

Experiment Number: 20305-01
Test Type: 18-33 DAYS
Route: INTRADUCTAL CANNULATION
Species/Strain: Mouse/BALB/C

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Adeno-associated viral vector (hEPO)
CAS Number: HEPO

Date Report Requested: 10/23/2014
Time Report Requested: 09:04:28
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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BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Disposition Summary										
Animals Initially In Study	21	12		21		21		21		21
Scheduled Sacrifice	13	9		11		13		13		11
Early Deaths										
Natural Death	3			4		2		3		4
Survivors										
Natural Death	1	1								
Terminal Sacrifice	4	2		6		6		5		6
Animals Examined Microscopically	21	12		21		21		21		21
ALIMENTARY SYSTEM										
Esophagus	(19)	(12)		(20)		(20)		(20)		(21)
Gallbladder	(19)	(10)		(19)		(19)		(20)		(21)
Intestine Large, Cecum	(21)	(12)		(21)		(21)		(20)		(20)
Intestine Large, Colon	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Large, Rectum	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Small, Duodenum	(20)	(12)		(21)		(21)		(20)		(21)
Intestine Small, Ileum	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Small, Jejunum	(20)	(12)		(21)		(21)		(21)		(21)
Liver	(21)	(12)		(21)		(21)		(21)		(21)
Hematopoietic Cell Proliferation										1 [3.0]
Hepatocyte, Necrosis						1 [1.0]				
Hepatocyte, Vacuolization Cytoplasmic Inflammation, Chronic Active	3 [2.0]	4 [1.5]		3 [1.3]		3 [1.0]		6 [1.2]		2 [1.0]
Necrosis, Focal				1 [1.0]				1 [1.0]		
Pancreas	(21)	(12)		(21)		(21)		(21)		(21)
Salivary Glands	(21)	(12)		(21)		(21)		(21)		(21)
Left, Parotid GI, Vacuolization Cytoplasmic		1 [1.0]		1 [1.0]		1 [1.0]		1 [1.0]		3 [1.7]
Left, Sublingual GI, Inflammation						1 [1.0]				

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BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Left, Submandibul GI, Inflammation						1 [1.0]				
Left, Submandibul GI, Regeneration							1 [1.0]			
Parotid GI, Right, Inflammation						2 [2.5]			1 [2.0]	
Parotid GI, Right, Vacuolization Cytoplasmic	1 [1.0]	1 [2.0]				1 [1.0]			1 [1.0]	
Right, Submandibul GI, Degeneration		1 [1.0]		1 [1.0]		2 [1.5]			2 [2.5]	
Right, Submandibul GI, Inflammation		1 [1.0]		4 [1.0]		2 [2.0]			2 [2.5]	
Right, Submandibul GI, Necrosis		1 [1.0]				2 [2.5]			2 [2.0]	
Right, Submandibul GI, Regeneration		2 [2.5]		3 [2.7]					1 [1.0]	
Stomach, Forestomach	(21)	(12)		(21)		(21)		(21)	(21)	
Stomach, Glandular	(21)	(12)		(21)		(21)		(21)	(21)	
CARDIOVASCULAR SYSTEM										
Blood Vessel	(21)	(12)		(21)		(21)		(21)	(20)	
Hemorrhage								1 [3.0]		
Heart	(21)	(12)		(21)		(21)		(21)	(21)	
Artery, Inflammation, Chronic Active						1 [2.0]			1 [2.0]	
Mineralization	4 [1.3]			9 [1.1]		4 [2.0]		3 [2.0]	10 [1.4]	
Ventricle, Thrombosis, Focal						1 [4.0]				
ENDOCRINE SYSTEM										
Adrenal Cortex	(21)	(11)		(21)		(21)		(20)	(21)	
Subcapsular, Hyperplasia, Focal	1 [1.0]			2 [1.0]		2 [1.0]		3 [1.0]	1 [1.0]	
Adrenal Medulla	(21)	(11)		(21)		(19)		(20)	(19)	
Islets, Pancreatic	(20)	(12)		(21)		(20)		(21)	(20)	
Parathyroid Gland	(11)	(4)		(11)		(11)		(13)	(16)	
Pituitary Gland	(17)	(10)		(16)		(19)		(19)	(16)	
Thyroid Gland	(20)	(11)		(21)		(21)		(21)	(21)	
Follicle, Cyst								1		
GENERAL BODY SYSTEM										

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Test Compound: Adeno-associated viral vector (hEPO)
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Lab: MBA

BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
None										
GENITAL SYSTEM										
Epididymis	(21)	(12)		(21)		(21)	(21)		(20)	
Penis	(1)	(0)		(0)		(0)	(0)		(0)	
Preputial Gland	(21)	(11)		(21)		(21)	(20)		(21)	
Inflammation, Chronic Active, Focal			1 [2.0]				2 [1.5]			
Prostate	(21)	(12)		(20)		(21)	(20)		(18)	
Inflammation, Chronic Active, Focal	1 [2.0]									
Seminal Vesicle	(21)	(12)		(21)		(21)	(21)		(21)	
Testes	(21)	(12)		(21)		(19)	(20)		(18)	
Germinal Epith, Degeneration, Focal					1 [2.0]					
HEMATOPOIETIC SYSTEM										
Bone Marrow	(21)	(12)		(21)		(21)	(21)		(21)	
Myeloid Cell, Hyperplasia									1 [2.0]	
Lymph Node, Mandibular	(17)	(11)		(14)		(15)	(19)		(10)	
Left, Necrosis, Lymphocyte									1 [2.0]	
Right, Hyperplasia, Lymphoid		1 [2.0]				1 [1.0]			2 [1.5]	
Right, Necrosis, Lymphocyte									1 [2.0]	
Lymph Node, Mesenteric	(20)	(12)		(19)		(21)	(19)		(17)	
Hyperplasia, Lymphoid	1 [2.0]						1 [2.0]			
Necrosis, Lymphocyte									1 [2.0]	
Spleen	(20)	(11)		(21)		(20)	(20)		(21)	
Congestion, Diffuse			1 [2.0]							
Hematopoietic Cell Proliferation	20 [1.3]	11 [1.1]	21 [1.4]		20 [1.6]		20 [2.3]		21 [2.9]	
Thymus	(20)	(12)		(21)		(21)	(20)		(20)	
Atrophy					2 [4.0]		2 [1.0]			
INTEGUMENTARY SYSTEM										
Skin	(21)	(12)		(21)		(21)	(21)		(21)	

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BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE	1-9 SALINE	1-10 SALINE
Dermis, Epidermis, Subcut Tiss, Inflammation, Acute, Focal						1 [4.0]
Epidermis, Ulcer, Focal Inflammation			1 [4.0]		1 [1.0]	
MUSCULOSKELETAL SYSTEM						
Bone	(21)	(12)	(21)	(20)	(21)	(21)
Hyperplasia						1 [2.0]
Skeletal Muscle	(0)	(0)	(1)	(0)	(0)	(0)
Hemorrhage, Focal			1 [3.0]			
Inflammation, Acute, Focal			1 [2.0]			
NERVOUS SYSTEM						
Brain	(21)	(12)	(21)	(21)	(21)	(21)
RESPIRATORY SYSTEM						
Lung	(21)	(12)	(21)	(21)	(21)	(21)
Alveolar Epith, Hyperplasia			1 [2.0]	1 [2.0]		
Alveolus, Inflammation, Acute, Focal	1 [2.0]		1 [1.0]			
Nose	(20)	(12)	(21)	(21)	(21)	(21)
Inflammation, Acute				2 [1.0]	1 [1.0]	1 [1.0]
Trachea	(14)	(11)	(13)	(17)	(15)	(18)
SPECIAL SENSES SYSTEM						
Eye	(21)	(11)	(21)	(21)	(19)	(21)
Harderian Gland	(20)	(12)	(21)	(21)	(21)	(21)
Degeneration						1 [2.0]
Inflammation						1 [2.0]
URINARY SYSTEM						
Kidney	(21)	(12)	(21)	(21)	(21)	(21)
Bilateral, Renal Tubule, Dilatation					1 [2.0]	

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BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE	1-9 SALINE	1-10 SALINE
Cyst					1	
Nephropathy					1 [1.0]	
Renal Tubule, Casts Protein						1 [3.0]
Right, Infarct, Multiple					1 [3.0]	
Urinary Bladder	(19)	(12)	(20)	(21)	(19)	(20)

END OF MALE DATA

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Disposition Summary										
Animals Initially In Study	21	12		21		21		21		21
Scheduled Sacrifice	15	9		13		15		14		15
Early Deaths										
Natural Death				2				1		2
Survivors										
Terminal Sacrifice	6	3		6		6		6		4
Animals Examined Microscopically	21	12		21		21		21		21
ALIMENTARY SYSTEM										
Esophagus	(21)	(12)		(20)		(21)		(21)		(21)
Gallbladder	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Large, Cecum	(21)	(12)		(21)		(21)		(21)		(20)
Intestine Large, Colon	(21)	(12)		(21)		(21)		(21)		(20)
Intestine Large, Rectum	(21)	(12)		(21)		(21)		(21)		(20)
Intestine Small, Duodenum	(21)	(12)		(21)		(21)		(21)		(19)
Intestine Small, Ileum	(21)	(12)		(21)		(21)		(21)		(19)
Intestine Small, Jejunum	(21)	(12)		(21)		(21)		(21)		(19)
Liver	(21)	(12)		(21)		(21)		(21)		(21)
Bile Duct, Concretion										1 [2.0]
Clear Cell Focus										1
Hematocyst										1
Inflammation, Chronic Active	1 [1.0]			1 [1.0]		2 [1.0]		1 [1.0]		
Necrosis, Focal						1 [1.0]				
Pancreas	(21)	(12)		(21)		(21)		(21)		(21)
Salivary Glands	(21)	(12)		(21)		(21)		(21)		(21)
Left, Parotid G1, Vacuolization Cytoplasmic										1 [1.0]
Left, Submandibul G1, Inflammation	1 [1.0]									
Left, Submandibul G1, Inflammation, Chronic		1 [1.0]								

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Parotid Gl, Right, Inflammation					1 [1.0]					
Parotid Gl, Right, Vacuolization Cytoplasmic	1 [1.0]									
Right, Submandibul Gl, Degeneration	3 [2.0]				1 [1.0]		1 [1.0]			
Right, Submandibul Gl, Inflammation	3 [1.0]	1 [1.0]			3 [1.0]		2 [1.0]		1 [1.0]	
Right, Submandibul Gl, Inflammation, Chronic		1 [1.0]								
Right, Submandibul Gl, Necrosis	2 [1.5]				1 [1.0]		1 [1.0]			
Right, Submandibul Gl, Regeneration					1 [2.0]		1 [4.0]			
Stomach, Forestomach	(21)	(12)		(21)	(21)		(21)		(21)	
Stomach, Glandular	(21)	(12)		(21)	(21)		(21)		(21)	
Tooth	(0)	(0)		(0)	(0)		(0)		(1)	
Peridont Tiss, Inflammation, Acute, Focal									1 [4.0]	
CARDIOVASCULAR SYSTEM										
Blood Vessel	(21)	(12)		(20)	(21)		(21)		(21)	
Heart	(20)	(12)		(21)	(21)		(21)		(21)	
Mineralization	1 [1.0]	4 [1.5]		4 [1.5]	3 [1.7]		8 [1.3]		2 [2.0]	
Valve, Thrombosis									1 [3.0]	
ENDOCRINE SYSTEM										
Adrenal Cortex	(21)	(12)		(21)	(21)		(20)		(21)	
Subcapsular, Hyperplasia, Focal	5 [1.0]	5 [1.0]		5 [1.0]	5 [1.0]		7 [1.0]		4 [1.0]	
Adrenal Medulla	(21)	(11)		(20)	(21)		(20)		(21)	
Islets, Pancreatic	(21)	(12)		(21)	(21)		(20)		(21)	
Parathyroid Gland	(18)	(9)		(13)	(14)		(12)		(17)	
Angiectasis									1 [1.0]	
Pituitary Gland	(19)	(10)		(19)	(21)		(17)		(15)	
Thyroid Gland	(21)	(12)		(19)	(20)		(20)		(21)	
GENERAL BODY SYSTEM										
None										

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
None										
GENITAL SYSTEM										
Clitoral Gland	(14)	(7)		(15)		(14)		(17)		(16)
Infiltration Cellular, Mononuclear Cl, Focal				1 [1.0]						
Ovary	(20)	(12)		(20)		(20)		(20)		(20)
Uterus	(21)	(12)		(21)		(21)		(21)		(20)
Endometrium, Hyperplasia, Cystic	1 [1.0]									
Endometrium, Hyperplasia, Cystic, Diffuse	1 [2.0]	1 [1.0]		2 [2.0]		2 [1.0]		3 [1.0]		1 [1.0]
HEMATOPOIETIC SYSTEM										
Bone Marrow	(21)	(12)		(21)		(20)		(20)		(20)
Depletion Cellular, Diffuse						1 [2.0]				1 [2.0]
Lymph Node, Mandibular	(15)	(10)		(11)		(19)		(17)		(19)
Left, Depletion Lymphoid								1 [2.0]		
Left, Hyperplasia, Lymphoid		1 [2.0]								1 [2.0]
Right, Hyperplasia, Lymphoid	1 [1.0]	1 [2.0]						1 [2.0]		
Lymph Node, Mesenteric	(20)	(11)		(19)		(21)		(20)		(18)
Spleen	(21)	(12)		(21)		(21)		(21)		(20)
Hematopoietic Cell Proliferation	21 [1.2]	12 [1.4]		21 [1.4]		21 [2.2]		21 [2.6]		20 [2.8]
Thymus	(21)	(12)		(21)		(21)		(21)		(18)
INTEGUMENTARY SYSTEM										
Mammary Gland	(21)	(12)		(20)		(21)		(21)		(21)
Skin	(21)	(12)		(21)		(21)		(21)		(21)
MUSCULOSKELETAL SYSTEM										
Bone	(21)	(12)		(21)		(20)		(20)		(21)
NERVOUS SYSTEM										
Brain	(21)	(12)		(21)		(21)		(21)		(21)
RESPIRATORY SYSTEM										

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Lung	(21)	(12)		(20)		(21)	(21)		(21)	
Nose	(21)	(11)		(21)		(21)	(21)		(21)	
Inflammation, Acute									1 [1.0]	
Trachea	(16)	(10)		(16)		(19)	(11)		(17)	
SPECIAL SENSES SYSTEM										
Eye	(21)	(12)		(21)		(21)	(19)		(19)	
Conjunctiva, Inflammation, Acute		1 [1.0]								
Harderian Gland	(21)	(12)		(21)		(21)	(21)		(21)	
URINARY SYSTEM										
Kidney	(21)	(12)		(21)		(21)	(21)		(21)	
Bilateral, Renal Tubule, Dilatation									1 [2.0]	
Urinary Bladder	(21)	(12)		(21)		(21)	(20)		(21)	

**** END OF REPORT ****

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