

TDMS No. 20311 - 01

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Date Report Requested: 06/30/2009

Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C Number: C20311
Lock Date: 12/01/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Male
TDMSE Version: 2.1.0

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZT-H to 0	AZT-M to 0	AZT-L to 0	AZT-H/3TC-H to 0	AZT-M/3TC-M to 0	AZT-L/3TC-L to 0
Disposition Summary						
Animals Initially in Study	48	48	48	48	48	51
Early Deaths						
Moribund Sacrifice	8	5	8	6	5	7
Natural Death	2	3		5	4	1
Survivors						
Moribund Sacrifice	1	1			1	3
Natural Death	1	1				
Terminal Sacrifice	35	38	39	34	35	39
Harvest	1		1	3	3	1
Animals Examined Microscopically	48	48	48	48	48	51

ALIMENTARY SYSTEM

Gallbladder	(45)	(44)	(48)	(44)	(42)	(49)
Intestine Large, Cecum	(45)	(45)	(48)	(43)	(45)	(50)
Intestine Large, Colon	(45)	(46)	(48)	(44)	(45)	(50)
Intestine Large, Rectum	(45)	(45)	(48)	(43)	(45)	(50)
Anus, Fibrosarcoma, Metastatic, Skin						
Intestine Small, Duodenum	(45)	(45)	(48)	(43)	(44)	(50)
Adenoma	1 (2%)					2 (4%)
Fibrous Histiocytoma						1 (2%)
Intestine Small, Ileum	(45)	(45)	(48)	(43)	(45)	(50)
Intestine Small, Jejunum	(45)	(44)	(48)	(43)	(46)	(50)
Adenocarcinoma						
Liver	(46)	(47)	(48)	(46)	(48)	(51)
Fibrous Histiocytoma						
Hemangioma					1 (2%)	
Hemangiosarcoma	1 (2%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Hepatoblastoma						
Hepatocellular Adenoma	8 (17%)	9 (19%)	9 (19%)	7 (15%)	5 (10%)	5 (10%)
Hepatocellular Adenoma, Multiple		1 (2%)	1 (2%)	2 (4%)		2 (4%)
Hepatocellular Carcinoma	9 (20%)	6 (13%)	6 (13%)	12 (26%)	9 (19%)	5 (10%)
Hepatocellular Carcinoma, Multiple		2 (4%)	2 (4%)	1 (2%)	1 (2%)	2 (4%)
Hepatocholangiocarcinoma	2 (4%)	2 (4%)		1 (2%)	1 (2%)	
Liposarcoma, Metastatic, Skin			1 (2%)			
Mesentery	(3)	(1)	(2)	(0)	(1)	(2)

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Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZT-H to 0	AZT-M to 0	AZT-L to 0	AZT-H/3TC-H to 0	AZT-M/3TC-M to 0	AZT-L/3TC-L to 0
Fibrosarcoma						
Hemangiosarcoma	1 (33%)					
Hemangiosarcoma, Metastatic, Liver						
Hepatocellular Carcinoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver		1 (100%)			1 (100%)	
Liposarcoma, Metastatic, Skin			1 (50%)			
Pancreas	(46)	(46)	(48)	(45)	(45)	(50)
Fibrous Histiocytoma						
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)	1 (2%)		1 (2%)		
Salivary Glands	(46)	(46)	(48)	(44)	(47)	(50)
Stomach, Forestomach	(46)	(46)	(48)	(45)	(45)	(50)
Squamous Cell Papilloma		3 (7%)	2 (4%)	1 (2%)		2 (4%)
Stomach, Glandular	(45)	(44)	(48)	(43)	(45)	(50)
Adenoma						
Tongue	(0)	(0)	(0)	(1)	(0)	(0)
Squamous Cell Carcinoma				1 (100%)		
CARDIOVASCULAR SYSTEM						
Blood Vessel	(47)	(47)	(48)	(46)	(48)	(50)
Fibrous Histiocytoma						
Hepatocholangiocarcinoma, Metastatic, Liver				1 (2%)		
Heart	(47)	(48)	(48)	(46)	(48)	(50)
Hemangiosarcoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)	1 (2%)		1 (2%)	1 (2%)	
Sarcoma, Metastatic, Lung		1 (2%)				
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)				
ENDOCRINE SYSTEM						
Adrenal Cortex	(47)	(45)	(48)	(45)	(46)	(50)
Fibrous Histiocytoma						
Hepatocholangiocarcinoma, Metastatic, Liver						

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZT-H to 0	AZT-M to 0	AZT-L to 0	AZT-H/3TC-H to 0	AZT-M/3TC-M to 0	AZT-L/3TC-L to 0
Subcapsular, Adenoma	2 (4%)	1 (2%)	1 (2%)		3 (7%)	2 (4%)
Subcapsular, Carcinoma			1 (2%)			
Adrenal Medulla	(45)	(45)	(46)	(43)	(46)	(49)
Pheochromocytoma Benign		1 (2%)				1 (2%)
Pheochromocytoma Malignant	1 (2%)					
Islets, Pancreatic	(47)	(48)	(48)	(45)	(44)	(50)
Adenoma						
Fibrous Histiocytoma						
Parathyroid Gland	(43)	(41)	(37)	(41)	(37)	(45)
Adenoma					1 (3%)	
Pituitary Gland	(45)	(48)	(47)	(45)	(44)	(50)
Pars Distalis, Adenoma	1 (2%)					
Pars Intermedia, Adenoma						
Thyroid Gland	(46)	(45)	(48)	(46)	(46)	(50)
Follicular Cell, Adenoma		1 (2%)	1 (2%)	1 (2%)		1 (2%)
Follicular Cell, Carcinoma						
GENERAL BODY SYSTEM						
Tissue NOS	(1)	(2)	(0)	(3)	(1)	(1)
Fibrous Histiocytoma						
Hepatocellular Carcinoma, Metastatic, Liver				1 (33%)		
Hepatocholangiocarcinoma, Metastatic, Liver				1 (33%)		
Sarcoma, Metastatic, Skeletal Muscle		1 (50%)				
Abdominal, Fibrous Histiocytoma						1 (100%)
Abdominal, Hemangiosarcoma						
Thoracic, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (100%)					
Thoracic, Fibrous Histiocytoma						
Thoracic, Hepatocholangiocarcinoma, Metastatic, Liver		1 (50%)				
GENITAL SYSTEM						
Coagulating Gland	(0)	(1)	(0)	(1)	(0)	(2)
Epididymis	(46)	(45)	(48)	(45)	(46)	(50)
Fibrosarcoma, Metastatic, Skin						

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Fibrous Histiocytoma						
Hemangioma			1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver				1 (2%)		
Preputial Gland	(46)	(44)	(48)	(44)	(46)	(50)
Adenoma					1 (2%)	
Hemangiosarcoma						
Sarcoma						1 (2%)
Prostate	(44)	(43)	(48)	(44)	(46)	(50)
Fibrous Histiocytoma						
Sarcoma						1 (2%)
Seminal Vesicle	(46)	(46)	(48)	(45)	(45)	(50)
Fibrous Histiocytoma						
Testes	(45)	(45)	(48)	(44)	(45)	(50)
Fibrous Histiocytoma						
Lipoma						
Sertoli Cell Tumor Benign						
HEMATOPOIETIC SYSTEM						
Bone Marrow	(46)	(46)	(48)	(44)	(46)	(51)
Hemangiosarcoma				1 (2%)		2 (4%)
Hemangiosarcoma, Metastatic, Mesentery	1 (2%)					
Hemangiosarcoma, Metastatic, Preputial Gland						
Hemangiosarcoma, Metastatic, Uncertain Primary Site			1 (2%)			
Lymph Node	(1)	(7)	(4)	(3)	(4)	(3)
Axillary, Fibrous Histiocytoma, Metastatic, Skin						
Lumbar, Fibrous Histiocytoma						
Lumbar, Hemangiosarcoma, Metastatic, Uncertain Primary Site			1 (25%)			
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung						
Mediastinal, Sarcoma, Metastatic, Lung		1 (14%)				
Mediastinal, Sarcoma, Metastatic, Skeletal Muscle		1 (14%)				
Renal, Fibrous Histiocytoma						

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Renal, Hemangiosarcoma, Metastatic, Uncertain Primary Site			1 (25%)			
Lymph Node, Mandibular	(43)	(45)	(46)	(45)	(46)	(50)
Lymph Node, Mesenteric	(45)	(46)	(48)	(44)	(46)	(50)
Fibrous Histiocytoma						1 (2%)
Hemangiosarcoma	1 (2%)	1 (2%)				
Hemangiosarcoma, Metastatic, Uncertain Primary Site			1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)					
Spleen	(46)	(45)	(48)	(45)	(47)	(50)
Fibrous Histiocytoma						1 (2%)
Hemangiosarcoma	1 (2%)	2 (4%)	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver				1 (2%)	1 (2%)	
Thymus	(37)	(39)	(43)	(38)	(43)	(48)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (3%)					
Fibrous Histiocytoma						
Hemangiosarcoma					1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (3%)	1 (3%)		1 (3%)	1 (2%)	
Sarcoma, Metastatic, Skeletal Muscle		1 (3%)				
INTEGUMENTARY SYSTEM						
Skin	(46)	(48)	(48)	(46)	(48)	(50)
Hemangiosarcoma					1 (2%)	
Squamous Cell Papilloma						
Ear, Squamous Cell Papilloma						
Subcutaneous Tissue, Fibroma	2 (4%)		1 (2%)	1 (2%)	1 (2%)	
Subcutaneous Tissue, Fibroma, Multiple		1 (2%)				
Subcutaneous Tissue, Fibrosarcoma	2 (4%)		2 (4%)	2 (4%)	1 (2%)	
Subcutaneous Tissue, Fibrosarcoma, Multiple						
Subcutaneous Tissue, Fibrous Histiocytoma						
Subcutaneous Tissue, Liposarcoma			1 (2%)			
Subcutaneous Tissue, Sarcoma		1 (2%)				
Subcutaneous Tissue, Schwannoma						

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Malignant						
MUSCULOSKELETAL SYSTEM						
Bone	(0)	(0)	(1)	(0)	(0)	(0)
Mandible, Osteosarcoma						
Skeletal Muscle	(3)	(4)	(1)	(0)	(1)	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (33%)	1 (25%)				
Hepatocholangiocarcinoma, Metastatic, Liver	2 (67%)	2 (50%)			1 (100%)	
Sarcoma		1 (25%)				
NERVOUS SYSTEM						
Brain, Cerebellum	(46)	(46)	(48)	(46)	(45)	(50)
Brain, Cerebrum	(46)	(46)	(48)	(45)	(45)	(50)
RESPIRATORY SYSTEM						
Lung	(47)	(46)	(48)	(48)	(47)	(50)
Alveolar/Bronchiolar Adenoma	5 (11%)	7 (15%)	7 (15%)	8 (17%)	5 (11%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)		1 (2%)			1 (2%)
Alveolar/Bronchiolar Carcinoma	4 (9%)	3 (7%)	1 (2%)	2 (4%)	3 (6%)	6 (12%)
Alveolar/Bronchiolar Carcinoma, Multiple				1 (2%)		
Fibrous Histiocytoma						
Fibrous Histiocytoma, Metastatic, Skin						
Hepatocellular Carcinoma, Metastatic, Liver			1 (2%)	1 (2%)	2 (4%)	1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver	2 (4%)	2 (4%)		1 (2%)	1 (2%)	
Liposarcoma, Metastatic, Skin			1 (2%)			
Sarcoma		1 (2%)				
Sarcoma, Metastatic, Skeletal Muscle		1 (2%)				
Nose	(47)	(48)	(48)	(46)	(46)	(51)
SPECIAL SENSES SYSTEM						

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Eye	(45)	(43)	(48)	(43)	(45)	(50)
Harderian Gland	(45)	(45)	(48)	(45)	(45)	(50)
Adenocarcinoma		1 (2%)				
Adenoma	4 (9%)	1 (2%)	3 (6%)	6 (13%)	5 (11%)	4 (8%)
Adenoma, Multiple			1 (2%)			
URINARY SYSTEM						
Kidney	(46)	(45)	(48)	(44)	(46)	(50)
Fibrous Histiocytoma						
Hepatocellular Carcinoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		1 (2%)	1 (2%)	
Urethra	(1)	(1)	(0)	(0)	(0)	(0)
Urinary Bladder	(46)	(45)	(48)	(45)	(46)	(50)
Fibrous Histiocytoma						
Transitional Epithelium, Papilloma				1 (2%)		
SYSTEMIC LESIONS						
Multiple Organs	*(48)	*(48)	*(48)	*(48)	*(48)	*(51)
Histiocytic Sarcoma	1 (2%)	2 (4%)		3 (6%)		1 (2%)
Lymphoma Malignant	5 (10%)	9 (19%)	7 (15%)	3 (6%)	14 (29%)	5 (10%)

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* Number of animals with any tissue examined microscopically

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
Disposition Summary						
Animals Initially in Study	50	48	48	15	51	48
Early Deaths						
Moribund Sacrifice	18	10	8	6	5	6
Natural Death	2	2	1	1	2	3
Survivors						
Moribund Sacrifice	5				5	1
Natural Death		1	1		1	
Terminal Sacrifice	25	35	37	6	36	37
Harvest			1	2	2	1
Animals Examined Microscopically	50	48	48	15	51	48

ALIMENTARY SYSTEM

Gallbladder	(47)	(44)	(45)	(13)	(47)	(45)
Intestine Large, Cecum	(48)	(45)	(47)	(14)	(48)	(45)
Intestine Large, Colon	(48)	(45)	(47)	(14)	(48)	(45)
Intestine Large, Rectum	(47)	(45)	(47)	(14)	(48)	(45)
Anus, Fibrosarcoma, Metastatic, Skin			1 (2%)			
Intestine Small, Duodenum	(48)	(45)	(47)	(14)	(48)	(45)
Adenoma		1 (2%)	2 (4%)		1 (2%)	1 (2%)
Fibrous Histiocytoma						
Intestine Small, Ileum	(48)	(45)	(47)	(14)	(48)	(45)
Intestine Small, Jejunum	(48)	(45)	(47)	(14)	(48)	(45)
Adenocarcinoma				1 (7%)		
Liver	(48)	(47)	(48)	(15)	(50)	(48)
Fibrous Histiocytoma				1 (7%)		1 (2%)
Hemangioma						
Hemangiosarcoma		1 (2%)	1 (2%)	2 (13%)	2 (4%)	1 (2%)
Hepatoblastoma			1 (2%)			
Hepatocellular Adenoma	9 (19%)	7 (15%)	7 (15%)	2 (13%)	5 (10%)	4 (8%)
Hepatocellular Adenoma, Multiple	3 (6%)		2 (4%)	1 (7%)	2 (4%)	1 (2%)
Hepatocellular Carcinoma	8 (17%)	8 (17%)	5 (10%)	2 (13%)	7 (14%)	8 (17%)
Hepatocellular Carcinoma, Multiple		3 (6%)	4 (8%)	2 (13%)	2 (4%)	
Hepatocholangiocarcinoma					1 (2%)	1 (2%)
Liposarcoma, Metastatic, Skin						
Mesentery	(1)	(0)	(1)	(0)	(2)	(0)

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Fibrosarcoma			1 (100%)			
Hemangiosarcoma						
Hemangiosarcoma, Metastatic, Liver						
Hepatocellular Carcinoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver					1 (50%)	
Liposarcoma, Metastatic, Skin						
Pancreas	(48)	(45)	(47)	(15)	(49)	(45)
Fibrous Histiocytoma			1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver					1 (2%)	
Salivary Glands	(48)	(45)	(47)	(15)	(50)	(46)
Stomach, Forestomach	(48)	(45)	(48)	(15)	(50)	(45)
Squamous Cell Papilloma	1 (2%)	1 (2%)			1 (2%)	1 (2%)
Stomach, Glandular	(47)	(45)	(47)	(14)	(48)	(45)
Adenoma						1 (2%)
Tongue	(0)	(0)	(0)	(0)	(0)	(0)
Squamous Cell Carcinoma						
CARDIOVASCULAR SYSTEM						
Blood Vessel	(48)	(47)	(47)	(15)	(50)	(48)
Fibrous Histiocytoma			1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver						
Heart	(48)	(47)	(47)	(15)	(50)	(48)
Hemangiosarcoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver						1 (2%)
Sarcoma, Metastatic, Lung						
Sarcoma, Metastatic, Skeletal Muscle						
ENDOCRINE SYSTEM						
Adrenal Cortex	(47)	(45)	(47)	(15)	(49)	(45)
Fibrous Histiocytoma			1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver					1 (2%)	

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Subcapsular, Adenoma		1 (2%)			1 (2%)	
Subcapsular, Carcinoma						
Adrenal Medulla	(46)	(44)	(46)	(13)	(47)	(44)
Pheochromocytoma Benign	2 (4%)		1 (2%)			
Pheochromocytoma Malignant						
Islets, Pancreatic	(48)	(45)	(47)	(15)	(50)	(45)
Adenoma		1 (2%)				
Fibrous Histiocytoma			1 (2%)			
Parathyroid Gland	(34)	(33)	(38)	(13)	(40)	(38)
Adenoma						
Pituitary Gland	(48)	(44)	(46)	(15)	(50)	(46)
Pars Distalis, Adenoma						
Pars Intermedia, Adenoma					1 (2%)	
Thyroid Gland	(48)	(45)	(48)	(15)	(50)	(46)
Follicular Cell, Adenoma		1 (2%)	1 (2%)			
Follicular Cell, Carcinoma						1 (2%)
GENERAL BODY SYSTEM						
Tissue NOS	(0)	(0)	(2)	(2)	(1)	(2)
Fibrous Histiocytoma						1 (50%)
Hepatocellular Carcinoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver					1 (100%)	
Sarcoma, Metastatic, Skeletal Muscle Abdominal, Fibrous Histiocytoma			1 (50%)			
Abdominal, Hemangiosarcoma						
Thoracic, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (50%)		
Thoracic, Fibrous Histiocytoma				1 (50%)		
Thoracic, Hepatocholangiocarcinoma, Metastatic, Liver						1 (50%)
GENITAL SYSTEM						
Coagulating Gland	(0)	(1)	(1)	(0)	(0)	(1)
Epididymis	(48)	(45)	(47)	(15)	(50)	(45)
Fibrosarcoma, Metastatic, Skin			1 (2%)			

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* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
Fibrous Histiocytoma			1 (2%)			
Hemangioma						
Hepatocholangiocarcinoma, Metastatic, Liver					1 (2%)	
Preputial Gland Adenoma	(48)	(44)	(48)	(15)	(50)	(47)
Hemangiosarcoma Sarcoma			3 (6%)			
Prostate Fibrous Histiocytoma Sarcoma	(48)	(43)	(47)	(15)	(48)	(44)
Seminal Vesicle Fibrous Histiocytoma	(49)	(45)	(48)	(15)	(49)	(46)
Testes Fibrous Histiocytoma	(49)	(45)	(47)	(15)	(49)	(45)
Lipoma	1 (2%)		1 (2%)			
Sertoli Cell Tumor Benign					1 (2%)	

HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(45)	(48)	(15)	(50)	(45)
Hemangiosarcoma	1 (2%)					
Hemangiosarcoma, Metastatic, Mesentery						
Hemangiosarcoma, Metastatic, Preputial Gland			1 (2%)			
Hemangiosarcoma, Metastatic, Uncertain Primary Site						
Lymph Node	(6)	(2)	(3)	(3)	(3)	(4)
Axillary, Fibrous Histiocytoma, Metastatic, Skin	1 (17%)					
Lumbar, Fibrous Histiocytoma				1 (33%)		
Lumbar, Hemangiosarcoma, Metastatic, Uncertain Primary Site						
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung						
Mediastinal, Sarcoma, Metastatic, Lung						
Mediastinal, Sarcoma, Metastatic, Skeletal Muscle						
Renal, Fibrous Histiocytoma				1 (33%)		

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
Renal, Hemangiosarcoma, Metastatic, Uncertain Primary Site						
Lymph Node, Mandibular	(47)	(45)	(46)	(14)	(49)	(46)
Lymph Node, Mesenteric	(48)	(45)	(46)	(14)	(48)	(46)
Fibrous Histiocytoma			1 (2%)	1 (7%)		2 (4%)
Hemangiosarcoma						
Hemangiosarcoma, Metastatic, Uncertain Primary Site						
Hepatocholangiocarcinoma, Metastatic, Liver					1 (2%)	
Spleen	(48)	(45)	(47)	(15)	(49)	(45)
Fibrous Histiocytoma				1 (7%)		1 (2%)
Hemangiosarcoma	2 (4%)	2 (4%)	1 (2%)		5 (10%)	2 (4%)
Hepatocholangiocarcinoma, Metastatic, Liver						
Thymus	(38)	(37)	(39)	(12)	(44)	(35)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung						
Fibrous Histiocytoma			1 (3%)			
Hemangiosarcoma						
Hepatocholangiocarcinoma, Metastatic, Liver					1 (2%)	1 (3%)
Sarcoma, Metastatic, Skeletal Muscle						
INTEGUMENTARY SYSTEM						
Skin	(48)	(48)	(47)	(15)	(51)	(48)
Hemangiosarcoma			1 (2%)			
Squamous Cell Papilloma						
Ear, Squamous Cell Papilloma						1 (2%)
Subcutaneous Tissue, Fibroma	2 (4%)		1 (2%)			
Subcutaneous Tissue, Fibroma, Multiple						
Subcutaneous Tissue, Fibrosarcoma	7 (15%)	5 (10%)	1 (2%)	1 (7%)	3 (6%)	1 (2%)
Subcutaneous Tissue, Fibrosarcoma, Multiple	1 (2%)	1 (2%)				
Subcutaneous Tissue, Fibrous Histiocytoma	2 (4%)	1 (2%)				
Subcutaneous Tissue, Liposarcoma						
Subcutaneous Tissue, Sarcoma						
Subcutaneous Tissue, Schwannoma				1 (7%)		

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
Malignant						
MUSCULOSKELETAL SYSTEM						
Bone	(0)	(0)	(0)	(0)	(0)	(1)
Mandible, Osteosarcoma						1 (100%)
Skeletal Muscle	(0)	(0)	(0)	(0)	(1)	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung						
Hepatocellular Carcinoma, Metastatic, Liver Sarcoma					1 (100%)	
NERVOUS SYSTEM						
Brain, Cerebellum	(48)	(47)	(47)	(15)	(50)	(46)
Brain, Cerebrum	(48)	(47)	(47)	(15)	(50)	(46)
RESPIRATORY SYSTEM						
Lung	(48)	(45)	(47)	(15)	(50)	(47)
Alveolar/Bronchiolar Adenoma	5 (10%)	3 (7%)	5 (11%)		4 (8%)	3 (6%)
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)				
Alveolar/Bronchiolar Carcinoma	1 (2%)	2 (4%)	1 (2%)	1 (7%)	1 (2%)	3 (6%)
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)		1 (2%)	
Fibrous Histiocytoma			1 (2%)			
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)					
Hepatocellular Carcinoma, Metastatic, Liver				3 (20%)	1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver					1 (2%)	1 (2%)
Liposarcoma, Metastatic, Skin						
Sarcoma						
Sarcoma, Metastatic, Skeletal Muscle						
Nose	(49)	(46)	(47)	(15)	(51)	(47)
SPECIAL SENSES SYSTEM						

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

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Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
Eye	(48)	(45)	(47)	(14)	(49)	(45)
Harderian Gland	(48)	(45)	(47)	(14)	(50)	(45)
Adenocarcinoma						
Adenoma	5 (10%)		5 (11%)	3 (21%)	7 (14%)	2 (4%)
Adenoma, Multiple		1 (2%)				
URINARY SYSTEM						
Kidney	(48)	(45)	(47)	(14)	(49)	(46)
Fibrous Histiocytoma			1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver						
Hepatocholangiocarcinoma, Metastatic, Liver					1 (2%)	
Urethra	(0)	(0)	(0)	(0)	(0)	(2)
Urinary Bladder	(48)	(46)	(47)	(15)	(50)	(46)
Fibrous Histiocytoma			1 (2%)			
Transitional Epithelium, Papilloma						2 (4%)
SYSTEMIC LESIONS						
Multiple Organs	*(50)	*(48)	*(48)	*(15)	*(51)	*(48)
Histiocytic Sarcoma						
Lymphoma Malignant	4 (8%)	4 (8%)	8 (17%)	4 (27%)	5 (10%)	7 (15%)

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AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE

SOLVENT to 0

Disposition Summary

Animals Initially in Study	65
Early Deaths	
Moribund Sacrifice	4
Natural Death	2
Survivors	
Moribund Sacrifice	10
Natural Death	1
Terminal Sacrifice	46
Harvest	2
Animals Examined Microscopically	65

ALIMENTARY SYSTEM

Gallbladder	(59)
Intestine Large, Cecum	(63)
Intestine Large, Colon	(63)
Intestine Large, Rectum	(63)
Anus, Fibrosarcoma, Metastatic, Skin	
Intestine Small, Duodenum	(63)
Adenoma	1 (2%)
Fibrous Histiocytoma	
Intestine Small, Ileum	(63)
Intestine Small, Jejunum	(62)
Adenocarcinoma	
Liver	(65)
Fibrous Histiocytoma	
Hemangioma	
Hemangiosarcoma	5 (8%)
Hepatoblastoma	1 (2%)
Hepatocellular Adenoma	15 (23%)
Hepatocellular Adenoma, Multiple	2 (3%)
Hepatocellular Carcinoma	10 (15%)
Hepatocellular Carcinoma, Multiple	2 (3%)
Hepatocholangiocarcinoma	
Liposarcoma, Metastatic, Skin	
Mesentery	(4)

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

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Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0
Fibrosarcoma	
Hemangiosarcoma	
Hemangiosarcoma, Metastatic, Liver	1 (25%)
Hepatocellular Carcinoma, Metastatic, Liver	1 (25%)
Hepatocholangiocarcinoma, Metastatic, Liver	
Liposarcoma, Metastatic, Skin	
Pancreas	(64)
Fibrous Histiocytoma	
Hepatocholangiocarcinoma, Metastatic, Liver	
Salivary Glands	(64)
Stomach, Forestomach	(64)
Squamous Cell Papilloma	1 (2%)
Stomach, Glandular	(63)
Adenoma	
Tongue	(0)
Squamous Cell Carcinoma	
CARDIOVASCULAR SYSTEM	
Blood Vessel	(65)
Fibrous Histiocytoma	
Hepatocholangiocarcinoma, Metastatic, Liver	
Heart	(65)
Hemangiosarcoma, Metastatic, Liver	1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver	
Sarcoma, Metastatic, Lung	
Sarcoma, Metastatic, Skeletal Muscle	
ENDOCRINE SYSTEM	
Adrenal Cortex	(63)
Fibrous Histiocytoma	
Hepatocholangiocarcinoma, Metastatic, Liver	

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0
Subcapsular, Adenoma	2 (3%)
Subcapsular, Carcinoma	
Adrenal Medulla	(63)
Pheochromocytoma Benign	
Pheochromocytoma Malignant	
Islets, Pancreatic	(65)
Adenoma	1 (2%)
Fibrous Histiocytoma	
Parathyroid Gland	(52)
Adenoma	
Pituitary Gland	(61)
Pars Distalis, Adenoma	
Pars Intermedia, Adenoma	
Thyroid Gland	(64)
Follicular Cell, Adenoma	
Follicular Cell, Carcinoma	
GENERAL BODY SYSTEM	
Tissue NOS	(1)
Fibrous Histiocytoma	
Hepatocellular Carcinoma, Metastatic, Liver	
Hepatocholangiocarcinoma, Metastatic, Liver	
Sarcoma, Metastatic, Skeletal Muscle	
Abdominal, Fibrous Histiocytoma	
Abdominal, Hemangiosarcoma	1 (100%)
Thoracic, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	
Thoracic, Fibrous Histiocytoma	
Thoracic, Hepatocholangiocarcinoma, Metastatic, Liver	
GENITAL SYSTEM	
Coagulating Gland	(2)
Epididymis	(63)
Fibrosarcoma, Metastatic, Skin	

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE

SOLVENT to 0

Fibrous Histiocytoma	
Hemangioma	
Hepatocholangiocarcinoma, Metastatic, Liver	
Preputial Gland	(64)
Adenoma	
Hemangiosarcoma	1 (2%)
Sarcoma	
Prostate	(64)
Fibrous Histiocytoma	
Sarcoma	
Seminal Vesicle	(63)
Fibrous Histiocytoma	
Testes	(64)
Fibrous Histiocytoma	
Lipoma	
Sertoli Cell Tumor Benign	

HEMATOPOIETIC SYSTEM

Bone Marrow	(64)
Hemangiosarcoma	
Hemangiosarcoma, Metastatic, Mesentery	
Hemangiosarcoma, Metastatic, Preputial Gland	
Hemangiosarcoma, Metastatic, Uncertain Primary Site	
Lymph Node	(7)
Axillary, Fibrous Histiocytoma, Metastatic, Skin	
Lumbar, Fibrous Histiocytoma	
Lumbar, Hemangiosarcoma, Metastatic, Uncertain Primary Site	
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (14%)
Mediastinal, Sarcoma, Metastatic, Lung	
Mediastinal, Sarcoma, Metastatic, Skeletal Muscle	
Renal, Fibrous Histiocytoma	

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AZT/Drug Combinations Transplacental Carcinogenesis Study

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Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE SOLVENT to 0

Renal, Hemangiosarcoma, Metastatic, Uncertain Primary Site	
Lymph Node, Mandibular	(63)
Lymph Node, Mesenteric	(63)
Fibrous Histiocytoma	
Hemangiosarcoma	1 (2%)
Hemangiosarcoma, Metastatic, Uncertain Primary Site	
Hepatocholangiocarcinoma, Metastatic, Liver	
Spleen	(63)
Fibrous Histiocytoma	
Hemangiosarcoma	2 (3%)
Hepatocholangiocarcinoma, Metastatic, Liver	
Thymus	(51)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	
Fibrous Histiocytoma	
Hemangiosarcoma	
Hepatocholangiocarcinoma, Metastatic, Liver	
Sarcoma, Metastatic, Skeletal Muscle	

INTEGUMENTARY SYSTEM

Skin	(65)
Hemangiosarcoma	
Squamous Cell Papilloma	3 (5%)
Ear, Squamous Cell Papilloma	
Subcutaneous Tissue, Fibroma	
Subcutaneous Tissue, Fibroma, Multiple	
Subcutaneous Tissue, Fibrosarcoma	2 (3%)
Subcutaneous Tissue, Fibrosarcoma, Multiple	
Subcutaneous Tissue, Fibrous Histiocytoma	
Subcutaneous Tissue, Liposarcoma	
Subcutaneous Tissue, Sarcoma	
Subcutaneous Tissue, Schwannoma	

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AZT/Drug Combinations Transplacental Carcinogenesis Study

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE

SOLVENT to 0

Malignant

MUSCULOSKELETAL SYSTEM

Bone	(0)
Mandible, Osteosarcoma	
Skeletal Muscle	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	
Hepatocholangiocarcinoma, Metastatic, Liver Sarcoma	

NERVOUS SYSTEM

Brain, Cerebellum	(64)
Brain, Cerebrum	(64)

RESPIRATORY SYSTEM

Lung	(64)
Alveolar/Bronchiolar Adenoma	6 (9%)
Alveolar/Bronchiolar Adenoma, Multiple	
Alveolar/Bronchiolar Carcinoma	7 (11%)
Alveolar/Bronchiolar Carcinoma, Multiple	
Fibrous Histiocytoma	
Fibrous Histiocytoma, Metastatic, Skin	
Hepatocellular Carcinoma, Metastatic, Liver	2 (3%)
Hepatocholangiocarcinoma, Metastatic, Liver	
Liposarcoma, Metastatic, Skin	
Sarcoma	
Sarcoma, Metastatic, Skeletal Muscle	
Nose	(65)

SPECIAL SENSES SYSTEM

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* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

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First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0
Eye	(62)
Harderian Gland	(64)
Adenocarcinoma	1 (2%)
Adenoma	5 (8%)
Adenoma, Multiple	
<hr/>	
URINARY SYSTEM	
Kidney	(64)
Fibrous Histiocytoma	
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver	
Urethra	(1)
Urinary Bladder	(65)
Fibrous Histiocytoma	
Transitional Epithelium, Papilloma	
<hr/>	
SYSTEMIC LESIONS	
Multiple Organs	*(65)
Histiocytic Sarcoma	1 (2%)
Lymphoma Malignant	9 (14%)

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Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

Route: IN-UTERO

CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZT-H to 0	AZT-M to 0	AZT-L to 0	AZT-H/3TC-H to 0	AZT-M/3TC-M to 0	AZT-L/3TC-L to 0
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	37	36	31	40	40	33
Total Primary Neoplasms	52	57	51	57	55	53
Total Animals with Benign Neoplasms	20	21	21	23	19	19
Total Benign Neoplasms	24	25	28	27	22	24
Total Animals with Malignant Neoplasms	25	23	20	27	27	21
Total Malignant Neoplasms	28	32	23	30	33	29
Total Animals with Metastatic Neoplasms	4	4	3	2	3	1
Total Metastatic Neoplasms	12	18	8	11	9	1
Total Animals with Malignant Neoplasms Uncertain Primary Site			1			
Total Animals with Neoplasms Uncertain-Benign or Malignant						
Total Uncertain Neoplasms						

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

Time Report Requested: 11:50:03

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CAS Number: AIDSTHERAPEU

First Dose M/F: 07/10/03 / NA

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	33	30	34	11	32	29
Total Primary Neoplasms	54	44	66	26	50	46
Total Animals with Benign Neoplasms	19	13	20	5	18	14
Total Benign Neoplasms	28	17	24	6	23	16
Total Animals with Malignant Neoplasms	22	23	23	11	24	24
Total Malignant Neoplasms	26	27	42	20	27	30
Total Animals with Metastatic Neoplasms	2		2	4	2	1
Total Metastatic Neoplasms	2		3	4	11	4
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain-Benign or Malignant						
Total Uncertain Neoplasms						

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

Test Type: CHRONIC

AZT/Drug Combinations Transplacental Carcinogenesis Study

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE

SOLVENT to 0

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	47
Total Primary Neoplasms	79
Total Animals with Benign Neoplasms	29
Total Benign Neoplasms	36
Total Animals with Malignant Neoplasms	36
Total Malignant Neoplasms	43
Total Animals with Metastatic Neoplasms	5
Total Metastatic Neoplasms	7
Total Animals with Malignant Neoplasms Uncertain Primary Site	
Total Animals with Neoplasms Uncertain-Benign or Malignant	
Total Uncertain Neoplasms	

*** END OF MALE ***

*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors