Test Type: CHRONIC

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Lab: NCTR

C Number: C20311

Lock Date: 12/01/2008

Cage Range: ALL

Species/Strain: MICE/B6C3F1/NCTR

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Female

TDMSE Version: 2.1.0

Date Report Requested: 06/29/2009

Time Report Requested: 16:30:20

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

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20

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

Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	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 (
Disposition Summary						
Animals Initially in Study Early Deaths	48	47	48	48	51	48
Moribund Sacrifice Natural Death	8 2	7 1	3 3	4 3	8 2	9 3
Survivors Moribund Sacrifice Natural Death		3 1	2	1	2 1	2
Terminal Sacrifice Harvest	37 1	28 7	38 2	35 5	35 3	32 2
Animals Examined Microscopically	48	47	47	48	51	48
ALIMENTARY SYSTEM						
Esophagus Gallbladder	(47) (46)	(47) (45)	(46) (44)	(48) (46)	(50)	(47) (45)
Cyst Degeneration, Hyaline	(46)	1 [1.0]	2 [2.0]	(46)	(48)	(45)
Infiltration Cellular, Lymphocyte Inflammation, Chronic		1 [2.0]	1 [1.0]			1 [1.0]
Intestine Large, Cecum Hyperplasia, Lymphoid Serosa, Hyperplasia	(46) 2 [2.0]	(46)	(46) 2 [2.0]	(46) 1 [2.0]	(49) 2 [2.0]	(46) 1 [2.0]
Intestine Large, Colon Intestine Large, Rectum	(46) (46)	(46) (46)	(46) (46)	(46) (46)	(50) (50)	(46) (46)
Hyperplasia, Lymphoid Intestine Small, Duodenum Diverticulum	(46)	(47)	(45) 1 [4.0]	1 [2.0] (45)	(49)	1 [2.0] (45)
Intestine Small, Ileum Hyperplasia, Lymphoid Inflammation, Chronic Active	(46) 1 [2.0]	(46)	(46) 2 [1.5]	(46)	(50)	(46) 1 [2.0]
Intestine Small, Jejunum Hyperplasia, Lymphoid	(46) 1 [2.0]	(45)	(46) 1 [4.0]	(46)	(48)	(46)
Epithelium, Hyperplasia Liver Angiectasis Autolysis	(47)	(46) 1 [1.0]	(46)	(48)	(50) 1 [2.0]	(47)

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Species/Strain: MICE/B6C3F1/NCTR

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Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	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 (
Basophilic Focus	2	2	3	7	3	2
Basophilic Focus, Multiple					1	
Clear Cell Focus				1	2	
Congestion	1 [2.0]				1 [2.0]	
Cyst						
Cyst Multilocular		1				
Deformity						
Eosinophilic Focus	2	1		2	1	1
Eosinophilic Focus, Multiple			1			
Fatty Change						
Hematocyst					1	
Hematopoietic Cell Proliferation	1 [3.0]	2 [2.5]			1 [4.0]	
Hemorrhage	1 [4.0]					
Hepatodiaphragmatic Nodule				1		
Infiltration Cellular, Histiocyte						
Infiltration Cellular, Lymphocyte	13 [1.1]	13 [1.1]	12 [1.1]	13 [1.4]	17 [1.3]	10 [1.1]
Inflammation, Chronic Active	2 [1.0]	2 [2.0]	3 [1.0]	2 [1.0]	2 [1.5]	2 [1.0]
Mineralization						
Mixed Cell Focus		2	1	1	2	2
Necrosis	2 [2.5]	5 [2.6]			1 [4.0]	1 [4.0]
Tension Lipidosis	11 [1.5]	2 [1.5]	5 [1.0]	6 [1.7]	6 [1.7]	8 [1.5]
Vacuolization Cytoplasmic	18 [1.6]	23 [1.8]	19 [1.5]	16 [1.9]	28 [1.9]	21 [1.7]
Mesentery	(8)	(4)	(11)	(6)	(7)	(11)
Cyst			1 [4.0]			
Hematocyst					1	
Hemorrhage			2 [4.0]	2 [3.5]	1 [2.0]	1 [4.0]
Infiltration Cellular, Lymphocyte				1 [3.0]	1 [3.0]	
Fat, Necrosis	8 [3.8]	3 [3.3]	11 [3.5]	5 [3.8]	6 [3.7]	9 [3.8]
Pancreas	(46)	(46)	(46)	(48)	(49)	(46)
Cyst			1 [4.0]			
Cytoplasmic Alteration	1 [1.0]					
Edema	40.54.03	45.14.03	1 [2.0]	40.54.03	40.54.03	40.54.03
Infiltration Cellular, Lymphocyte	18 [1.2]	15 [1.3]	13 [1.1]	18 [1.2]	19 [1.3]	16 [1.2]
Inflammation, Chronic Active			1 [4.0]			
Mineralization			4.54.03			
Necrosis	4 [0 0]	4 [0 0]	1 [4.0]		4.54.01	4 [4 0]
Acinus, Degeneration	1 [2.0]	1 [3.0]	2 [1.5]		1 [1.0]	1 [1.0]
Duct, Dilatation			4 [0 0]			
Fat, Necrosis	(47)	(45)	1 [3.0]	(40)	(50)	(40)
Salivary Glands	(47)	(45)	(46)	(48)	(50)	(46)

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Infiltration Cellular, Lymphocyte Polyarteritis	38 [1.6]	40 [1.4]	39 [1.6]	39 [1.4]	46 [1.6]	38 [1.6]
Acinus, Degeneration Stomach, Forestomach Hyperkeratosis Hyperplasia	(46)	1 [2.0] (47)	(45)	1 [2.0] (47) 2 [2.0]	(50)	(46)
Inflammation, Chronic Active Keratin Cyst Ulcer					1	
Epithelium, Hyperplasia Stomach, Glandular Degeneration, Hyaline	(46)	1 [2.0] (46)	(45)	1 [2.0] (46) 2 [3.0]	(48)	2 [2.0] (46)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active			1 [2.0]	2 [2.5]		2 [2.0]
Mineralization Epithelium, Hyperplasia		1 [1.0]	1 [2.0]	2 [3.0]		2 [3.0]
CARDIOVASCULAR SYSTEM						_
Blood Vessel Heart Cardiomyopathy Inflammation, Suppurative	(48) (47)	(46) (47)	(46) (46)	(48) (48)	(49) (50) 1 [2.0]	(45) (48)
Inflammation, Chronic Active Mineralization Necrosis Polyarteritis	1 [2.0]				1 [2.0]	1 [1.0]
	. [2.0]					
ENDOCRINE SYSTEM Adrenal Cortex	(47)	(47)	(46)	(47)	(50)	(47)
Accessory Adrenal Cortical Nodule Angiectasis	4	4 1 [2.0]	3	1	1	2
Cyst Hypertrophy			1 [1.0]			2 [1.5] 1 [2.0]
Vacuolization Cytoplasmic Subcapsular, Hyperplasia Adrenal Medulla Hyperplasia	6 [3.0] 46 [2.0] (46)	4 [2.0] 46 [1.8] (45)	6 [3.2] 45 [1.9] (43)	1 [3.0] 44 [2.0] (46)	3 [2.3] 49 [1.7] (47)	1 [4.0] 47 [1.7] (46)

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Islets, Pancreatic	(47)	(46)	(46)	(48)	(49)	(46)
Hyperplasia Infiltration Cellular, Lymphocyte	2 [1.0] 1 [1.0]	3 [1.0]	4 [1.3]	1 [2.0]	3 [1.0]	4 [1.5]
Parathyroid Gland	(45)	(44)	(40)	(38)	(40)	(36)
Cyst Hyperplasia Hypertrophy Infiltration Cellular, Lymphocyte			1 [1.0]			1 [2.0]
Pituitary Gland Hemorrhage	(46)	(44)	(44) 1 [4.0]	(46)	(49)	(45)
Pars Distalis, Angiectasis Pars Distalis, Cyst Pars Distalis, Hyperplasia	1 [2.0] 1 [2.0] 10 [2.2]	1 [3.0] 2 [2.0] 10 [2.1]	1 [4.0] 1 [1.0] 6 [2.2] 7 [1.9]	2 [1.5] 3 [1.7] 10 [1.8]	1 [1.0] 2 [3.0] 11 [2.3]	2 [1.5] 6 [2.3]
Rathke's Cleft, Dilatation Thyroid Gland Cyst Ectopic Thymus	(47) 1 [2.0]	(46)	(46)	(47)	(50) 1 [2.0] 1	(46)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Polyarteritis	4 [1.0]		1 [1.0]	2 [1.0]	'	
C-cell, Hyperplasia Follicle, Degeneration Follicular Cell, Hyperplasia Follicular Cell, Hypertrophy	9 [1.3]	4 [1.5]	7 [1.0] 1 [1.0]	1 [1.0] 8 [1.4] 1 [1.0]	4 [1.3] 2 [2.5] 1 [2.0]	6 [1.5]
GENERAL BODY SYSTEM						
Tissue NOS Hemorrhage Infiltration Cellular, Lymphocyte Abdominal, Fibrosis Abdominal, Inflammation, Chronic Active	(1)	(2)	(1)	(1) 1 [4.0] 1 [4.0]	(2)	(0)
Abdominal, Inflammation, Chronic Active Abdominal, Keratin Cyst Fat, Necrosis	1 [4.0]					
GENITAL SYSTEM						
Clitoral Gland Atrophy	(46) 2 [3.0]	(43)	(44)	(44) 1 [4.0]	(49)	(44) 1 [2.0]

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	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
Degeneration	39 [3.8]	41 [3.8]	41 [3.7]	42 [3.8]	45 [3.8]	41 [3.7]
Inflammation, Suppurative						
Ovary	(47)	(45)	(45)	(48)	(50)	(43)
Angiectasis		1 [2.0]				
Atrophy	44 [3.3]	39 [3.1]	44 [3.2]	39 [3.1]	42 [3.1]	36 [3.3]
Cyst	13 [3.0]	11 [3.7]	14 [3.3]	15 [3.0]	17 [3.3]	13 [3.0]
Cyst Dermoid						
Hematocyst		2		4	1	3
Infiltration Cellular, Lymphocyte		2 [3.0]				
Inflammation, Chronic Active						
Bilateral, Cyst	4 [3.3]	4 [3.3]	3 [3.3]	1 [3.0]	2 [2.0]	3 [2.3]
Fat, Necrosis						1 [4.0]
Germinal Epithelium, Hyperplasia		2 [3.0]				
Parenchymal Cell, Degeneration			41	4.5-1		
Uterus	(47)	(47)	(46)	(48)	(50)	(46)
Angiectasis			1 [4.0]		1 [2.0]	1 [2.0]
Autolysis	0.14.01	4.54.03	5.14.03	0.54.03	4.54.03	4.54.03
Hydrometra	6 [4.0]	4 [4.0]	5 [4.0]	6 [4.0]	1 [4.0]	1 [4.0]
Thrombosis	44 [0 7]	40 [0 7]	1 [4.0]	44 [0 7]	40 [0 0]	44 [0 0]
Endometrium, Hyperplasia, Cystic	41 [2.7]	42 [2.7]	38 [2.8]	41 [2.7]	49 [2.8]	41 [2.6]
EMATOPOIETIC SYSTEM						
Bone Marrow	(46)	(47)	(46)	(46)	(50)	(46)
Hyperplasia		3 [3.0]	2 [2.0]		3 [2.7]	1 [3.0]
Pigmentation				1 [3.0]		
Lymph Node	(8)	(12)	(5)	(5)	(10)	(9)
Cyst					1 [4.0]	
Hemorrhage		1 [2.0]			1 [4.0]	
Hyperplasia, Lymphoid		1 [2.0]				
Axillary, Autolysis						
Axillary, Hyperplasia, Lymphoid	2 [2.5]		1 [2.0]			
Bronchial, Autolysis						
Iliac, Autolysis						
Lumbar, Autolysis						
Lumbar, Cyst					4 [0 0]	
Lumbar, Fibrosis	0 [0 5]	4 [0 0]		4 [0 0]	1 [2.0]	0.14.53
Lumbar, Hyperplasia, Lymphoid	2 [2.5]	1 [2.0]		1 [3.0]	1 [2.0]	2 [1.5]
Lumbar, Infiltration Cellular, Plasma Cell				1 [3.0]		

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Lumbar, Infiltration Cellular, Polymorphonuclear						
Lumbar, Inflammation, Chronic Active						
Lumbar, Polyarteritis Mediastinal, Autolysis						
Mediastinal, Autorysis Mediastinal, Hyperplasia, Lymphoid				1 [2.0]		2 [1.5]
Mediastinal, Infiltration Cellular, Plasma Cell				. [=.0]		_ [0]
Pancreatic, Hyperplasia, Lymphoid			1 [3.0]		1 [2.0]	
Renal, Autolysis						
Renal, Hyperplasia, Lymphoid	2 [2.5]	1 [2.0]		1 [3.0]		2 [2.0]
Renal, Infiltration Cellular, Plasma Cell Renal, Infiltration Cellular,				1 [3.0]		
Polymorphonuclear						
Sinus, Dilatation		2 [3.0]				
Lymph Node, Mandibular	(47)	(44)	(46)	(48)	(49)	(45)
Autolysis	()	, ,	()	,	,	()
Erythrophagocytosis		1 [2.0]				
Hyperplasia, Lymphoid	9 [1.8]	9 [1.6]	12 [1.8]	12 [1.6]	16 [1.9]	15 [1.5]
Infiltration Cellular, Plasma Cell					4 [0 0]	1 [2.0]
Infiltration Cellular, Polymorphonuclear Pigmentation					1 [2.0]	
Lymph Node, Mesenteric	(45)	(46)	(45)	(45)	(48)	(46)
Angiectasis	1 [3.0]	(40)	(40)	(40)	(40)	1 [2.0]
Autolysis	1 [4.0]					. [=.0]
Cyst			1 [4.0]			
Hematopoietic Cell Proliferation						
Hemorrhage			2 [2.5]	1 [2.0]		
Hyperplasia	40 [4 0]	1 [3.0]	40 [4 0]	04 [0 0]	00 [0.4]	10.01.00
Hyperplasia, Lymphoid Infiltration Cellular, Histiocyte	16 [1.9] 2 [3.5]	17 [1.8] 1 [2.0]	16 [1.6] 2 [3.0]	21 [2.0] 1 [2.0]	23 [2.1] 1 [4.0]	20 [2.0] 1 [2.0]
Infiltration Cellular, Plasma Cell	2 [3.3]	1 [2.0] 1 [2.0]	2 [3.0] 1 [3.0]	3 [2.7]	2 [2.5]	3 [3.3]
Infiltration Cellular, Polymorphonuclear	2 [2.0]	1 [2.0]	1 [2.0]	0 [2.7]	2 [1.5]	0 [0.0]
Inflammation, Chronic Active	_ [=.0]		. [=.0]	2 [4.0]	_[]	
Thrombosis						
Sinus, Dilatation	1 [3.0]		1 [4.0]			
Spleen	(47)	(47)	(46)	(47)	(50)	(48)
Autolysis	1 [4.0]					
Erythrophagocytosis Hematopoietic Cell Proliferation	11 [2.5]	13 [3.0]	8 [2.6]	13 [2.5]	17 [2.9]	10 [2.7]
Hematopoletic Celi FTOIIIEI attori	11 [2.3]	13 [3.0]	0 [2.0]	10 [2.0]	17 [2.8]	10 [2.1]

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Hemorrhage	20 [2 4]	25 [2 7]	25 [2 7]	27 [2 4]	22 [2 0]	24 [2 0]
Hyperplasia, Lymphoid Necrosis	28 [3.1]	25 [2.7] 1 [4.0]	25 [2.7]	27 [3.1]	32 [2.9]	31 [2.9]
Pigmentation		i [+.0]	1 [2.0]			
Thrombosis						
Thymus	(46)	(42)	(44)	(45)	(47)	(43)
Angiectasis	40 [0 5]	40 [0.7]	1 [2.0]	40 [0 4]	40 [0 0]	45 [0.5]
Atrophy Autolysis	16 [2.5] 1 [4.0]	12 [2.7]	13 [2.7]	18 [2.4]	13 [2.9]	15 [2.5]
Hyperplasia, Lymphoid	5 [2.2]	6 [2.2]	12 [2.4]	3 [2.0]	9 [1.4]	7 [2.1]
Mineralization	1 [1.0]	0 [2.2]	[]	0 [2.0]	o []	, [=]
Fat, Necrosis	1 [4.0]					
INTEGUMENTARY SYSTEM						
Mammary Gland	(47)	(46)	(45)	(45)	(50)	(45)
Galactocele					1 [3.0]	
Lactation Metaplacia, Squamous		1 [2.0]	2 [2.0]			
Metaplasia, Squamous Alveolus, Hyperplasia	1 [1.0]	2 [3.5]	1 [3.0]	1 [4.0]	1 [3.0]	
Skin	(48)	(47)	(46)	(48)	(50)	(46)
Fibrosis	(10)	(,	(10)	1 [2.0]	(00)	(10)
Infiltration Cellular, Lymphocyte						
Inflammation, Chronic Active		1 [2.0]				
Ulcer		1 [3.0]				
MUSCULOSKELETAL SYSTEM						
Bone, Femur	(48)	(47)	(47)	(48)	(51)	(48)
Fibro-Osseous Lesion		1 [1.0]	1 [4.0]	1 [2.0]	1 [2.0]	1 [4.0]
Skeletal Muscle	(0)	(0)	(0)	(1)	(1)	(1)
NERVOUS SYSTEM						
Brain, Brain Stem	(47)	(46)	(46)	(47)	(49)	(47)
Compression	1 [1.0]	3 [2.0]	1 [3.0]	1 [4.0]	2 [2.0]	
Degeneration						

Hemorrhage

1 [2.0]

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TDMS No. 20311 - 02
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Brain, Cerebellum	(47)	(46)	(46)	(47)	(49)	(47)
Hemorrhage						
Infiltration Cellular, Lymphocyte Vacuolization Cytoplasmic						
Meninges, Infiltration Cellular,	1 [1.0]					
Lymphocyte	,					
Ventricle, Dilatation						
Brain, Cerebrum	(47)	(46)	(46)	(47)	(49)	(47)
Cyst Epithelial Inclusion						
Hemorrhage Mineralization	22 [1.0]	22 [1.0]	26 [1.0]	25 [1.0]	25 [1.1]	28 [1.0]
Meninges, Infiltration Cellular,	1 [1.0]	22 [1.0]	20 [1.0]	23 [1.0]	20 [1.1]	20 [1.0]
Lymphocyte	. [0]					
Ventricle, Dilatation						
Peripheral Nerve	(0)	(0)	(0)	(0)	(1)	(1)
Axon, Degeneration	(0)	(0)	(0)	(0)	(4)	(4)
Spinal Cord Degeneration	(0)	(0)	(0)	(0)	(1)	(1)
Inflammation, Chronic Active						
Axon, Degeneration						
ESPIRATORY SYSTEM						
Lung	(48)	(47)	(46)	(48)	(50)	(48)
Autolysis	1 [4.0]		,	,	, ,	, ,
Congestion		1 [4.0]			1 [2.0]	
Crystals	3 [3.0]	3 [3.0]	1 [4.0]	2 [4.0]	4 [0 0]	2 [3.0]
Hemorrhage Infiltration Cellular, Histiocyte	1 [2.0] 4 [2.8]	4 [3.0]	1 [4.0]	2 [4.0]	1 [2.0]	3 [2.7]
Infiltration Cellular, Lymphocyte	14 [1.6]	13 [1.7]	14 [1.5]	2 [4.0] 14 [1.4]	16 [1.4]	14 [1.3]
Inflammation, Chronic	[0]		[0]	1 [1.0]	. • []	[0]
Inflammation, Chronic Active	1 [3.0]		2 [1.5]		1 [1.0]	1 [2.0]
Metaplasia, Osseous						
Alveolar Epithelium, Hyperplasia	1 [1.0]	2 [1.5]	1 [2.0]	1 [1.0]	2 [1.5]	1 [2.0]
Bronchiole, Hyperplasia Nose	(48)	(47)	(46)	(48)	(51)	(46)
Inflammation, Suppurative	(40)	(41)	(40)	(40)	(31)	(40)
Posterior To Upper Incisor, Dysplasia		1 [3.0]				

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	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
SPECIAL SENSES SYSTEM						
Eye Cataract Degeneration Inflammation, Chronic Active Metaplasia, Squamous	(46) 1 [1.0]	(45) 1 [2.0]	(46) 1 [1.0]	(46) 1 [1.0]	(49) 1 [1.0]	(45) 1 [2.0]
Bilateral, Cataract Cornea, Inflammation, Chronic Active Cornea, Necrosis Cornea, Ulcer	1 [2.0] 1 [2.0]	1 [1.0] 1 [1.0]		1 [1.0]		1 [1.0] 1 [1.0]
Retina, Degeneration Harderian Gland	(46)	(47)	(46)	(47)	(50)	(46)
Cyst Infiltration Cellular, Lymphocyte	6 [1.0]	8 [1.0]	6 [1.0]	4 [1.0]	1 [2.0] 4 [1.3]	2 [1.5]
Inflammation, Chronic Inflammation, Chronic Active Acinus, Degeneration Acinus, Hyperplasia Epithelium, Hyperplasia	1 [4.0]			1 [2.0]	1 [1.0]	1 [4.0]
RINARY SYSTEM						
Kidney Amyloid Deposition Hemorrhage	(46)	(46)	(46) 1 [4.0] 1 [4.0]	(46)	(50)	(46)
Hyaline Droplet Hydronephrosis Hyperplasia, Lymphoid	1 [3.0]	2 [3.0]	1 [4.0]	1 [3.0]	1 [4.0]	2 [3.5]
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	12 [1.3]	16 [1.3]	15 [1.6]	16 [1.3]	17 [1.1]	13 [1.2]
Metaplasia, Osseous Nephropathy Polyarteritis	3 [2.0] 25 [1.2]	27 [1.2]	3 [1.7] 23 [1.3]	1 [2.0] 18 [1.1]	2 [1.5] 23 [1.1]	1 [1.0] 26 [1.2]
Adventitia, Inflammation, Chronic Active Adventitia, Fat, Necrosis Urinary Bladder	(46)	(46)	1 [4.0] 1 [4.0] (46)	(46)	(49)	(45)
Edema Infiltration Cellular, Lymphocyte	20 [1.2]	1 [3.0] 19 [1.1]	21 [1.1]	22 [1.2]	26 [1.1]	24 [1.1]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20

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

Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	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
Inflammation, Chronic Active Polyarteritis Lumen, Dilatation		1 [3.0]				1 [3.0]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

2 [2.0]

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE AZTH/3TCH/NVPH/0 AZTM/3TCM/NVPM/0 AZTL/3TCL/NVPL/0 AZTH/3TCH/NFVH/0 AZTM/3TCM/NFVM/0 AZTL/3TCL/NFVL/0 **FEMALE Disposition Summary Animals Initially in Study** 49 48 48 26 49 50 **Early Deaths Moribund Sacrifice** 5 12 3 7 4 8 **Natural Death** 2 2 5 Survivors 5 Moribund Sacrifice 2 2 4 **Natural Death** 1 **Terminal Sacrifice** 37 39 34 31 30 16 Harvest 1 3 3 3 2 3 49 49 **Animals Examined Microscopically** 48 48 26 50 ALIMENTARY SYSTEM Esophagus (48)(47)(47)(25)(48)(49)Gallbladder (45)(45)(45)(25)(47)(46)Cyst 1 [1.0] Degeneration, Hyaline 1 [3.0] Infiltration Cellular, Lymphocyte 1 [1.0] 1 [1.0] Inflammation, Chronic Intestine Large, Cecum (45)(46)(45)(25)(47)(45)Hyperplasia, Lymphoid 1 [2.0] 3 [2.0] 2 [2.0] 3 [2.0] Serosa, Hyperplasia Intestine Large, Colon (45)(46)(46)(25)(47)(46)Intestine Large, Rectum (46)(25)(47)(45)(46)(46)Hyperplasia, Lymphoid Intestine Small, Duodenum (45)(46)(46)(25)(47)(45)Diverticulum Intestine Small, Ileum (45)(46)(46)(25)(47)(45)Hyperplasia, Lymphoid Inflammation, Chronic Active Intestine Small, Jejunum (46)(46)(46)(25)(47)(45)Hyperplasia, Lymphoid 2 [1.5] Epithelium, Hyperplasia 1 [2.0] Liver (47)(47)(46)(26)(48)(50)

Angiectasis

Autolysis

1 [4.0]

1 [4.0]

1 [2.0]

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Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20

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

Date Report Requested: 06/29/2009

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL
Basophilic Focus Basophilic Focus, Multiple Clear Cell Focus	7	4	3	1	2	1
Congestion Cyst Cyst Multilocular Deformity	1		1 [2.0] 1 [4.0]		1 [2.0]	
Eosinophilic Focus Eosinophilic Focus, Multiple	ı	1		1	3	
Fatty Change Hematocyst Hematopoietic Cell Proliferation Hemorrhage Hepatodiaphragmatic Nodule		1 [4.0]	2 [1.5]		2 [1.0]	2 [2.5]
Infiltration Cellular, Histiocyte Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Mineralization	16 [1.3] 3 [1.3]	12 [1.3]	13 [1.2] 4 [1.0]	6 [1.3] 4 [1.3]	15 [1.2] 7 [1.3]	13 [1.1] 1 [2.0]
Mixed Cell Focus Necrosis Tension Lipidosis Vacuolization Cytoplasmic Mesentery Cyst	1 1 [2.0] 9 [1.6] 10 [1.6] (3)	1 1 [2.0] 10 [1.2] 24 [1.8] (8)	1 [2.0] 7 [1.4] 26 [1.4] (1)	1 3 [2.0] 11 [1.3] (5)	1 3 [2.3] 5 [1.2] 25 [1.9] (7)	1 3 [2.0] 6 [1.5] 19 [1.6] (7)
Hematocyst Hemorrhage Infiltration Cellular, Lymphocyte Fat, Necrosis Pancreas Cyst Cytoplasmic Alteration	3 [4.0] (47)	8 [3.6] (46)	1 [4.0] (45) 1 [4.0]	5 [3.4] (25)	1 [3.0] 5 [4.0] (46) 2 [1.5]	1 [2.0] 5 [3.4] (47) 1 [2.0]
Edema Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	14 [1.4]	14 [1.3]	20 [1.3]	10 [1.3]	14 [1.1]	19 [1.3]
Mineralization Necrosis	1 [1.0]		4 [0.0]	2 [4 5]	0 [0 0]	2 [2 7]
Acinus, Degeneration Duct, Dilatation Fat, Necrosis	3 [1.0]		1 [2.0]	2 [1.5]	2 [3.0]	3 [3.7] 1 [3.0]
Salivary Glands	(46)	(47)	(47)	(25)	(47)	(47)

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

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Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/
Infiltration Cellular, Lymphocyte Polyarteritis Acinus, Degeneration	38 [1.3]	36 [1.5]	33 [1.4]	21 [1.5]	40 [1.5]	36 [1.7] 1 [2.0]
Stomach, Forestomach	(47)	(46)	(46)	(25)	(47)	(47)
Hyperkeratosis Hyperplasia Inflammation, Chronic Active Keratin Cyst		1 [3.0] 1	1 [2.0]			
Ulcer Epithelium, Hyperplasia Stomach, Glandular Degeneration, Hyaline Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	4 [2.0] (46)	1 [2.0] 1 [2.0] (46)	3 [1.7] (46)	(25)	1 [2.0] (47)	1 [2.0] 1 [2.0] (46)
Mineralization Epithelium, Hyperplasia			1 [3.0]			
CARDIOVASCULAR SYSTEM						
Blood Vessel Heart Cardiomyopathy	(48) (49) 1 [1.0]	(47) (47)	(47) (46)	(25) (25) 1 [1.0]	(48) (48)	(50) (50) 1 [3.0]
Inflammation, Suppurative Inflammation, Chronic Active Mineralization		1 [1.0]				
Necrosis Polyarteritis						1 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex Accessory Adrenal Cortical Nodule Angiectasis	(48) 1	(46) 1	(45) 4	(25)	(49) 1	(48) 2
Cyst	4 [2 0]	4 [4 0]		1 [1.0]	1 [3.0]	
Hypertrophy Vacuolization Cytoplasmic	1 [3.0]	1 [1.0] 1 [3.0]	2 [3.0]		2 [3.0]	1 [3.0]
Subcapsular, Hyperplasia Adrenal Medulla Hyperplasia	46 [1.9] (44) 1 [2.0]	46 [1.8] (45)	45 [1.9] (43)	25 [1.8] (25)	47 [1.8] (47) 1 [2.0]	47 [1.9] (46)

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Route: IN-UTERO

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

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Date Report Requested: 06/29/2009

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL
Islets, Pancreatic Hyperplasia	(47) 4 [2.3]	(46) 4 [1.5]	(45) 3 [1.7]	(25)	(46) 1 [2.0]	(47)
Infiltration Cellular, Lymphocyte Parathyroid Gland Cyst	(41)	(44)	(38)	(21) 1 [2.0]	(42)	(42)
Hyperplasia Hypertrophy	1 [2.0]					
Infiltration Cellular, Lymphocyte Pituitary Gland	1 [1.0] (42)	1 [2.0] (46)	1 [1.0] (43)	1 [1.0] (23)	(45)	(47)
Hemorrhage Pars Distalis, Angiectasis	4 [2.0]	1 [2.0]	4 [0 0]		4 [1.5]	1 [3.0]
Pars Distalis, Cyst Pars Distalis, Hyperplasia Rathke's Cleft, Dilatation	4 [1.5] 13 [1.9]	7 [2.0] 1 [3.0]	1 [3.0] 8 [1.8]	2 [2.0]	11 [1.5]	11 [1.7]
Thyroid Gland Cyst	(47) 1 [2.0]	(45) 1 [2.0]	(46) 1 [2.0]	(25)	(48) 2 [2.0]	(47) 1 [2.0]
Ectopic Thymus Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	1 [2.0]	1 3 [1.0]	1 [2.0] 1 [1.0]	1 [1.0]	1 [2.0] 1 [1.0]	5 [1.2]
Polyarteritis C-cell, Hyperplasia				1 [2.0]	1 [1.0]	1 [2.0]
Follicle, Degeneration Follicular Cell, Hyperplasia Follicular Cell, Hypertrophy	9 [1.8] 1 [1.0]	7 [1.6]	9 [1.7]	7 [1.7]	4 [1.5]	7 [1.1]
ENERAL BODY SYSTEM						
Tissue NOS Hemorrhage	(0)	(0)	(1)	(0)	(1)	(2)
Infiltration Cellular, Lymphocyte Abdominal, Fibrosis Abdominal, Inflammation, Chronic Active Abdominal, Keratin Cyst Fat, Necrosis					1 [4.0] 1 [4.0]	1 [4.0] 1 [4.0] 1 [4.0]
ENITAL SYSTEM						
Clitoral Gland Atrophy	(46)	(46) 1 [4.0]	(46) 1 [4.0]	(25)	(47) 1 [4.0]	(46)

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Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20

Date Report Requested: 06/29/2009

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

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/
Degeneration	45 [3.7]	43 [3.8]	42 [3.7]	24 [3.8]	43 [3.7]	42 [3.6]
Inflammation, Suppurative	(4.5)	1 [1.0]	(12)	1 [1.0]	(12)	(>
Ovary	(48)	(47)	(46)	(25)	(48)	(47)
Angiectasis	40 [2 2]	40 [0 4]	10.01.00	10.01.00	40 [0 0]	40 [0 4]
Atrophy	40 [3.3]	42 [3.4]	38 [3.2]	23 [3.3]	43 [3.3]	40 [3.1]
Cyst Parmaid	21 [2.9]	20 [2.8]	21 [3.2]	8 [3.0]	19 [2.8]	13 [3.4]
Cyst Dermoid			1			1 [4.0]
Hematocyst Infiltration Cellular, Lymphocyte	1 [2.0]	2 [3.0]	I		1 [3.0]	2 [2 5]
Inflammation, Chronic Active	1 [2.0]	2 [3.0]			1 [3.0] 1 [4.0]	2 [2.5]
Bilateral, Cyst	8 [3.3]	2 [2.0]	5 [2.8]	4 [3.5]	2 [2.5]	3 [3.7]
Fat, Necrosis	0 [3.3]	2 [2.0]	5 [2.6]	4 [3.5]	2 [2.5]	3 [3.7]
Germinal Epithelium, Hyperplasia						
Parenchymal Cell, Degeneration	1 [4.0]					
Uterus	(48)	(46)	(46)	(26)	(48)	(48)
Angiectasis	(40)	(40)	(40)	(20)	(40)	2 [2.5]
Autolysis				1 [4.0]		رد.ن]
Hydrometra	1 [4.0]	4 [4.0]	1 [4.0]	2 [4.0]	7 [3.9]	6 [4.0]
Thrombosis	1 [4.0]	4 [4.0]	1 [4.0]	۲ [۲.0]	7 [5.9]	0 [4.0]
Endometrium, Hyperplasia, Cystic	44 [2.8]	42 [2.8]	44 [2.7]	22 [2.6]	40 [2.6]	42 [2.4]
EMATOPOIETIC SYSTEM						
Bone Marrow	(48)	(46)	(46)	(25)	(47)	(47)
Hyperplasia	1 [2.0]	1 [2.0]	1 [2.0]	1 [2.0]	2 [2.5]	3 [2.3]
Pigmentation						
Lymph Node	(4)	(5)	(11)	(3)	(6)	(13)
Cyst						
Hemorrhage	1 [3.0]					
Hyperplasia, Lymphoid	1 [2.0]					
Axillary, Autolysis						
Axillary, Hyperplasia, Lymphoid						1 [3.0]
Bronchial, Autolysis						
Iliac, Autolysis						
Lumbar, Autolysis					4 [4 0]	
Lumbar, Cyst					1 [4.0]	
Lumbar, Fibrosis						0 [0 []
Lumbar, Hyperplasia, Lymphoid						2 [2.5]
Lumbar, Infiltration Cellular, Plasma Cell						1 [2.0]

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Route: IN-UTERO

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AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Lab: NCTR

Date Report Requested: 06/29/2009

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

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/
Lumbar, Infiltration Cellular,						
Polymorphonuclear					4.54.01	
Lumbar, Inflammation, Chronic Active					1 [4.0]	4 [0 0]
Lumbar, Polyarteritis Mediastinal, Autolysis						1 [2.0]
Mediastinal, Autorysis Mediastinal, Hyperplasia, Lymphoid		1 [2.0]				
Mediastinal, Infiltration Cellular, Plasma		1 [2.0] 1 [2.0]				
Cell		1 [2.0]				
Pancreatic, Hyperplasia, Lymphoid						1 [4.0]
Renal, Autolysis						1 [4.0]
Renal, Hyperplasia, Lymphoid						2 [3.0]
Renal, Infiltration Cellular, Plasma Cell						2 [0.0]
Renal, Infiltration Cellular,						
Polymorphonuclear						
Sinus, Dilatation	1 [2.0]					
Lymph Node, Mandibular	(47)	(47)	(47)	(25)	(48)	(48)
Autolysis	(11)	()	()	(23)	(10)	(10)
Erythrophagocytosis						
Hyperplasia, Lymphoid	18 [1.8]	18 [1.9]	11 [1.8]	6 [1.7]	14 [1.8]	13 [2.1]
Infiltration Cellular, Plasma Cell	1 [2.0]	1 [2.0]	1 [2.0]	0[]	[0]	1 [3.0]
Infiltration Cellular, Polymorphonuclear	. [2.0]	. [2.0]	. [2.0]			. [0.0]
Pigmentation	1 [2.0]					
Lymph Node, Mesenteric	(47)	(46)	(46)	(25)	(47)	(48)
Angiectasis	(,	1 [3.0]	(10)	(=3)	(,	()
Autolysis		. [e.e]				
Cyst						
Hematopoietic Cell Proliferation		1 [2.0]				
Hemorrhage		. [=]				
Hyperplasia						
Hyperplasia, Lymphoid	18 [2.0]	21 [1.7]	10 [1.8]	11 [2.1]	21 [1.8]	27 [2.1]
Infiltration Cellular, Histiocyte	[]	[]		[]	2 [2.0]	[1
Infiltration Cellular, Plasma Cell	2 [2.0]	1 [3.0]			1 [3.0]	4 [3.0]
Infiltration Cellular, Polymorphonuclear	,	1			11	11
Inflammation, Chronic Active						
Thrombosis						
Sinus, Dilatation		2 [3.0]				
Spleen	(48)	(47)	(47)	(25)	(48)	(50)
Autolysis	• •	, ,	· ,	, ,	1 [4.0]	` '
Erythrophagocytosis						
Hematopoietic Cell Proliferation	9 [3.0]	15 [2.4]	10 [3.2]	8 [2.1]	9 [3.3]	12 [2.7]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/
Hemorrhage Hyperplasia, Lymphoid Necrosis	30 [3.1]	30 [3.2]	25 [2.7]	14 [2.9]	1 [4.0] 27 [2.9] 1 [4.0]	32 [3.2]
Pigmentation Thrombosis Thymus	(40)	1 [3.0] (44)	(44)	(25)	(48)	(44)
Angiectasis Atrophy Autolysis	1 [2.0] 6 [2.3]	11 [2.8]	11 [2.5]	7 [3.1]	6 [2.3]	18 [2.7]
Autorysis Hyperplasia, Lymphoid Mineralization Fat, Necrosis	10 [2.0]	10 [2.2]	4 [1.8]	4 [1.8]	13 [2.2]	8 [2.3]
INTEGUMENTARY SYSTEM						_
Mammary Gland Galactocele Lactation	(47)	(47)	(47)	(24)	(48)	(47) 1 [2.0]
Metaplasia, Squamous Alveolus, Hyperplasia Skin Fibrosis	1 [2.0] 2 [2.0] (49) 1 [2.0]	1 [2.0] (47)	(47)	(25)	3 [2.0] (48)	1 [4.0] (49)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Ulcer	1 [2.0] 1 [3.0]					1 [3.0]
MUSCULOSKELETAL SYSTEM						
Bone, Femur Fibro-Osseous Lesion Skeletal Muscle	(49) (1)	(48) 1 [2.0] (2)	(48) 2 [3.0] (0)	(26) 1 [3.0] (0)	(49) (0)	(50) (0)
NERVOUS SYSTEM						
Brain, Brain Stem Compression Degeneration Hemorrhage	(47) 2 [2.5]	(46) 1 [4.0] 1 [1.0]	(46)	(25)	(48) 3 [3.0]	(47) 2 [2.0]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Lab: NCTR

Date Report Requested: 06/29/2009

Time Report Requested: 16:30:20

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

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL
Brain, Cerebellum	(47)	(46)	(46)	(25)	(48)	(47)
Hemorrhage Infiltration Cellular, Lymphocyte Vacuolization Cytoplasmic Meninges, Infiltration Cellular,				1 [1.0] 1 [1.0]		1 [1.0]
Lymphocyte Ventricle, Dilatation Brain, Cerebrum	(47)	(46)	(46)	(25)	1 [2.0] (48)	(47)
Cyst Epithelial Inclusion Hemorrhage Mineralization	19 [1.0]	16 [1.0]	25 [1.0]	5 [1.0]	18 [1.0]	1 1 [1.0] 25 [1.0]
Meninges, Infiltration Cellular, Lymphocyte Ventricle, Dilatation Peripheral Nerve	(1)	1 [2.0] (1)	(0)	(0)	1 [2.0] (0)	(0)
Axon, Degeneration	1 [1.0]	(1)	(0)	(0)	(0)	(0)
Spinal Cord Degeneration Inflammation, Chronic Active	(1)	(1) 1 [3.0] 1 [4.0]	(0)	(0)	(0)	(0)
Axon, Degeneration	1 [1.0]	1 [4.0]				
ESPIRATORY SYSTEM						_
Lung Autolysis	(48) 1 [4.0]	(47)	(46)	(25)	(47)	(50)
Congestion Crystals Hemorrhage	1 [2.0]	2 [3.0] 1 [3.0]		2 [3.0]	1 [3.0] 1 [2.0]	1 [2.0]
Infiltration Cellular, Histiocyte Infiltration Cellular, Lymphocyte Inflammation, Chronic	1 [2.0] 13 [1.7]	3 [2.3] 15 [1.6]	1 [2.0] 8 [1.3]	2 [3.0] 4 [1.8]	4 [2.0] 9 [1.7]	1 [2.0] 14 [1.4]
Inflammation, Chronic Inflammation, Chronic Active Metaplasia, Osseous		1 [2.0]	1 [1.0]			1 [1.0]
Alveolar Epithelium, Hyperplasia Bronchiole, Hyperplasia	1 [1.0]	2 [1.5]	2 [2.0] 1 [2.0]	1 [1.0]	1 [3.0]	1 [1.0]
Nose Inflammation, Suppurative	(49)	(47)	(48) 1 [2.0]	(26)	(47)	(48)
Posterior To Upper Incisor, Dysplasia		1 [3.0]				

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/
SPECIAL SENSES SYSTEM						
Eye Cataract Degeneration Inflammation, Chronic Active	(45) 1 [2.0]	(45) 2 [1.5]	(45) 1 [1.0]	(25) 1 [1.0]	(47) 1 [2.0] 1 [3.0] 1 [2.0]	(45) 1 [4.0]
Metaplasia, Squamous Bilateral, Cataract Cornea, Inflammation, Chronic Active	1 [3.0]	1 [1.0] 1 [1.0]	1 [1.0] 2 [2.0]	1 [2.0] 1 [1.0]	1 [1.0]	
Cornea, Necrosis Cornea, Ulcer Retina, Degeneration	1 [3.0]	1 [4.0]	1 [2.0]			
Harderian Gland Cyst	(46)	(45)	(45)	(25)	(46)	(46) 1 [4.0]
Infiltration Cellular, Lymphocyte Inflammation, Chronic	5 [1.2]	5 [1.0]	5 [1.0]	2 [1.0]	4 [1.0]	4 [1.3] 1 [2.0]
Inflammation, Chronic Active Acinus, Degeneration Acinus, Hyperplasia Epithelium, Hyperplasia	1 [2.0]	1 [1.0]		1 [3.0]		1 [1.0] 2 [3.5]
JRINARY SYSTEM						_
Kidney Amyloid Deposition Hemorrhage	(47)	(47)	(48) 1 [4.0]	(25)	(47)	(47)
Hyaline Droplet Hydronephrosis	1 [2.0]			1 [2 0]	1 [4.0]	2 [3.5]
Hyperplasia, Lymphoid Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	11 [1.1]	15 [1.3]	15 [1.3]	1 [2.0] 5 [1.0]	15 [1.2] 1 [4.0]	7 [1.3]
Metaplasia, Osseous Nephropathy Polyarteritis Adventitia, Inflammation, Chronic Active	30 [1.1]	22 [1.3]	1 [1.0] 19 [1.4]	12 [1.3]	23 [1.2]	1 [2.0] 30 [1.4] 1 [2.0]
Adventitia, Fat, Necrosis Urinary Bladder Edema	(46)	(46)	(47)	(25)	(47)	(47)
Infiltration Cellular, Lymphocyte	21 [1.1]	25 [1.2]	24 [1.3]	10 [1.3]	23 [1.3]	19 [1.1]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

TDMS No. 20311 - 02
Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Benert Benuested: 16:20:20

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Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	AZTH/3TCH/NVPH/0	AZTM/3TCM/NVPM/0	AZTL/3TCL/NVPL/0	AZTH/3TCH/NFVH/0	AZTM/3TCM/NFVM/0	AZTL/3TCL/NFVL/0
Inflammation, Chronic Active Polyarteritis Lumen, Dilatation						1 [1.0]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

TDMS No. 20311 - 02
Test Type: CHRONIC

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0
Disposition Summary	
Animals Initially in Study	64
Early Deaths Moribund Sacrifice	7
Natural Death	3
Survivors Moribund Sacrifice	6
Natural Death	1
Terminal Sacrifice	45
Harvest Animals Examined Microscopically	2 64
,,	
ALIMENTARY SYSTEM	
Esophagus	(62)
Gallbladder Cyst	(60)
Degeneration, Hyaline	
Infiltration Cellular, Lymphocyte	
Inflammation, Chronic Intestine Large, Cecum	(60)
Hyperplasia, Lymphoid	(00)
Serosa, Hyperplasia	1 [2.0]
Intestine Large, Colon	(60)
Intestine Large, Rectum Hyperplasia, Lymphoid	(60)
Intestine Small, Duodenum	(60)
Diverticulum	(60)
Intestine Small, Ileum Hyperplasia, Lymphoid	(60)
Inflammation, Chronic Active	1 [2.0]
Intestine Small, Jejunum	(60)
Hyperplasia, Lymphoid Epithelium, Hyperplasia	1 [3.0]
Liver	(61)
Angiectasis	
Autolysis	

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Test Type: CHRONIC

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0
Basophilic Focus Basophilic Focus, Multiple Clear Cell Focus	2
Congestion Cyst Cyst Multilocular	1 [2.0]
Deformity Eosinophilic Focus Eosinophilic Focus, Multiple Fatty Change	3
Hematocyst Hematopoietic Cell Proliferation Hemorrhage	2 [1.5]
Hepatodiaphragmatic Nodule Infiltration Cellular, Histiocyte Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	1 [2.0] 18 [1.1]
Mineralization Mixed Cell Focus Necrosis	5 [1.2] 1 [1.0] 1 3 [1.3]
Tension Lipidosis Vacuolization Cytoplasmic Mesentery	7 [1.4] 32 [1.6] (8)
Cyst Hematocyst Hemorrhage	(0)
Infiltration Cellular, Lymphocyte Fat, Necrosis Pancreas Cyst	8 [3.4] (62) 1 [2.0]
Cyst Cytoplasmic Alteration Edema Infiltration Cellular, Lymphocyte	1 [2.0] 23 [1.0]
Inflammation, Chronic Active Mineralization Necrosis	20 [1.0]
Acinus, Degeneration Duct, Dilatation Fat, Necrosis	2 [1.5]
Salivary Glands	(62)

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Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0	
Infiltration Cellular, Lymphocyte Polyarteritis Acinus, Degeneration	47 [1.7]	
Stomach, Forestomach Hyperkeratosis Hyperplasia Inflammation, Chronic Active Keratin Cyst	(62)	
Ulcer	1 [2.0]	
Epithelium, Hyperplasia	2 [2.5]	
Stomach, Glandular	(60)	
Degeneration, Hyaline Infiltration Cellular, Lymphocyte	1 [1.0]	
Inflammation, Chronic Active	, [1.0]	
Mineralization		
Epithelium, Hyperplasia		
CARDIOVASCULAR SYSTEM		
Blood Vessel Heart	(62) (63)	
Cardiomyopathy		
Inflammation, Suppurative	1 [4.0]	
Inflammation, Chronic Active Mineralization		
Necrosis		
Polyarteritis		
ENDOCRINE SYSTEM		
Adrenal Cortex	(61)	
Accessory Adrenal Cortical Nodule	6	
Angiectasis	-	
Cyst		
Hypertrophy	1 [1.0]	
Vacuolization Cytoplasmic	3 [3.0]	
Subcapsular, Hyperplasia	60 [1.9]	
Adrenal Medulla	(60)	
Hyperplasia		

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Time Bonert Bonested: 10:20:20

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0
Islets, Pancreatic	(62)
Hyperplasia	1 [2.0]
Infiltration Cellular, Lymphocyte	1 [1.0]
Parathyroid Gland	(54)
Cyst	1 [2.0]
Hyperplasia	
Hypertrophy	1 [2.0]
Infiltration Cellular, Lymphocyte	
Pituitary Gland	(60)
Hemorrhage	
Pars Distalis, Angiectasis	1 [2.0]
Pars Distalis, Cyst	2 [3.0]
Pars Distalis, Hyperplasia	8 [1.5]
Rathke's Cleft, Dilatation	
Thyroid Gland	(59)
Cyst	
Ectopic Thymus	1 [1.0]
Infiltration Cellular, Lymphocyte	2 [2.0]
Inflammation, Chronic Active	
Polyarteritis	
C-cell, Hyperplasia	
Follicle, Degeneration	9 [1.2]
Follicular Cell, Hyperplasia	
Follicular Cell, Hypertrophy	2 [1.5]
ENERAL BODY SYSTEM	
Tissue NOS	(3)
Hemorrhage	(3)
Infiltration Cellular, Lymphocyte	
Abdominal, Fibrosis	
Abdominal, Inflammation, Chronic Active	1 [4.0]
Abdominal, Keratin Cyst	1 [1.0]
Fat, Necrosis	
ENITAL SYSTEM	
Clitoral Gland	(60)
Cilloral Giario	

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

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ETIC SYSTEM
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lyperplasia, Lymphoid 5 [2.6]
filtration Cellular, Plasma Cell 1 [2.0]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

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Date Report Requested: 06/29/2009

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0	
Lumbar, Infiltration Cellular,	2 [2.0]	
Polymorphonuclear		
Lumbar, Inflammation, Chronic Active		
Lumbar, Polyarteritis		
Mediastinal, Autolysis	1 [4.0]	
Mediastinal, Hyperplasia, Lymphoid	1 [2.0]	
Mediastinal, Infiltration Cellular, Plasma Cell		
Pancreatic, Hyperplasia, Lymphoid		
Renal, Autolysis	1 [4.0]	
Renal, Hyperplasia, Lymphoid	1 [2.0]	
Renal, Infiltration Cellular, Plasma Cell		
Renal, Infiltration Cellular,	1 [2.0]	
Polymorphonuclear		
Sinus, Dilatation	1 [4.0]	
Lymph Node, Mandibular	(61)	
Autolysis	1 [4.0]	
Erythrophagocytosis	1 [3.0]	
Hyperplasia, Lymphoid	16 [2.0]	
Infiltration Cellular, Plasma Cell	1 [3.0]	
Infiltration Cellular, Polymorphonuclear	1 [2.0]	
Pigmentation	(00)	
Lymph Node, Mesenteric	(60)	
Angiectasis	4 [4 0]	
Autolysis	1 [4.0]	
Cyst		
Hematopoietic Cell Proliferation Hemorrhage		
нетогтаде Hyperplasia		
нурегріазіа Hyperplasia, Lymphoid	20 [2.0]	
Infiltration Cellular, Histiocyte	20 [2.0] 1 [3.0]	
Infiltration Cellular, Plasma Cell	1 [3.0] 1 [3.0]	
Infiltration Cellular, Polymorphonuclear	1 [2.0]	
Inflammation, Chronic Active	1 [Z.V]	
Thrombosis	1 [4.0]	
Sinus, Dilatation	. [•]	
Spleen	(62)	
Autolysis	1 [4.0]	
Erythrophagocytosis	1 [4.0]	
Hematopoietic Cell Proliferation	14 [3.2]	

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

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TDMS No. 20311 - 02
Test Type: CHRONIC

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Species/Strain: MICE/B6C3F1/NCTR

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Date Report Requested: 06/29/2009

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

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0	
Hemorrhage Hyperplasia, Lymphoid Necrosis Pigmentation Thrombosis	32 [2.9]	
Thymus Angiectasis	(55)	
Atrophy Autolysis	13 [2.6]	
Hyperplasia, Lymphoid Mineralization Fat, Necrosis	12 [2.0]	
INTEGUMENTARY SYSTEM		
Mammary Gland Galactocele Lactation Metaplasia, Squamous Alveolus, Hyperplasia Skin Fibrosis Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Ulcer	(63)	
	2 [2.5] 2 [3.0] (63)	
MUSCULOSKELETAL SYSTEM		
Bone, Femur Fibro-Osseous Lesion Skeletal Muscle	(64)	
	(1)	
NERVOUS SYSTEM		
Brain, Brain Stem Compression Degeneration	(61) 1 [3.0]	
Hemorrhage	1 [1.0]	

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

TDMS No. 20311 - 02
Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009

Time Report Requested: 16:30:20 First Dose M/F: NA / 07/10/03

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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

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Date Report Requested: 06/29/2009

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0
SPECIAL SENSES SYSTEM	
Eye Cataract Degeneration Inflammation, Chronic Active Metaplasia, Squamous Bilateral, Cataract	(59)
Cornea, Inflammation, Chronic Active Cornea, Necrosis Cornea, Ulcer Retina, Degeneration	1 [1.0]
Harderian Gland Cyst	(60)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Inflammation, Chronic Active Acinus, Degeneration Acinus, Hyperplasia Epithelium, Hyperplasia	7 [1.0]
URINARY SYSTEM	
Kidney Amyloid Deposition Hemorrhage Hyaline Droplet Hydronephrosis Hyperplasia, Lymphoid	(62) 1 [2.0]
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	17 [1.2]
Metaplasia, Osseous Nephropathy Polyarteritis Adventitia, Inflammation, Chronic Active Adventitia, Fat, Necrosis	2 [1.5] 31 [1.2]
Urinary Bladder Edema	(60)
Infiltration Cellular, Lymphocyte	20 [1.1]

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TDMS No. 20311 - 02
Test Type: CHRONIC

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AZT/Drug Combinations Transplacental Carcinogenesis Study

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

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Species/Strain: MICE/B6C3F1/NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	SOLVENT to 0
Inflammation, Chronic Active Polyarteritis Lumen, Dilatation	1 [3.0]

*** END OF REPORT ***

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)