

Appendix 4 Hematology

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Reticulocyte (%)	Reticulocyte (%)	Reticulocyte (%)	Reticulocyte (%)	Reticulocyte (10 ⁹ /L)	Platelet Count (10 ³ /uL)						
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10401	0.73	1.16	0.75	.	45.5	67.9	512	.	337	277	497	.
10402	0.43	0.40	0.40	.	21.9	21.7	27.0	.	453	385	654	.
10403	0.66	0.79	.	.	36.2	44.1	.	.	413	400	.	.

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Male Day(s) Relative to Start Date

500 mg/kg	Hematology											
	PT (sec)	PT (sec)	PT (sec)	PT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	White Blood Cell Count (10 ³ /uL)			
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10401	8.4	8.7	10.5	.	21.8	22.8	27.6	.	7.52	9.66	11.85	.
10402	9.7	10.4	8.8	.	26.0	27.0	30.3	.	5.98	5.90	12.29	.
10403	10.2	10.0	.	.	19.6	19.7	.	.	10.38	9.15	.	.

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Male Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10401	67.8	74.0	38.8 ! ¹	.	28.7	21.5	54.1 ! ¹	.	0.1	0.4	0.0 ! ¹	.
10402	51.0	69.0	33.7	.	45.9	28.4	62.3	.	0.3	0.7	0.0	.
10403	37.9	43.7	.	.	55.6	50.3	.	.	0.5	1.7	.	.

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:The data was obtained from the smear specimen.]

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Sex: Male Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Basophil	Basophil	Basophil	Basophil	Monocyte	Monocyte	Monocyte	Monocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(10 ³ /uL)	(10 ³ /uL)	(10 ³ /uL)	(10 ³ /uL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10401	0.1	0.0	0.0 ! ¹	.	3.3	4.1	7.1 ! ¹	.	5.10	7.15	4.60 ! ¹	.
10402	0.0	0.0	0.0	.	2.8	1.9	4.0	.	3.05	4.07	4.14	.
10403	0.1	0.0	.	.	5.9	4.3	.	.	3.93	4.00	.	.

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:The data was obtained from the smear specimen.]

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Sex: Male Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Neutrophil (10 ³ /uL)	Neutrophil (10 ³ /uL)	Neutrophil (10 ³ /uL)	Neutrophil (10 ³ /uL)	Eosinophil (10 ³ /uL)	Eosinophil (10 ³ /uL)	Eosinophil (10 ³ /uL)	Eosinophil (10 ³ /uL)	Basophil (10 ³ /uL)	Basophil (10 ³ /uL)	Basophil (10 ³ /uL)	Basophil (10 ³ /uL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10401	2.15	2.07	6.41 ! ¹	.	0.01	0.04	0.00 ! ¹	.	0.01	0.00	0.00 ! ¹	.
10402	2.74	1.68	7.66	.	0.02	0.04	0.00	.	0.00	0.00	0.00	.
10403	5.78	4.60	.	.	0.05	0.16	.	.	0.01	0.00	.	.

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:The data was obtained from the smear specimen.]

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Hematology			
	Monocyte (10 ³ /uL)	Monocyte (10 ³ /uL)	Monocyte (10 ³ /uL)	Monocyte (10 ³ /uL)
	-46	-4	11	14
10401	0.25	0.40	0.84 ¹	.
10402	0.17	0.11	0.49	.
10403	0.61	0.39	.	.

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:The data was obtained from the smear specimen.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Red Blood Cell Count (10 ⁶ /uL)	Hemoglobin conc. (g/dL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	6.24	6.09	.	.	.	6.04	13.6	13.0	.	.	.	13.1
50102	5.54	5.44	.	.	.	5.32	13.0	12.9	.	.	.	12.6
50103	5.41	5.63	.	.	.	4.98	12.9	13.6	.	.	.	12.3

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Hematocrit	Hematocrit	Hematocrit	Hematocrit	Hematocrit	Hematocrit	MCV	MCV	MCV	MCV	MCV	MCV
	(%)	(%)	(%)	(%)	(%)	(%)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	45.6	43.0	.	.	.	42.7	73.1	70.6	.	.	.	70.7
50102	44.4	43.8	.	.	.	43.1	80.1	80.5	.	.	.	81.0
50103	44.5	46.7	.	.	.	41.4	82.3	82.9	.	.	.	83.1

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	MCH	MCH	MCH	MCH	MCH	MCH	MCHC	MCHC	MCHC	MCHC	MCHC	MCHC
	(pg)	(pg)	(pg)	(pg)	(pg)	(pg)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	21.8	21.3	.	.	.	21.7	29.8	30.2	.	.	.	30.7
50102	23.5	23.7	.	.	.	23.7	29.3	29.5	.	.	.	29.2
50103	23.8	24.2	.	.	.	24.7	29.0	29.1	.	.	.	29.7

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte						
	(%)	(%)	(%)	(%)	(%)	(%)	(10 ⁹ /L)					
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	1.29	0.96	.	.	.	1.87	80.5	58.5	.	.	.	112.9
50102	1.36	0.76	.	.	.	1.44	75.3	41.3	.	.	.	76.6
50103	0.56	0.64	.	.	.	1.22	30.3	36.0	.	.	.	60.8

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Platelet Count (10 ³ /uL)	PT (sec)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	279	204	.	.	.	245	8.8	9.2	.	.	.	8.5
50102	421	442	.	.	.	394	8.3	8.5	.	.	.	8.4
50103	342	339	.	.	.	370	8.5	8.7	.	.	.	8.6

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	White Blood Cell Count (10 ³ /uL)					
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	21.3	22.4	.	.	.	21.8	12.84	10.86	.	.	.	9.93
50102	22.2	23.8	.	.	.	22.4	12.54	9.63	.	.	.	7.09
50103	20.9	21.2	.	.	.	21.7	9.39	8.73	.	.	.	6.79

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	56.0	71.0	.	.	.	64.5	39.9	23.1	.	.	.	28.6
50102	37.9	56.7	.	.	.	45.6	58.3	39.7	.	.	.	50.2
50103	47.1	52.5	.	.	.	49.0	49.4	43.2	.	.	.	47.8

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	0.9	1.9	.	.	.	1.7	0.1	0.1	.	.	.	0.1
50102	0.6	1.0	.	.	.	0.6	0.1	0.1	.	.	.	0.1
50103	0.3	0.7	.	.	.	0.4	0.0	0.0	.	.	.	0.0

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Monocyte	Monocyte	Monocyte	Monocyte	Monocyte	Monocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte
	(%)	(%)	(%)	(%)	(%)	(%)	(10 ³ /uL)					
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	3.1	3.9	.	.	.	5.1	7.19	7.71	.	.	.	6.40
50102	3.1	2.5	.	.	.	3.5	4.75	5.46	.	.	.	3.23
50103	3.2	3.6	.	.	.	2.8	4.42	4.58	.	.	.	3.33

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Neutrophil (10 ³ /uL)	Eosinophil (10 ³ /uL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	5.13	2.51	.	.	.	2.84	0.11	0.21	.	.	.	0.17
50102	7.31	3.82	.	.	.	3.56	0.08	0.10	.	.	.	0.04
50103	4.64	3.78	.	.	.	3.24	0.03	0.06	.	.	.	0.03

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Hematology											
	Basophil (10 ³ /uL)	Monocyte (10 ³ /uL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50101	0.01	0.01	.	.	.	0.01	0.40	0.42	.	.	.	0.51
50102	0.01	0.01	.	.	.	0.01	0.39	0.24	.	.	.	0.25
50103	0.00	0.00	.	.	.	0.00	0.30	0.31	.	.	.	0.19

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

50 mg/kg	Hematology											
	Red Blood Cell Count (10 ⁶ /uL)	Hemoglobin conc. (g/dL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50201	5.36	5.72	.	6.71	.	.	11.7	12.8	.	14.6	.	.
50202	5.64	5.41	.	.	.	6.01	13.5	13.3	.	.	.	14.4
50203	5.52	5.35	.	.	.	6.26	14.0	13.6	.	.	.	15.6

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

50 mg/kg	Hematology											
	Hematocrit	Hematocrit	Hematocrit	Hematocrit	Hematocrit	Hematocrit	MCV	MCV	MCV	MCV	MCV	MCV
	(%)	(%)	(%)	(%)	(%)	(%)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50201	41.0	43.6	.	42.1	.	.	76.5	76.2	.	62.7	.	.
50202	45.1	43.7	.	.	.	45.7	80.0	80.8	.	.	.	76.0
50203	45.8	45.0	.	.	.	45.6	83.0	84.1	.	.	.	72.8

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

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Sex: Female Day(s) Relative to Start Date

50 mg/kg	Hematology											
	MCH	MCH	MCH	MCH	MCH	MCH	MCHC	MCHC	MCHC	MCHC	MCHC	MCHC
	(pg)	(pg)	(pg)	(pg)	(pg)	(pg)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50201	21.8	22.4	.	21.8	.	.	28.5	29.4	.	34.7	.	.
50202	23.9	24.6	.	.	.	24.0	29.9	30.4	.	.	.	31.5
50203	25.4	25.4	.	.	.	24.9	30.6	30.2	.	.	.	34.2

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]