

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:42

First Dose M/F: NA / NA

Lab: MBA

C Number: C20305

Lock Date: 08/29/2005

Cage Range: All

Date Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

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Alimentary System

Esophagus	+	M	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	19	
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	I	19
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	20
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	20
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	20
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	20
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	20
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Hepatocyte, Vacuolization Cytoplasmic													2		2		2			3	2.0
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Parotid GI, Right, Vacuolization Cytoplasmic													1							1	1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Cardiovascular System																					
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Mineralization													1		1		1	2		4	1.3

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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		DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
			0	0	0	3	3	3	0	0	3	3	5	5	5	1	9	9	5	5	
			2	2	3	0	0	0	3	3	0	0	5	5	5	7	2	2	5	5	
BALB/C Mouse Male ISORMCONSALINE	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	
*TOTALS																					
Adrenal Cortex		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Subcapsular, Hyperplasia, Focal																				1	
Adrenal Medulla		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Islets, Pancreatic		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	
Parathyroid Gland		+	M	+	+	M	M	M	+	M	M	+	+	+	M	+	+	M	M	11	
Pituitary Gland		+	+	+	+	+	+	+	+	+	I	I	+	I	+	+	I	+	+	17	
Thyroid Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	20	
General Body System																					
NONE																					
Genital System																					
Epididymis		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Penis																				1	
Preputial Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Prostate		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Inflammation, Chronic Active, Focal																				1 2.0	
Seminal Vesicle		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Testes		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Hematopoietic System																					
Bone Marrow																					
Lymph Node, Mandibular		+	M	+	+	+	+	+	+	I	+	I	+	+	+	I	+	+	+	17	
Lymph Node, Mesenteric		+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	20	

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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X ..Lesion present

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1) Minimal 3) Moderate

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First Dose M/F: NA / NA

Lab: MBA

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BALB/C Mouse Male ISORMCONSALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	3	0	0	3	3	5	5	5	1	9	9	5	5	9	9	9	9
		2	2	3	0	0	0	3	3	0	0	5	5	5	7	2	2	5	5	2	2	1	
		ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BALB/C Mouse Male ISORMCONSALINE	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	2	2
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	

Urinary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

± .. Tissue examined microscopically

M ..Missing tissue

1-4 ..Lesion qualified as:

X ..Lesion present

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1) Minimal 3) Moderate

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Lab: MBA

BALB/C Mouse Male
TRTRMCONSALINE

DAY ON TEST	0 0 0 0 0 0 0 0 0 0 0 0													
	0 0 0 0 0 0 0 0 0 0 0 0													
		0 0 0 3 3 3 5 5 5 9 9 9			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			
		3 3 3 0 0 0 5 5 5 1 2 2			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			
		ANIMAL ID	0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0		
			2 2 2 2 2 2 2 2 2 3 3 3			2 3 4 5 6 7 8 9 0 1 2 3			2 3 4 5 6 7 8 9 0 1 2 3			*TOTALS		

Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	12
Gallbladder	+	+	+	+	+	+	+	M	+	A	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	12
Liver	+	+	+	+	+	+	+	+	+	+	+	+	12
Hepatocyte, Vacuolization Cytoplasmic							1	2		2	1		4 1.5
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	12
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	12
Left, Parotid GI, Vacuolization Cytoplasmic							1				1	1.0	
Parotid GI, Right, Vacuolization Cytoplasmic							2				1	2.0	
Right, Submandibul GI, Degeneration	1										1	1.0	
Right, Submandibul GI, Inflammation	1										1	1.0	
Right, Submandibul GI, Necrosis	1										1	1.0	
Right, Submandibul GI, Regeneration						3	2				2	2.5	
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	12
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	12

Cardiovascular System

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Lab: MBA

**BALB/C Mouse Male
TRTRMCONSALINE**

DAY ON TEST	BALB/C Mouse Male TRTRMCONSALINE											
	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	3	3	3	5	5	5	9	9	9
	3	3	3	0	0	0	5	5	5	1	2	2
	2	2	2	2	2	2	2	2	3	3	3	3
	2	3	4	5	6	7	8	9	0	1	2	3
	*TOTALS											
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	12
Heart	+	+	+	+	+	+	+	+	+	+	+	12
Endocrine System												
Adrenal Cortex	+	+	+	+	I	+	+	+	+	+	+	11
Adrenal Medulla	+	+	+	+	I	+	+	+	+	+	+	11
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	12
Parathyroid Gland	+	M	M	M	M	M	M	+	M	+	M	4
Pituitary Gland	+	+	+	+	+	I	+	+	+	+	I	10
Thyroid Gland	+	+	M	+	+	+	+	+	+	+	+	11
General Body System												
NONE												
Genital System												
Epididymis	+	+	+	+	+	+	+	+	+	+	+	12
Preputial Gland	+	+	+	+	I	+	+	+	+	+	+	11
Prostate	+	+	+	+	+	+	+	+	+	+	+	12
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	12
Testes	+	+	+	+	+	+	+	+	+	+	+	12
Hematopoietic System												
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	12
Lymph Node, Mandibular	+	I	+	+	+	+	+	+	+	+	+	11
Right, Hyperplasia, Lymphoid					2				1	2.0		

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
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First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male
TRTRMCONSALINE

DAY ON TEST												
	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	3	3	3	3
	2	3	4	5	6	7	8	9	0	1	2	3

***TOTALS**

Right, Hyperplasia, Lymphoid	2	1	2.0
Lymph Node, Mesenteric	+	+	12
Spleen	+	+	11
Hematopoietic Cell Proliferation	1	1	11
Thymus	+	+	12
Integumentary System			
Mammary Gland	M	M	0
Skin	+	+	12
Musculoskeletal System			
Bone	+	+	12
Nervous System			
Brain	+	+	12
Respiratory System			
Lung	+	+	12
Nose	+	+	12
Trachea	+	+	11
Special Senses System			
Eye	+	+	11
Harderian Gland	+	+	12

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**BALB/C Mouse Male
TRTRMCONSALINE**

DAY ON TEST												
	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	3	3	3	3
	2	3	4	5	6	7	8	9	0	1	2	3

*TOTALS

Urinary System

Kidney	+	+	+	+	+	+	+	+	+	+	+	12
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	12

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BALB/C Mouse Male 1-7 SALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	2	0	0	3	3	5	5	5	9	9	9	5	5	9
	2	2	2	0	0	9	3	3	0	0	5	5	5	2	2	2	5	5	2	2
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	5	5
		4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2

Alimentary System

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BALB/C Mouse Male 1-7 SALINE	DAY ON TEST	0 0																	
		0 0 0 0 3 2 0 0 3 3 5 5 5 9 9 9 5 5 9 9 9 9 9 9																	
ANIMAL ID	2 2 2 0 0 9 3 0 0 5 5 5 2 2 2 5 5 5 2 2 2 2 2 2	*TOTALS																	
	0 0																		
Heart	+ +	21																	
Mineralization	1 1	9 1.1																	
Endocrine System																			
Adrenal Cortex	+ +	21																	
Subcapsular, Hyperplasia, Focal		1 1																	
Adrenal Medulla	+ +	21																	
Islets, Pancreatic	+ +	21																	
Parathyroid Gland	M M M M M M M + + M + M + + + + + + + + + + + +	11																	
Pituitary Gland	+ + + + + + M + + + + M + M + + + + + + + + + +	16																	
Thyroid Gland	+ +	21																	
General Body System																			
NONE																			
Genital System																			
Epididymis	+ +	21																	
Preputial Gland	+ +	21																	
Inflammation, Chronic Active, Focal		2																	
Prostate	+ +	20																	
Seminal Vesicle	+ +	21																	
Testes	+ +	21																	
Hematopoietic System																			
Bone Marrow	+ +	21																	

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:43

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-7 SALINE	DAY ON TEST	0 0																		
		0 0 0 0 3 2 0 0 3 3 5 5 5 9 9 9 5 5 9 9 9 9 9 9																		
ANIMAL ID	2 2 2 0 0 9 3 0 0 5 5 5 2 2 2 5 5 5 2 2 2 2 2 2	0 0																		
	0 0	0 0																		
*TOTALS																				
Bone Marrow		+ +																		21
Lymph Node, Mandibular		+ + + I + + + I + + + + + + + + + + + + + + + + +																		14
Lymph Node, Mesenteric		+ I +																		19
Spleen		+ +																		21
Congestion, Diffuse		2																		1 2.0
Hematopoietic Cell Proliferation		1 2 1 2 2 1 1 1 1 1 1 2 1 1 2 1 1 3 1 2 2																		21 1.4
Thymus		+ +																		21
Integumentary System																				
Mammary Gland		M M																		0
Skin		+ +																		21
Epidermis, Ulcer, Focal		4																		1 4.0
Musculoskeletal System																				
Bone		+ +																		21
Skeletal Muscle		+																		1
Hemorrhage, Focal		3																		1 3.0
Inflammation, Acute, Focal		2																		1 2.0
Nervous System																				
Brain		+ +																		21
Respiratory System																				
Lung		+ +																		21
Alveolar Epith, Hyperplasia		2																		1 2.0

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:43

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-7 SALINE	DAY ON TEST	0 0																		
		0 0																		
		0 0 0 3 3 2 0 0 3 3 5 5 5 9 9 9 5 5 9 9 9 9 9 9																		
		2 2 2 0 0 9 3 0 0 5 5 5 2 2 2 5 5 2 2 2 2 2 2 2																		
		0 0																		
		ANIMAL ID																		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	5	5	
		4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	
		*TOTALS																		
		1 1 1.0																		
Alveolus, Inflammation, Acute, Focal		+ +																		
Nose		+ +																		
Trachea		+ + I I M I I I + I + + I + + + + + + + + + + + +																		
Special Senses System		+ +																		
Eye		+ +																		
Harderian Gland		+ +																		
Urinary System		+ +																		
Kidney		+ +																		
Urinary Bladder		+ +																		

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:43

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-8 SALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	3	0	0	3	3	5	5	5	9	9	9	5	5	9
		3	2	2	0	0	0	3	3	0	0	5	5	5	2	2	2	5	5	2
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7
		5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3

Alimentary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:43

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-8 SALINE	DAY ON TEST																				
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	3	0	0	3	3	5	5	5	9	9	9	5	5	9	9
		3	2	2	0	0	0	3	3	0	0	5	5	5	2	2	2	5	5	2	2
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		5	5	5	5	5	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4
																				*TOTALS	
Stomach, Forestomach		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Stomach, Glandular		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Cardiovascular System																					
Blood Vessel		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Heart		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Artery, Inflammation, Chronic Active																					1 2.0
Mineralization																					4 2.0
Ventricle, Thrombosis, Focal																					1 4.0
Endocrine System																					
Adrenal Cortex		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Subcapsular, Hyperplasia, Focal																					2 1.0
Adrenal Medulla		+	I	+	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	+	19
Islets, Pancreatic		+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	20
Parathyroid Gland		+	M	M	M	+	+	M	M	M	M	+	M	M	+	M	+	+	+	+	11
Pituitary Gland		+	+	+	+	+	I	+	+	+	I	+	+	+	+	+	+	+	+	+	19
Thyroid Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
General Body System																					
NONE																					
Genital System																					
Epididymis		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Preputial Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

Respiratory System

Special Senses System

Urinary System

* Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade.

± .. Tissue examined microscopically

M .. Missing tissue

X - Lesion present

A - Autolysis precludes evaluation

| ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as

1) Minimal 3) Moderate

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Route: INTRADUCTAL CANNULATION

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Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-9 SALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	2	0	0	3	3	5	5	5	7	9	9	5	5	9
		3	3	3	0	0	9	3	3	0	0	5	5	5	6	2	2	5	4	2
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		7	7	7	7	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4

Alimentary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

1-4 ..Lesion qualified as:

X ..Lesion present

A ..Autolysis precludes evaluation

1) Minimal 3) Moderate

I ..Insufficient tissue

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Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

Special Senses System

Urinary System

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Bilateral, Renal Tubule, Dilatation																					1 2.0
Cyst	X																				1
Nephropathy																					1 1.0
Right, Infarct, Multiple																					1 3.0
Urinary Bladder	+	+	+	+	+	+	+	+	+		+	+	+	A	+	+	+	+	+	+	19

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

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Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:44

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-10 SALINE		DAY ON TEST	Incidence of Lesions																				
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	3	2	3	0	0	3	3	5	5	5	9	9	9	5	5	9	9	9	9	
3	3	3	0	9	0	2	2	0	0	0	5	5	5	2	2	2	5	5	2	2	2	2	
0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
9	9	9	9	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	
7	8	9	9	0	1	2	3	4	5	6	7	8	9	0	1	1	2	3	4	5	6	7	

Alimentary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

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Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:45

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-10 SALINE	DAY ON TEST																				
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	2	3	0	0	3	3	5	5	5	9	9	9	5	5	9	9
		3	3	3	0	9	0	2	2	0	0	5	5	2	2	2	5	5	2	2	2
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		9	9	9	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1
		7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	1	2	3	4	5
		*TOTALS																			
Stomach, Glandular		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Cardiovascular System																					
Blood Vessel		+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	20
Heart		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Artery, Inflammation, Chronic Active																					1 2.0
Mineralization		2	2		1						1	1	1	2		1	2		1		10 1.4
Endocrine System																					
Adrenal Cortex		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Subcapsular, Hyperplasia, Focal																					1 1.0
Adrenal Medulla		+	+	+	+	+	I	+	+	+	+	+	+	+	+	+	+	+	I	+	19
Islets, Pancreatic		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	+	20
Parathyroid Gland		M	I	M	+	M	+	+	M	+	+	+	+	+	+	+	+	+	+	+	16
Pituitary Gland		+	+	+	+	+	+	+	+	+	I	+	+	M	+	I	+	+	I	+	16
Thyroid Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
General Body System																					
NONE																					
Genital System																					
Epididymis		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	+	20
Preputial Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Prostate		+	+	+	I	+	+	+	+	+	+	+	+	I	+	+	+	I	+	+	18
Seminal Vesicle		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:45

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-10 SALINE	DAY ON TEST	0 0																				
		0 0																				
	ANIMAL ID	0 0 0 3 2 3 0 0 3 3 5 5 5 9 9 9 5 5 9 9 9 9 9 9																				
		3 3 3 0 9 0 2 2 0 0 5 5 2 2 2 5 5 2 2 2 2 2 2 2																				
		0 0																				
*TOTALS																						
Seminal Vesicle		+ +																				21
Testes		+ +																				18
Hematopoietic System																						
Bone Marrow		+ +																				21
Myeloid Cell, Hyperplasia																						2
Lymph Node, Mandibular		I + I M + I + + + M + + + M + I I I M M +																				10
Left, Necrosis, Lymphocyte																						2
Right, Hyperplasia, Lymphoid																						1
Right, Necrosis, Lymphocyte																						1.5
Lymph Node, Mesenteric		+ + + + I + I + I + + + + + + + + + + + + + + + +																				17
Necrosis, Lymphocyte																						2.0
Spleen		+ +																				21
Hematopoietic Cell Proliferation		1 2 2 3 3 3 2 1 3 3 3 4 3 4 3 3 3 3 4 4 3 4																				21
Thymus		+ +																				2.9
Integumentary System																						
Mammary Gland		M M																				0
Skin		+ +																				21
Dermis, Epidermis, Subcut Tiss,																						4
Inflammation, Acute, Focal																						1 4.0
Musculoskeletal System																						
Bone		+ +																				21

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

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Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:45

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Male 1-10 SALINE	DAY ON TEST	0 0																		
		0 0																		
	ANIMAL ID	0 0 0 3 2 3 0 0 3 3 5 5 5 9 9 9 5 5 9 9 9 9 9 9																		
		3 3 3 0 9 0 2 2 0 0 5 5 2 2 2 5 5 2 2 2 2 2 2 2																		
		0 0																		
Hyperplasia																			2	
Nervous System																			1 2.0	
Brain																			21	
Respiratory System																			21	
Lung																			21	
Nose																			21	
Inflammation, Acute																			1 1.0	
Trachea																			18	
Special Senses System																			21	
Eye																			21	
Harderian Gland																			21	
Degeneration																			1 2.0	
Inflammation																			1 2.0	
Urinary System																			2	
Kidney																			21	
Renal Tubule, Casts Protein																			1 3.0	
Urinary Bladder																			20	
END OF MALE DATA																				

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:45

First Dose M/F: NA / NA

Lab: MBA

Alimentary System

Cardiovascular System

* ..Total animals with tissue examined microscopically: Total animals with lesion and mean severity grade

± .. Tissue examined microscopically

M ..Missing tissue

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CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:45

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Female ISORMCONSALINE	DAY ON TEST	0 0																		
		0 0																		
		0 0 0 3 3 3 0 0 3 3 5 5 5 9 9 9 5 5 9 9 9 9 9 9																		
		3 3 3 0 0 0 3 0 0 3 0 5 5 5 2 2 2 5 5 5 2 2 2 2																		
		0 0																		
		0 0																		
		0 0																		
		1 1																		
		1 1 2 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3																		
		8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8																		

***TOTALS**

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	20
Mineralization																			1	1.0	

Endocrine System

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Subcapsular, Hyperplasia, Focal																				5	1.0
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	M	M	+	18	
Pituitary Gland	+	+	+	+	+	+	+	M	+	+	+	+	I	+	+	+	+	+	+	19	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	

General Body System

NONE

Genital System

Clitoral Gland	+	+	+	I	+	I	+	+	+	M	I	+	+	+	+	M	+	+	+	M	M	14
Ovary	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	+	+	+	+	20
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Endometrium, Hyperplasia, Cystic																			1	1.0		
Endometrium, Hyperplasia, Cystic, Diffuse																				1	2.0	

Hematopoietic System

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Lymph Node, Mandibular	+	+	+	+	M	+	+	I	+	+	+	M	+	+	I	+	+	+	+	I	I	15

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:45

First Dose M/F: NA / NA

Lab: MBA

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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1-4 ..Lesion qualified as:

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

Urinary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

± .. Tissue examined microscopically

M ..Missing tissue

1-4 ..Lesion qualified as:

X - Lesion present

A. Autolysis precludes evaluation

1) Minimal 3) Moderate

| Insufficient tissue

BLANK - Not examined microscopically

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Female TRTRMCONSALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	3	5	5	5	9	9
		3	3	3	0	0	0	5	5	5	2	2
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1	1
		3	4	4	4	4	4	4	4	4	4	5
		9	0	1	2	3	4	5	6	7	8	9
		*TOTALS										

Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	+	12
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	12
Liver	+	+	+	+	+	+	+	+	+	+	+	12
Pancreas	+	+	+	+	+	+	+	+	+	+	+	12
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	12
Left, Submandibul GI, Inflammation, Chronic							1					1 1.0
Right, Submandibul GI, Inflammation								1				1 1.0
Right, Submandibul GI, Inflammation, Chronic							1					1 1.0

Cardiovascular System

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	12
Heart	+	+	+	+	+	+	+	+	+	+	+	12
Mineralization				1			2	1		2		4 1.5

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

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1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Female TRTRMCONSALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	3	5	5	9	9	9
		3	3	3	0	0	0	5	5	2	2	2
		9	0	1	2	3	4	5	6	7	8	9

TOTALS*Endocrine System**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	12
Subcapsular, Hyperplasia, Focal					1	1	1	1	1	1	1	5 1.0
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	1	11
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	12
Parathyroid Gland	+	M	+	+	+	+	M	+	+	M	+	9
Pituitary Gland	+	+	+	+	+	+	+	I	+	I	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	12

General Body System

NONE												
Genital System												
Clitoral Gland	+	+	+	+	M	+	M	M	+	+	M	7
Ovary	+	+	+	+	+	+	+	+	+	+	+	12
Uterus	+	+	+	+	+	+	+	+	+	+	+	12
Endometrium, Hyperplasia, Cystic, Diffuse					1				1	1	1.0	

Hematopoietic System

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	12
Lymph Node, Mandibular	+	+	+	+	+	+	+	I	I	+	+	10
Left, Hyperplasia, Lymphoid					2					1	2.0	
Right, Hyperplasia, Lymphoid					2					1	2.0	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	M	+	11

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Female TRTRMCONSALINE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0
		0	0	0	3	3	3	5	5	5	9	9
		3	3	3	0	0	0	5	5	5	2	2
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1	1
		3	4	4	4	4	4	4	4	4	4	5
		9	0	1	2	3	4	5	6	7	8	9
		*TOTALS										

Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	M	+	+	11
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	12
Hematopoietic Cell Proliferation	2	2	1	2	2	1	1	1	2	1	1	1	12
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	12

Integumentary System

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	12
Skin	+	+	+	+	+	+	+	+	+	+	+	+	12

Musculoskeletal System

Bone	+	+	+	+	+	+	+	+	+	+	+	+	12
------	---	---	---	---	---	---	---	---	---	---	---	---	----

Nervous System

Brain	+	+	+	+	+	+	+	+	+	+	+	+	12
-------	---	---	---	---	---	---	---	---	---	---	---	---	----

Respiratory System

Lung	+	+	+	+	+	+	+	+	+	+	+	+	12
Nose	+	+	+	+	+	+	+	+	+	+	I	+	11
Trachea	+	I	+	+	+	+	+	+	+	+	+	I	10

Special Senses System

Eye	+	+	+	+	+	+	+	+	+	+	+	+	12
Conjunctiva, Inflammation, Acute	1										1	1.0	
Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	12

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

	DAY ON TEST	BALB/C Mouse Female											
		0	0	0	0	0	0	0	0	0	0	0	0
TRTRMCONSALINE	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	3	3	3	5	5	5	9	9	9	9
	3	3	3	0	0	0	5	5	5	2	2	2	2
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
	9	0	0	1	2	3	4	5	6	7	8	9	0

*TOTALS

Urinary System

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	12
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	12

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

Alimentary System

Cardiovascular System

Blood Vessel	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	20
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21
Mineralization							2			2						1		1			4	1.5

Endocrine System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

1-4 ..Lesion qualified as:

X ..Lesion present

A ..Autolysis precludes evaluation

1) Minimal 3) Moderate

| ..Insufficient tissue

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2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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Date Report Requested: 10/23/2014

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First Dose M/F: NA / NA

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:46

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Female 1-8 SALINE		DAY ON TEST	TOE CLIP DATA																			
			L1		L2		L3		L4		L5		L6		L7		L8		L9		L10	
			Day	Clip	Day	Clip	Day	Clip	Day	Clip	Day	Clip	Day	Clip	Day	Clip	Day	Clip	Day	Clip	Day	Clip
			3	3	3	3	3	3	3	3	3	5	5	5	5	9	9	9	5	5	9	9
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	3	3	3	3	0	0	3	3	5	5	5	5	9	9	9	5	5	9	9	9
3	3	3	0	0	0	3	3	0	0	5	5	5	5	2	2	2	5	5	2	2	2	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
7	7	7	7	7	7	7	7	7	8	8	8	8	8	8	8	8	8	8	8	8	8	9
2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4

*TOTALS

Alimentary System

Cardiovascular System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

1-4 „Lesion qualified as:

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Test Type: 18-33 DAYS

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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:47

First Dose M/F: NA / NA

Lab: MBA

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Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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Date Report Requested: 10/23/2014

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First Dose M/F: NA / NA

Lab: MBA

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Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:47

First Dose M/F: NA / NA

Lab: MBA

Urinary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

± ..Tissue examined microscopically

M ..Missing tissue

1-4 ..Lesion qualified as:

X - Lesion present

A. Autolysis precludes evaluation

1) Minimal 3) Moderate

| Insufficient tissue

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Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:47

First Dose M/F: NA / NA

Lab: MBA

BALB/C Mouse Female 1-9 SALINE		DAY ON TEST	TO																				
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	3	3	3	0	0	3	3	5	5	5	5	9	9	9	0	5	9	9	9	9	
3	3	3	0	0	0	3	3	0	0	5	5	5	5	2	2	2	1	5	2	2	2	2	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
9	9	9	9	9	9	9	9	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	
3	4	5	6	7	8	9	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	*TO	

*TOTALS

Alimentary System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

M ..Missing tissue

1-4 „Lesion qualified as:

X ..Lesion present

A ..Autolysis precludes evaluation

1) Minimal 3) Moderate

I ..Insufficient tissue

BLANK ..Not examined microscopically

2) Mild 4) Marked

Experiment Number: 20305-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Mouse/BALB/C

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adeno-associated viral vector (hEPO)

CAS Number: HEPO

Date Report Requested: 10/23/2014

Time Report Requested: 09:07:47

First Dose M/F: NA / NA

Lab: MBA

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Urinary System

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Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21		
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	20		
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	20		
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	20		
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	20		
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	A	19	
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	A	19	
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	A	19	
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21		
Bile Duct, Concretion																	2		1	2.0	
Clear Cell Focus																	X			1	
Hematocyst																	X			1	
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21		
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21		
Left, Parotid GI, Vacuolization Cytoplasmic																		1		1	1.0
Right, Submandibul GI, Inflammation	1																			1	1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21		
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21		
Tooth																	+			1	
Peridont Tiss, Inflammation, Acute, Focal																	4			1	4.0

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BALB/C Mouse Female 1-10 SALINE	DAY ON TEST	0 0
		0 0
		0 0 0 3 3 3 0 0 3 3 5 5 5 9 9 9 5 5 6 9 6
		3 3 3 0 0 0 3 3 0 0 5 5 5 2 2 2 5 5 9 2 2
	ANIMAL ID	0 0
		0 0
		2 2
		1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3
		4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 3 3 3 4

TOTALS*Hematopoietic System**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	20			
Depletion Cellular, Diffuse																				2	1	2.0	
Lymph Node, Mandibular	+	M	+	+	+	+	+	+	I	+	+	+	+	+	+	+	+	+	+	19			
Left, Hyperplasia, Lymphoid																				2	1	2.0	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	A	18			
Spleen	+	+	+	I	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	20			
Hematopoietic Cell Proliferation	2	2	2	4	3	2	1	1	1	4	4	4	4	4	1	3	4	3	3	4	4	20	2.8
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	I	+	+	+	A	+	M	18		

Integumentary System

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	

Musculoskeletal System

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	----	--

Nervous System

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
-------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	----	--

Respiratory System

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	21	
Inflammation, Acute																				1	1.0

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