

Animal: 10202

Sex: Male

Dose: 1 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Sublingual Gland : Cell infiltration; lymphocyte, focal, minimal

Spleen : Pigment deposition; brown, red pulp, minimal

Bone Marrow (Femur) : Pigment deposition; brown, minimal

Testis : Spermatid retention; minimal

Testis : Degeneration; tubule, focal, minimal

Thyroid : Cell infiltration; macrophage, follicle, minimal

Eyeball : Cell infiltration; mononuclear cell, focal, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Kidney; Urinary Bladder; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb

Animal: 50201

Sex: Female

Dose: 1 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Thyroid : Cell infiltration; lymphocyte, focal, minimal

Thyroid : Cell infiltration; macrophage, follicle, minimal

Eyeball : Cell infiltration; mononuclear cell, focal, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Kidney; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb

Animal: 50202

Sex: Female

Dose: 1 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Histo Pathology Observations [Correlation] (Continued):

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal
 Parotid Gland : Cell infiltration; lymphocyte, focal, minimal
 Bone Marrow (Femur) : Pigment deposition; brown, minimal
 Heart : Cell infiltration; inflammatory, focal, minimal
 Kidney : Hyaline cast; minimal
 Thyroid : Cyst

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland;
 Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric Lymph Node; Aorta; Urinary Bladder;
 Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland;
 Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb;
 Administered Site, Left Hindlimb

Animal: 10301

Sex: Male

Dose: 10 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
 Administered Site, Left Hindlimb : Thrombus (TGL)

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal
 Kidney : Cell infiltration; lymphocyte, focal, minimal
 Thyroid : Ectopic thymic tissue
 Administered Site, Left Hindlimb : Hemorrhage; minimal
 Administered Site, Left Hindlimb : Thrombus; moderate : red thrombus [Administered Site, Left Hindlimb : Thrombus (G)]
 Administered Site, Left Hindlimb : Cell infiltration; inflammatory, perivascular, mild

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland;
 Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric
 Lymph Node; Heart; Aorta; Urinary Bladder; Testis; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain;
 Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb;
 Administered Site, Right Hindlimb; Administered Site, Left Forelimb

Animal: 10302

Sex: Male

Dose: 10 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
 Spleen : Enlargement
 Administered Site, Left Forelimb : Induration; perivascular
 Administered Site, Left Hindlimb : Thrombus : by fixed tissue observation (TGL)

Histo Pathology Observations [Correlation]:

Liver : Cell infiltration; inflammatory, focal, minimal
 Parotid Gland : Cell infiltration; lymphocyte, focal, minimal
 Lungs (And Bronchus) : Granuloma; minimal

Histo Pathology Observations [Correlation] (Continued):

Thymus : Involution; minimal

Bone Marrow (Sternum) : Pigment deposition; brown, minimal

Mandibular Lymph Node : Extramedullary hematopoiesis; minimal

Epididymis : Cell infiltration; inflammatory, focal, mild

Pituitary : Cyst

Brain : Pigment deposition; brown, perivascular, focal, minimal

Administered Site, Right Forelimb : Cell infiltration; inflammatory, perivascular, mild : including foamy macrophages

Administered Site, Right Hindlimb : Proliferation; intima, vascular wall, moderate

Administered Site, Left Forelimb : Necrosis; mild : vascular wall, connective tissue around the blood vessel

Administered Site, Left Forelimb : Ulcer; moderate

Administered Site, Left Forelimb : Hemorrhage; mild

Administered Site, Left Forelimb : Cell infiltration; inflammatory, perivascular, severe : including foamy macrophages

Administered Site, Left Hindlimb : Hemorrhage; mild

Administered Site, Left Hindlimb : Proliferation; intima, vascular wall, moderate [Administered Site, Left Hindlimb : Thrombus : by fixed tissue observation (G)]

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Trachea; Spleen; Bone Marrow (Femur); Mesenteric Lymph Node; Heart; Aorta; Kidney; Urinary Bladder; Testis; Prostate; Seminal Vesicle; Mammary Gland; Thyroid; Parathyroid; Adrenal; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin

Animal: 50301

Sex: Female

Dose: 10 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Administered Site, Right Hindlimb : Dark reddish change; perivascular (TGL)

Administered Site, Left Forelimb : Thrombus (TGL)

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal

Spleen : Pigment deposition; brown, red pulp, minimal

Mandibular Lymph Node : Extramedullary hematopoiesis; minimal

Heart : Cell infiltration; inflammatory, focal, minimal

Kidney : Cell infiltration; lymphocyte, focal, minimal

Brain : Pigment deposition; brown, perivascular, focal, minimal

Eyeball : Cell infiltration; mononuclear cell, focal, minimal

Administered Site, Right Hindlimb : Hemorrhage; moderate [Administered Site, Right Hindlimb : Dark reddish change; perivascular (G)]

Administered Site, Left Forelimb : Hemorrhage; minimal

Administered Site, Left Forelimb : Thrombus; moderate : red thrombus [Administered Site, Left Forelimb : Thrombus (G)]

Administered Site, Left Forelimb : Cell infiltration; inflammatory, perivascular, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Bone Marrow (Femur); Bone Marrow (Sternum); Mesenteric Lymph Node; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Spinal Cord; Optic Nerve; Sciatic Nerve; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Left Hindlimb

Animal: 50302

Sex: Female

Dose: 10 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
 Administered Site, Right Forelimb : Thrombus (TGL)
 Administered Site, Left Forelimb : Thrombus (TGL)

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal
 Mesenteric Lymph Node : Increase; pigmentophagy, minimal
 Kidney : Arteritis; minimal
 Ovary : Mineralization; minimal
 Femoral Muscle : Degeneration; muscle fiber, focal, minimal
 Administered Site, Right Forelimb : Proliferation; intima, vascular wall, moderate [Administered Site, Right Forelimb : Thrombus (G)]
 Administered Site, Left Forelimb : Hemorrhage; mild
 Administered Site, Left Forelimb : Proliferation; intima, vascular wall, moderate [Administered Site, Left Forelimb : Thrombus (G)]
 Administered Site, Left Forelimb : Cell infiltration; inflammatory, perivascular, minimal
 Administered Site, Left Hindlimb : Proliferation; intima, vascular wall, minimal
 Administered Site, Left Hindlimb : Cell infiltration; inflammatory, perivascular, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Heart; Aorta; Urinary Bladder; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femur; Sternum; Skin; Administered Site, Right Hindlimb

Animal:	10401	Sex: Male
	Dose: 30 mg/kg	
	Removal Reason: Scheduled Sacrifice	
	Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
 Spleen : Enlargement
 Thyroid : Defect; right
 Administered Site, Left Forelimb : Thrombus : by fixed tissue observation (TGL)

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal
 Sublingual Gland : Cell infiltration; lymphocyte, focal, minimal
 Mandibular Lymph Node : Extramedullary hematopoiesis; minimal
 Kidney : Basophilic tubule; minimal
 Urinary Bladder : Cell infiltration; lymphocyte, focal, minimal
 Testis : Degeneration; tubule, diffuse, mild
 Brain : Pigment deposition; brown, perivascular, focal, minimal
 Lacrimal Gland : Cell infiltration; lymphocyte, focal, minimal
 Administered Site, Right Forelimb : Proliferation; intima, vascular wall, severe
 Administered Site, Left Forelimb : Hemorrhage; mild
 Administered Site, Left Forelimb : Proliferation; intima, vascular wall, moderate [Administered Site, Left Forelimb : Thrombus : by fixed tissue observation (G)]
 Administered Site, Left Forelimb : Cell infiltration; inflammatory, perivascular, minimal
 Administered Site, Left Hindlimb : Necrosis; minimal : intima of vascular wall
 Administered Site, Left Hindlimb : Hemorrhage; minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mesenteric Lymph Node; Heart; Aorta; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Hindlimb

Animal: 10402

Sex: Male

Dose: 30 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Administered Site, Left Forelimb : Nodule; perivascular (TGL)

Histo Pathology Observations [Correlation]:

Liver : Cell infiltration; inflammatory, focal, minimal

Lungs (And Bronchus) : Granuloma; minimal

Bone Marrow (Femur) : Increase; hematopoietic cell, mild

Bone Marrow (Sternum) : Increase; hematopoietic cell, minimal

Urinary Bladder : Cell infiltration; lymphocyte, focal, minimal

Thyroid : Cell infiltration; macrophage, follicle, minimal

Parathyroid : Cell infiltration; lymphocyte, focal, minimal

Administered Site, Right Forelimb : Cell infiltration; inflammatory, perivascular, mild : including foamy macrophages

Administered Site, Right Hindlimb : Hemorrhage; mild

Administered Site, Right Hindlimb : Proliferation; intima, vascular wall, moderate

Administered Site, Right Hindlimb : Cell infiltration; inflammatory, perivascular, minimal

Administered Site, Left Forelimb : Necrosis; severe : vascular wall, connective tissue around the blood vessel [Administered Site, Left Forelimb :

Nodule; perivascular (G)]

Administered Site, Left Forelimb : Hemorrhage; mild

Administered Site, Left Forelimb : Cell infiltration; inflammatory, perivascular, severe : including foamy macrophages [Administered Site, Left Forelimb :

Nodule; perivascular (G)]

Administered Site, Left Hindlimb : Proliferation; intima, vascular wall, moderate

Administered Site, Left Hindlimb : Cell infiltration; inflammatory, perivascular, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Spleen; Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Kidney; Testis; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin

Animal: 50401

Sex: Female

Dose: 30 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Administered Site, Left Hindlimb : Dark reddish change (TGL)

Histo Pathology Observations [Correlation]:

Esophagus : Cell infiltration; lymphocyte, focal, minimal

Bone Marrow (Sternum) : Increase; hematopoietic cell, minimal

Kidney : Cyst

Mammary Gland : Cell infiltration; lymphocyte, focal, minimal

Pituitary : Cyst

Histo Pathology Observations [Correlation] (Continued):

Administered Site, Left Forelimb : Proliferation; intima, vascular wall, moderate
 Administered Site, Left Forelimb : Cell infiltration; inflammatory, perivascular, minimal : including foamy macrophages
 Administered Site, Left Hindlimb : Necrosis; mild : vascular wall, connective tissue around the blood vessel
 Administered Site, Left Hindlimb : Hemorrhage; mild [Administered Site, Left Hindlimb : Dark reddish change (G)]
 Administered Site, Left Hindlimb : Cell infiltration; inflammatory, perivascular, mild : including foamy macrophages

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb

Animal:	50402	Sex: Female
	Dose: 30 mg/kg	
	Removal Reason: Scheduled Sacrifice	
	Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
 Thyroid : Dark reddish patch; left, one (TGL)
 Administered Site, Right Forelimb : Thrombus (TGL)
 Administered Site, Right Hindlimb : Thrombus (TGL)
 Administered Site, Left Forelimb : Thrombus (TGL)
 Administered Site, Left Hindlimb : Thrombus (TGL)

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal
 Liver : Pigment deposition; kupffer cell, minimal
 Lungs (And Bronchus) : Granuloma; minimal
 Spleen : Pigment deposition; brown, red pulp, minimal
 Bone Marrow (Sternum) : Increase; hematopoietic cell, minimal
 Parathyroid : Congestion; minimal [Thyroid : Dark reddish patch; left, one (G)]
 Brain : Cell infiltration; inflammatory, choroid plexus, focal, minimal
 Administered Site, Right Forelimb : Hemorrhage; mild
 Administered Site, Right Forelimb : Proliferation; intima, vascular wall, severe [Administered Site, Right Forelimb : Thrombus (G)]
 Administered Site, Right Hindlimb : Hemorrhage; mild
 Administered Site, Right Hindlimb : Proliferation; intima, vascular wall, mild [Administered Site, Right Hindlimb : Thrombus (G)]
 Administered Site, Left Forelimb : Proliferation; intima, vascular wall, moderate [Administered Site, Left Forelimb : Thrombus (G)]
 Administered Site, Left Hindlimb : Hemorrhage; minimal
 Administered Site, Left Hindlimb : Thrombus; moderate : red thrombus [Administered Site, Left Hindlimb : Thrombus (G)]
 Administered Site, Left Hindlimb : Cell infiltration; inflammatory, perivascular, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Kidney; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Adrenal; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin

Date	Calibration curve			Back ground (% of LLOQ)			QC sample			
	Concentration (ng/mL)		Accuracy (%)	Sample	Peak area		Concentration (ng/mL)			Accuracy (%)
	Nominal	Measured			P092	IS	Nominal	No. Measured		
2014/11/6	5	4.992	99.8	Blank	0	0	10	1	9.779	97.8
	10	10.08	100.8		(0.0)	(0.0)		2	11.18	111.8
	20	19.11	95.6	Zero	0	178594	50	1	56.55	113.1
	50	54.82	109.6		(0.0)	--		2	59.66	119.3
	100	100.2	100.2	LLOQ	862	177907	800	1	856.6	107.1
	200	197.5	98.8					2	875.2	109.4
	500	485.1	97.0							
	1000	982.8	98.3							
2014/11/7	5	4.904	98.1	Blank	0	0	10	1	8.267	82.7
	10	10.08	100.8		(0.0)	(0.0)		2	10.26	102.6
	20	20.33	101.7	Zero	0	144151	50	1	54.24	108.5
	50	56.66	113.3		(0.0)	--		2	53.13	106.3
	100	98.40	98.4	LLOQ	640	133531	800	1	785.3	98.2
	200	195.0	97.5					2	787.7	98.5
	500	463.4	92.7							
	1000	975.6	97.6							
2014/12/1	5	4.843	96.9	Blank	0	0	10	1	10.82	108.2
	10	10.78	107.8		(0.0)	(0.0)		2	9.116	91.2
	20	19.72	98.6	Zero	0	438989	50	1	50.71	101.4
	50	48.69	97.4		(0.0)	--		2	51.21	102.4
	100	98.84	98.8	LLOQ	2543	408627	800	1	848.2	106.0
	200	192.3	96.2					2	889.0	111.1
	500	495.2	99.0							
	1000	1053	105.3							
2014/12/2	5	4.702	94.0	Blank	0	0	10	1	10.04	100.4
	10	11.35	113.5		(0.0)	(0.0)		2	9.018	90.2
	20	19.72	98.6	Zero	0	480022	50	1	43.67	87.3
	50	49.13	98.3		(0.0)	--		2	40.89	81.8
	100	96.75	96.8	LLOQ	2998	457524	800	1	694.7	86.8
	200	191.6	95.8					2	673.5	84.2
	500	472.6	94.5							
	1000	1085	108.5							

LLOQ: Lower limit of quantification

Accuracy (%) = measured value/nominal value×100

The value in parenthesis denotes peak area ratio (%) of back ground peak area to that in LLOQ.

--: Not applicable

Key Page

Code	Description
BD	Before dosing
T10	About 30 minutes after dosing
T20	About 4 hours after dosing

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date																
					-3 Day	-2 Day	-1 Day	1 BD	1 T10	1 T20	2 Day	3 Day	4 Day	5 BD	5 T10	5 T20	6 Day	7 Day	8 BD	8 T10	8 T20
1	m	29001	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Erythema	Right Hindlimb
			Swelling	Right Hindlimb
			Hematuria	

Severity Codes: X = Present

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date																	
					10 Day	11 Day	12 BD	12 T10	12 T20	13 Day	14 Day	15 Day	16 Day	17 Day	18 Day	19 Day	20 BD	20 T10	20 T20	21 Day	22 Day	23 Day
1	m	29001	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	.	.	.	X	X
			Erythema	Right Hindlimb	X	X	.	.	.
			Swelling	Right Hindlimb	X	X	.	.
			Hematuria		X	.	.	.

Severity Codes: X = Present

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	24 Day	25 Day	26 Day	27 Day	28 Day
1	m	29001	No Abnormalities Detected		X	X	X	X	X
			Erythema	Right Hindlimb
			Swelling	Right Hindlimb
			Hematuria	

Severity Codes: X = Present

Appendix 13 Body Weight (Preliminary study) B130235

Sex: Male Bodyweight (kg)

Group: 1	Day(s) Relative to Start Date				
	1	5	8	12	20
29001	4.5	4.5	4.6	4.7	4.7

Appendix 14 Food Consumption (Preliminary study)

B130235

Sex: Male Food Consumption (g/day)

Group: 1	Day(s) Relative to Start Date													
	-3 → -2	-2 → -1	-1 → 1	1 → 2	2 → 3	3 → 4	4 → 5	5 → 6	6 → 7	7 → 8	8 → 9	9 → 10	10 → 11	11 → 12
29001	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Appendix 14 Food Consumption (Preliminary study)

B130235

Sex: Male Food Consumption (g/day)

Group: 1	Day(s) Relative to Start Date													
	12 → 13	13 → 14	14 → 15	15 → 16	16 → 17	17 → 18	18 → 19	19 → 20	20 → 21	21 → 22	22 → 23	23 → 24	24 → 25	25 → 26
29001	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Sex: Male Food Consumption (g/day)

Group: 1	Day(s) Relative to Start Date	
	26 → 27	27 → 28
29001	100	100

Appendix 15 Hematology (Preliminary study)

B130235

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Red Blood Cell Count (10 ⁶ /μL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)
	1	2	5	6	8	9	12	13	20	21	1	2	5	6
29001	5.64	5.54	5.30	5.05	5.13	4.84	5.06	4.66	4.89	3.95	14.6	14.5	13.7	13.0

Appendix 15 Hematology (Preliminary study)

B130235

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hematocrit (%)	Hematocrit (%)	Hematocrit (%)	Hematocrit (%)	Hematocrit (%)	Hematocrit (%)	Hematocrit (%)	Hematocrit (%)
	8	9	12	13	20	21	1	2	5	6	8	9	12	13
29001	13.3	12.4	13.1	12.1	12.7	10.4	46.6	45.5	44.1	42.3	43.7	42.0	43.7	40.7

Appendix 15 Hematology (Preliminary study)

B130235

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Hematocrit	Hematocrit	MCV	MCV	MCV	MCV	MCV	MCV	MCV	MCV	MCV	MCV	MCH	MCH
	(%)	(%)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)	(pg)	(pg)
	20	21	1	2	5	6	8	9	12	13	20	21	1	2
29001	42.3	34.4	82.6	82.1	83.2	83.8	85.2	86.8	86.4	87.3	86.5	87.1	25.9	26.2

Appendix 15 Hematology (Preliminary study)

B130235

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	MCH	MCH	MCH	MCH	MCH	MCH	MCH	MCH	MCHC	MCHC	MCHC	MCHC	MCHC	MCHC
	(pg)	(pg)	(pg)	(pg)	(pg)	(pg)	(pg)	(pg)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)
	5	6	8	9	12	13	20	21	1	2	5	6	8	9
29001	25.8	25.7	25.9	25.6	25.9	26.0	26.0	26.3	31.3	31.9	31.1	30.7	30.4	29.5

Appendix 15 Hematology (Preliminary study)

B130235

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	MCHC	MCHC	MCHC	MCHC	Platelet Count	Platelet Count	Platelet Count	Platelet Count	Platelet Count	Platelet Count	Platelet Count	Platelet Count	Platelet Count	Platelet Count
	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)
	12	13	20	21	1	2	5	6	8	9	12	13	20	21
29001	30.0	29.7	30.0	30.2	283	257	226	221	225	230	303	283	463	378