TDMS No. 20311 - 01 Test Type: CHRONIC Route: IN-UTERO Species/Strain: MICE/B6C3F1/NCTF	२	P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) AZT/Drug Combinations Transplacental Carcinogenesis Study CAS Number: AIDSTHERAPEU	Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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		

TDMS No. 20311 - 01 Test Type: CHRONIC Route: IN-UTERO

Species/Strain: MICE/B6C3F1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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 (
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 Harvest	35 1	38	39 1	34 3	35 3	39 1
Animals Examined Microscopically	48	48	48	48	48	51
ALIMENTARY SYSTEM						
Gallbladder	(45)	(44)	(48)	(44)	(42)	(49)
Vacuolization Cytoplasmic						
Epithelium, Hyperplasia Intestine Large, Cecum	(45)	(45)	(48)	1 (2%) (43)	(45)	(50)
Hyperplasia, Lymphoid	(+3)	1 (2%)	2 (4%)	2 (5%)	5 (11%)	2 (4%)
Intestine Large, Colon	(45)	(46)	(48)	(44)	(45)	(50)
Hyperplasia, Lymphoid				1 (2%)	4 (00()	
Inflammation, Chronic Active Ulcer					1 (2%) 1 (2%)	
Intestine Large, Rectum	(45)	(45)	(48)	(43)	(45)	(50)
Anus, Hemorrhage	(-)	(-)	1 (2%)		(-)	()
Anus, Inflammation, Chronic			1 (2%)			
Anus, Necrosis Intestine Small, Duodenum	(45)	(45)	1 (2%) (48)	(43)	(44)	(50)
Hyperplasia, Lymphoid	1 (2%)	(45)	1 (2%)	(43)	(44)	(50)
Infiltration Cellular, Plasma Cell	. (_,,,)		. (_ /)			1 (2%)
Infiltration Cellular, Polymorphonuclear			4 (00()			
Inflammation, Chronic Active Epithelium, Hyperplasia			1 (2%)		1 (2%)	
Intestine Small, Ileum	(45)	(45)	(48)	(43)	(45)	(50)
Hyperplasia, Lymphoid				1 (2%)		
Infiltration Cellular, Polymorphonuclear						
Inflammation, Suppurative Inflammation, Chronic Active						
Intestine Small, Jejunum	(45)	(44)	(48)	(43)	(46)	(50)
Hyperplasia, Lymphoid		(• •)	()	()	()	
Inflammation, Chronic Active	1 (2%)		(((12)	1 (2%)
Liver	(46)	(47)	(48)	(46)	(48)	(51)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Angiectasis	4 (00()	C (400())	0 (49()	4 (00/.)	1 (2%)	C (4.09()
Basophilic Focus Basophilic Focus, Multiple	4 (9%)	6 (13%)	2 (4%)	4 (9%)	5 (10%) 1 (2%)	6 (12%)
Cholangiofibrosis Clear Cell Focus				1 (2%)		1 (2%)
Clear Cell Focus, Multiple Cyst						1 (2%)
Cyst Multilocular	4 (00()		4 (00()	0 (40()	0 (10())	0 (00()
Eosinophilic Focus	1 (2%)		4 (8%)	2 (4%)	2 (4%)	3 (6%)
Eosinophilic Focus, Multiple Fatty Change		1 (2%)		1 (2%)		
Fatty Change Fibrosis		1 (2%)			1 (2%)	
Focal Cellular Change					1 (278)	
Hematopoietic Cell Proliferation	1 (2%)					3 (6%)
Hepatodiaphragmatic Nodule	1 (270)					0 (070)
Infiltration Cellular, Lymphocyte	1 (2%)	3 (6%)	4 (8%)	3 (7%)	4 (8%)	4 (8%)
Inflammation, Chronic	- (_,,)	1 (2%)			(2,2)	
Inflammation, Chronic Active	1 (2%)	()	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Mineralization			1 (2%)		× ,	
Mixed Cell Focus				1 (2%)	2 (4%)	
Necrosis	4 (9%)	2 (4%)	2 (4%)	2 (4%)	2 (4%)	
Tension Lipidosis	10 (22%)	11 (23%)	12 (25%)	10 (22%)	6 (13%)	8 (16%)
Vacuolization Cytoplasmic	5 (11%)	1 (2%)	2 (4%)	3 (7%)		4 (8%)
Oval Cell, Hyperplasia						
Mesentery	(3)	(1)	(2)	(0)	(1)	(2)
Hemorrhage						
Necrosis						- (
Fat, Necrosis	1 (33%)	(1 (50%)		1 (100%)	2 (100%)
Pancreas	(46)	(46)	(48)	(45)	(45)	(50)
Cyst			1 (2%)		1 (2%)	
Cytoplasmic Alteration						
Edema						
Fibrosis Infiltration Cellular, Lymphocyte	4 (00()	2(49())	6 (139/)	6 (120/)	5 (11%)	6 (12%)
Inflammation, Chronic Active	4 (9%)	2 (4%)	6 (13%)	6 (13%)		6 (12%)
Acinus, Degeneration	1 (2%)	5 (11%)	7 (15%)	4 (9%)	1 (2%) 5 (11%)	6 (12%)
Salivary Glands	(46)	(46)	(48)	4 (9%) (44)	(47)	(50)
Fibrosis	(40)	(40)	(48)	(44)	1 (2%)	(50)
Infiltration Cellular, Lymphocyte	40 (87%)	38 (83%)	45 (94%)	38 (86%)	41 (87%)	44 (88%)
Inflammation, Chronic Active	40 (07 /0)	30 (03 %)	40 (0470)	38 (88 %)	1 (2%)	++ (0070)
Mineralization					1 (270)	
Stomach, Forestomach	(46)	(46)	(48)	(45)	(45)	(50)
Cyst Epithelial Inclusion	(,	()	()	()	()	()
Hyperkeratosis		1 (2%)				
Hyperplasia		. (=,		1 (2%)		
Inflammation, Chronic Active		1 (2%)		(=)		

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Ulcer Epithelium, Hyperplasia	1 (2%)	1 (2%)		1 (2%)		1 (2%) 2 (4%)
Stomach, Glandular Degeneration Infiltration Cellular, Polymorphonuclear	(45)	(44) 1 (2%)	(48)	(43)	(45)	(50)
Inflammation, Suppurative Inflammation, Chronic Active Necrosis Ulcer			1 (2%)		1 (2%)	
Epithelium, Hyperplasia Glands, Hyperplasia						2 (4%)
Tongue	(0)	(0)	(0)	(1)	(0)	(0)
CARDIOVASCULAR SYSTEM						
Blood Vessel Hemorrhage Polyarteritis	(47)	(47)	(48)	(46) 1 (2%)	(48)	(50)
Heart Cardiomyopathy	(47)	(48) 1 (2%)	(48) 2 (4%)	(46)	(48) 2 (4%)	(50) 1 (2%)
Inflammation Inflammation, Chronic Active Necrosis		1 (2%)				
Polyarteritis Ventricle, Dilatation			1 (2%)			2 (4%)
ENDOCRINE SYSTEM						
Adrenal Cortex Accessory Adrenal Cortical Nodule	(47) 1 (2%)	(45)	(48) 1 (2%)	(45) 3 (7%)	(46) 2 (4%)	(50)
Cyst Depletion	. (_/0)		. (= /0)	1 (2%)		1 (2%)
Hyperplasia Hypertrophy	2 (4%)		4 (8%)	1 (2%)	2 (4%) 4 (9%)	3 (6%)
Inflammation, Chronic Active Subcapsular, Hyperplasia Adrenal Medulla Hyperplasia	38 (81%) (45)	33 (73%) (45)	38 (79%) (46)	34 (76%) (43)	36 (78%) (46)	37 (74%) (49)
Islets, Pancreatic Hyperplasia	(47) 5 (11%)	(48) 6 (13%)	(48) 5 (10%)	(45) 8 (18%)	(44) 9 (20%)	(50) 12 (24%)
Parathyroid Gland Cyst Infiltration Cellular, Lymphocyte	(43)	(41) 1 (2%)	(37) 1 (3%) 2 (5%)	(41)	(37)	(45)
Pituitary Gland	(45)	(48)	2 (5%) (47)	(45)	1 (3%) (44)	1 (2%) (50)

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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
Pars Distalis, Cyst Pars Distalis, Hyperplasia Thyroid Gland	3 (7%) 1 (2%) (46)	3 (6%) (45)	7 (15%) 1 (2%) (48)	7 (16%) (46)	3 (7%) 1 (2%) (46)	1 (2%) 3 (6%) (50)
Depletion Ectopic Thymus Infiltration Cellular, Lymphocyte	1 (2%) 1 (2%)		1 (2%) 1 (2%)	1 (2%)	1 (2%)	
Inflammation, Chronic Active Polyarteritis	1 (270)		1 (270)		1 (2%)	1 (2%)
Follicle, Cyst Follicle, Degeneration Follicular Cell, Hyperplasia	5 (11%)	1 (2%) 6 (13%)	7 (15%)	3 (7%)	6 (13%)	4 (8%)
ENERAL BODY SYSTEM						
Tissue NOS Abdominal, Fibrosis Abdominal, Infiltration Cellular, Polymorphonuclear Abdominal, Inflammation, Granulomatous Abdominal, Inflammation, Chronic Active	(1)	(2)	(0)	(3)	(1)	(1)
ENITAL SYSTEM						
Coagulating Gland Lumen, Dilatation	(0)	(1) 1 (100%)	(0)	(1) 1 (100%)	(0)	(2) 2 (100%)
Epididymis Atrophy	(46)	(45)	(48)	(45)	(46)	(50)
Fibrosis					1 (2%)	1 (2%)
Hypospermia Infiltration Cellular, Lymphocyte		3 (7%)	1 (2%) 2 (4%)	2 (4%)	2 (4%)	4 (8%) 1 (2%)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Inflammation, Chronic Active		3 (7%)		2 (4%)		
Infiltration Cellular, Lymphocyte Inflammation, Chronic Inflammation, Chronic Active Mineralization Polyarteritis Spermatocele		3 (7%)	2 (4%)	2 (4%) 1 (2%)	2 (4%)	
Infiltration Cellular, Lymphocyte Inflammation, Chronic Inflammation, Chronic Active Mineralization Polyarteritis Spermatocele Duct, Degeneration Preputial Gland Cyst Degeneration Infiltration Cellular, Lymphocyte	(46) 2 (4%) 16 (35%) 3 (7%)	3 (7%) (44) 10 (23%) 19 (43%) 1 (2%)	2 (4%) 1 (2%) 1 (2%) (48) 7 (15%) 17 (35%) 1 (2%)	1 (2%) (44) 1 (2%) 19 (43%) 1 (2%)	2 (4%) 1 (2%)	
Infiltration Cellular, Lymphocyte Inflammation, Chronic Inflammation, Chronic Active Mineralization Polyarteritis Spermatocele Duct, Degeneration Preputial Gland Cyst Degeneration	2 (4%) 16 (35%)	(44) 10 (23%) 19 (43%)	2 (4%) 1 (2%) 1 (2%) (48) 7 (15%) 17 (35%)	1 (2%) (44) 1 (2%) 19 (43%)	2 (4%) 1 (2%) 1 (2%) (46) 2 (4%) 21 (46%)	1 (2%) (50) 5 (10%)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Fat, Degeneration	1 (2%)					
Fat, Necrosis	(4 4)	(40)	1 (2%)	(4.4)	(40)	(50)
Prostate Dilatation	(44)	(43)	(48)	(44)	(46)	(50)
Infiltration Cellular, Lymphocyte Inflammation, Suppurative	5 (11%)	8 (19%)	6 (13%)	7 (16%)	4 (9%)	9 (18%)
Inflammation, Chronic Active Polyarteritis					1 (2%)	
Seminal Vesicle Amyloid Deposition	(46)	(46)	(48)	(45)	(45)	(50)
Atrophy Infiltration Cellular, Lymphocyte	1 (2%) 1 (2%)			1 (2%)	1 (2%)	1 (2%)
Inflammation, Chronic Active Lumen, Dilatation Testes	3 (7%)	3 (7%)	1 (2%)	5 (11%)	1 (2%) 3 (7%)	2 (4%)
Mineralization Seminiferous Tubule, Degeneration	(45) 2 (4%)	(45) 6 (13%)	(48) 5 (10%)	(44) 3 (7%)	(45) 5 (11%)	(50) 9 (18%)
Fibrosis Hyperplasia Pigmentation Lymph Node	5 (11%) (1)	3 (7%) (7)	1 (2%) (4)	1 (2%) (3)	1 (2%) 2 (4%) (4)	3 (6%) (3)
Lymph Node Hemorrhage Axillary, Hyperplasia, Lymphoid Axillary, Infiltration Cellular, Histiocyte Axillary, Infiltration Cellular, Plasma Cell Axillary, Infiltration Cellular, Polymorphonuclear Inguinal, Hyperplasia, Lymphoid Inguinal, Infiltration Cellular, Plasma Cell Inguinal, Infiltration Cellular,	(1) 1 (100%)	(7) 1 (14%)	(4) 2 (50%)	(3)	(4)	(3)
Polymorphonuclear Inguinal, Pigmentation Lumbar, Hemorrhage Lumbar, Hyperplasia, Lymphoid Lumbar, Infiltration Cellular, Plasma Cell Mediastinal, Hyperplasia, Lymphoid Mediastinal, Infiltration Cellular, Histiocyte		1 (14%) 1 (14%)		1 (33%)		
Mediastinal, Inflammation, Chronic Active Pancreatic, Hyperplasia, Lymphoid Pancreatic, Infiltration Cellular, Histiocyte Pancreatic, Sinus, Dilatation			1 (25%)		1 (25%)	

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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
Renal, Hemorrhage						
Renal, Hyperplasia, Lymphoid		1 (14%)		1 (33%)		
Renal, Infiltration Cellular, Histiocyte						
Renal, Infiltration Cellular, Plasma Cell						
Renal, Infiltration Cellular, Polymorphonuclear						
Renal, Inflammation, Chronic Active						
_ymph Node, Mandibular	(43)	(45)	(46)	(45)	(46)	(50)
Hemorrhage						
Hyperplasia, Lymphoid	6 (14%)	9 (20%)	9 (20%)	9 (20%)	4 (9%)	9 (18%)
Hyperplasia, Plasma Cell						
Infiltration Cellular, Mast Cell					1 (2%)	
Infiltration Cellular, Plasma Cell	2 (5%)			1 (2%)		
Infiltration Cellular, Polymorphonuclear						
Inflammation, Chronic Active						
Necrosis						
Pigmentation	(1 -)	(()	(1 2)		(10)	(= 0)
_ymph Node, Mesenteric	(45)	(46)	(48)	(44)	(46)	(50)
Angiectasis	4 (9%)	6 (13%)	8 (17%)	7 (16%)	4 (9%)	5 (10%)
Fibrosis				4 (22())		
Hematopoietic Cell Proliferation	10 (000()	10 (000()	10 (000()	1 (2%)	40 (000()	7 (4 40()
Hemorrhage	10 (22%)	18 (39%)	16 (33%)	15 (34%)	13 (28%)	7 (14%)
Hyperplasia, Lymphoid	24 (53%)	28 (61%)	29 (60%)	23 (52%)	23 (50%)	34 (68%)
Infiltration Cellular, Histiocyte	3 (7%)	4 (9%)	3 (6%)	3 (7%)	2 (4%)	4 (8%)
Infiltration Cellular, Mast Cell		1 (00()	1 (2%)	1 (2%)	1 (2%)	4 (00()
Infiltration Cellular, Plasma Cell		1 (2%)		2 (5%)	2 (4%)	1 (2%)
Infiltration Cellular, Polymorphonuclear				1 (2%)	3 (7%)	1 (2%)
Inflammation, Granulomatous Inflammation, Chronic Active						
Necrosis		1 (20()				
Polyarteritis	1 (2%)	1 (2%)				
Thrombosis	1 (2%)		1 (2%)			
Sinus, Dilatation	5 (11%)	5 (11%)	5 (10%)	9 (20%)	4 (9%)	4 (8%)
Spleen	(46)	(45)	(48)	9 (20%) (45)	(47)	(50)
Accessory Spleen	(40)	(43)	(48)	(43)	(47)	(50)
Angiectasis						
Atrophy						
Congestion				1 (2%)		
Depletion Lymphoid				1 (270)		
Hematopoietic Cell Proliferation	8 (17%)	6 (13%)	7 (15%)	9 (20%)	6 (13%)	11 (22%)
Hyperplasia, Lymphoid	13 (28%)	16 (36%)	14 (29%)	20 (44%)	17 (36%)	19 (38%)
Inflammation, Chronic Active	10 (2070)	10 (0070)		20 (11/0)	1 (2%)	10 (0070)
Thymus	(37)	(39)	(43)	(38)	(43)	(48)
Atrophy	13 (35%)	19 (49%)	18 (42%)	21 (55%)	20 (47%)	25 (52%)
Cyst				_ (00/0)		1 (2%)
Hyperplasia, Lymphoid	2 (5%)	1 (3%)	2 (5%)	2 (5%)		3 (6%)
Infiltration Cellular, Plasma Cell	= (= · · ·)	. (-,-,	= (/	= (-,-)		- ()

T DMS No. 20311 - 01 Test Type: CHRONIC Route: IN-UTERO Species/Strain: MICE/B6C3F1/NCTR		E RATES OF NON-NEO Drug Combinations Trar CAS Number:	Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Infiltration Cellular, Polymorphonuclear Inflammation, Chronic Active Necrosis						
INTEGUMENTARY SYSTEM						
Skin Fibrosis Hemorrhage Hyperkeratosis	(46)	(48) 1 (2%)	(48) 1 (2%)	(46)	(48) 1 (2%)	(50) 1 (2%)
Inflammation, Suppurative Inflammation, Chronic Active Metaplasia, Osseous	1 (2%)		1 (2%)	1 (2%) 1 (2%)	1 (2%) 1 (2%)	
Mineralization Necrosis Ulcer Epithelium, Hyperplasia	1 (2%) 2 (4%) 1 (2%)		1 (2%) 1 (2%)	1 (2%) 2 (4%) 1 (2%)	1 (2%)	
MUSCULOSKELETAL SYSTEM						
Bone Skeletal Muscle	(0) (3)	(0) (4)	(1) (1)	(0) (0)	(0) (1)	(0) (0)
NERVOUS SYSTEM						
Brain, Cerebellum Autolysis Hemorrhage	(46)	(46)	(48)	(46) 1 (2%) 1 (2%)	(45)	(50)
Brain, Cerebrum Degeneration Gliosis	(46)	(46)	(48)	(45)	(45) 1 (2%) 1 (2%)	(50)
Mineralization Polyarteritis	26 (57%)	25 (54%)	16 (33%)	18 (40%)	22 (49%)	29 (58%)
RESPIRATORY SYSTEM						
Lung Autolysis	(47)	(46)	(48)	(48) 1 (2%)	(47)	(50)
Congestion Crystals Hemorrhage	1 (2%) 3 (6%)	1 (2%)	4 (001)		3 (6%)	4 (8%) 1 (2%)
Infiltration Cellular, Histiocyte	3 (6%)		1 (2%)		5 (11%)	6 (12%)

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Test Type: CHRONIC

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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
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active		1 (2%)	1 (2%)	4 (8%)	5 (11%) 1 (2%)	3 (6%)
Pigmentation Alveolar Epithelium, Hyperplasia Nose Inflammation, Chronic Active	1 (2%) (47)	2 (4%) (48)	4 (8%) (48)	(46)	2 (4%) (46) 1 (2%)	1 (2%) 4 (8%) (51)
Mucosa, Dysplasia Posterior To Upper Incisor, Dysplasia	1 (2%)	1 (2%)	4 (8%)		1 (2%) 1 (2%)	6 (12%)
SPECIAL SENSES SYSTEM						
Eye Cataract Degeneration	(45) 1 (2%)	(43)	(48) 2 (4%)	(43)	(45) 1 (2%)	(50) 2 (4%)
Bilateral, Cataract Cornea, Inflammation, Suppurative	1 (2%)				1 (2%)	1 (2%) 1 (2%)
Cornea, Inflammation, Chronic Active Cornea, Ulcer Retina, Degeneration Harderian Gland Cyst Cyst Multilocular	2 (4%) 1 (2%) (45)	(45)	(48)	(45)	(45)	1 (2%) 1 (2%) (50) 1 (2%)
Foreign Body Hyperplasia Infiltration Cellular, Lymphocyte Infiltration Cellular, Polymorphonuclear	3 (7%)	2 (4%)	8 (17%)	3 (7%)	1 (2%) 5 (11%) 1 (2%)	3 (6%)
Inflammation, Chronic Active Acinus, Degeneration			1 (2%) 2 (4%)		1 (2%) 1 (2%)	1 (2%)
URINARY SYSTEM						
Kidney Amyloid Deposition	(46)	(45)	(48)	(44)	(46)	(50) 1 (2%)
Cyst Fibrosis	1 (2%)	3 (7%)	1 (2%)	2 (5%)	3 (7%) 1 (2%)	1 (270)
Hyaline Droplet Infiltration Cellular, Lymphocyte Inflammation, Suppurative	1 (2%) 9 (20%)	1 (2%) 7 (16%)	3 (6%)	5 (11%) 1 (2%)	6 (13%)	3 (6%)
Inflammation, Chronic Active Metaplasia, Osseous	3 (7%)	1 (2%)	2 (4%)	4 (00)	1 (2%)	
Necrosis Nephropathy Polyarteritis	34 (74%)	31 (69%) 1 (2%)	39 (81%)	1 (2%) 33 (75%) 1 (2%)	32 (70%)	42 (84%)
Pelvis, Dilatation		1 (270)	1 (2%)	1 (270)	1 (2%)	

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AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

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
Urethra Dilatation	(1) 1 (100%)	(1)	(0)	(0)	(0)	(0)
Bulbourethral Gland, Cyst Bulbourethral Gland, Hemorrhage		1 (100%)				
Bulbourethral Gland, Necrosis Bulbourethral Gland, Epithelium, Hyperplasia		1 (100%)				
Urinary Bladder Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	(46) 3 (7%)	(45) 6 (13%)	(48) 2 (4%)	(45) 5 (11%)	(46) 5 (11%) 1 (2%)	(50) 8 (16%)
Polyarteritis Lumen, Dilatation	1 (2%)	3 (7%)	2 (4%)	1 (2%)	2 (4%)	2 (4%)

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Disposition Summary						
Animals Initially in Study	50	48	48	15	51	48
Early Deaths Moribund Sacrifice Natural Death	18 2	10 2	8 1	6 1	5 2	6 3
Survivors Moribund Sacrifice	5				5	1
Natural Death Terminal Sacrifice Harvest	25	1 35	1 37 1	6 2	1 36 2	37 1
Animals Examined Microscopically	50	48	48	15	51	48
ALIMENTARY SYSTEM						
Gallbladder Vacuolization Cytoplasmic Epithelium, Hyperplasia	(47)	(44)	(45)	(13)	(47)	(45)
Intestine Large, Cecum Hyperplasia, Lymphoid	(48)	(45) 1 (2%)	(47) 6 (13%)	(14) 2 (14%)	(48) 2 (4%)	(45) 1 (2%)
Intestine Large, Colon Hyperplasia, Lymphoid Inflammation, Chronic Active Ulcer	(48)	(45)	(47)	(14)	(48)	(45)
Intestine Large, Rectum Anus, Hemorrhage Anus, Inflammation, Chronic Anus, Necrosis	(47)	(45)	(47)	(14)	(48)	(45)
Intestine Small, Duodenum Hyperplasia, Lymphoid Infiltration Cellular, Plasma Cell	(48)	(45)	(47)	(14)	(48) 1 (2%)	(45)
Infiltration Cellular, Polymorphonuclear Inflammation, Chronic Active			1 (2%)			
Epithelium, Hyperplasia Intestine Small, Ileum Hyperplasia, Lymphoid Infiltration Cellular, Polymorphonuclear	(48) 1 (2%)	(45)	1 (2%) (47) 1 (2%)	(14)	(48) 1 (2%)	(45)
Inflammation, Suppurative Inflammation, Chronic Active Intestine Small, Jejunum Hyperplasia, Lymphoid	(48)	1 (2%) (45) 1 (2%)	1 (2%) (47) 1 (2%)	(14) 1 (7%)	(48)	(45)
Inflammation, Chronic Active Liver	(48)	(47)	(48)	(15)	(50)	(48)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

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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
Angiectasis Basophilic Focus Basophilic Focus, Multiple Cholangiofibrosis	4 (8%) 1 (2%)	5 (11%)	5 (10%) 1 (2%) 1 (2%)		3 (6%)	2 (4%) 1 (2%)
Clear Cell Focus Clear Cell Focus, Multiple Cyst			1 (270)		2 (4%) 1 (2%)	
Cyst Multilocular Eosinophilic Focus Eosinophilic Focus, Multiple Fatty Change	1 (2%)	2 (4%)	4 (8%)	1 (7%)	1 (2%)	2 (4%)
Fibrosis Focal Cellular Change Hematopoietic Cell Proliferation			1 (2%)			1 (2%)
Hepatodiaphragmatic Nodule Infiltration Cellular, Lymphocyte Inflammation, Chronic	1 (2%) 1 (2%)	1 (2%) 4 (9%)	3 (6%)	3 (20%)	3 (6%)	6 (13%)
Inflammation, Chronic Active Mineralization	1 (270)		1 (2%)		2 (4%)	3 (6%)
Mixed Cell Focus Necrosis Tension Lipidosis Vacuolization Cytoplasmic	2 (4%) 8 (17%) 2 (4%)	11 (23%) 1 (2%)	1 (2%) 10 (21%) 2 (4%)		1 (2%) 2 (4%) 7 (14%) 1 (2%)	2 (4%) 13 (27%) 2 (4%)
Oval Cell, Hyperplasia Mesentery	(1)	(0)	1 (2%) (1)	(0)	(2)	(0)
Hemorrhage Necrosis Fat, Necrosis	1 (100%)				1 (50%)	
Pancreas Cyst Cytoplasmic Alteration Edema	(48)	(45)	(47) 1 (2%) 1 (2%) 1 (2%)	(15)	(49)	(45)
Fibrosis Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	7 (15%)	4 (9%)	3 (6%) 1 (2%)	1 (7%)	1 (2%) 6 (12%) 1 (2%)	1 (2%) 4 (9%) 2 (4%)
Acinus, Degeneration Salivary Glands Fibrosis	2 (4%) (48)	3 (7%) (45)	5 (11%) (47)	2 (13%) (15)	4 (8%) (50)	5 (11%) (46)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	38 (79%)	35 (78%)	39 (83%)	11 (73%)	40 (80%)	38 (83%) 1 (2%)
Mineralization Stomach, Forestomach Cyst Epithelial Inclusion	1 (2%) (48)	(45)	(48)	(15)	(50)	(45) 1 (2%)
Cyst Epitheliai Inclusion Hyperkeratosis Hyperplasia Inflammation, Chronic Active			1 (2%)			1 (2%)

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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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
Ulcer Epithelium, Hyperplasia Stomach, Glandular Degeneration Infiltration Cellular, Polymorphonuclear	3 (6%) (47)	(45)	1 (2%) 2 (4%) (47) 2 (4%)	(14)	1 (2%) (48)	(45) 1 (2%)
Inflammation, Suppurative Inflammation, Chronic Active			2 (4%) 1 (2%)	1 (7%)		
Necrosis Ulcer	- ()			1 (7%)		1 (2%)
Epithelium, Hyperplasia Glands, Hyperplasia	3 (6%)		1 (2%) 1 (2%)	1 (7%)	1 (2%)	
Tongue	(0)	(0)	(0)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM						
Blood Vessel Hemorrhage	(48)	(47)	(47)	(15)	(50)	(48)
Polyarteritīs Heart Cardiomyopathy	(48)	(47)	(47) 2 (4%)	1 (7%) (15)	(50)	(48) 1 (2%)
Inflammation Inflammation, Chronic Active Necrosis Polyarteritis Ventricle, Dilatation	1 (2%)			1 (7%)		1 (2%) 1 (2%)
ENDOCRINE SYSTEM						
Adrenal Cortex Accessory Adrenal Cortical Nodule Cyst	(47) 3 (6%)	(45) 4 (9%)	(47) 1 (2%)	(15)	(49)	(45) 1 (2%)
Depletion	1 (2%)					
Hyperplasia Hypertrophy Inflammation, Chronic Active	1 (2%)	2 (4%)	3 (6%) 1 (2%)		2 (4%)	4 (9%) 1 (2%)
Subcapsular, Hyperplasia Adrenal Medulla	33 (70%) (46)	37 (82%) (44)	38 (81%) (46)	12 (80%) (13)	29 (59%) (47)	36 (80%) (44)
Hyperplasia Islets, Pancreatic Hyperplasia Parathyroid Gland Cyst	1 (2%) (48) (34)	(45) 9 (20%) (33)	(47) 8 (17%) (38) 1 (3%)	(15) 1 (7%) (13)	1 (2%) (50) 9 (18%) (40)	(45) 6 (13%) (38)
Infiltration Cellular, Lymphocyte Pituitary Gland	(48)	2 (6%) (44)	(46)	(15)	(50)	(46)

TDMS No. 20311 - 01 Test Type: CHRONIC Route: IN-UTERO

Species/Strain: MICE/B6C3F1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Pars Distalis, Cyst Pars Distalis, Hyperplasia Thyroid Gland Depletion	1 (2%) (48)	2 (5%) (45)	2 (4%) 1 (2%) (48)	(15)	2 (4%) 1 (2%) (50)	1 (2%) 2 (4%) (46)
Ectopic Thymus Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	1 (2%)		1 (2%) 2 (4%)	1 (7%)	1 (2%)	1 (2%)
Polyarteritis Follicle, Cyst Follicle, Degeneration Follicular Cell, Hyperplasia	1 (2%) 2 (4%)	3 (7%)	5 (10%)	1 (7%) 1 (7%) 2 (13%)	6 (12%) 1 (2%)	2 (4%) 1 (2%)
GENERAL BODY SYSTEM						
Tissue NOS Abdominal, Fibrosis Abdominal, Infiltration Cellular, Polymorphonuclear	(0)	(0)	(2) 1 (50%) 1 (50%)	(2)	(1)	(2)
Abdominal, Inflammation, Granulomatous Abdominal, Inflammation, Chronic Active			1 (50%) 1 (50%)			
GENITAL SYSTEM						
Coagulating Gland Lumen, Dilatation Epididymis Atrophy	(0) (48)	(1) 1 (100%) (45)	(1) 1 (100%) (47) 1 (2%)	(0) (15)	(0) (50)	(1) 1 (100%) (45)
Fibrosis Hypospermia Infiltration Cellular, Lymphocyte Inflammation, Chronic	1 (2%)	1 (2%) 3 (7%)	1 (2%) 2 (4%) 4 (9%) 1 (2%)	1 (7%)	1 (2%) 1 (2%)	1 (2%) 2 (4%)
Inflammation, Chronic Active Mineralization Polyarteritis		1 (2%) 1 (2%)	1 (2%)	1 (7%)		1 (2%)
Spermatocele Duct, Degeneration		1 (2%) 1 (2%)	2 (4%)			
Preputial Gland Cyst Degeneration Infiltration Cellular, Lymphocyte	(48) 5 (10%) 14 (29%) 1 (2%)	(44) 8 (18%) 22 (50%)	(48) 3 (6%) 27 (56%) 3 (6%)	(15) 2 (13%) 6 (40%)	(50) 4 (8%) 20 (40%)	(47) 2 (4%) 21 (45%) 2 (4%)
Inflammation, Suppurative Inflammation, Chronic Active Bilateral, Cyst Duct, Dilatation	2 (4%)	1 (2%) 3 (7%)	3 (6%) 2 (4%)	1 (7%)	7 (14%) 1 (2%)	2 (4%)

TDMS No. 20311 - 01 Test Type: CHRONIC Route: IN-UTERO

Species/Strain: MICE/B6C3F1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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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
Fat, Degeneration						
Fat, Necrosis Prostate	(48)	(43)	(47)	(15)	(48)	(44)
Dilatation	(40)	(43)	(47)	(13)	2 (4%)	(44)
Infiltration Cellular, Lymphocyte	3 (6%)	2 (5%)	4 (9%)	3 (20%)	9 (19%)	3 (7%)
Inflammation, Suppurative Inflammation, Chronic Active			1 (2%)			1 (00/)
Polyarteritis				1 (7%)		1 (2%)
Seminal Vesicle	(49)	(45)	(48)	(15)	(49)	(46)
Amyloid Deposition	4 (22())		1 (2%)			4 (004)
Atrophy Infiltration Cellular, Lymphocyte	1 (2%)		1 (2%)			1 (2%)
Inflammation, Chronic Active			1 (2%)			1 (2%)
Lumen, Dilatation	3 (6%)	1 (2%)	7 (15%)		3 (6%)	5 (11%)
Testes	(49)	(45)	(47)	(15)	(49)	(45)
Mineralization Seminiferous Tubule, Degeneration	1 (2%) 4 (8%)	7 (16%)	10 (21%)	2 (13%)	6 (12%)	3 (7%)
	+ (070)	7 (1078)	10 (2170)	2 (1370)	0 (1270)	3 (176)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(48)	(45)	(48)	(15)	(50)	(45)
Fibrosis	(10)	(10)	(10)	(10)	(00)	(10)
Hyperplasia	3 (6%)	1 (2%)		1 (7%)	2 (4%)	
Pigmentation Lymph Node	(6)	(2)	1 (2%) (3)	(2)	(3)	(4)
Hemorrhage	(0)	(2)	(3)	(3)	(3) 1 (33%)	(4)
Axillary, Hyperplasia, Lymphoid		1 (50%)	1 (33%)		. (00,0)	
Axillary, Infiltration Cellular, Histiocyte			(())			
Axillary, Infiltration Cellular, Plasma Cell Axillary, Infiltration Cellular,			1 (33%) 1 (33%)			
Polymorphonuclear			1 (3376)			
Inguinal, Hyperplasia, Lymphoid	2 (33%)	1 (50%)	1 (33%)	1 (33%)	1 (33%)	
Inguinal, Infiltration Cellular, Plasma Cell			1 (33%)			
Inguinal, Infiltration Cellular, Polymorphonuclear			1 (33%)			
Inguinal, Pigmentation	1 (17%)					
Lumbar, Hemorrhage						
Lumbar, Hyperplasia, Lymphoid	1 (17%)	1 (50%)	1 (33%)			
Lumbar, Infiltration Cellular, Plasma Cell Mediastinal, Hyperplasia, Lymphoid			1 (33%)			
Mediastinal, Infiltration Cellular, Histiocyte						
Mediastinal, Inflammation, Chronic Active						1 (25%)
Pancreatic, Hyperplasia, Lymphoid						
Pancreatic, Infiltration Cellular, Histiocyte Pancreatic, Sinus, Dilatation						

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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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
Renal, Hemorrhage Renal, Hyperplasia, Lymphoid		1 (50%)	1 (33%)		1 (33%)	
Renal, Infiltration Cellular, Histiocyte Renal, Infiltration Cellular, Plasma Cell Renal, Infiltration Cellular, Polymorphonuclear			1 (33%) 1 (33%)			
Renal, Inflammation, Chronic Active Lymph Node, Mandibular	(47)	(45)	(46)	(14)	(49)	1 (25%) (46)
Hemorrhage	4 (0%)	1 (2%) 13 (29%)		2 (1 49/)		
Hyperplasia, Lymphoid Hyperplasia, Plasma Cell Infiltration Cellular, Mast Cell	4 (9%)	13 (29%)	10 (22%)	2 (14%)	10 (20%)	4 (9%)
Infiltration Cellular, Plasma Cell Infiltration Cellular, Polymorphonuclear		2 (4%)	3 (7%) 1 (2%)			2 (4%)
Inflammation, Chronic Active Necrosis	1 (2%)		1 (270)			1 (2%)
Pigmentation	1 (2%)					
Lymph Node, Mesenteric Angiectasis	(48) 6 (13%)	(45) 11 (24%)	(46) 10 (22%)	(14) 4 (29%)	(48) 12 (25%)	(46) 6 (13%)
Fibrosis	0(13%)	11 (24%)	10 (22%)	4 (29%)	12 (23%)	1 (2%)
Hematopoietic Cell Proliferation		10 (000)	1 (2%)	4 (70()	10 (000()	
Hemorrhage Hyperplasia, Lymphoid	15 (31%) 19 (40%)	13 (29%) 21 (47%)	13 (28%) 29 (63%)	1 (7%) 6 (43%)	16 (33%) 31 (65%)	11 (24%) 25 (54%)
Infiltration Cellular, Histiocyte	1 (2%)	2 (4%)	2 (4%)		3 (6%)	1 (2%)
Infiltration Cellular, Mast Cell Infiltration Cellular, Plasma Cell	1 (2%) 2 (4%)	1 (2%)	3 (7%)	2 (14%)	1 (2%) 3 (6%)	1 (2%) 1 (2%)
Infiltration Cellular, Polymorphonuclear	1 (2%)	(270)	2 (4%)	2 (1170)	0 (070)	(),
Inflammation, Granulomatous Inflammation, Chronic Active			1 (2%)			1 (2%) 1 (2%)
Necrosis	1 (2%)		1 (270)			1 (270)
Polyarteritis		((22 ()		1 (7%)	(22()	
Thrombosis Sinus, Dilatation	5 (10%)	1 (2%) 5 (11%)	8 (17%)		1 (2%) 5 (10%)	8 (17%)
Spleen	(48)	(45)	(47)	(15)	(49)	(45)
Accessory Spleen					1 (2%)	
Angiectasis Atrophy	1 (2%)					
Congestion	. (= /0)					
Depletion Lymphoid	40 (05%)	0 (400()	1 (2%)	0 (500()	40 (200()	F (440/)
Hematopoietic Cell Proliferation Hyperplasia, Lymphoid	12 (25%) 20 (42%)	8 (18%) 20 (44%)	7 (15%) 20 (43%)	8 (53%) 4 (27%)	10 (20%) 24 (49%)	5 (11%) 21 (47%)
Inflammation, Chronic Active						1 (2%)
Thymus	(38)	(37)	(39)	(12)	(44)	(35)
Átrophy Cyst	17 (45%)	19 (51%)	18 (46%)	8 (67%)	14 (32%)	15 (43%)
Hyperplasia, Lymphoid	1 (3%)					
Infiltration Cellular, Plasma Cell			1 (3%)			

TDMS No. 20311 - 01 Test Type: CHRONIC Route: IN-UTERO Species/Strain: MICE/B6C3F1/NCTR		E RATES OF NON-NEO Drug Combinations Trar CAS Number:	Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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
Infiltration Cellular, Polymorphonuclear Inflammation, Chronic Active Necrosis	1 (3%)		1 (3%) 1 (3%)			
INTEGUMENTARY SYSTEM						
Skin Fibrosis Hemorrhage	(48) 2 (4%)	(48)	(47) 2 (4%)	(15)	(51) 1 (2%)	(48) 1 (2%)
Hyperkeratosis Inflammation, Suppurative Inflammation, Chronic Active Metaplasia, Osseous	2 (4%) 3 (6%)	1 (2%)		1 (7%)	1 (2%)	1 (2%)
Mineralization Necrosis Ulcer Epithelium, Hyperplasia	5 (10%) 2 (4%)	1 (2%)		1 (7%)	1 (2%)	1 (2%)
MUSCULOSKELETAL SYSTEM						
Bone Skeletal Muscle	(0) (0)	(0) (0)	(0) (0)	(0) (0)	(0) (1)	(1) (0)
NERVOUS SYSTEM						
Brain, Cerebellum Autolysis	(48)	(47)	(47)	(15)	(50)	(46)
Hemorrhage Brain, Cerebrum Degeneration	(48)	(47)	(47)	(15)	(50)	(46)
Gliosis Mineralization Polyarteritis	15 (31%)	27 (57%)	20 (43%)	3 (20%) 1 (7%)	17 (34%)	23 (50%)
RESPIRATORY SYSTEM						
Lung Autolysis	(48)	(45)	(47)	(15)	(50)	(47)
Congestion Crystals Hemorrhage		1 (2%)	1 (2%)	1 (7%)	1 (2%) 2 (4%)	2 (4%)
Infiltration Cellular, Histiocyte		1 (2%)		2 (13%)	2 (4%)	2 (4%)

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

Species/Strain: MICE/B6C3F1/NCTR

Route: IN-UTERO

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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
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Pigmentation	3 (6%)	2 (4%)	2 (4%) 1 (2%)	3 (20%)	3 (6%)	4 (9%) 1 (2%)
Alveolar Epithelium, Hyperplasia Nose Inflammation, Chronic Active	1 (2%) (49)	2 (4%) (46)	2 (4%) (47)	2 (13%) (15)	1 (2%) (51)	(47)
Mucosa, Dysplasia Posterior To Upper Incisor, Dysplasia		2 (4%)	2 (4%)		1 (2%)	4 (9%)
SPECIAL SENSES SYSTEM						
Eye Cataract	(48)	(45)	(47) 2 (4%)	(14)	(49)	(45)
Degeneration Bilateral, Cataract		1 (2%)	1 (2%)			
Cornea, Inflammation, Suppurative Cornea, Inflammation, Chronic Active Cornea, Ulcer			1 (2%)			1 (2%) 1 (2%)
Retina, Degeneration Harderian Gland	(48)	(45)	(47)	(14)	(50)	(45)
Cyst Cyst Multilocular Foreign Body Hyperplasia	1 (2%)			1 (7%)		
Infiltration Cellular, Lymphocyte	9 (19%)	2 (4%)	1 (2%)	3 (21%)	4 (8%)	3 (7%)
Infiltration Cellular, Polymorphonuclear Inflammation, Chronic Active Acinus, Degeneration			1 (2%) 1 (2%)	2 (14%)	1 (2%) 1 (2%)	2 (4%)
URINARY SYSTEM						
Kidney	(48)	(45)	(47)	(14)	(49)	(46)
Amyloid Deposition Cyst Fibrosis	3 (6%)	3 (7%)	1 (2%) 1 (2%)			3 (7%) 1 (2%)
Hyaline Droplet Infiltration Cellular, Lymphocyte	7 (15%)	9 (20%)	2 (4%)	1 (7%)	3 (6%)	5 (11%)
Inflammation, Suppurative Inflammation, Chronic Active Metaplasia, Osseous			1 (2%)	1 (7%)	1 (2%)	2 (4%) 3 (7%)
Necrosis Nephropathy	32 (67%)	31 (69%)	38 (81%)	12 (86%)	41 (84%)	35 (76%)
Polyarteritis Pelvis, Dilatation		1 (2%)	1 (2%)	1 (7%)		1 (2%)

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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/
Urethra Dilatation	(0)	(0)	(0)	(0)	(0)	(2)
Bulbourethral Gland, Cyst Bulbourethral Gland, Hemorrhage Bulbourethral Gland, Necrosis Bulbourethral Gland, Epithelium, Hyperplasia						1 (50%)
Urinary Bladder Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	(48) 7 (15%)	(46) 11 (24%)	(47) 7 (15%) 1 (2%)	(15) 2 (13%)	(50) 4 (8%)	(46) 2 (4%)
Polyarteritis Lumen, Dilatation	3 (6%)	1 (2%)	1 (2%)	1 (7%) 2 (13%)	5 (10%)	2 (4%)

Route: IN-UTERO

Species/Strain: MICE/B6C3F1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT/Drug Combinations Transplacental Carcinogenesis Study

CAS Number: AIDSTHERAPEU

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:06 First Dose M/F: 07/10/03 / NA 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 Vacuolization Cytoplasmic	(59) 1 (2%)
Epithelium, Hyperplasia Intestine Large, Cecum	(63)
Hyperplasia, Lymphoid	6 (10%)
Intestine Large, Colon	(63)
Hyperplasia, Lymphoid	
Inflammation, Chronic Active	
Ulcer	()
Intestine Large, Rectum	(63)
Anus, Hemorrhage	
Anus, Inflammation, Chronic	
Anus, Necrosis Intestine Small, Duodenum	(62)
Hyperplasia, Lymphoid	(63)
Infiltration Cellular, Plasma Cell	
Infiltration Cellular, Polymorphonuclear	
Inflammation, Chronic Active	
Epithelium, Hyperplasia	
Intestine Small, Ileum	(63)
Hyperplasia, Lymphoid	
Infiltration Cellular, Polymorphonuclear	
Inflammation, Suppurative	
Inflammation, Chronic Active	
Intestine Small, Jejunum	(62)
Hyperplasia, Lymphoid	2 (3%)
Inflammation, Chronic Active	(65)
Liver	(65)

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Angiectasis		
Basophilic Focus	7 (11%)	
Basophilic Focus, Multiple	(
Cholangiofibrosis		
Clear Cell Focus	1 (2%)	
Clear Cell Focus, Multiple		
Cyst	1 (2%)	
Cyst Multilocular		
Eosinophilic Focus	1 (2%)	
Eosinophilic Focus, Multiple		
Fatty Change		
Fibrosis		
Focal Cellular Change		
Hematopoietic Cell Proliferation		
Hepatodiaphragmatic Nodule		
Infiltration Cellular, Lymphocyte	3 (5%)	
Inflammation, Chronic	- ()	
Inflammation, Chronic Active		
Mineralization		
Mixed Cell Focus		
Necrosis		
Tension Lipidosis	12 (18%)	
Vacuolization Cytoplasmic	2 (3%)	
Oval Cell, Hyperplasia	()	
Mesentery	(4)	
Hemorrhage	1 (25%)	
Necrosis	1 (25%)	
Fat, Necrosis	1 (25%)	
Pancreas	(64)	
Cyst	2 (3%)	
Cytoplasmic Alteration	、 <i>、</i>	
Edema		
Fibrosis		
Infiltration Cellular, Lymphocyte	7 (11%)	
Inflammation, Chronic Active	· · · ·	
Acinus, Degeneration	6 (9%)	
Salivary Glands	(64)	
Fibrosis		
Infiltration Cellular, Lymphocyte	54 (84%)	
Inflammation, Chronic Active		
Mineralization		
Stomach, Forestomach	(64)	
Cyst Epithelial Inclusion	· · ·	
Hyperkeratosis		
Hyperplasia Inflammation, Chronic Active		

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Ulcer	2 (3%)			
Epithelium, Hyperplasia	2 (3%)			
Stomach, Glandular	(63)			
Degeneration	1 (2%)			
Infiltration Cellular, Polymorphonuclear				
Inflammation, Suppurative Inflammation, Chronic Active	2 (29/)			
Necrosis	2 (3%)			
Ulcer				
Epithelium, Hyperplasia	1 (2%)			
Glands, Hyperplasia				
Tongue	(0)			
	(-)			
ARDIOVASCULAR SYSTEM	,		 	
ARDIOVASCULAR SYSTEM Blood Vessel				
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage	(65)			
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage Polyarteritis	(65) 1 (2%)			
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage Polyarteritis Heart	(65) 1 (2%) (65)			
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage Polyarteritis Heart Cardiomyopathy	(65) 1 (2%) (65) 1 (2%)			
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage Polyarteritis Heart Cardiomyopathy Inflammation	(65) 1 (2%) (65)			
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage Polyarteritis Heart Cardiomyopathy	(65) 1 (2%) (65) 1 (2%)			
ARDIOVASCULAR SYSTEM Blood Vessel Hemorrhage Polyarteritis Heart Cardiomyopathy Inflammation Inflammation, Chronic Active	(65) 1 (2%) (65) 1 (2%)			

Adrenal Cortex Accessory Adrenal Cortical Nodule Cyst Depletion	(63) 1 (2%) 1 (2%)
Hyperplasia	
Hypertrophy Inflammation, Chronic Active	6 (10%)
Subcapsular, Hyperplasia	47 (75%)
Adrenal Medulla	(63)
Hyperplasia Islets, Pancreatic	(65)
Hyperplasia	7 (11%)
Parathyroid Gland Cvst	(52)
Infiltration Cellular, Lymphocyte	(
Pituitary Gland	(61)

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0		
Pars Distalis, Cyst Pars Distalis, Hyperplasia Thyroid Gland Depletion	2 (3%) (64)		
Ectopic Thymus Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Polyarteritis	3 (5%)		
Follicle, Cyst Follicle, Degeneration Follicular Cell, Hyperplasia	1 (2%) 10 (16%)		
ENERAL BODY SYSTEM			
Tissue NOS Abdominal, Fibrosis Abdominal, Infiltration Cellular, Polymorphonuclear Abdominal, Inflammation, Granulomatous Abdominal, Inflammation, Chronic Active	(1)		
ENITAL SYSTEM			
Coagulating Gland Lumen, Dilatation Epididymis Atrophy Fibrosis	(2) 2 (100%) (63)		
Hypospermia Infiltration Cellular, Lymphocyte Inflammation, Chronic	2 (3%) 3 (5%)		
Inflammation, Chronic Active Mineralization Polyarteritis	1 (2%)		
Spermatocele Duct, Degeneration Preputial Gland Cyst Degeneration Infiltration Cellular, Lymphocyte	1 (2%) 1 (2%) (64) 4 (6%) 32 (50%) 1 (2%)		
Inflammation, Suppurative Inflammation, Chronic Active Bilateral, Cyst Duct, Dilatation	6 (9%)		

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0	
Fat, Degeneration		
Fat, Necrosis	(24)	
Prostate Dilatation	(64)	
Infiltration Cellular, Lymphocyte Inflammation, Suppurative Inflammation, Chronic Active	9 (14%)	
Polyarteritis	1 (2%)	
Seminal Vesicle Amyloid Deposition	(63)	
Atrophy Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	1 (2%)	
Lumen, Dilatation	8 (13%)	
Testes	(64)	
Mineralization	- (, , , , ,)	
Seminiferous Tubule, Degeneration	7 (11%)	
HEMATOPOIETIC SYSTEM		
Bone Marrow Fibrosis	(64)	
Hyperplasia	6 (9%)	
Pigmentation		
Lymph Node Hemorrhage	(7)	
Axillary, Hyperplasia, Lymphoid Axillary, Infiltration Cellular, Histiocyte Axillary, Infiltration Cellular, Plasma Cell Axillary, Infiltration Cellular, Polymorphonuclear		
Inguinal, Hyperplasia, Lymphoid Inguinal, Infiltration Cellular, Plasma Cell Inguinal, Infiltration Cellular, Polymorphonuclear Inguinal, Pigmentation		
Lumbar, Hemorrhage	1 (14%)	
Lumbar, Hyperplasia, Lymphoid Lumbar, Infiltration Cellular, Plasma Cell	3 (43%)	
Mediastinal, Hyperplasia, Lymphoid	2 (29%)	
Mediastinal, Infiltration Cellúlar, Histiocyte Mediastinal, Inflammation, Chronic Active	1 (14%)	
Pancreatic, Hyperplasia, Lymphoid	1 (14%)	
Pancreatic, Infiltration Cellular, Histiocyte Pancreatic, Sinus, Dilatation	1 (14%) 1 (14%)	
	1 (14/0)	

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0
Renal, Hemorrhage	1 (14%)
Renal, Hyperplasia, Lymphoid	2 (29%)
Renal, Infiltration Cellular, Histiocyte Renal, Infiltration Cellular, Plasma Cell	1 (14%)
Renal, Infiltration Cellular, Plasma Cell Renal, Infiltration Cellular, Polymorphonuclear	
Renal, Inflammation, Chronic Active	
Lymph Node, Mandibular	(63)
Hemorrhage	
Hyperplasia, Lymphoid	9 (14%)
Hyperplasia, Plasma Cell	1 (2%)
Infiltration Cellular, Mast Cell Infiltration Cellular, Plasma Cell	1 (2%)
Infiltration Cellular, Polymorphonuclear	1 (270)
Inflammation, Chronic Active	
Necrosis	
Pigmentation	
Lymph Node, Mesenteric	(63)
Angiectasis	10 (16%)
Fibrosis Hematopoietic Cell Proliferation	
Hemorrhage	19 (30%)
Hyperplasia, Lymphoid	37 (59%)
Infiltration Cellular, Histiocyte	4 (6%)
Infiltration Cellular, Mast Cell	1 (2%)
Infiltration Cellular, Plasma Cell	2 (3%)
Infiltration Cellular, Polymorphonuclear Inflammation, Granulomatous	1 (2%)
Inflammation, Chronic Active	
Necrosis	
Polyarteritis	
Thrombosis	1 (2%)
Sinus, Dilatation	8 (13%)
Spleen Accessory Spleen	(63)
Accessory Spieen	1 (2%)
Atrophy	1 (270)
Congestion	
Depletion Lymphoid	
Hematopoietic Cell Proliferation	11 (17%)
Hyperplasia, Lymphoid Inflammation, Chronic Active	30 (48%)
Thymus	(51)
Atrophy	23 (45%)
	- ()
Cyst	

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Infiltration Cellular, Polymorphonuclear Inflammation, Chronic Active Necrosis		
INTEGUMENTARY SYSTEM		
Skin Fibrosis Hemorrhage Hyperkeratosis Inflammation, Suppurative Inflammation, Chronic Active Metaplasia, Osseous Mineralization Necrosis Ulcer Epithelium, Hyperplasia	(65) 1 (2%) 1 (2%) 1 (2%)	
MUSCULOSKELETAL SYSTEM		
Bone Skeletal Muscle	(0) (0)	
NERVOUS SYSTEM		
Brain, Cerebellum Autolysis	(64)	
Hemorrhage Brain, Cerebrum Degeneration Gliosis	(64)	
Gliosis Mineralization Polyarteritis	35 (55%)	
RESPIRATORY SYSTEM		
Lung Autolysis	(64)	
Congestion		
Crystals Hemorrhage	3 (5%)	
Infiltration Cellular, Histiocyte	3 (5%)	

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Infiltration Cellular, Lymphocyte	3 (5%)
Inflammation, Chronic Active Pigmentation	1 (2%)
Alveolar Epithelium, Hyperplasia Nose	4 (6%)
Inflammation, Chronic Active	(65)
Mucosa, Dysplasia Posterior To Upper Incisor, Dysplasia	2 (3%)
	2 (070)
SPECIAL SENSES SYSTEM	
Еуе	(62)
Cataract Degeneration	1 (2%)
Bilateral, Cataract	1 (2%)
Cornea, Inflammation, Suppurative Cornea, Inflammation, Chronic Active	
Cornea, Ulcer	
Retina, Degeneration Harderian Gland	(64)
Cyst Cyst Multilocular	
Foreign Body	
Hyperplasia Infiltration Cellular, Lymphocyte	5 (8%)
Infiltration Cellular, Polymorphonuclear	
Inflammation, Chronic Active Acinus, Degeneration	1 (2%)

Kidney	(64)
Amyloid Deposition	
Cyst	3 (5%)
Fibrosis	
Hyaline Droplet	
Infiltration Cellular, Lymphocyte	6 (9%)
Inflammation, Suppurative	
Inflammation, Chronic Active	
Metaplasia, Osseous	
Necrosis	
Nephropathy	54 (84%)
Polyarteritis	1 (2%)
Pelvis, Dilatation	

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	SOLVENT to 0
Urethra	(1)
Dilatation	
Bulbourethral Gland, Cyst	1 (100%)
Bulbourethral Gland, Hemorrhage	1 (100%)
Bulbourethral Gland, Necrosis	1 (100%)
Bulbourethral Gland, Epithelium, Hyperplasia	
Urinary Bladder	(65)
Infiltration Cellular, Lymphocyte	3 (5%)
Inflammation, Chronic Active	- ()
Polyarteritis	
Lumen, Dilatation	6 (9%)
Edition, Dilatation	0 (070)

*** END OF MALE ***

*** END OF REPORT ***