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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	204	2 (<1%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	145	2 (1%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
TACHYCARDIA	≤63 Days (All)	204	2 (<1%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	145	2 (1%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
VASCULAR (EXTRACARDIAC) DISORDERS									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
VASCULAR (EXTRACARDIAC) DISORDERS (cont.)									
FLUSHING	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	6 (3%)	0.4929	6	3 (50%)	2 (33%)	1 (17%)	0
	≤49 Days (Group 1)	145	6 (4%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	204	2 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RHINITIS	≤63 Days (All)	204	2 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	145	2 (1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
SINUSITIS	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	204	8 (4%)	0.2089	8	3 (38%)	2 (25%)	3 (38%)	0
	≤49 Days (Group 1)	145	4 (3%)		4	0	2 (50%)	2 (50%)	0
	50-56 Days (Group 2)	40	3 (8%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
ANAEMIA	≤63 Days (All)	204	7 (3%)	0.5313	7	2 (29%)	2 (29%)	3 (43%)	0
	≤49 Days (Group 1)	145	4 (3%)		4	0	2 (50%)	2 (50%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	204	1 (<1%)	0.2892	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDERS (cont.)									
EPISTAXIS	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	3 (1%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	145	3 (2%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DYSURIA	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
URINE ABNORMAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	204	29 (14%)	0.0012	33	10 (30%)	8 (24%)	15 (45%)	0
	≤49 Days (Group 1)	145	14 (10%)		16	5 (31%)	6 (38%)	5 (31%)	0
	50-56 Days (Group 2)	40	7 (18%)		8	4 (50%)	1 (13%)	3 (38%)	0
	57-63 Days (Group 3)	19	8 (42%)		9	1 (11%)	1 (11%)	7 (78%)	0
BREAST PAIN FEMALE	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
CERVICAL DYSPLASIA	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
ENDOMETRITIS	≤63 Days (All)	204	3 (1%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	204	3 (1%)	1.0000	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	145	3 (2%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
OVARIAN DISORDER	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SEXUAL FUNCTION ABNORMAL	≤63 Days (All)	204	1 (<1%)	0.2892	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	14 (7%)	0.0004	14	0	1 (7%)	13 (93%)	0
	≤49 Days (Group 1)	145	5 (3%)		5	0	1 (20%)	4 (80%)	0
	50-56 Days (Group 2)	40	3 (8%)		3	0	0	3 (100%)	0
	57-63 Days (Group 3)	19	6 (32%)		6	0	0	6 (100%)	0
VAGINITIS	≤63 Days (All)	204	8 (4%)	0.0213	8	5 (63%)	2 (25%)	1 (13%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	40	2 (5%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	19	3 (16%)		3	1 (33%)	1 (33%)	1 (33%)	0
NEOPLASM									
ANY EVENT	≤63 Days (All)	204	5 (2%)	0.5701	5	1 (20%)	3 (60%)	1 (20%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
NEOPLASM (cont.)									
CERVICAL SMEAR TEST POSITIVE	≤63 Days (All)	204	4 (2%)	0.3287	4	0	3 (75%)	1 (25%)	0
	≤49 Days (Group 1)	145	2 (1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
OVARIAN CYST	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	204	197 (97%)	0.4317	596	203 (34%)	231 (39%)	162 (27%)	0
	≤49 Days (Group 1)	145	138 (95%)		406	150 (37%)	153 (38%)	103 (25%)	0
	50-56 Days (Group 2)	40	40 (100%)		137	38 (28%)	58 (42%)	41 (30%)	0
	57-63 Days (Group 3)	19	19 (100%)		53	15 (28%)	20 (38%)	18 (34%)	0
ABDOMINAL PAIN	≤63 Days (All)	204	195 (96%)	0.2077	527	171 (32%)	206 (39%)	150 (28%)	0
	≤49 Days (Group 1)	145	136 (94%)		351	123 (35%)	133 (38%)	95 (27%)	0
	50-56 Days (Group 2)	40	40 (100%)		128	35 (27%)	55 (43%)	38 (30%)	0
	57-63 Days (Group 3)	19	19 (100%)		48	13 (27%)	18 (38%)	17 (35%)	0
ASTHENIA	≤63 Days (All)	204	5 (2%)	0.4316	5	1 (20%)	2 (40%)	2 (40%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	204	14 (7%)	0.9015	22	7 (32%)	10 (45%)	5 (23%)	0
	≤49 Days (Group 1)	145	11 (8%)		19	6 (32%)	9 (47%)	4 (21%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
CHEST PAIN	≤63 Days (All)	204	5 (2%)	1.0000	6	3 (50%)	2 (33%)	1 (17%)	0
	≤49 Days (Group 1)	145	4 (3%)		5	2 (40%)	2 (40%)	1 (20%)	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	204	12 (6%)	0.7890	12	9 (75%)	2 (17%)	1 (8%)	0
	≤49 Days (Group 1)	145	10 (7%)		10	7 (70%)	2 (20%)	1 (10%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FEVER	≤63 Days (All)	204	6 (3%)	1.0000	7	3 (43%)	3 (43%)	1 (14%)	0
	≤49 Days (Group 1)	145	5 (3%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HOT FLUSHES	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
LEG PAIN	≤63 Days (All)	204	2 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
MALAISE	≤63 Days (All)	204	1 (<1%)	0.0931	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
PAIN	≤63 Days (All)	204	3 (1%)	0.0411	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	2 (11%)		2	0	2 (100%)	0	0
RIGORS	≤63 Days (All)	204	4 (2%)	0.7159	5	3 (60%)	1 (20%)	1 (20%)	0
	≤49 Days (Group 1)	145	4 (3%)		5	3 (60%)	1 (20%)	1 (20%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	204	4 (2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	204	5 (2%)	1.0000	5	5 (100%)	0	0	0
	≤49 Days (Group 1)	145	4 (3%)		4	4 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
INFECTION BACTERIAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	204	4 (2%)	1.0000	4	4 (100%)	0	0	0
	≤49 Days (Group 1)	145	3 (2%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SECONDARY TERMS									
ANY EVENT	≤63 Days (All)	204	2 (<1%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
SECONDARY TERMS (cont.)									
INFLICTED INJURY	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
POST-OPERATIVE PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	238	237 (>99%)	1.0000	1899	655 (34%)	737 (39%)	506 (27%)	1 (<1%)
	≤49 Days (Group 1)	81	81 (100%)		598	226 (38%)	230 (38%)	141 (24%)	1 (<1%)
	50-56 Days (Group 2)	89	88 (99%)		694	251 (36%)	250 (36%)	193 (28%)	0
	57-63 Days (Group 3)	68	68 (100%)		607	178 (29%)	257 (42%)	172 (28%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	238	9 (4%)	0.5823	10	2 (20%)	4 (40%)	4 (40%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	3 (3%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	68	4 (6%)		4	1 (25%)	1 (25%)	2 (50%)	0
PHOTOSENSITIVITY REACTION	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PRURITUS GENITAL	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
RASH	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
SKIN AND APPENDAGES DISORDERS (cont.)									
SWEATING INCREASED	≤63 Days (All)	238	5 (2%)	1.0000	6	0	3 (50%)	3 (50%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	2 (2%)		3	0	2 (67%)	1 (33%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
URTICARIA	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	5 (2%)	0.3849	6	2 (33%)	2 (33%)	2 (33%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	68	3 (4%)		3	1 (33%)	2 (67%)	0	0
ARTHRALGIA	≤63 Days (All)	238	3 (1%)	0.1954	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
ARTHRITIS	≤63 Days (All)	238	1 (<1%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
SKELETAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	89 (37%)	0.7435	163	51 (31%)	89 (55%)	23 (14%)	0
	≤49 Days (Group 1)	81	33 (41%)		53	18 (34%)	31 (58%)	4 (8%)	0
	50-56 Days (Group 2)	89	32 (36%)		62	22 (35%)	29 (47%)	11 (18%)	0
	57-63 Days (Group 3)	68	24 (35%)		48	11 (23%)	29 (60%)	8 (17%)	0
DIZZINESS	≤63 Days (All)	238	21 (9%)	0.4057	25	10 (40%)	10 (40%)	5 (20%)	0
	≤49 Days (Group 1)	81	9 (11%)		11	4 (36%)	5 (45%)	2 (18%)	0
	50-56 Days (Group 2)	89	5 (6%)		5	3 (60%)	0	2 (40%)	0
	57-63 Days (Group 3)	68	7 (10%)		9	3 (33%)	5 (56%)	1 (11%)	0
HEADACHE	≤63 Days (All)	238	77 (32%)	0.8668	131	40 (31%)	74 (56%)	17 (13%)	0
	≤49 Days (Group 1)	81	28 (35%)		42	14 (33%)	26 (62%)	2 (5%)	0
	50-56 Days (Group 2)	89	27 (30%)		51	18 (35%)	25 (49%)	8 (16%)	0
	57-63 Days (Group 3)	68	22 (32%)		38	8 (21%)	23 (61%)	7 (18%)	0
HYPERTONIA	≤63 Days (All)	238	3 (1%)	0.5061	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (cont.)									
MIGRAINE	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TREMOR	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	0	2 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
EAR ACHE	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TINNITUS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
SPECIAL SENSES OTHER, DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TASTE PERVERSION	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	238	16 (7%)	0.4621	21	5 (24%)	10 (48%)	6 (29%)	0
	≤49 Days (Group 1)	81	4 (5%)		7	0	3 (43%)	4 (57%)	0
	50-56 Days (Group 2)	89	5 (6%)		7	2 (29%)	4 (57%)	1 (14%)	0
	57-63 Days (Group 3)	68	7 (10%)		7	3 (43%)	3 (43%)	1 (14%)	0
ANOREXIA	≤63 Days (All)	238	2 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	238	3 (1%)	0.2868	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	0	2 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)									
APPETITE INCREASED	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	6 (3%)	0.5880	6	1 (17%)	4 (67%)	1 (17%)	0
	≤49 Days (Group 1)	81	3 (4%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
HALLUCINATION	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
INSOMNIA	≤63 Days (All)	238	6 (3%)	1.0000	7	2 (29%)	2 (29%)	3 (43%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	89	2 (2%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	0	1 (50%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	178 (75%)	0.0688	503	201 (40%)	192 (38%)	110 (22%)	0
	≤49 Days (Group 1)	81	53 (65%)		134	59 (44%)	46 (34%)	29 (22%)	0
	50-56 Days (Group 2)	89	71 (80%)		217	95 (44%)	78 (36%)	44 (20%)	0
	57-63 Days (Group 3)	68	54 (79%)		152	47 (31%)	68 (45%)	37 (24%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	6 (3%)	1.0000	7	1 (14%)	4 (57%)	2 (29%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	89	2 (2%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		3	0	3 (100%)	0	0
CONSTIPATION	≤63 Days (All)	238	2 (<1%)	0.0808	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	0	1 (50%)	1 (50%)	0
DIARRHEA	≤63 Days (All)	238	61 (26%)	0.6832	80	44 (55%)	28 (35%)	8 (10%)	0
	≤49 Days (Group 1)	81	22 (27%)		25	16 (64%)	6 (24%)	3 (12%)	0
	50-56 Days (Group 2)	89	20 (22%)		32	18 (56%)	13 (41%)	1 (3%)	0
	57-63 Days (Group 3)	68	19 (28%)		23	10 (43%)	9 (39%)	4 (17%)	0
DYSPEPSIA	≤63 Days (All)	238	10 (4%)	0.4327	13	6 (46%)	6 (46%)	1 (8%)	0
	≤49 Days (Group 1)	81	4 (5%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	89	5 (6%)		8	4 (50%)	3 (38%)	1 (13%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	238	4 (2%)	0.2625	5	0	3 (60%)	2 (40%)	0
	≤49 Days (Group 1)	81	3 (4%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	89	1 (1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMATEMESIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMORRHOIDS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	238	154 (65%)	0.0088	270	107 (40%)	94 (35%)	69 (26%)	0
	≤49 Days (Group 1)	81	42 (52%)		70	29 (41%)	23 (33%)	18 (26%)	0
	50-56 Days (Group 2)	89	66 (74%)		117	51 (44%)	39 (33%)	27 (23%)	0
	57-63 Days (Group 3)	68	46 (68%)		83	27 (33%)	32 (39%)	24 (29%)	0
TOOTH ACHE	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
VOMITING	≤63 Days (All)	238	85 (36%)	0.1411	123	42 (34%)	54 (44%)	27 (22%)	0
	≤49 Days (Group 1)	81	22 (27%)		30	12 (40%)	13 (43%)	5 (17%)	0
	50-56 Days (Group 2)	89	36 (40%)		53	20 (38%)	19 (36%)	14 (26%)	0
	57-63 Days (Group 3)	68	27 (40%)		40	10 (25%)	22 (55%)	8 (20%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.3861	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		2	0	2 (100%)	0	0
DEHYDRATION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
THIRST	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
WEIGHT DECREASE	≤63 Days (All)	238	1 (<1%)	0.2857	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		2	0	2 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HYPOTENSION	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TACHYCARDIA	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	18 (8%)	0.1493	30	14 (47%)	12 (40%)	4 (13%)	0
	≤49 Days (Group 1)	81	10 (12%)		17	10 (59%)	5 (29%)	2 (12%)	0
	50-56 Days (Group 2)	89	4 (4%)		7	3 (43%)	3 (43%)	1 (14%)	0
	57-63 Days (Group 3)	68	4 (6%)		6	1 (17%)	4 (67%)	1 (17%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
COUGHING	≤63 Days (All)	238	3 (1%)	0.0610	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	81	3 (4%)		4	1 (25%)	2 (50%)	1 (25%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	238	1 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMOPTYSIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	238	4 (2%)	0.0190	4	3 (75%)	1 (25%)	0	0
	≤49 Days (Group 1)	81	4 (5%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PLEURAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
PULMONARY CONGESTION	≤63 Days (All)	238	2 (<1%)	0.1957	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	2 (2%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RHINITIS	≤63 Days (All)	238	5 (2%)	0.3257	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	81	3 (4%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	238	7 (3%)	0.0673	9	3 (33%)	4 (44%)	2 (22%)	0
	≤49 Days (Group 1)	81	4 (5%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	3 (4%)		5	1 (20%)	3 (60%)	1 (20%)	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
ANAEMIA	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
WHITE CELL AND RES DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
LYMPHADENOPATHY	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PLATELET,BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.7444	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
EPISTAXIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PURPURA	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.6361	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MICTURITION FREQUENCY	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	238	2 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	238	81 (34%)	0.6484	101	16 (16%)	33 (33%)	52 (51%)	0
	≤49 Days (Group 1)	81	25 (31%)		32	3 (9%)	15 (47%)	14 (44%)	0
	50-56 Days (Group 2)	89	30 (34%)		34	10 (29%)	6 (18%)	18 (53%)	0
	57-63 Days (Group 3)	68	26 (38%)		35	3 (9%)	12 (34%)	20 (57%)	0
CERVICITIS	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
LEUKORRHOEA	≤63 Days (All)	238	3 (1%)	0.7790	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MENSTRUAL DISORDER	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
OVARIAN DISORDER	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PREMENSTRUAL TENSION	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
UTERINE DISORDER NOS	≤63 Days (All)	238	2 (<1%)	0.5298	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
UTERINE HAEMORRHAGE	≤63 Days (All)	238	54 (23%)	0.8212	63	2 (3%)	9 (14%)	52 (83%)	0
	≤49 Days (Group 1)	81	17 (21%)		20	1 (5%)	5 (25%)	14 (70%)	0
	50-56 Days (Group 2)	89	20 (22%)		21	1 (5%)	2 (10%)	18 (86%)	0
	57-63 Days (Group 3)	68	17 (25%)		22	0	2 (9%)	20 (91%)	0
VAGINITIS	≤63 Days (All)	238	27 (11%)	0.8149	29	11 (38%)	18 (62%)	0	0
	≤49 Days (Group 1)	81	8 (10%)		10	2 (20%)	8 (80%)	0	0
	50-56 Days (Group 2)	89	10 (11%)		10	7 (70%)	3 (30%)	0	0
	57-63 Days (Group 3)	68	9 (13%)		9	2 (22%)	7 (78%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	237 (>99%)	1.0000	1024	356 (35%)	370 (36%)	297 (29%)	1 (<1%)
	≤49 Days (Group 1)	81	81 (100%)		336	131 (39%)	122 (36%)	82 (24%)	1 (<1%)
	50-56 Days (Group 2)	89	88 (99%)		345	115 (33%)	118 (34%)	112 (32%)	0
	57-63 Days (Group 3)	68	68 (100%)		343	110 (32%)	130 (38%)	103 (30%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	236 (>99%)	1.0000	932	322 (35%)	332 (36%)	277 (30%)	1 (<1%)
	≤49 Days (Group 1)	81	80 (99%)		301	115 (38%)	111 (37%)	74 (25%)	1 (<1%)
	50-56 Days (Group 2)	89	88 (99%)		323	106 (33%)	110 (34%)	107 (33%)	0
	57-63 Days (Group 3)	68	68 (100%)		308	101 (33%)	111 (36%)	96 (31%)	0
ALLERGY	≤63 Days (All)	238	5 (2%)	0.0354	6	1 (17%)	5 (83%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	4 (6%)		5	0	5 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ASTHENIA	≤63 Days (All)	238	2 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
BACK PAIN	≤63 Days (All)	238	19 (8%)	0.6919	24	8 (33%)	11 (46%)	5 (21%)	0
	≤49 Days (Group 1)	81	8 (10%)		12	4 (33%)	5 (42%)	3 (25%)	0
	50-56 Days (Group 2)	89	7 (8%)		7	1 (14%)	5 (71%)	1 (14%)	0
	57-63 Days (Group 3)	68	4 (6%)		5	3 (60%)	1 (20%)	1 (20%)	0
CHEST PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
FATIGUE	≤63 Days (All)	238	16 (7%)	0.8504	20	12 (60%)	5 (25%)	3 (15%)	0
	≤49 Days (Group 1)	81	6 (7%)		9	5 (56%)	1 (11%)	3 (33%)	0
	50-56 Days (Group 2)	89	5 (6%)		5	4 (80%)	1 (20%)	0	0
	57-63 Days (Group 3)	68	5 (7%)		6	3 (50%)	3 (50%)	0	0
FEVER	≤63 Days (All)	238	9 (4%)	0.0215	10	4 (40%)	5 (50%)	1 (10%)	0
	≤49 Days (Group 1)	81	4 (5%)		5	2 (40%)	3 (60%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	5 (7%)		5	2 (40%)	2 (40%)	1 (20%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
HOT FLUSHES	≤63 Days (All)	238	2 (<1%)	1.0000	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HYPOVOLAEMIA	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	238	4 (2%)	1.0000	5	1 (20%)	2 (40%)	2 (40%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		3	1 (33%)	0	2 (67%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
MALAISE	≤63 Days (All)	238	2 (<1%)	0.5298	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
OEDEMA	≤63 Days (All)	238	2 (<1%)	0.0808	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	0	2 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
PAIN	≤63 Days (All)	238	3 (1%)	0.1954	4	2 (50%)	0	2 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		3	1 (33%)	0	2 (67%)	0
RIGORS	≤63 Days (All)	238	7 (3%)	0.2989	7	1 (14%)	4 (57%)	2 (29%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	68	4 (6%)		4	0	2 (50%)	2 (50%)	0
SYNCOPE	≤63 Days (All)	238	5 (2%)	0.7401	5	0	1 (20%)	4 (80%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	2 (3%)		2	0	1 (50%)	1 (50%)	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	238	14 (6%)	1.0000	17	2 (12%)	15 (88%)	0	0
	≤49 Days (Group 1)	81	5 (6%)		6	1 (17%)	5 (83%)	0	0
	50-56 Days (Group 2)	89	5 (6%)		6	1 (17%)	5 (83%)	0	0
	57-63 Days (Group 3)	68	4 (6%)		5	0	5 (100%)	0	0
HERPES SIMPLEX	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS (cont.)									
INFECTION BACTERIAL	≤63 Days (All)	238	4 (2%)	0.6841	6	1 (17%)	5 (83%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		3	0	3 (100%)	0	0
INFECTION VIRAL	≤63 Days (All)	238	10 (4%)	0.6091	10	1 (10%)	9 (90%)	0	0
	≤49 Days (Group 1)	81	5 (6%)		5	0	5 (100%)	0	0
	50-56 Days (Group 2)	89	3 (3%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	0	2 (100%)	0	0
SECONDARY TERMS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	1.0000	5	0	2 (40%)	3 (60%)	0
	≤49 Days (Group 1)	81	1 (1%)		3	0	1 (33%)	2 (67%)	0
	50-56 Days (Group 2)	89	1 (1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
INFLICTED INJURY	≤63 Days (All)	238	2 (<1%)	1.0000	4	0	2 (50%)	2 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
POST-OPERATIVE PAIN	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	164	164 (100%)		1326	428 (32%)	517 (39%)	372 (28%)	9 (<1%)
	≤49 Days (Group 1)	65	65 (100%)		482	163 (34%)	196 (41%)	118 (24%)	5 (1%)
	50-56 Days (Group 2)	65	65 (100%)		527	171 (32%)	200 (38%)	154 (29%)	2 (<1%)
	57-63 Days (Group 3)	34	34 (100%)		317	94 (30%)	121 (38%)	100 (32%)	2 (<1%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	164	5 (3%)	0.8418	7	3 (43%)	2 (29%)	2 (29%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	3 (5%)		5	3 (60%)	2 (40%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
RASH MACULO-PAPULAR	≤63 Days (All)	164	1 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	164	4 (2%)	1.0000	4	1 (25%)	1 (25%)	2 (50%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
VERRUCA	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	7 (4%)	1.0000	10	3 (30%)	5 (50%)	2 (20%)	0
	≤49 Days (Group 1)	65	3 (5%)		5	3 (60%)	1 (20%)	1 (20%)	0
	50-56 Days (Group 2)	65	3 (5%)		4	0	3 (75%)	1 (25%)	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
ARTHRALGIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	164	4 (2%)	1.0000	6	2 (33%)	2 (33%)	2 (33%)	0
	≤49 Days (Group 1)	65	2 (3%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
SKELETAL PAIN	≤63 Days (All)	164	2 (1%)	0.3532	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	79 (48%)	0.7743	116	37 (32%)	54 (47%)	21 (18%)	4 (3%)
	≤49 Days (Group 1)	65	33 (51%)		46	17 (37%)	22 (48%)	5 (11%)	2 (4%)
	50-56 Days (Group 2)	65	29 (45%)		41	15 (37%)	15 (37%)	11 (27%)	0
	57-63 Days (Group 3)	34	17 (50%)		29	5 (17%)	17 (59%)	5 (17%)	2 (7%)

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (cont.)									
DIZZINESS	≤63 Days (All)	164	22 (13%)	0.6377	25	9 (36%)	10 (40%)	6 (24%)	0
	≤49 Days (Group 1)	65	7 (11%)		8	3 (38%)	3 (38%)	2 (25%)	0
	50-56 Days (Group 2)	65	9 (14%)		9	5 (56%)	2 (22%)	2 (22%)	0
	57-63 Days (Group 3)	34	6 (18%)		8	1 (13%)	5 (63%)	2 (25%)	0
HEADACHE	≤63 Days (All)	164	62 (38%)	0.7295	82	28 (34%)	40 (49%)	11 (13%)	3 (4%)
	≤49 Days (Group 1)	65	26 (40%)		37	14 (38%)	19 (51%)	2 (5%)	2 (5%)
	50-56 Days (Group 2)	65	22 (34%)		28	10 (36%)	12 (43%)	6 (21%)	0
	57-63 Days (Group 3)	34	14 (41%)		17	4 (24%)	9 (53%)	3 (18%)	1 (6%)
HYPOAESTHESIA	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
MIGRAINE	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (cont.)									
NEURALGIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PARAESTHESIA	≤63 Days (All)	164	2 (1%)	0.6839	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
STUPOR	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	0	0	1 (100%)
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	0	1 (100%)
TREMOR	≤63 Days (All)	164	2 (1%)	0.3532	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
VISION DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
VISION DISORDERS (cont.)									
EYE PAIN	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	164	9 (5%)	1.0000	10	3 (30%)	6 (60%)	1 (10%)	0
	≤49 Days (Group 1)	65	4 (6%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	65	3 (5%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	34	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
ANXIETY	≤63 Days (All)	164	2 (1%)	0.6839	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		2	1 (50%)	1 (50%)	0	0
APPETITE INCREASED	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	164	4 (2%)	0.6835	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
PSYCHIATRIC DISORDERS (cont.)									
EMOTIONAL LABILITY	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
INSOMNIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	135 (82%)	0.1372	374	109 (29%)	149 (40%)	116 (31%)	0
	≤49 Days (Group 1)	65	49 (75%)		121	37 (31%)	55 (45%)	29 (24%)	0
	50-56 Days (Group 2)	65	55 (85%)		150	40 (27%)	60 (40%)	50 (33%)	0
	57-63 Days (Group 3)	34	31 (91%)		103	32 (31%)	34 (33%)	37 (36%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	6 (4%)	0.7492	12	6 (50%)	4 (33%)	2 (17%)	0
	≤49 Days (Group 1)	65	2 (3%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	2 (6%)		7	4 (57%)	1 (14%)	2 (29%)	0
CONSTIPATION	≤63 Days (All)	164	3 (2%)	0.8010	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	65	2 (3%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
DIARRHEA	≤63 Days (All)	164	37 (23%)	0.9129	44	15 (34%)	23 (52%)	6 (14%)	0
	≤49 Days (Group 1)	65	14 (22%)		18	6 (33%)	10 (56%)	2 (11%)	0
	50-56 Days (Group 2)	65	16 (25%)		17	7 (41%)	7 (41%)	3 (18%)	0
	57-63 Days (Group 3)	34	7 (21%)		9	2 (22%)	6 (67%)	1 (11%)	0
DYSPEPSIA	≤63 Days (All)	164	6 (4%)	0.4439	7	4 (57%)	3 (43%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	4 (6%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		2	1 (50%)	1 (50%)	0	0
FLATULENCE	≤63 Days (All)	164	3 (2%)	0.2304	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	65	3 (5%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
MELAENA	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	164	120 (73%)	0.1269	221	73 (33%)	76 (34%)	72 (33%)	0
	≤49 Days (Group 1)	65	42 (65%)		73	25 (34%)	30 (41%)	18 (25%)	0
	50-56 Days (Group 2)	65	50 (77%)		90	27 (30%)	31 (34%)	32 (36%)	0
	57-63 Days (Group 3)	34	28 (82%)		58	21 (36%)	15 (26%)	22 (38%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
TOOTH ACHE	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
VOMITING	≤63 Days (All)	164	61 (37%)	0.0147	81	9 (11%)	38 (47%)	34 (42%)	0
	≤49 Days (Group 1)	65	17 (26%)		20	2 (10%)	11 (55%)	7 (35%)	0
	50-56 Days (Group 2)	65	25 (38%)		34	3 (9%)	16 (47%)	15 (44%)	0
	57-63 Days (Group 3)	34	19 (56%)		27	4 (15%)	11 (41%)	12 (44%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	2 (1%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
THIRST	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	164	2 (1%)	0.6839	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
TACHYCARDIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	8 (5%)	0.9019	12	4 (33%)	6 (50%)	2 (17%)	0
	≤49 Days (Group 1)	65	3 (5%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	65	4 (6%)		8	2 (25%)	5 (63%)	1 (13%)	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0	0	0
COUGHING	≤63 Days (All)	164	2 (1%)	0.3532	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		5	2 (40%)	2 (40%)	1 (20%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	164	2 (1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	164	4 (2%)	1.0000	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	164	6 (4%)	0.2081	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	3 (9%)		4	1 (25%)	3 (75%)	0	0
ANAEMIA	≤63 Days (All)	164	6 (4%)	0.2081	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	3 (9%)		4	1 (25%)	3 (75%)	0	0
WHITE CELL AND RES DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	0	1 (100%)
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	0	1 (100%)
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
LYMPHADENOPATHY	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	0	1 (100%)
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	0	1 (100%)
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
PLATELET,BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDERS (cont.)									
EPISTAXIS	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
MICTURITION FREQUENCY	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	164	38 (23%)	0.7020	64	22 (34%)	33 (52%)	9 (14%)	0
	≤49 Days (Group 1)	65	13 (20%)		23	9 (39%)	12 (52%)	2 (9%)	0
	50-56 Days (Group 2)	65	17 (26%)		27	9 (33%)	13 (48%)	5 (19%)	0
	57-63 Days (Group 3)	34	8 (24%)		14	4 (29%)	8 (57%)	2 (14%)	0
BREAST ENGORGEMENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
BREAST ENLARGEMENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
BREAST PAIN FEMALE	≤63 Days (All)	164	2 (1%)	0.3532	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	65	2 (3%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
ENDOMETRITIS	≤63 Days (All)	164	11 (7%)	0.8471	11	5 (45%)	6 (55%)	0	0
	≤49 Days (Group 1)	65	4 (6%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	65	4 (6%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	34	3 (9%)		3	1 (33%)	2 (67%)	0	0
LEUKORRHOEA	≤63 Days (All)	164	14 (9%)	0.3440	14	8 (57%)	6 (43%)	0	0
	≤49 Days (Group 1)	65	5 (8%)		5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	65	8 (12%)		8	5 (63%)	3 (38%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
OVARIAN DISORDER	≤63 Days (All)	164	2 (1%)	0.3532	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE, DISORDERS, FEMALE (cont.)									
SALPINGITIS	≤63 Days (All)	164	2 (1%)	0.3532	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	164	15 (9%)	0.2023	16	1 (6%)	7 (44%)	8 (50%)	0
	≤49 Days (Group 1)	65	3 (5%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	65	7 (11%)		7	0	2 (29%)	5 (71%)	0
	57-63 Days (Group 3)	34	5 (15%)		6	1 (17%)	3 (50%)	2 (33%)	0
VAGINAL DISCOMFORT	≤63 Days (All)	164	2 (1%)	0.3532	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
VAGINITIS	≤63 Days (All)	164	7 (4%)	1.0000	8	2 (25%)	6 (75%)	0	0
	≤49 Days (Group 1)	65	3 (5%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	65	3 (5%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
NEOPLASM									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
OVARIAN CYST	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	162 (99%)	1.0000	702	237 (34%)	243 (35%)	218 (31%)	4 (<1%)
	≤49 Days (Group 1)	65	64 (98%)		268	91 (34%)	96 (36%)	79 (29%)	2 (<1%)
	50-56 Days (Group 2)	65	64 (98%)		278	96 (35%)	94 (34%)	86 (31%)	2 (<1%)
	57-63 Days (Group 3)	34	34 (100%)		156	50 (32%)	53 (34%)	53 (34%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	162 (99%)	1.0000	571	202 (35%)	183 (32%)	183 (32%)	3 (<1%)
	≤49 Days (Group 1)	65	64 (98%)		218	74 (34%)	77 (35%)	66 (30%)	1 (<1%)
	50-56 Days (Group 2)	65	64 (98%)		230	81 (35%)	72 (31%)	75 (33%)	2 (<1%)
	57-63 Days (Group 3)	34	34 (100%)		123	47 (38%)	34 (28%)	42 (34%)	0
ALLERGY	≤63 Days (All)	164	2 (1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ASTHENIA	≤63 Days (All)	164	9 (5%)	0.1575	12	2 (17%)	3 (25%)	7 (58%)	0
	≤49 Days (Group 1)	65	5 (8%)		8	1 (13%)	2 (25%)	5 (63%)	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	3 (9%)		3	0	1 (33%)	2 (67%)	0
BACK PAIN	≤63 Days (All)	164	20 (12%)	0.2630	26	7 (27%)	13 (50%)	5 (19%)	1 (4%)
	≤49 Days (Group 1)	65	5 (8%)		7	2 (29%)	2 (29%)	2 (29%)	1 (14%)
	50-56 Days (Group 2)	65	11 (17%)		14	5 (36%)	8 (57%)	1 (7%)	0
	57-63 Days (Group 3)	34	4 (12%)		5	0	3 (60%)	2 (40%)	0
FATIGUE	≤63 Days (All)	164	26 (16%)	0.5747	33	9 (27%)	15 (45%)	9 (27%)	0
	≤49 Days (Group 1)	65	13 (20%)		16	6 (38%)	8 (50%)	2 (13%)	0
	50-56 Days (Group 2)	65	9 (14%)		9	3 (33%)	3 (33%)	3 (33%)	0
	57-63 Days (Group 3)	34	4 (12%)		8	0	4 (50%)	4 (50%)	0
FEVER	≤63 Days (All)	164	12 (7%)	0.4021	15	5 (33%)	7 (47%)	3 (20%)	0
	≤49 Days (Group 1)	65	5 (8%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	65	3 (5%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	34	4 (12%)		5	1 (20%)	3 (60%)	1 (20%)	0
HOT FLUSHES	≤63 Days (All)	164	6 (4%)	0.5732	6	1 (17%)	3 (50%)	2 (33%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	3 (5%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	2 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
LEG PAIN	≤63 Days (All)	164	3 (2%)	0.1093	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	2 (100%)	0	0
MALAISE	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	164	2 (1%)	0.6839	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	1 (100%)	0	0	0
PAIN	≤63 Days (All)	164	6 (4%)	1.0000	9	3 (33%)	5 (56%)	1 (11%)	0
	≤49 Days (Group 1)	65	3 (5%)		5	3 (60%)	1 (20%)	1 (20%)	0
	50-56 Days (Group 2)	65	2 (3%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
RIGORS	≤63 Days (All)	164	15 (9%)	0.5693	15	4 (27%)	8 (53%)	3 (20%)	0
	≤49 Days (Group 1)	65	4 (6%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	65	7 (11%)		7	1 (14%)	4 (57%)	2 (29%)	0
	57-63 Days (Group 3)	34	4 (12%)		4	1 (25%)	2 (50%)	1 (25%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	164	5 (3%)	0.1536	5	1 (20%)	1 (20%)	3 (60%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	3 (5%)		3	1 (33%)	0	2 (67%)	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	1 (50%)	1 (50%)	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	164	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
APPLICATION SITE DISORDERS [4]									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
INJECTION SITE PAIN	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	164	11 (7%)	0.5200	13	5 (38%)	8 (62%)	0	0
	≤49 Days (Group 1)	65	6 (9%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	65	4 (6%)		6	3 (50%)	3 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS - Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS (cont.)									
HERPES SIMPLEX	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
INFECTION FUNGAL	≤63 Days (All)	164	3 (2%)	0.8010	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	164	9 (5%)	0.8246	9	4 (44%)	5 (56%)	0	0
	≤49 Days (Group 1)	65	4 (6%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	65	4 (6%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS - Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: TYSON (#4)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	102	102 (100%)		673	267 (40%)	273 (41%)	133 (20%)	0
	≤49 Days (Group 1)	68	68 (100%)		465	191 (41%)	187 (40%)	87 (19%)	0
	50-56 Days (Group 2)	25	25 (100%)		171	64 (37%)	73 (43%)	34 (20%)	0
	57 63 Days (Group 3)	9	9 (100%)		37	12 (32%)	13 (35%)	12 (32%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	102	4 (4%)	1.0000	4	0	4 (100%)	0	0
	≤49 Days (Group 1)	68	3 (4%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
RASH	≤63 Days (All)	102	2 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	102	2 (2%)	0.5578	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	4 (4%)	0.5135	5	1 (20%)	3 (60%)	1 (20%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	25	2 (8%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
MYALGIA	≤63 Days (All)	102	2 (2%)	0.5578	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
SKELETAL PAIN	≤63 Days (All)	102	2 (2%)	0.5578	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	44 (43%)	0.1052	76	21 (28%)	48 (63%)	7 (9%)	0
	≤49 Days (Group 1)	68	33 (49%)		57	16 (28%)	34 (60%)	7 (12%)	0
	50-56 Days (Group 2)	25	10 (40%)		18	5 (28%)	13 (72%)	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
DIZZINESS	≤63 Days (All)	102	12 (12%)	0.3219	16	8 (50%)	7 (44%)	1 (6%)	0
	≤49 Days (Group 1)	68	6 (9%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	25	5 (20%)		9	5 (56%)	4 (44%)	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
HEADACHE	≤63 Days (All)	102	37 (36%)	0.0144	55	11 (20%)	40 (73%)	4 (7%)	0
	≤49 Days (Group 1)	68	30 (44%)		46	11 (24%)	31 (67%)	4 (9%)	0
	50-56 Days (Group 2)	25	7 (28%)		9	0	9 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (cont.)									
MIGRAINE	≤63 Days (All)	102	2 (2%)	1.0000	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
TREMOR	≤63 Days (All)	102	3 (3%)	0.6683	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	68	3 (4%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
VISION DISORDERS									
ANY EVENT	≤63 Days (All)	102	2 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
CONJUNCTIVITIS	≤63 Days (All)	102	2 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS (cont.)									
EAR ACHE	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.2788	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	68	6 (9%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0
ANXIETY	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	102	1 (<1%)	0.0882	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0
INSOMNIA	≤63 Days (All)	102	5 (5%)	0.4397	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	68	5 (7%)		5	2 (40%)	3 (60%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	77 (75%)	0.3778	181	78 (43%)	63 (35%)	40 (22%)	0
	≤49 Days (Group 1)	68	53 (78%)		122	55 (45%)	40 (33%)	27 (22%)	0
	50-56 Days (Group 2)	25	19 (76%)		50	20 (40%)	20 (40%)	10 (20%)	0
	57-63 Days (Group 3)	9	5 (56%)		9	3 (33%)	3 (33%)	3 (33%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	3 (3%)	1.0000	3	0	0	3 (100%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
CONSTIPATION	≤63 Days (All)	102	3 (3%)	1.0000	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	102	24 (24%)	1.0000	28	18 (64%)	5 (18%)	5 (18%)	0
	≤49 Days (Group 1)	68	16 (24%)		19	14 (74%)	2 (11%)	3 (16%)	0
	50-56 Days (Group 2)	25	6 (24%)		7	3 (43%)	3 (43%)	1 (14%)	0
	57-63 Days (Group 3)	9	2 (22%)		2	1 (50%)	0	1 (50%)	0
DYSPEPSIA	≤63 Days (All)	102	3 (3%)	1.0000	5	1 (20%)	1 (20%)	3 (60%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	25	1 (4%)		3	0	0	3 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	102	2 (2%)	1.0000	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	102	67 (66%)	0.4063	93	46 (49%)	28 (30%)	19 (20%)	0
	≤49 Days (Group 1)	68	46 (68%)		65	32 (49%)	18 (28%)	15 (23%)	0
	50-56 Days (Group 2)	25	17 (68%)		24	12 (50%)	9 (38%)	3 (13%)	0
	57-63 Days (Group 3)	9	4 (44%)		4	2 (50%)	1 (25%)	1 (25%)	0
VOMITING	≤63 Days (All)	102	31 (30%)	0.8906	45	9 (20%)	26 (58%)	10 (22%)	0
	≤49 Days (Group 1)	68	21 (31%)		28	5 (18%)	16 (57%)	7 (25%)	0
	50-56 Days (Group 2)	25	8 (32%)		14	4 (29%)	8 (57%)	2 (14%)	0
	57-63 Days (Group 3)	9	2 (22%)		3	0	2 (67%)	1 (33%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	102	2 (2%)	0.5578	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	102	2 (2%)	0.5578	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.8307	8	4 (50%)	3 (38%)	1 (13%)	0
	≤49 Days (Group 1)	68	6 (9%)		7	3 (43%)	3 (43%)	1 (14%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
BRONCHITIS	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	102	3 (3%)	0.6683	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	68	3 (4%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	102	3 (3%)	0.6683	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	68	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	102	14 (14%)	0.2954	15	3 (20%)	5 (33%)	7 (47%)	0
	≤49 Days (Group 1)	68	7 (10%)		7	2 (29%)	3 (43%)	2 (29%)	0
	50-56 Days (Group 2)	25	5 (20%)		6	1 (17%)	1 (17%)	4 (67%)	0
	57-63 Days (Group 3)	9	2 (22%)		2	0	1 (50%)	1 (50%)	0
BREAST ENLARGEMENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
ENDOMETRITIS	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
OVARIAN DISORDER	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	102	8 (8%)	0.0209	8	0	1 (13%)	7 (88%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	25	5 (20%)		5	0	1 (20%)	4 (80%)	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	0	1 (100%)	0
VAGINAL DISCOMFORT	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINITIS	≤63 Days (All)	102	1 (<1%)	0.0882	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	102	102 (100%)		362	151 (42%)	138 (38%)	73 (20%)	0
	≤49 Days (Group 1)	68	68 (100%)		250	109 (44%)	95 (38%)	46 (18%)	0
	50-56 Days (Group 2)	25	25 (100%)		90	36 (40%)	35 (39%)	19 (21%)	0
	57-63 Days (Group 3)	9	9 (100%)		22	6 (27%)	8 (36%)	8 (36%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	101 (>99%)	1.0000	313	129 (41%)	116 (37%)	68 (22%)	0
	≤49 Days (Group 1)	68	67 (99%)		211	91 (43%)	79 (37%)	41 (19%)	0
	50-56 Days (Group 2)	25	25 (100%)		80	32 (40%)	29 (36%)	19 (24%)	0
	57-63 Days (Group 3)	9	9 (100%)		22	6 (27%)	8 (36%)	8 (36%)	0
ALLERGY	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
ASTHENIA	≤63 Days (All)	102	6 (6%)	0.3885	6	3 (50%)	2 (33%)	1 (17%)	0
	≤49 Days (Group 1)	68	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	25	3 (12%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	102	12 (12%)	0.5534	14	3 (21%)	10 (71%)	1 (7%)	0
	≤49 Days (Group 1)	68	10 (15%)		12	3 (25%)	8 (67%)	1 (8%)	0
	50-56 Days (Group 2)	25	2 (8%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
CHEST PAIN	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	102	7 (7%)	0.8307	8	3 (38%)	3 (38%)	2 (25%)	0
	≤49 Days (Group 1)	68	6 (9%)		7	3 (43%)	2 (29%)	2 (29%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
FEVER	≤63 Days (All)	102	2 (2%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	102	2 (2%)	1.0000	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	68	2 (3%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
MALAISE	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
PAIN	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
RIGORS	≤63 Days (All)	102	9 (9%)	0.7440	10	6 (60%)	4 (40%)	0	0
	≤49 Days (Group 1)	68	6 (9%)		7	4 (57%)	3 (43%)	0	0
	50-56 Days (Group 2)	25	3 (12%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	102	7 (7%)	0.6825	8	4 (50%)	3 (38%)	1 (13%)	0
	≤49 Days (Group 1)	68	5 (7%)		6	2 (33%)	3 (50%)	1 (17%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS (cont.)									
INFECTION BACTERIAL	≤63 Days (All)	102	1 (<1%)	0.0882	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0
INFECTION VIRAL	≤63 Days (All)	102	6 (6%)	1.0000	7	3 (43%)	3 (43%)	1 (14%)	0
	≤49 Days (Group 1)	68	5 (7%)		6	2 (33%)	3 (50%)	1 (17%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
SECONDARY TERMS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	0.0882	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0
POST-OPERATIVE PAIN	≤63 Days (All)	102	1 (<1%)	0.0882	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BLUMENTHAL (#5)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	44	44 (100%)		270	128 (47%)	110 (41%)	32 (12%)	0
	≤49 Days (Group 1)	13	13 (100%)		77	35 (45%)	35 (45%)	7 (9%)	0
	50-56 Days (Group 2)	23	23 (100%)		149	67 (45%)	59 (40%)	23 (15%)	0
	57-63 Days (Group 3)	8	8 (100%)		44	26 (59%)	16 (36%)	2 (5%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	44	2 (5%)	0.4165	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
FOLLICULITIS	≤63 Days (All)	44	1 (2%)	0.1818	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
PRURITUS GENITAL	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.4773	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
ARTHRALGIA	≤63 Days (All)	44	1 (2%)	0.4773	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	11 (25%)	0.8068	20	4 (20%)	12 (60%)	4 (20%)	0
	≤49 Days (Group 1)	13	4 (31%)		7	1 (14%)	5 (71%)	1 (14%)	0
	50-56 Days (Group 2)	23	6 (26%)		12	2 (17%)	7 (58%)	3 (25%)	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
DIZZINESS	≤63 Days (All)	44	4 (9%)	0.6366	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	13	2 (15%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	23	2 (9%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	44	10 (23%)	0.7095	16	3 (19%)	10 (63%)	3 (19%)	0
	≤49 Days (Group 1)	13	4 (31%)		5	1 (20%)	4 (80%)	0	0
	50-56 Days (Group 2)	23	5 (22%)		10	1 (10%)	6 (60%)	3 (30%)	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)									
DEPRESSION	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	36 (82%)	0.5781	98	46 (47%)	38 (39%)	14 (14%)	0
	≤49 Days (Group 1)	13	12 (92%)		32	15 (47%)	13 (41%)	4 (13%)	0
	50-56 Days (Group 2)	23	18 (78%)		51	20 (39%)	22 (43%)	9 (18%)	0
	57-63 Days (Group 3)	8	6 (75%)		15	11 (73%)	3 (20%)	1 (7%)	0
DIARRHEA	≤63 Days (All)	44	7 (16%)	0.8558	10	3 (30%)	4 (40%)	3 (30%)	0
	≤49 Days (Group 1)	13	3 (23%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	23	3 (13%)		6	1 (17%)	3 (50%)	2 (33%)	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
FLATULENCE	≤63 Days (All)	44	1 (2%)	1.0000	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		3	0	2 (67%)	1 (33%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	44	34 (77%)	0.3097	60	35 (58%)	19 (32%)	6 (10%)	0
	≤49 Days (Group 1)	13	12 (92%)		21	11 (52%)	8 (38%)	2 (10%)	0
	50-56 Days (Group 2)	23	17 (74%)		31	17 (55%)	10 (32%)	4 (13%)	0
	57-63 Days (Group 3)	8	5 (63%)		8	7 (88%)	1 (13%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
VOMITING	≤63 Days (All)	44	16 (36%)	1.0000	25	8 (32%)	13 (52%)	4 (16%)	0
	≤49 Days (Group 1)	13	5 (38%)		8	3 (38%)	4 (50%)	1 (13%)	0
	50-56 Days (Group 2)	23	8 (35%)		11	2 (18%)	7 (64%)	2 (18%)	0
	57-63 Days (Group 3)	8	3 (38%)		6	3 (50%)	2 (33%)	1 (17%)	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	2 (5%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	44	2 (5%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0
URINARY TRACT INFECTION	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	44	4 (9%)	1.0000	6	3 (50%)	3 (50%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	23	2 (9%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
BREAST ENGORGEMENT	≤63 Days (All)	44	1 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	44	2 (5%)	0.4165	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
LEUKORRHOEA	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
VAGINITIS	≤63 Days (All)	44	1 (2%)	0.4773	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BLUMENTHAL (#5)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	44	44 (100%)		137	70 (51%)	53 (39%)	14 (10%)	0
	≤49 Days (Group 1)	13	13 (100%)		34	17 (50%)	15 (44%)	2 (6%)	0
	50-56 Days (Group 2)	23	23 (100%)		79	41 (52%)	27 (34%)	11 (14%)	0
	57-63 Days (Group 3)	8	8 (100%)		24	12 (50%)	11 (46%)	1 (4%)	0
ABDOMINAL PAIN	≤63 Days (All)	44	43 (98%)	0.1818	126	68 (54%)	45 (36%)	13 (10%)	0
	≤49 Days (Group 1)	13	13 (100%)		29	17 (59%)	10 (34%)	2 (7%)	0
	50-56 Days (Group 2)	23	23 (100%)		75	40 (53%)	25 (33%)	10 (13%)	0
	57-63 Days (Group 3)	8	7 (88%)		22	11 (50%)	10 (45%)	1 (5%)	0
FATIGUE	≤63 Days (All)	44	3 (7%)	0.4182	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	13	2 (15%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
FEVER	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	44	3 (7%)	0.0533	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	2 (25%)		2	1 (50%)	1 (50%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BLUMENTHAL (#5)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
MALAISE	≤63 Days (All)	44	1 (2%)	0.4773	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	44	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
PAIN	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
APPLICATION SITE DISORDERS [4]									
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.4773	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
INJECTION SITE PAIN	≤63 Days (All)	44	1 (2%)	0.4773	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0
INFECTION VIRAL	≤63 Days (All)	44	1 (2%)	0.1818	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	64	63 (98%)	0.4375	405	166 (41%)	159 (39%)	80 (20%)	0
	≤49 Days (Group 1)	36	36 (100%)		222	95 (43%)	79 (36%)	48 (22%)	0
	50-56 Days (Group 2)	16	15 (94%)		102	44 (43%)	35 (34%)	23 (23%)	0
	57-63 Days (Group 3)	12	12 (100%)		81	27 (33%)	45 (56%)	9 (11%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RASH	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
ARTHRALGIA	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	21 (33%)	0.2961	40	16 (40%)	17 (43%)	7 (18%)	0
	≤49 Days (Group 1)	36	9 (25%)		13	4 (31%)	7 (54%)	2 (15%)	0
	50-56 Days (Group 2)	16	7 (44%)		19	9 (47%)	5 (26%)	5 (26%)	0
	57-63 Days (Group 3)	12	5 (42%)		8	3 (38%)	5 (63%)	0	0
DIZZINESS	≤63 Days (All)	64	5 (8%)	1.0000	5	4 (80%)	1 (20%)	0	0
	≤49 Days (Group 1)	36	3 (8%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	64	16 (25%)	0.1827	33	11 (33%)	15 (45%)	7 (21%)	0
	≤49 Days (Group 1)	36	6 (17%)		8	1 (13%)	5 (63%)	2 (25%)	0
	50-56 Days (Group 2)	16	6 (38%)		18	8 (44%)	5 (28%)	5 (28%)	0
	57-63 Days (Group 3)	12	4 (33%)		7	2 (29%)	5 (71%)	0	0
PARAESTHESIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
TREMOR	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	64	5 (8%)	0.2235	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	36	5 (14%)		5	2 (40%)	3 (60%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
ANOREXIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	64	2 (3%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	45 (70%)	0.3651	122	47 (39%)	44 (36%)	31 (25%)	0
	≤49 Days (Group 1)	36	27 (75%)		77	28 (36%)	26 (34%)	23 (30%)	0
	50 56 Days (Group 2)	16	9 (56%)		25	12 (48%)	7 (28%)	6 (24%)	0
	57-63 Days (Group 3)	12	9 (75%)		20	7 (35%)	11 (55%)	2 (10%)	0
DIARRHEA	≤63 Days (All)	64	13 (20%)	0.5833	15	7 (47%)	6 (40%)	2 (13%)	0
	≤49 Days (Group 1)	36	8 (22%)		9	4 (44%)	3 (33%)	2 (22%)	0
	50-56 Days (Group 2)	16	4 (25%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	12	1 (8%)		2	1 (50%)	1 (50%)	0	0
DYSPEPSIA	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
FLATULENCE	≤63 Days (All)	64	1 (2%)	0.1875	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	0	1 (100%)	0
NAUSEA	≤63 Days (All)	64	39 (61%)	0.6108	76	31 (41%)	26 (34%)	19 (25%)	0
	≤49 Days (Group 1)	36	23 (64%)		46	17 (37%)	15 (33%)	14 (30%)	0
	50-56 Days (Group 2)	16	8 (50%)		17	8 (47%)	5 (29%)	4 (24%)	0
	57-63 Days (Group 3)	12	8 (67%)		13	6 (46%)	6 (46%)	1 (8%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
VOMITING	≤63 Days (All)	64	19 (30%)	0.4601	28	9 (32%)	10 (36%)	9 (32%)	0
	≤49 Days (Group 1)	36	13 (36%)		21	7 (33%)	7 (33%)	7 (33%)	0
	50-56 Days (Group 2)	16	3 (19%)		4	2 (50%)	0	2 (50%)	0
	57-63 Days (Group 3)	12	3 (25%)		3	0	3 (100%)	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	2 (3%)	0.6875	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
COUGHING	≤63 Days (All)	64	1 (2%)	0.4375	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	64	2 (3%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA	≤63 Days (All)	64	2 (3%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	64	12 (19%)	0.9061	14	4 (29%)	9 (64%)	1 (7%)	0
	≤49 Days (Group 1)	36	6 (17%)		7	2 (29%)	4 (57%)	1 (14%)	0
	50-56 Days (Group 2)	16	3 (19%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	12	3 (25%)		4	0	4 (100%)	0	0
CERVICITIS	≤63 Days (All)	64	3 (5%)	0.0441	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	2 (100%)	0	0
LEUKORRHOEA	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINAL DISCOMFORT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
VAGINITIS	≤63 Days (All)	64	7 (11%)	0.6468	8	2 (25%)	6 (75%)	0	0
	≤49 Days (Group 1)	36	3 (8%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	16	2 (13%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	2 (100%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	64	60 (94%)	0.8096	212	90 (42%)	82 (39%)	40 (19%)	0
	≤49 Days (Group 1)	36	33 (92%)		113	54 (48%)	37 (33%)	22 (19%)	0
	50-56 Days (Group 2)	16	15 (94%)		52	20 (38%)	21 (40%)	11 (21%)	0
	57-63 Days (Group 3)	12	12 (100%)		47	16 (34%)	24 (51%)	7 (15%)	0
ABDOMINAL PAIN	≤63 Days (All)	64	59 (92%)	0.8202	173	75 (43%)	65 (38%)	33 (19%)	0
	≤49 Days (Group 1)	36	32 (89%)		91	45 (49%)	28 (31%)	18 (20%)	0
	50-56 Days (Group 2)	16	15 (94%)		41	15 (37%)	17 (41%)	9 (22%)	0
	57-63 Days (Group 3)	12	12 (100%)		41	15 (37%)	20 (49%)	6 (15%)	0
BACK PAIN	≤63 Days (All)	64	5 (8%)	1.0000	9	4 (44%)	3 (33%)	2 (22%)	0
	≤49 Days (Group 1)	36	3 (8%)		6	2 (33%)	2 (33%)	2 (33%)	0
	50-56 Days (Group 2)	16	1 (6%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FATIGUE	≤63 Days (All)	64	13 (20%)	0.9149	17	3 (18%)	11 (65%)	3 (18%)	0
	≤49 Days (Group 1)	36	7 (19%)		8	0	7 (88%)	1 (13%)	0
	50-56 Days (Group 2)	16	3 (19%)		6	2 (33%)	3 (50%)	1 (17%)	0
	57-63 Days (Group 3)	12	3 (25%)		3	1 (33%)	1 (33%)	1 (33%)	0
FEVER	≤63 Days (All)	64	2 (3%)	0.6875	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
HOT FLUSHES	≤63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
LEG PAIN	≤63 Days (All)	64	2 (3%)	0.6875	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
MALAISE	≤63 Days (All)	64	3 (5%)	1.0000	4	3 (75%)	1 (25%)	0	0
	≤49 Days (Group 1)	36	2 (6%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
RIGORS	≤63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
SYNCOPE	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	64	5 (8%)	0.6966	5	4 (80%)	1 (20%)	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	2 (13%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0
INFECTION	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
INFECTION BACTERIAL	≤63 Days (All)	64	2 (3%)	0.4018	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: BORGATTA (#6)

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: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS (cont.)									
INFECTION FUNGAL	≤63 Days (All)	64	1 (2%)	0.4375	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	64	1 (2%)	0.4375	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: MALLOY (#7)

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: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	52	52 (100%)		389	147 (38%)	151 (39%)	91 (23%)	0
	≤49 Days (Group 1)	19	19 (100%)		127	50 (39%)	47 (37%)	30 (24%)	0
	50-56 Days (Group 2)	11	11 (100%)		77	37 (48%)	28 (36%)	12 (16%)	0
	57-63 Days (Group 3)	22	22 (100%)		185	60 (32%)	76 (41%)	49 (26%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	0.5769	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	19	1 (5%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
ARTHRALGIA	≤63 Days (All)	52	1 (2%)	0.5769	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	52	1 (2%)	0.5769	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	22 (42%)	0.7140	43	15 (35%)	22 (51%)	6 (14%)	0
	≤49 Days (Group 1)	19	7 (37%)		9	3 (33%)	6 (67%)	0	0
	50-56 Days (Group 2)	11	4 (36%)		8	7 (88%)	0	1 (13%)	0
	57-63 Days (Group 3)	22	11 (50%)		26	5 (19%)	16 (62%)	5 (19%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (cont.)									
DIZZINESS	≤63 Days (All)	52	9 (17%)	1.0000	12	6 (50%)	5 (42%)	1 (8%)	0
	≤49 Days (Group 1)	19	3 (16%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	11	2 (18%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	22	4 (18%)		7	3 (43%)	3 (43%)	1 (14%)	0
HEADACHE	≤63 Days (All)	52	17 (33%)	0.7440	31	9 (29%)	17 (55%)	5 (16%)	0
	≤49 Days (Group 1)	19	5 (26%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	11	4 (36%)		6	5 (83%)	0	1 (17%)	0
	57-63 Days (Group 3)	22	8 (36%)		19	2 (11%)	13 (68%)	4 (21%)	0
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
TINNITUS	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	52	4 (8%)	0.8217	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	19	2 (11%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
PSYCHIATRIC, DISORDERS (cont.)									
INSOMNIA	≤63 Days (All)	52	4 (8%)	0.8217	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	19	2 (11%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	40 (77%)	1.0000	118	44 (37%)	37 (31%)	37 (31%)	0
	≤49 Days (Group 1)	19	15 (79%)		37	16 (43%)	11 (30%)	10 (27%)	0
	50-56 Days (Group 2)	11	8 (73%)		24	11 (46%)	10 (42%)	3 (13%)	0
	57-63 Days (Group 3)	22	17 (77%)		57	17 (30%)	16 (28%)	24 (42%)	0
CONSTIPATION	≤63 Days (All)	52	2 (4%)	0.5023	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	0	0	2 (100%)	0
DIARRHEA	≤63 Days (All)	52	12 (23%)	0.4046	13	7 (54%)	3 (23%)	3 (23%)	0
	≤49 Days (Group 1)	19	6 (32%)		6	4 (67%)	2 (33%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	5 (23%)		6	2 (33%)	1 (17%)	3 (50%)	0
DYSPEPSIA	≤63 Days (All)	52	1 (2%)	0.5769	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	52	2 (4%)	0.3281	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	52	37 (71%)	0.7318	70	27 (39%)	22 (31%)	21 (30%)	0
	≤49 Days (Group 1)	19	13 (68%)		23	10 (43%)	5 (22%)	8 (35%)	0
	50-56 Days (Group 2)	11	7 (64%)		13	6 (46%)	6 (46%)	1 (8%)	0
	57-63 Days (Group 3)	22	17 (77%)		34	11 (32%)	11 (32%)	12 (35%)	0
VOMITING	≤63 Days (All)	52	17 (33%)	0.7440	30	10 (33%)	10 (33%)	10 (33%)	0
	≤49 Days (Group 1)	19	5 (26%)		6	2 (33%)	3 (50%)	1 (17%)	0
	50-56 Days (Group 2)	11	4 (36%)		9	4 (44%)	3 (33%)	2 (22%)	0
	57-63 Days (Group 3)	22	8 (36%)		15	4 (27%)	4 (27%)	7 (47%)	0
ENDOCRINE DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
ENDOCRINE DISORDER NOS	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50 56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
TACHYCARDIA	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57 63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	2 (4%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
PHARYNGITIS	≤63 Days (All)	52	1 (2%)	0.5769	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	2 (18%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
ANAEMIA	≤63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	2 (18%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	2 (4%)	0.6848	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	1 (5%)		2	1 (50%)	0	1 (50%)	0
MICTURITION FREQUENCY	≤63 Days (All)	52	1 (2%)	0.2115	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	52	1 (2%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		2	1 (50%)	0	1 (50%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	52	11 (21%)	0.5082	11	5 (45%)	5 (45%)	1 (9%)	0
	≤49 Days (Group 1)	19	5 (26%)		5	2 (40%)	2 (40%)	1 (20%)	0
	50-56 Days (Group 2)	11	3 (27%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	22	3 (14%)		3	2 (67%)	1 (33%)	0	0
BREAST PAIN FEMALE	≤63 Days (All)	52	1 (2%)	0.2115	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
CERVICITIS	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
LEUKORRHOEA	≤63 Days (All)	52	1 (2%)	0.5769	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
VAGINITIS	≤63 Days (All)	52	8 (15%)	0.5428	8	4 (50%)	4 (50%)	0	0
	≤49 Days (Group 1)	19	4 (21%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	11	2 (18%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	2 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	52	51 (98%)	1.0000	197	76 (39%)	78 (40%)	43 (22%)	0
	≤49 Days (Group 1)	19	19 (100%)		67	29 (43%)	22 (33%)	16 (24%)	0
	50-56 Days (Group 2)	11	11 (100%)		38	16 (42%)	14 (37%)	8 (21%)	0
	57-63 Days (Group 3)	22	21 (95%)		92	31 (34%)	42 (46%)	19 (21%)	0
ABDOMINAL PAIN	≤63 Days (All)	52	50 (96%)	0.5023	167	68 (41%)	59 (35%)	40 (24%)	0
	≤49 Days (Group 1)	19	19 (100%)		61	27 (44%)	18 (30%)	16 (26%)	0
	50-56 Days (Group 2)	11	11 (100%)		34	14 (41%)	13 (38%)	7 (21%)	0
	57-63 Days (Group 3)	22	20 (91%)		72	27 (38%)	28 (39%)	17 (24%)	0
ALLERGY	≤63 Days (All)	52	4 (8%)	0.5229	4	0	4 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	3 (14%)		3	0	3 (100%)	0	0
ASTHENIA	≤63 Days (All)	52	3 (6%)	0.7919	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	1 (50%)	1 (50%)	0	0
BACK PAIN	≤63 Days (All)	52	7 (13%)	0.0838	8	2 (25%)	6 (75%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	2 (18%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	22	5 (23%)		6	1 (17%)	5 (83%)	0	0

[1] Included all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FATIGUE	≤63 Days (All)	52	5 (10%)	0.8328	5	1 (20%)	3 (60%)	1 (20%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	3 (14%)		3	0	2 (67%)	1 (33%)	0
FEVER	≤63 Days (All)	52	3 (6%)	0.7919	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	0	2 (100%)	0	0
HOT FLUSHES	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
LEG PAIN	≤63 Days (All)	52	2 (4%)	1.0000	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
RIGORS	≤63 Days (All)	52	2 (4%)	0.6848	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	52	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	0	1 (100%)	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	52	2 (4%)	0.1704	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	19	2 (11%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
INFECTION BACTERIAL	≤63 Days (All)	52	1 (2%)	0.5769	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
INFECTION PARASITIC	≤63 Days (All)	52	1 (2%)	0.5769	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	52	1 (2%)	0.5769	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: ROTHENBERG (#8)

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: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	21	21 (100%)		98	38 (39%)	37 (38%)	23 (23%)	0
	≤49 Days (Group 1)	13	13 (100%)		48	25 (52%)	17 (35%)	6 (13%)	0
	50-56 Days (Group 2)	5	5 (100%)		31	7 (23%)	16 (52%)	8 (26%)	0
	57-63 Days (Group 3)	3	3 (100%)		19	6 (32%)	4 (21%)	9 (47%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	9 (43%)	0.3870	16	0	13 (81%)	3 (19%)	0
	≤49 Days (Group 1)	13	4 (31%)		8	0	7 (88%)	1 (13%)	0
	50-56 Days (Group 2)	5	3 (60%)		6	0	5 (83%)	1 (17%)	0
	57-63 Days (Group 3)	3	2 (67%)		2	0	1 (50%)	1 (50%)	0
DIZZINESS	≤63 Days (All)	21	1 (5%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	21	9 (43%)	0.3870	14	0	11 (79%)	3 (21%)	0
	≤49 Days (Group 1)	13	4 (31%)		6	0	5 (83%)	1 (17%)	0
	50-56 Days (Group 2)	5	3 (60%)		6	0	5 (83%)	1 (17%)	0
	57-63 Days (Group 3)	3	2 (67%)		2	0	1 (50%)	1 (50%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	16 (76%)	0.7892	37	19 (51%)	10 (27%)	8 (22%)	0
	≤49 Days (Group 1)	13	9 (69%)		18	12 (67%)	3 (17%)	3 (17%)	0
	50-56 Days (Group 2)	5	4 (80%)		12	3 (25%)	6 (50%)	3 (25%)	0
	57-63 Days (Group 3)	3	3 (100%)		7	4 (57%)	1 (14%)	2 (29%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.
Appendix A.1, Tables 16 and 25

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

Center: ROTHENBERG (#8)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
CONSTIPATION	≤63 Days (All)	21	1 (5%)	0.3810	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	21	5 (24%)	0.7892	7	5 (71%)	2 (29%)	0	0
	≤49 Days (Group 1)	13	4 (31%)		5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	5	1 (20%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	21	11 (52%)	0.0383	18	10 (56%)	4 (22%)	4 (22%)	0
	≤49 Days (Group 1)	13	4 (31%)		8	5 (63%)	1 (13%)	2 (25%)	0
	50-56 Days (Group 2)	5	4 (80%)		6	1 (17%)	3 (50%)	2 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		4	4 (100%)	0	0	0
VOMITING	≤63 Days (All)	21	7 (33%)	0.4466	10	3 (30%)	3 (30%)	4 (40%)	0
	≤49 Days (Group 1)	13	3 (23%)		4	3 (75%)	0	1 (25%)	0
	50-56 Days (Group 2)	5	2 (40%)		3	0	2 (67%)	1 (33%)	0
	57-63 Days (Group 3)	3	2 (67%)		3	0	1 (33%)	2 (67%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: ROTHENBERG (#8)

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: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	21	20 (95%)	1.0000	44	18 (41%)	14 (32%)	12 (27%)	0
	≤49 Days (Group 1)	13	12 (92%)		21	12 (57%)	7 (33%)	2 (10%)	0
	50-56 Days (Group 2)	5	5 (100%)		13	4 (31%)	5 (38%)	4 (31%)	0
	57-63 Days (Group 3)	3	3 (100%)		10	2 (20%)	2 (20%)	6 (60%)	0
ABDOMINAL PAIN	≤63 Days (All)	21	20 (95%)	1.0000	38	17 (45%)	12 (32%)	9 (24%)	0
	≤49 Days (Group 1)	13	12 (92%)		19	11 (58%)	6 (32%)	2 (11%)	0
	50-56 Days (Group 2)	5	5 (100%)		12	4 (33%)	4 (33%)	4 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		7	2 (29%)	2 (29%)	3 (43%)	0
BACK PAIN	≤63 Days (All)	21	3 (14%)	0.3158	5	0	2 (40%)	3 (60%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	1 (33%)		3	0	0	3 (100%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

Appendix A.1, Tables 16 and 25

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

Center: ROTHENBERG (#8)

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			
						Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
LEG PAIN	≤63 Days (All)	21	1 (5%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	204	146 (72%)	0.0301	279	99 (35%)	110 (39%)	70 (25%)	0
	≤49 Days (Group 1)	145	99 (68%)		199	74 (37%)	78 (39%)	47 (24%)	0
	50-56 Days (Group 2)	40	35 (88%)		57	17 (30%)	25 (44%)	15 (26%)	0
	57-63 Days (Group 3)	19	12 (63%)		23	8 (35%)	7 (30%)	8 (35%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	18 (9%)	0.6062	19	9 (47%)	7 (37%)	3 (16%)	0
	≤49 Days (Group 1)	145	15 (10%)		16	7 (44%)	6 (38%)	3 (19%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
DIZZINESS	≤63 Days (All)	204	7 (3%)	0.4317	8	4 (50%)	2 (25%)	2 (25%)	0
	≤49 Days (Group 1)	145	7 (5%)		8	4 (50%)	2 (25%)	2 (25%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	204	11 (5%)	1.0000	11	5 (45%)	5 (45%)	1 (9%)	0
	≤49 Days (Group 1)	145	8 (6%)		8	3 (38%)	4 (50%)	1 (13%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	204	2 (<1%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	145	2 (1%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)								
INSOMNIA	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	84 (41%)	0.2197	127	34 (27%)	42 (33%)	51 (40%)	0
	≤49 Days (Group 1)	145	57 (39%)		86	25 (29%)	27 (31%)	34 (40%)	0
	50-56 Days (Group 2)	40	21 (53%)		32	8 (25%)	12 (38%)	12 (38%)	0
	57-63 Days (Group 3)	19	6 (32%)		9	1 (11%)	3 (33%)	5 (56%)	0
ABDOMINAL PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	204	2 (<1%)	0.0450	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0
DYSPEPSIA	≤63 Days (All)	204	2 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
FLATULENCE	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	204	79 (39%)	0.0539	89	25 (28%)	23 (26%)	41 (46%)	0
	≤49 Days (Group 1)	145	54 (37%)		62	20 (32%)	14 (23%)	28 (45%)	0
	50-56 Days (Group 2)	40	21 (53%)		23	5 (22%)	8 (35%)	10 (43%)	0
	57-63 Days (Group 3)	19	4 (21%)		4	0	1 (25%)	3 (75%)	0
VOMITING	≤63 Days (All)	204	27 (13%)	0.2676	31	5 (16%)	17 (55%)	9 (29%)	0
	≤49 Days (Group 1)	145	16 (11%)		20	2 (10%)	12 (60%)	6 (30%)	0
	50-56 Days (Group 2)	40	7 (18%)		7	2 (29%)	3 (43%)	2 (29%)	0
	57-63 Days (Group 3)	19	4 (21%)		4	1 (25%)	2 (50%)	1 (25%)	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RHINITIS	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MISHELL (#1)

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: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	204	3 (1%)	0.3435	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	145	2 (1%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0
LEUKORRHOEA	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	1 (<1%)	0.0931	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0
VAGINITIS	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	204	106 (52%)	0.8520	125	54 (43%)	56 (45%)	15 (12%)	0
	≤49 Days (Group 1)	145	75 (52%)		90	40 (44%)	40 (44%)	10 (11%)	0
	50-56 Days (Group 2)	40	22 (55%)		23	8 (35%)	12 (52%)	3 (13%)	0
	57-63 Days (Group 3)	19	9 (47%)		12	6 (50%)	4 (33%)	2 (17%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.