63 Days (Group 3)	57	13	(23%)		13	8	(62%)	4	(31%)	1	(84)	0
ANAEMIA HYPOCHROMIC		≤63 Days (All)	179	1	(<1%)	0.6480	1	1	(100%)	0		0		0
THE STATE OF THE S		≤49 Days (Group 1)	63	0			0	0		0		0		0
		50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0		0		0
		57-63 Days (Group 3)	57	0			0	0		0		0		0
RIMARY SYSTEM DISORDERS				_	/==1			_	(678)		(228)			0
ANY EVENT	'	≤63 Days (All)	179	3	(2%)	0.7746	3	2	(67%)	. 1	(33%)	0		0
		s49 Days (Group 1)	63	2	(3%)		Ž	ı	(50%)	1	(50%)	0		0
		50-56 Days (Group 2)	59	1	(2%)		ł		(100%)	0		0		0
		57-63 Days (Group 3)	57	0		÷	0	0		0		0		U
URINARY TRACT INFECTION		≤63 Days (All)	179	3	(2%)	0.7746	3	2	(67%)	1	(33%)	0		0
OKTIMAL TIGICS THE DOTS OF		≤49 Days (Group 1)	63	2	(3%)		2	1	(50%)	1	(50%)	0		0
		50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0		0		0
		57-63 Days (Group 3)	57	0			0	0		0		0		0
REPRODUCTIVE DISORDERS, FEM.	LE							_		_	<b></b>			_
ANY EVENT		≤63 Days (All)	179		(11*)	0.9103	23	6	(26%)		(26%)	11		0
		≤49 Days (Group 1)	63	6	(10%)		8	4	(50%)	1	(13%)	3	(38%)	0
		50-56 Days (Group 2)	59		(10%)		7	2	(29%)	2	(29%)	3	(43%)	0
		57-63 Days (Group 3)	57	7	(12%)		8	0		3	(38%)	5	(63%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Center: SHEEHAN (#26)

	i - b i -	1	Gestational Age	Total Number	Numi of		Fisher's exact	Number			Severity	5 ×	• i i j • j	
Body System/Event [2]	·		Group [3]	of Pts	w/E	vent	p value	of Events	Mild	Mode	rate	Sev	er <b>e</b>	Unknown
EPRODUCTIVE DISORDERS, FEN	ALE (cont.)	)					-							
BREAST DISCHARGE			≤63 Days (All)	179	2	(1%)	1.0000	2	2 (100%)	0		0		, 0
•			≰49 Days (Group 1)	63	1	(2%)		1	1 (100%)	0		0		0
			50-56 Days (Group 2)	59	1	(2%)		1	1 (100%)	0		0		0
			57-63 Days (Group 3)	57	0			0	0	0		0	•	0
BREAST ENLARGEMENT			≤63 Days (All)	179	1	(<1%)	0.6480	1	1 (100%)	0		0		0
			s49 Days (Group 1)	63	0			0	0	0		0		0
			50-56 Days (Group 2)	59	1	(2%)		1	1 (100%)	0		0		0
			57-63 Days (Group 3)	57	0	İ		0	0	0		0		0
BREAST PAIN FEMALE			≤63 Days (All)	179	1	(<1%)	1.0000	1	1 (100%)	0		0		0
			≤49 Days (Group 1)	63	1	(2%)		1	1 (100%)	. 0		0		0
			50-56 Days (Group 2)	59	0			0	0	0	-	0		0
			57-63 Days (Group 3)	57	0			0	o	0		0		0
LEUKORRHOEA			≤63 Days (All)	179	1	(<1%)	1.0000	1	1 (100%)	0		0		0
			≤49 Days (Group 1)	63	1	(2%)		1	1 (100%)	0		0		0
			50-56 Days (Group 2)	59	0			0	0	0		0		0
			57 63 Days (Group 3)	57	0			0	0	0		0		0
UTERINE ATONY			≤63 Days (All)	179	2	(1%)	0.1002	2	0	1	(50%)	1	(50%)	0
			≤49 Days (Group 1)	63	0			0	0	0		0		0
			50-56 Days (Group 2)	59	0			0	0	0		0		0
			57-63 Days (Group 3)	57	2	(4%)		2	0	1	(501)	1	(50%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: SHEEHAN (#26)

	i i	1	Gestational	Total	Numi	ber	Fisher's						Y	• • •		
	1.7	, .	Age	Number	of I	Pts	exact	Number	<b></b> -			Severit	y :	· <u>.</u>		
Body System/Event [2]	·		Group [3]	of Pts	w/E	vent	p value	of Events	Mi	1d .	Mode	rate	Seye	ere	Unk	nown
PRODUCTIVE DISORDERS, PEN	ALE (cont.	)													_	
uterine haemorrhage			≤63 Days (All)	179	10	(6%)	0.1981	11	0		2	(18%)		(82%)	, 0	
			≤49 Days (Group 1)	63	1	(2%)		2	0		0			(100%)	0	
			50-56 Days (Group 2)	59	5	(8%)		5	0		2	(40%)	3	(60%)	0	
			57-63 Days (Group 3)	57	4	(7%)		4	0		0		4	(100%)	0	
VAGINAL DISCOMFORT			≤63 Days (All)	179	1	(<1%)	1.0000	1	0		0		1	(100%)	. 0	
			≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0	
			50-56 Days (Group 2)	59	0			o o	0		0		0		0	
		,	57-63 Days (Group 3)	57	0			0	0		0		0		0	
VAGINITIS			≤63 Days (All)	179	3	(21)	0.4189	3	1	(33%)	2	(67%)	0		0	
			≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	. 0		0		0	
			50-56 Days (Group 2)	59	0			0	0		0		0		0	
			57-63 Days (Group 3)	57	2	(4%)		2	0	1	2	(100%)	0		0	
VULVITIS			≤63 Days (All)	179	1		1.0000	. 1	0		1	(100%)	0		0	
			≤49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
			50-56 Days (Group 2)	59	0			0	0		0		0		0	
			57-63 Days (Group 3)	57	0			0	0		0		0		0	
DDY AS A WHOLE - GENERAL D	ISORDERS															
ANY EVENT			≰63 Days (All)	179	177	(99%)	1.0000	645	237	(37%)	295	(46%)	111	(17%)	2	(<1
			≤49 Days (Group 1)	63	62	(98%)		212	82	(39%)	99	(47%)	29	(14%)	2	(<1
			50-56 Days (Group 2)	59	58	(98%)		207	71	(34%)	96	(46%)	40	(19%)	0	
			57-63 Days (Group 3)	57	57	(100%)		226	84	(37%)	100	(44%)	42	(19%)	0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

	i i	Gestational	Total	Number	Fisher's				, • · · · · · · · · · · · · · · · · · ·	
Body System/Event [2]	. i.	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL	DISORDERS	(cont.)				·				
ABDOMINAL PAIN		≤63 Days (All)	179	177 (99%)	1.0000	5 <b>97</b>	216 (36%)	277 (46%)	102 (17%)	' 2 {<1%
		≰49 Days (Group 1)	63	62 (98%)		193	75 (39%)	89 (46%)	27 (14%)	2 (1%
		50-56 Days (Group 2)	59	58 (98%)		193	64 (33%)	93 (48%)	36 (19%)	0
		57-63 Days (Group 3)	57	57 (100%)		211	77 (36%)	95 (45%)	39 (18%)	0
ALLERGY		s63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
		≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
		50-56 Days (Group 2)	59	0		0	0	0	0	0
		57-63 Days (Group 3)	57	0		0	0	0	0	0
ASTHENIA		≤63 Days (All)	179	3 (2%)	1.0000	3	o	1 (33%)	2 (67%)	0
	1	s49 Days (Group 1)	63	1 (2%)		1	0	· 0 (	1 (100%)	0
		50-56 Days (Group 2)	59	1 (2%)		1	0	0	1 (100%)	0
	1	57-63 Days (Group 3)	57	1 (2%)		1	o	1 (100%)	0	0
BACK PAIN		≤63 Days (All)	179	12 (7%)	0.3682	15	7 (47%)	7 (47%)	1 (7%)	0
		≤49 Days (Group 1)	63	4 (6%)		6	1 (17%)	5 (83%)	0	0
		50-56 Days (Group 2)	59	6 (10%)		7	4 (57%)	2 (29%)	1 (14%)	0
<b>!</b>		57-63 Days (Group 3)	57	2 (4%)		2	2 (100%)	0	0	0
FATIGUE		≤63 Days (All)	179	14 (8%)	0.5725	14	7 (50%)	5 (36%)	2 (14%)	0
		≰49 Days (Group 1)	63	5 (8%)		5	2 (40%)	2 (40%)	1 (20%)	0
		50-56 Days (Group 2)	59	3 (5%)	ļ	3	2 (67%)	0	1 (33%)	0
		57-63 Days (Group 3)	57	6 (11%)	1	6	3 (50%)	3 (50%)	0	0

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Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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	i - u	Gestational Age	Total Number	Number of Pts	Fisher's exact	s Number		Severit	<b>•</b> • • • • • • • • • • • • • • • • • •	
Body System/Event [2]		Group [3]	of Pts	w/Even			Mild '	Moderate	Severe	Unknow
ODY AS A WHOLE - GENERAL	DISORDERS	(cont.)								
FEVER 4		≤63 Days (All)	179	5 (	1) 0.2837	5	3 (60%)	2 (40%)	ο ,	, 0
		≤49 Days (Group 1)	63	3 (	*)	. 3	2 (67%)	1 (33%)	0	0
		50-56 Days (Group 2)	59	0		0	0	0	0	0
		57-63 Days (Group 3)	57	2 (	*)	2	1 (50%)	1 (50%)	ο ΄	0
HYPOVOLAEMIA		≤63 Days (All)	179	1 (<	1) 0.3184	1	0,	0	1 (1001)	0
		≤49 Days (Group 1)	63	0		0	0	0	0 ~	0
		50-56 Days (Group 2)	59	0		0	0	0	0	0
		57-63 Days (Group 3)	57	1 (	<b>t</b> )	1	0	0	1 (100%)	0
LEG PAIN		≤63 Days (All)	179	2 (	1) 0.7667	2	1 (50%)	1 (50%)	o	0
		≰49 Days (Group 1)	63	1 (	*)	1	0	1 (100%)	0	0
		50-56 Days (Group 2)	59	0		0	0	0 '	0	0
		57-63 Days (Group 3)	57	1 (2	<b>*</b> )	1	1 (100%)	0	0	0
MALAISE		≤63 Days (All)	179	1 (<	1) 0.6480	1	1 (100%)	0	o	0
		<pre>s49 Days (Group 1)</pre>	63	0		0	0	0	0	0
		50-56 Days (Group 2)	59	1 (	*)	1	1 (100%)	0	0	0
		57-63 Days (Group 3)	57	0		0	0	0	0	0

≤63 Days (All)

≤49 Days (Group 1)

50-56 Days (Group 2)

57-63 Days (Group 1)

63

59

57

0

2

0

(3%)

Source Data: Appendix A.1, Tables 16 and 25

FINAL

0

0

0

0

(50%)

(50%)

0

1

0

1 (50%)

1

(50%)

OEDEMA

0.2076

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: SHEEHAN (#26)

. ''		Total Number	Number of Pts	Fisher's exact	Number		Severit		
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
DY AS A WHOLE - GENERAL DISORDERS (COD	t.)							·	
PAIN	≤63 Days (All)	179	2 (1%)	0.7667	2	1 (50%)	0	1 (50°%)	, O
	≰49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	ñ
	50-56 Days (Group 2)	59	0		0	0	0	0 .	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
RIGORS	≰63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	<pre>s49 Days (Group 1)</pre>	63	1 (2%)		1	0	1 (100%)	ō	n
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	ō	ō
SYNCOPE	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0 ,	0	o
	50-56 Days (Group 2)	59	0		0	0	0	Ô	Ô
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	ō
SISTANCE MECHANISM DISORDERS				-					
ANY EVENT	≤63 Days (All)	179	6 (3%)	0.2504	6	2 (33%)	3 (50%)	1 (17%)	0
	≤49 Days (Group 1)	63	3 (5%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	59	3 (5%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	57	ο ',		0	0	0	o ·	0
INFECTION VIRAL	≤63 Days (All)	179	5 (3%)	0.3275	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	59	3 (5%)		3	1 (33%)	2 (67%)	0	n
	57-63 Days (Group 3)	57	0		0	0	0	0	0

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Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Center: SHEEHAN (#26)

			Gestational Age	Total Number	Num of		Fisher's exact	Number		Save	rity	
Body System/Event [2]	. 1.		Group (3)	of Pts		vent	p value	of Events	Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISOR	DERS (cont	.)								,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
MONILIAŠIS GENITAL			≤63 Days (All)	179	1	(<1%)	1.0000	1	0	1 (100%)	0 .	· O
			≤49 Days (Group 1)	63	1	(Ž\$)		1	0	1 (100%)	0	0
			50-56 Pays (Group 2)	59	0	1		0	0	0	0	0
			57-63 Days (Group 3)	57	0			0	0	0	0 '	О
SECONDARY TERMS												
ANY EVENT			≤63 Days (All)	179	2	(1%)	0.5413	2	0	2 (100%)	0	0
			≤49 Days (Group 1)	63	0			0	0	0	0	0
			\$0-56 Days (Group 2)	59	1	(2%)		1	0	1 (100%)	0	0
			57-63 Days (Group 3)	57	1	(2%)		1	0	1 (100%)	0	0
INFLICTED INJURY	*		≤63 Days (All)	179	1	(<1%)	0.3184	1	0	1 (100%)	0	0
			≤49 Days (Group 1)	63	0			0	0	0	0	0
			50-56 Days (Group 2)	59	0			0	0	0	0	0
			57-63 Days (Group 3)	57	1	(2%)		1	0	1 (100%)	o	0
POST-OPERATIVE PAIN			s63 Days (All)	179	1	(<1%)	0.6480	1	0	1 (100%)	0	0
			≤49 Days (Group 1)	63	0			0	0	0	0	0
			50-56 Days (Group 2)	59	1	(2%)		1	0	1 (100%)	0	0
			57-63 Days (Group 3)	57	0			0	0	0	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: DEAN (#27)

i de	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Caua-1		*		
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events		1 <b>d</b>		Severi rate	-	ere	Unkr	nown
•													
ANY EVENT	≤63 Days (All)	191	190 (>99%)	0.5340	1456	498	(34%)	578	(40%)	343	(24%)	37	(3%)
	≰ <b>49 Days</b> (Group 1)	29	29 (100%)		203	65	(32%)	99	(49%)	39	(19%)	0	
	50 56 Days (Group 2)	73	72 (99%)		541	201	(37%)	215	(40%)	110	(20%)	15	(3%)
	57-63 Days (Group 3)	89	89 (100%)		712	232	(33%)	264	(37%)	194	(27%)	22	(3%)
KIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	191	4 (2%)	0.8085	4	3	(75%)	0		1	(25%)	0	
	≰49 Days (Group 1)	29	1 (3%)		1	1	(100%)	0		0		0	
	50 56 Days (Group 2)	73	1 (1%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	89	2 (2%)		2	1	(50%)	0		1	(50%)	0	
PRURITUS	≤63 Days (All)	191	1 (<1%)	1.0000	1	1	(100%)	. 0	t	O		0	
	s49 Days (Group 1)	29	0		0	0		0		n		Ô	
	50-56 Days (Group 2)	73	0		0	0		0		ò		n	
	57-63 Days (Group 3)	89	1 (1%)		1	1	(100%)	0		ō		o	
RASH	≤63 Days (All)	191	1 (<1%)	0.1518	1	1	(100%)	0		0		0	
	s49 Days (Group 1)	29	1 (3%)		1		(100%)	0		n		n	
	50-56 Days (Group 2)	73	0		0	0	,	0		0		Ô	
	57-63 Days (Group 3)	89	0		0	0		0		0		0	
SWEATING INCREASED	≤63 Days (All)	191	1 (<1%)	1.0000	1	0		0		1	(100%)	0	
	≤49 Days (Group 1)	29	0		0	0		0		0	,	n	
	50-56 Days (Group 2)	73	0		0	0		ō		0		0	
	57-63 Days (Group 3)	89	1 (1%)	,	1	0		ō		1	(100%)	0	

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Source Data: Appendix A.1, Tables 16 and 25

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<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: DEAN (#27)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild '	Moderate	Severe	Unknown
KIN AND APPENDAGES DISORDERS (cont.)									
URTICARIA .	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	Ο,	. 0
	≤49 Days (Group 1)	29	0		0	0	0	0 .	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	ο ,	0
JSCULO-SKELETAL SYSTEM DISORDERS								i	1
ANY EVENT	≤63 Days (All)	191	2 (1%)	0.4261	3	0	3 (100%)	0	; o
	≤49 Days (Group 1)	29	0		; O	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
MYALGIA .	≤63 Days (All)	191	1 (<1%)	0.5340	2	0	2 (100%)	0	0
	<pre>\$49 Days (Group 1)</pre>	29	0		0	0	0 '	0	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	<b>0</b> i	0	0	0
SKELETAL PAIN	s63 Days (All)	191	1 (<1%)	0.5340	. 1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	65 (34%)	0.9565	119	29 (24%)	69 (58%)	18 (15%)	3 (3
	≤49 Days (Group 1)	29	9 (31%)		17	3 (18%)	13 (76%)	1 (6%)	0
	50-56 Days (Group 2)	73	25 (34%)		41	12 (29%)	23 (56%)	4 (10%)	2 (5
	57-63 Days (Group 3)	89	31 (35%)		61	14 (23%)	33 (54%)	13 (21%)	1 (2)

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling. Source Data: 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: DEAN (#27)

j · 6	Gestational	Total	Number	Fisher's				, ,	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	y Š Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISOR	DERS (cont.)				A= - N			· · · · · · · · · · · · · · · · · · ·	
DIZZINESS	≤63 Days (All)	191	16 (8%)	0.2497	20	3 (15%)	11 (55%)	6 (30%)	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	4 (5%)		5	1 (20%)	3 (60%)	1 (20%)	0
	57-63 Days (Group 3)	89	11 (12%)		14	2 (14%)	7 (50%)	5 (36%)	0
HEADACHE	≤63 Days (All)	191	58 (30%)	0.9766	97	25 (26%)	58 (60%)	11 (11%)	3 (3%)
	≤49 Days (Group 1)	29	9 (31%)		16	3 (19%)	12 (75%)	1 (6%)	0
	50 56 Days (Group 2)	73	23 (32%)		35	10 (29%)	20 (57%)	3 (9%)	2 (6%)
	57-63 Days (Group 3)		26 (29%)		46	12 (26%)	26 (57%)	7 (15%)	1 (2%)
MENINGITIS	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	· 0 '	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
!	57-63 Days (Group 3)	89	1 (1%)		1	0	o	1 (100%)	0
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	191	. 1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
!	57-63 Days (Group 3)	89	0		0	0	0	0	Q
VISION DISORDERS						,			
ANY EVENT	≤63 Days (All)	191	1 (<1%)	0.151,8	ı	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	0	1	0	0	0	0	0
	57 63 Days (Group 3)	89	0		0	0	0	0	0

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[1]</sup> Includes all adverse event's reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center:	DEVN	(827

		(Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severil	<b>v</b>	
Body System/Event [2]	· · ·	Group [3]	of Pts	w/Event	p value	of Events	Mild '	Moderate	Severe	Unknowr
VISION DISORDERS (cont.)						-		<u> </u>	, , , , , , , , , , , , , , , , , , , ,	
MYDRIAS NG		≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	, 0
	,	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	, 0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	0		0	0	0	o ·	0
PECIAL SENSES OTHER, DISORD	ERS									
ANY EVENT		≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≰49 Days (Group 1)	29	0		0	ď	0 (1041)	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
TASTE PERVERSION	•	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	
		≰49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	0		0	ō	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	ō	0
SYCHIATRIC DISORDERS					•					
ANY EVENT		≤63 Days (All)	191	4 (2%)	0.8085	6	0	3 (50%)	2 /508)	•
		s49 Days (Group 1)	29	0 (21)	0.000	0	0	3 (3U\$)	3 (50%)	0
		50-56 Days (Group 2)	73	1 (1%)		3	0	1 (33%)	0 (675)	0
		57-63 Days (Group 3)	89	3 (3%)		1	0	2 (67%)	2 (67%) 1 (33%)	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: DEAN (#27)

Gestational	Total	Number	r	Fisher's			,						
Age	Number			exact	Number					ty	<b>.</b>		
Group [3]	of Pts	w/Ever	nt	p value	of Events	Mi	ld	Mode	rate	Sev	ere	Unk	known
≤63 Days (All)	191	1 (-	<1%)	1.0000	1	0		1	(100%)	0	,	, ο	
≤49 Days (Group 1)	29	0			. 0	0		0		0		0	
50-56 Days (Group 2)	73	0			0	0		0		0	1	0	
57-63 Days (Group 3)	89	1	(1%)		1	0		1	(100%)	0		0	
s63 Days (All)	191	1 (	<14)	0.5340	1	0		0		1	(100%)	n	
≤49 Days (Group 1)	29	0			0	0				0	(2000)	_	
50-56 Days (Group 2)	73	1	(1%)	•	1	0		0		1	(100%)	-	
57-63 Days (Group 3)	89	0			0	0		0		0	(2000)	0	
s63 Days (All)	191	3	(2%)	1.0000	4	0		2	(50%)	2	(50%)	n	
≤49 Days (Group 1)	29	0			0	0		. 0	1		(300)		
50-56 Days (Group 2)	73	1 (	(1%)		2	0		1	(50k)		(50%)	_	
57-63 Days (Group 3)	89				2	0		1	(50%)	_		0	
			•										
≤63 Days (All)	191	141 (7	74%)	0.1370	454	159	(35%)	180	(40%)	113	(25%)	2	(<1%
≤49 Days (Group 1)	29	17 (5	59%)		55								1.2.
50-56 Days (Group 2)	73	55 (7	75%)		159	60							
57-63 Days (Group 3)	89	69 (7	78%)		240	79	(33%)	86	(364)	73	(30%)		(<1%
≤63 Days (All)	191	56 (2	291)	0.3786	72	37	(51%)	26	(36%)	q	(13%)	0	
≤49 Days (Group 1)	29				7	5		1		. 1			
50-56 Days (Group 2)	73				27			Ā		1		-	
57-63 Days (Group 3)	89				38	16	(42%)	17	(45%)		(13%)	ŏ	
_	Age Group [3]  #63 Days (All) #49 Days (Group 1) 50 56 Days (Group 2) 57-63 Days (Group 3)  #63 Days (All) #49 Days (Group 1) 50-56 Days (Group 3)  #63 Days (All) #49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 2) 57-63 Days (Group 3)  #63 Days (All) #49 Days (Group 1) 50-56 Days (Group 2) 57-63 Days (Group 3)  #63 Days (Group 3)  #63 Days (Group 3)  #63 Days (Group 3)	Age Group [3]  #63 Days (All)  #49 Days (Group 1)  #50 56 Days (Group 2)  #50 7-63 Days (Group 3)  #63 Days (All)  #63 Days (Group 1)  #649 Days (Group 1)  #65 Days (Group 2)  #65 Days (Group 3)  #66 Days (Group 3)  #67 Days (Group 3)  #68 Days (All)  #69 Days (Group 1)  #69 Days (Group 1)  #69 Days (Group 2)  #65 Days (Group 3)  #65 Days (Group 3)  #66 Days (Group 3)  #67 Days (Group 3)  #68 Days (Group 3)  #68 Days (Group 3)  #69 Days (Group 3)  #69 Days (Group 3)  #69 Days (Group 3)  #60 Days (Group 3)  #60 Days (Group 3)  #61 Days (Group 3)  #62 Days (Group 3)  #63 Days (All)  #63 Days (All)  #64 Days (Group 1)  #65 Days (Group 1)  #66 Days (Group 1)  #67 Days (Group 2)  #67 Days (Group 2)  #68 Days (Group 1)  #69 Days (Group 1)  #69 Days (Group 2)  #68 Days (Group 2)  #69 Days (Group 2)	Age Group [3]  self and a self an	Age Group [3]  *63 Days (All)  *49 Days (Group 1)  *63 Days (Group 2)  50-56 Days (Group 3)  *63 Days (All)  *49 Days (Group 1)  *63 Days (All)  *49 Days (Group 1)  *63 Days (Group 1)  *63 Days (Group 1)  50-56 Days (Group 2)  57-63 Days (Group 3)  *63 Days (Group 3)  *63 Days (All)  *49 Days (Group 3)  *63 Days (Group 1)  50-56 Days (Group 2)  50-56 Days (Group 2)  573 1 (1%)  *63 Days (Group 1)  59 0  50-56 Days (Group 2)  73 1 (1%)  57-63 Days (Group 3)  *89 2 (2%)  *63 Days (All)  *63 Days (Group 1)  50-56 Days (Group 2)  73 55 (75%)  57-63 Days (Group 3)  *63 Days (Group 3)  *69 69 (78%)  *63 Days (All)  *63 Days (Group 1)  50-56 Days (Group 1)  50-56 Days (Group 2)  *63 Days (Group 3)  *649 Days (Group 3)  *650 Days (Group 1)  *651 Days (Group 1)  *652 Days (Group 2)  *653 Days (All)  *653 Days (Group 3)  *653 Days (Group 3)  *654 Days (Group 3)  *655 Days (Group 3)  *655 Days (Group 1)  *656 Days (Group 1)  *657 Days (Group 2)  *658 Days (Group 2)  *659 Days (Group 3)	Age Group [3]  *63 Days (All)  *49 Days (Group 1)  *63 Days (Group 2)  50-56 Days (Group 3)  *63 Days (Group 1)  *63 Days (Group 1)  *649 Days (Group 1)  *65 Days (Group 3)  *65 Days (Group 1)  *65 Days (Group 1)  *65 Days (Group 2)  50-56 Days (Group 2)  50-56 Days (Group 3)  *65 Days (Group 3)  *65 Days (Group 3)  *65 Days (Group 1)  *65 Days (Group 1)  *65 Days (Group 1)  *65 Days (Group 2)  *65 Days (Group 2)  *65 Days (Group 3)  *67 Days (Group 3)  *68 Days (Group 3)  *69 Days (Group 3)  *69 Days (Group 3)  *60 Days	Age Group [3]	Age Group [3]	Age Group [3]    Number of Pts   Pts   P value   Of Events   Mild	Age Group [3]  Number of Pts w/Event p value of Events Mild Mode  #63 Days (All)  #49 Days (Group 1)  #63 Days (Group 2)  57-63 Days (Group 3)  #649 Days (Group 1)  #653 Days (Group 1)  #653 Days (Group 1)  #654 Days (Group 1)  #655 Days (Group 2)  #655 Days (Group 3)  #656 Days (Group 3)  #657-63 Days (Group 3)  #658 Days (Group 3)  #659 Days (Group 3)  #659 Days (Group 3)  #650 Days	Age Group [3]	Age Group [3]	Age Group [3]	Age Group [3]

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: DEAN (#27)

	1.0	i,		Total		ber	Fisher's						j, v	* · · · · · · · · · · · · · · · · · · ·		
Body System/Event [2]	. ,		Age Group [3]	Number of Pts		Pts vent	exact p-value	Number of Events	Mi	1d	Mode	Severit rate	- 1	ere	Unl	known
ASTRO-INTESTINAL SYSTEM D	ISORDERS (c	ont.)		-					.,							
DYSPEPSIA			≤63 Days (All)	191	3	(2%)	0.7499	3	0		0		2	(67%)	' 1	(33%
			≤49 Days (Group 1)	29	0			0	0		0		0		0	
			50-56 Days (Group 2)	73	2	(3%)		2	0		0		2	(100%)	0	
			57-63 Days (Group 3)	89	1	(1%)		1	0		0		0		1	(100%
FLATULENCE			£63 Days (All)	191	3	(2%)	0.3805	4	0		2	(50%)	1	(25%)	1	(25%
			≰49 Days (Group 1)	29	0			0	0		0		0		0	
			50 56 Days (Group 2)	73	0			0	0		0		0		0	
			57-63 Days (Group 3)	89	3	(3%)		4	0		2	(50%)	1	(25%)	1	(25%
NAUSEA			≤63 Days (All)	191	122	(641)	0.1784	259	101	(39%)	99	(38%)	59	(23%)	0	
			≤49 Days (Group 1)	29	14	(48%)		37	13	(35%)	. 18	(49,8)	6	(16%)	0	
			50-56 Days (Group 2)	73	48	(66%)		90	38	(42%)	40	(44%)	12	(13%)	0	
			57-63 Days (Group 3)	89	60	(67%)		132	50	(38%)	41	(31%)	41	(31%)	0	
TOOTH ACHE			≤63 Days (All)	191	1	(<1%)	0.1518	1	0		1	(100%)	0		0	
			≤49 Days (Group 1)	29	1	(3%)		1	0		1	(100%)	0		0	
			50-56 Days (Group 2)	73	0			0	0		0		0		0	
			57-63 Days (Group 3)	89	0			0	0		0		0		0	
VOMITING			≤63 Days (All)	191	66	(35%)	0.3144	115	21	(18%)	52	(45%)	42	(37%)	0	
			≰49 Days (Group 1)	29	7	(24%)		10	2	(20%)	3	(30%)	5	(50%)	0	
			50-56 Days (Group 2)	73	24	(33%)		40	6	(15%)	23	(58%)	11	(28%)	0	
			57-63 Days (Group 3)	89	35	(39%)		65	13	(20%)	26	(40%)	26	(40%)	0	

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: DEAN (#27)

		Gestational	Total	Number	Fisher's	M				
Body System/Event [2]	, ''	Age Group [3]	Number of Pts	of Pts w/Event	exact   p value	Number of Events	Mild	Severit Moderate	Severe	Unknown
ESPIRATORY SYSTEM DISORDERS										
ANY EVENT		≤63 Days (All)	191	7 (4%)	0.8756	9	3 (33%)	3 (33%)	1 (11%)	' 2 (22%
•		≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
		50-56 Days (Group 2)	73	2 (3%)		4	0	1 (25%)	1 (25%)	2 (50%
		57-63 Days (Group 3)	89	4 (4%)		4	2 (50%)	2 (50%)	0	0
COUGHING		s63 Days (All)	191	1 (<1%)	0.5340	1	0	0	o	1 (100%
		≰49 Days (Group 1)	29	0		0	0	0	0	0
		50 56 Days (Group 2)	73	1 (1%)		1	0	0	0	1 (100%
		57-63 Days (Group 3)	89	0		0	0	0	0	0
DYSPNOEA		≤63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	0	0
		≰49 Days (Group 1)	29	1 (3%)		1	1 (100%)	· 0 '	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	0		0	0	0	0	0
HYPERVENTILATION		≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
PHARYNGITIS		≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: DEAN (#27)							:			
	; · .	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Severit	y	
Body System/Event [2]	. '	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDE	RS (cont.)								, , , , , , , , , , , , , , , , , , , ,	<del></del>
RHINITIS T		≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	0 .	. 1 (100%)
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	1 (1%)		1	0	0	0	1 (100%)
		57-63 Days (Group 3)	89	0		0	0	0	0	0
SINUSITIS		s63 Days (All)	191	3 (2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	1 (1%)		: 2	0	1 (50%)	1 (50%)	0
		57-63 Days (Group 3)	89	2 (2%)		2	2 (100%)	0	0	0
RED BLOOD CELL DISORDERS					,					
ANY EVENT		≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
ANAEMIA		≤63 Days (All)	191	1 (<1%)	1.0000	. 1	0	1 (100%)	0	0
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
URINARY SYSTEM DISORDERS										
ANY EVENT		≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
		≤49 Days (Group 1)	29	0		0	0	0	0	0
		50-56 Days (Group 2)	73	0		0	0	0	0	0
		57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: DEAN (#27)

i i	Gestational	Total	Number	Fisher's							
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p value	Number of Events	Mild	Moderate	Severe :	Unknow		
RINARY SYSTEM DISORDERS (cont.)				, T				-			
URINARY TRACT INFECTION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0 ,	, o		
	≰49 Days (Group 1)	29	0		0	0	0	0	0		
	50-56 Days (Group 2)	73	0		0	0	! o	0	0		
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0		
EPRODUCTIVE DISORDERS, FEMALE											
ANY EVENT	≤63 Days (All)	191	16 (8%)	0.0115	22	2 (9%)	10 (45%)	10 (45%)	0		
	≤49 Days (Group 1)	29	3 (10%)		5	1 (20%)	1 (20%)	3 (601)	0		
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0		
	57-63 Days (Group 3)	89	12 (13%)		15	1 (7%)	7 (47%)	7 (47%)	0		
LEUKORRHOEA	≤63 Days (All)	191	3 (2%)	0.5453	3	2 (67%)	1 (33%)	0	0		
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0		
į	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0		
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0		
UTERINE HAEMORRHAGE	≤63 Days (All)	191	11 (6%)	0.0088	15	0	7 (47%)	8 (53%)	0		
	≤49 Days (Group 1)	29	2 (7%)		4	0	1 (25%)	3 (75%)	0		
	50-56 Days (Group 2)	73	0		0	0	0	0	0		
1	57-63 Days (Group 3)	89	9 (10%)		11	0	6 (55%)	5 (45%)	0		
VAGINAL DISCOMFORT	≤63 Days (All)	191	1 (<1%)	1.0000	2	0	0	2 (100%)	0		
	<b>s49 Days</b> (Group 1)	29	0	1	0	0	0	0	0		
	50-56 Days (Group 2)	73	0	\	0	0	0	0	0		
	57-63 Days (Group 3)	89	1 (1%)	•	2	0	0	2 (100%)	0		

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[1]</sup> Includes all adverse event's reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: DEAN (#27)

,	1			Number		Fisher's										
Body System/Event [2]		Age Group [3]	Number of Pts			exact p value	Number of Events	Mi	1d		Severi rate	•	ere	Unk	nown	
REPRODUCTIVE DISORDERS, FEMALE (cont.	)			<u> </u>								,				
VAGINITIS		≤63 Days (All)	191	2	(1%)	1.0000	2	0		2	(100%)	0		' 0		
		≤49 Days (Group 1)	29	0			0	0		0		0		0		
		50-56 Days (Group 2)	73	1	(1%)		1	0		1	(100%)	0		0		
		57-63 Days (Group 3)	89	1	(1%)		1	0		1	(100%)	0	•	0		
BODY AS A WHOLE - GENERAL DISORDERS																
ANY EVENT		≤63 Days (All)	191	190	(>99%)	0.5340	830	300	(36%)	304	(37%)	196	(24%)	30	(4%)	
		≤49 Days (Group 1)	29	29	(100%)		121	38	(31%)	60	(50¥)	, 23	(19%)	0		
		50-56 Days (Group 2)	73	72	(99%)		325	127	(39%)	113	(35%)	74	(23%)	11	(3%)	
		57-63 Days (Group 3)	89	89	(100%)		384	135	(35%)	131	(34%)	99	(26%)	19	(5%)	
ABDOMINAL PAIN		≤63 Days (All)	191	190	(>99%)	0.5340	772	281	(36%)	280	(36%)	186	(24%)	25	(3%)	
		≤49 Days (Group 1)	29	29	(100%)		112	34	(30%)	55	(49%)	23	(21%)	0		
		50-56 Days (Group 2)	73	72	(99%)		298	118	(40%)	99	(33%)	70	(23%)	11	(4%)	
		57-63 Days (Group 3)	89	89	(100%)	-	362	129	(36%)	126	(35%)	93	(26%)	14	(4%)	
ALLERGY		≤63 Days (All)	191	1	(<1%)	1.0000	1	0		0		0		1	(100%)	
		≤49 Days (Group 1)	29	0			0	0		0		0		0		
		50-56 Days (Group 2)	73	0			0	0		0		0		0		
		57-63 Days (Group 3)	89	1	(1%)		1	0		0		0		1	(100%)	
ASTHENIA		≤63 Days (All)	191	5	(3%)	0.4621	6	2	(33%)	4	(67%)	0		0		
		s49 Days (Group 1)	29	0			0	0		0		0		0		
		50-56 Days (Group 2)	73	1	(1%)		2	0		2	(100%)	0		0		
		57-63 Days (Group 3)	89	4	(4%)		4	2	(50%)	2	(50%)	0		0		

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> 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: DEAN (#27)

	; ·•	Gestational	Total	Number	Fisher's		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	
ODY AS A WHOLE - GENERAL	DISORDERS (	cont.)								····	
BACK PAIN		≤63 Days (All)	191	17 (9%)	0.8336	31	9 (29%)	13 (42%)	5 (16%)	4 (13%	
		≤49 Days (Group 1)	29	3 (10%)		5	3 (60%)	2 (40%)	0	0	
		50-56 Days (Group 2)	73	7 (10%)		16	5 (31%)	9 (56%)	2 (13%)	0	
		57-63 Days (Group 3)	89	7 (8%)		10	1 (10%)	2 (20%)	3 (30%)	4 (40)	
FATIGUE		≤63 Days (All)	191	7 (4%)	0.1139	7	2 (29%)	5 (71%)	0	0	
		<pre>s49 Days (Group 1)</pre>	29	3 (10%)		3	0	3 (100%)	0	0	
		50-56 Days (Group 2)	73	2 (3%)		2	1 (50%)	1 (50%)	0	0	
		57-63 Days (Group 3)	89	2 (2%)		2	1 (50%)	1 (50%)	0	0	
FEVER		≤63 Days (All)	191	4 (2%)	0.3736	5	4 (80%)	1 (20%)	0	0	
	•	≤49 Days (Group 1)	29	0		0	0	· 0 ,	0	0	
		50-56 Days (Group 2)	73	3 (4%)		4	3 (75%)	1 (25%)	0	0	
		57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0	
HOT FLUSHES		≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0	
		≤49 Days (Group 1)	29	0		0	0	0	0	0	
		50-56 Days (Group 2)	73	0		0	0	0	0	0	
		57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0	
MALAISE		s63 Days (All)	191	1 (<1\$)	0.5340	1	0	0	1 (100%)	0	
		≤49 Days (Group 1)	29	0		0	0	0	0	0	
		50-56 Days (Group 2)	73	1 (1%)		1	0	0	1 (100%)	0	
		57-63 Days (Group 3)	89	0		0	0	0	0	0	

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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Center: DEAN (#27)

i - a i - a	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		····Severit	y	
Body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (	cont.)						V- 11.		
PAIN	≰63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	ο ,	. 0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	0 ;		0	0	0	0	o
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	191	4 (2%)	1.0000	5	1 (20%)	1 (20%)	3 (60%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		3	1 (33%)	0	2 (67%)	0
ESISTANCE MECHANISM DISORDERS	•								
ANY EVENT	s63 Days (All)	191	5 (3%)	0.0457	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	89	0		O	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	191	5 (3%)	0.0457	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%).	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	ō
	57-63 Days (Group 3)	89	0		0	0	0	0	0

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Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

<sup>[2]</sup> NOS = Not otherwise specified

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

<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

Center: CREININ (#28)

) · b	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severity		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	115	115 (100%)		953	397 (42%)	335 (35%)	221 (23%)	, o
	≰49 Days (Group 1)	23	23 (100%)		154	64 (42%)	56 (36%)	34 (22%)	0
	50-56 Days (Group 2)	50	50 (100%)		432	163 (38%)	160 (37%)	109 (25%)	0
	57-63 Days (Group 3)	42	42 (100%)		367	170 (46%)	119 (32%)	78 (21%)	0
KIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	115	4 (3%)	0.1059	4	0	3 (75%)	1 (25%)	0
	≰49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	4 (8%)		4	0	3 (75%)	1 (25%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
RASH	≤63 Days (All)	115	1: (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	o
	57-63 Days (Group 3)	42	0	v.	0	o	0	0	o
SKIN DISORDER	≤63 Days (All)	115	1 (<1%)	1.0000	1	o	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	n
	57-63 Days (Group 3)	42	0		0	0	0	0	o
SWEATING INCREASED	≤63 Days (All)	115	2 (2%)	0.6796	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	Ô

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Source Data: Appendix A.1, Tables 16 and 25

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

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Center: CREININ (#28)

	Gestational	Total	Number	Fisher's		* ***	7				
	Age	Number	of Pts	exact	Number		Severity	, <u>,</u>			
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown		
USCULO-SEELETAL SYSTEM DISORDI	irs										
ANY EVENT	≤63 Days (All)	115	3 (31	0.7916	3	0	2 (67%)	1 (3'3%)	, o		
	≰49 Days (Group 1)	23	1 (4)	)	1	0	1 (100%)	0	0		
	50-56 Days (Group 2)	50	1 (21	)	1	0	0	1 (100%)	0		
	57-63 Days (Group 3)	42	1 (21	)	1	0	1 (100%)	0	0		
BONE DISORDER	≤63 Days (All)	115	1 (<1	) 1.0000	1	0	0	1 (100%)	i 0		
	≤49 Days (Group 1)	23	0		0	0	0	0	, 0		
•	50-56 Days (Group 2)	50	1 (25	)	1	0	0	1 (100%)	n		
	57-63 Days (Group 3)	42	0		0	0	0	0	0		
SKELETAL PAIN	≤63 Days (All)	115	2 (21	) 0.3173	2	0	2 (100%)	0	0		
•	≤49 Days (Group 1)	23	1 (49	)	1	0	1 (100%)	0	Ö		
	50-56 Days (Group 2)	50	0		0	0	0	Ô	Ô		
	57-63 Days (Group 3)	42	1 (21	)	1	0	1 (100%)	0	0		
INTR & PERIPH MERVOUS SYSTEM D	DISORDERS			•		,					
ANY EVENT	≤63 Days (All)	115	54 (471	0.4374	86	37 (43%)	40 (47%)	9 (10%)	0		
	≤49 Days (Group 1)	23	9 (391	)	12	7 (58%)	5 (42%)	0	Ô		
	50-56 Days (Group 2)	50	22 (441	)	43	15 (35%)	21 (49%)	7 (16%)	0		
	57-63 Days (Group 3)	42	23 (551	)	31	15 (48%)	14 (45%)	2 (6%)	0		
DIZZINESS	≤63 Days (All)	115	19 (17	0.4389	21	16 (76%)	4 (19%)	1 (5%)	0		
	≤49 Days (Group 1)	23	2 (91	)	2	2 (100%)	0	0	Ô		
	50-56 Days (Group 2)	50	8 (16)	)	. 10	8 (80%)	2 (20%)	0	ň		
	57-63 Days (Group 3)	42	9 (211		• 9	6 (67%)	2 (22%)	1 (11%)	0		

<sup>[1]</sup> Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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<sup>[4]</sup> Events in this body system occurred during the study blood sampling.

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