TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

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

AZT+3TC combination CAS Number: AZT3TCCOMBO Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR

C Number:	C20310B
Lock Date:	04/20/2010
Cage Range:	ALL
Date Range:	ALL
Reasons For Removal:	ALL
Removal Date Range:	ALL
Treatment Groups:	Include ALL
Study Gender:	Male
TDMSE Version:	2.2.0

TDMS No. 20310 - 03	P03: INCIDENCE R	ATES OF NON-NEOP	LASTIC LESIONS BY	ANATOMIC SITE(a)	Date Report Requ	ested: 05/04/2010
Test Type: 26-39 WEEKS		AZT+3TC	combination		Time Report Requ	lested: 12:30:53
Route: GAVAGE		CAS Number:	AZT3TCCOMBO		First Dose M/F: 12	2/22/06 / NA
Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)					Lab: NCTR	
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Disposition Summary						
Animals Initially In Study	25	25	25	26	25	25
Early Deaths						
Moribund Sacrifice	1	2			1	
Natural Death	1	1	1	4		
Survivors						
Moribund Sacrifice	1	2			2	
Natural Death	2	2	1		1	1
Terminal Sacrifice	20	18	23	22	21	24
Animals Examined Microscopically	25	25	25	26	25	25
ALIMENTARY SYSTEM						
Intestine Large, Cecum	(22)	(22)	(24)	(22)	(24)	(24)
Intestine Large, Colon	(22)	(22)	(25)	(23)	(24)	(24)
Intestine Large, Rectum	(22)	(22)	(23)	(22)	(24)	(24)
Intestine Small, Duodenum	(23)	(22)	(23)	(22)	(24)	(24)
Ectopic Pancreas						
Intestine Small, Jejunum	(23)	(22)	(23)	(22)	(24)	(24)
Liver	(25)	(24)	(25)	(25)	(25)	(25)
Basophilic Focus			1 (4%)	1 (4%)	1 (4%)	
Hematopoietic Cell Proliferation	1 (4%)					1 (4%)
Infiltration Cellular, Lymphocyte				1 (4%)		1 (4%)
Inflammation, Suppurative						
Inflammation, Chronic Active			1 (4%)		1 (4%)	1 (4%)
Mixed Cell Focus			1 (4%)		1 (4%)	
Necrosis	1 (4%)		1 (4%)			1 (4%)
Tension Lipidosis		1 (4%)		1 (4%)	1 (4%)	2 (8%)
Vacuolization Cytoplasmic	19 (76%)	18 (75%)	20 (80%)	20 (80%)	21 (84%)	21 (84%)
Centrilobular, Degeneration	15 (60%)	16 (67%)	18 (72%)	17 (68%)	17 (68%)	20 (80%)
Mesentery	(3)	(0)	(0)	(1)	(2)	(1)
Inflammation, Chronic Active					1 (50%)	
Fat, Necrosis	1 (33%)				1 (50%)	
Pancreas	(24)	(23)	(25)	(25)	(24)	(25)
Cyst	1 (4%)	1 (4%)				

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)	P03: INCIDENCE R	AZT+3TC o	LASTIC LESIONS BY A combination AZT3TCCOMBO	ANATOMIC SITE(a)	Date Report Requ Time Report Requ First Dose M/F: 12 Lab: NCTR	ested: 12:30:53
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Hemorrhage					1 (4%)	
Infiltration Cellular, Lymphocyte					1 (4%)	2 (8%)
Acinus, Degeneration		1 (4%)	1 (4%)			
Salivary Glands	(25)	(23)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte	18 (72%)	12 (52%)	13 (52%)	18 (72%)	11 (46%)	14 (56%)
Stomach, Forestomach	(25)	(23)	(25)	(23)	(24)	(25)
Hyperkeratosis		1 (4%)				
Ulcer					1 (4%)	
Epithelium, Hyperplasia	1 (4%)				1 (4%)	
Stomach, Glandular	(23)	(22)	(24)	(22)	(24)	(24)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(25)	(24)	(25)	(25)	(24)	(25)
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Mineralization	()	()	()	()	(= ')	1 (4%)
ENDOCRINE SYSTEM			·			
Adrenal Cortex	(25)	(24)	(25)	(25)	(23)	(25)
Accessory Adrenal Cortical Nodule	1 (4%)					
Cyst					1 (4%)	
Hypertrophy		1 (4%)				
Subcapsular, Hyperplasia	13 (52%)	12 (50%)	13 (52%)	7 (28%)	11 (48%)	14 (56%)
Adrenal Medulla	(25)	(23)	(25)	(23)	(21)	(25)
Islets, Pancreatic	(24)	(24)	(25)	(25)	(24)	(25)
Hyperplasia	13 (54%)	10 (42%)	15 (60%)	10 (40%)	14 (58%)	9 (36%)
Parathyroid Gland	(23)	(21)	(24)	(18)	(19)	(23)
Cyst			1 (4%)			
Pituitary Gland	(24)	(22)	(25)	(25)	(24)	(25)
Thyroid Gland	(25)	(23)	(25)	(23)	(23)	(25)
Ectopic Thymus	2 (8%)		1 (4%)			
Follicle, Degeneration						

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)	P03: INCIDENCE R	AZT+3TC	PLASTIC LESIONS BY combination AZT3TCCOMBO	ANATOMIC SITE(a)	Date Report Requ Time Report Requ First Dose M/F: 12 Lab: NCTR	lested: 12:30:53
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
GENERAL BODY SYSTEM						
Tissue NOS	(1)	(0)	(1)	(3)	(0)	(0)
Abscess Abdominal, Fat, Necrosis			1 (100%)	1 (33%)		
GENITAL SYSTEM						
Epididymis Exfoliated Germ Cell Hypospermia Inflammation, Chronic Active	(25)	(23) 1 (4%)	(25)	(25)	(24)	(25)
Preputial Gland Cyst	(25)	(24)	(25)	(25)	(24)	(25) 1 (4%)
Infiltration Cellular, Lymphocyte Infiltration Cellular, Plasma Cell Inflammation, Suppurative		1 (4%) 1 (4%)	1 (4%)			1 (4%)
Inflammation, Chronic Active Keratin Cyst	1 (4%)	1 (4%)				1 (4%)
Acinus, Degeneration	3 (12%)	2 (8%)	3 (12%)	3 (12%)	1 (4%)	4 (16%)
Duct, Ectasia Prostate Infiltration Cellular, Lymphocyte Inflammation, Suppurative	3 (12%) (25)	2 (8%) (23)	2 (8%) (25) 1 (4%) 1 (4%)	4 (16%) (25)	1 (4%) (24)	3 (12%) (25)
Seminal Vesicle Testes Seminiferous Tubule, Degeneration	(25) (25)	(23) (24) 1 (4%)	(24) (24) 1 (4%)	(25) (25) 2 (8%)	(24) (24)	(25) (25)
HEMATOPOIETIC SYSTEM						
Bone Marrow Hyperplasia Lymph Node Axillary, Hyperplasia, Lymphoid	(23) 3 (13%) (2)	(24) 3 (13%) (2)	(24) 1 (4%) (1)	(25) 2 (8%) (1)	(24) 2 (8%) (2)	(25) 2 (8%) (3) 1 (33%)

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Mediastinal, Hyperplasia, Lymphold 1 (50%) 1 (100%) 2 (67%) Mediastinal, Infitration Cellular, Plasma Cell 1 (338) 1 (338) Lymph Node, Mandibular (25) (23) (25) (24) (26%) Hyperplasia, Lymphoid 2 (8%) 1 (4%) 2 (8%) 1 (4%) 11 (46%) 10 (40) 1 (4%) 11 (46%) 10 (40) 1 (4%)	C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Hyperplasia, Lymphoid 2 (8%) 1 (4%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 2 (8%) 1 (4%) 11 (4%) 10 (40) (25) (26) (24) (25) (26) (24) (25) (26) (24) (25) (26) (24) (25) (24) (25) (24) (25) (24) (14%) 11 (48%) 10 (40) (14%) 11 (48%) 13 (56) 11 (48%) 12 (48%) 13 (56) 13 (56) 13 (56) 13 (56) 1 (48%)<	Mediastinal, Hyperplasia, Lymphoid Mediastinal, Infiltration Cellular, Plasma Cell	1 (50%)			1 (100%)		1 (33%) 2 (67%) 1 (33%) 1 (33%)
Initiation Cellular, Plasma Cell Lymph Node, Mesenteric (24) (23) (25) (24) (25) Congestion 1 (4%) 11 (4%) 11 (44%) 11 (46%) 10 (40) Hyperplasia, Lymphoid 9 (38%) 5 (22%) 12 (48%) 11 (44%) 11 (46%) 10 (40) Infiltration Cellular, Plasma Cell 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Spleen (25) (23) (24) (25) (24) (25) Congestion 7 (28%) 11 (48%) 4 (17%) 5 (20%) 11 (46%) 9 (36%) Hematopoietic Cell Proliferation 7 (28%) 11 (48%) 16 (67%) 18 (72%) 14 (65%) 15 (60) Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) NTEGUMENTARY SYSTEM 1 1 (4%) 1 (4%) 3 (14%) 3 (129) MUSCULOSKELETAL SYSTEM 1 1 (4%) 1 (4%) 1 (4%) Bone (3) (1) (1) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25)	Lymph Node, Mandibular	(25)	(23)	(25)	(25)	(24)	(25)
Lymph Node, Mesenteric (24) (23) (25) (24) (25) Congestion 1 (4%) 11 (4%) 11 (4%) 11 (4%) 11 (4%) 10 (40') Hyperplasia, Lymphoid 9 (38%) 5 (22%) 12 (48%) 11 (44%) 11 (4%) 11 (4%) 9 (36) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 3 (14%) 3 (12%) 1 (4%) 3 (14%) 3 (12%) 1 (4%) 3 (14%) 3 (12%) 1 (4%) 3 (14%) 3 (12%) 1 (4%) 1 (4%) 1 (4%)	Hyperplasia, Lymphoid	2 (8%)			2 (8%)		2 (8%)
Congestion 1 (4%) Hyperplasia, Lymphoid 9 (38%) 5 (22%) 12 (48%) 11 (44%) 11 (46%) 10 (40°) Infiltration Cellular, Plasma Cell 1 (4%) 2 (8%) 1 (4%) 9 (36°) Hematopoietic Cell Proliferation 7 (28%) 1 1 (48%) 4 (17%) 5 (20%) 1 1 (4%) 9 (36°) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 3 (12°) 1 (4%) 3 (12°) 1 (4%) 3 (12°) 1 (4%) 3 (12°) 1 (4%) 3 (12°) 1 (4%) 1 (4%) 3 (12°) 1 (4%)	Infiltration Cellular, Plasma Cell						
Hyperplasia Lymphoid 9 (38%) 5 (22%) 12 (48%) 11 (4%) 11 (4%) 10 (40° Infiltration Cellular, Plasma Cell 1 (4%) 9 (36%) 9 (36%) 9 (36%) 1 (4%) 9 (36%) 9 (36%) 9 (36%) 1 (4%) 9 (36%) 1 (4%) 9 (36%) 1 (4%) 9 (36%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) 1 (4%) 1 (4%) 1 (4%) <td< td=""><td>Lymph Node, Mesenteric</td><td>(24)</td><td>(23)</td><td>(25)</td><td>(25)</td><td>(24)</td><td>(25)</td></td<>	Lymph Node, Mesenteric	(24)	(23)	(25)	(25)	(24)	(25)
Infiltration Cellular, Plasma Cell 1 (4%) 2 (8%) 1 (4%) 1 (4%) Infiltration Cellular, Polymorphonuclear (25) (23) (24) (25) (24) (25) Congestion 1 (4%) 1 (4%) 1 (4%) 9 (36) Hematopoietic Cell Proliferation 7 (28%) 11 (48%) 4 (17%) 5 (20%) 11 (48%) 9 (36) Hyperplasia, Lymphoid 12 (48%) 14 (61%) 16 (67%) 18 (72%) 14 (58%) 9 (36) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) 1 (6%) 16 (67%) 18 (72%) 14 (58%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 3 (12) (22) (25) (25) (25) (25) (26) 1 (4%) 3 (14%) 3 (12) Myperplasia, Lymphoid 2 (8%) 1 (5%) 1 (4%) 3 (14%) 3 (12) 1 (4%) 3 (14) 3 (12) Skin (25) (25) (25) <t< td=""><td>Congestion</td><td></td><td>1 (4%)</td><td></td><td></td><td></td><td></td></t<>	Congestion		1 (4%)				
Infiltration Cellular, Polymorphonuclear (25) (23) (24) (25) (24) (25) Spleen (25) (23) (24) (25) (24) (25) Congestion 1 (4%) 1 (4%) 1 (4%) 1 (4%) 9 (38) Hyperplasia, Lymphoid 12 (48%) 14 (61%) 16 (67%) 18 (72%) 14 (58%) 15 (60) Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) Cyst 1 1 (5%) 1 (4%) 3 (12%) 1 (4%) 3 (12%) INTEGUMENTARY SYSTEM Skin (25) (25) (25) (25) (24) (25) Skin (25) (25) (25) (25) (24) (25) Granuloma 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Inflammation, Suppurative Epithelium, Hyperplasia 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%)	Hyperplasia, Lymphoid	9 (38%)	5 (22%)	12 (48%)	11 (44%)	11 (46%)	10 (40%)
Spleen (25) (23) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (24) (25) (14%) Hematopoietic Cell Proliferation 7 (28%) 11 (48%) 4 (17%) 5 (20%) 11 (46%) 9 (36) Hyperplasia, Lymphoid 12 (48%) 14 (61%) 16 (67%) 18 (72%) 14 (68%) 15 (60) Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (4%) 3 (14%) 3 (12%) Cyst 1 (5%) 1 (5%) 1 (4%) 3 (14%) 3 (12%) 1 (4%) Inflammation, Suppurative 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Inflammation, Suppurative 1 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Bone (3) (1)	Infiltration Cellular, Plasma Cell			1 (4%)	2 (8%)	1 (4%)	1 (4%)
Congestion 1 (4%) Hematopoietic Cell Proliferation 7 (28%) 11 (48%) 4 (17%) 5 (20%) 11 (46%) 9 (36%) Hyperplasia, Lymphoid 12 (48%) 14 (61%) 16 (67%) 18 (72%) 14 (58%) 15 (60%) Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) 3 (14%) 3 (12%) Hyperplasia, Lymphoid 2 (8%) 1 (5%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM Skin (25) (25) (25) (26) (24) (25) Skin (25) (25) (25) (25) (24) (25) Cyst 1 (4%)	Infiltration Cellular, Polymorphonuclear						
Hernatopoietic Cell Proliferation 7 (28%) 11 (48%) 4 (17%) 5 (20%) 11 (46%) 9 (36%) Hyperplasia, Lymphoid 12 (48%) 14 (61%) 16 (67%) 18 (72%) 14 (58%) 15 (60%) Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) Cyst 1 (5%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM 2 (8%) 1 (4%) 3 (14%) 3 (12%) Skin (25) (25) (25) (25) (24) (25) Granuloma 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Inflammation, Suppurative Epithelium, Hyperplasia 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Bone (3) (1) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25) (25)	Spleen	(25)	(23)	(24)	(25)	(24)	(25)
Hyperplasia, Lymphoid 12 (48%) 14 (61%) 16 (67%) 18 (72%) 14 (58%) 15 (60°) Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) Cyst 1 (5%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM 2 (8%) 1 (4%) 3 (14%) 3 (12%) Skin (25) (25) (25) (25) (24) (25) Cyst 1 (4%) 1 (4%) 3 (14%) 3 (12%) 1 (4%) 3 (14%) 3 (12%) MUSCULOSKELETAL SYSTEM 1 (4%) <t< td=""><td>Congestion</td><td></td><td></td><td></td><td></td><td>1 (4%)</td><td></td></t<>	Congestion					1 (4%)	
Thymus (24) (22) (24) (23) (22) (25) Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) Cyst 1 (5%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM Integration 2 (8%) 1 (4%) 3 (14%) 3 (12%) Skin (25) (25) (25) (25) (25) (26) (26) Cyst 1 (4%) 1 (4%) 1 (4%) 1 (4%) (25) (25) (25) (26) (26) (27) (24) (25) MUSCULOSKELETAL SYSTEM Inflammation, Suppurative Epithelium, Hyperplasia Image: State Sta	Hematopoietic Cell Proliferation	7 (28%)	11 (48%)	4 (17%)	5 (20%)	11 (46%)	9 (36%)
Atrophy 2 (8%) 1 (5%) 1 (4%) 1 (5%) 1 (4%) Cyst 1 (5%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM Integration 2 (25) (25) (25) (25) (26) (26) (26) (27) (26) (26) (26) (27) (26) (26) (27) (26) (26) (26) (27) (27) (27) (26) (26) (27)	Hyperplasia, Lymphoid	12 (48%)	14 (61%)	16 (67%)	18 (72%)	14 (58%)	15 (60%)
Cyst 1 (5%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM (25) (25) (25) (24) (25) Skin (25) (25) (25) (24) (25) Cyst 1 (4%) 1 (4%) (4%) (25) (24) (25) Skin (25) 1 (4%) 1 (4%) (25) (26) (26) (26) Granuloma 1 (4%) 1 (4%) 1 (4%) (4%) (25) (25) (26) (26) MUSCULOSKELETAL SYSTEM Bone (3) (1) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25) (25) (25)	Thymus	(24)	(22)	(24)	(23)	(22)	(25)
Hyperplasia, Lymphoid 2 (8%) 1 (4%) 3 (14%) 3 (12%) INTEGUMENTARY SYSTEM (25) (25) (25) (24) (25) Skin (25) (25) (25) (24) (25) Cyst 1 (4%) 1 (4%) 1 (4%) (25) Granuloma 1 (4%) 1 (4%) 1 (4%) (25) Inflammation, Suppurative Epithelium, Hyperplasia V V V MUSCULOSKELETAL SYSTEM (3) (1) (1) (1) (0) (0) Bone (3) (1) (1) (1) (0) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25) (25)	Atrophy	2 (8%)	1 (5%)		1 (4%)	1 (5%)	1 (4%)
INTEGUMENTARY SYSTEM Skin (25) (25) (25) (25) (24) (25) Cyst 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) 1 (4%) Inflammation, Suppurative Epithelium, Hyperplasia 1 (4%) 1 (4%) 1 (4%) 1 (4%) MUSCULOSKELETAL SYSTEM Image: Constraint of the system o	Cyst		1 (5%)				
Skin (25) (25) (25) (25) (24) (25) Cyst 1 (4%) 1 (4	Hyperplasia, Lymphoid	2 (8%)			1 (4%)	3 (14%)	3 (12%)
Cyst 1 (4%) Granuloma 1 (4%) Inflammation, Suppurative 1 (4%) Epithelium, Hyperplasia 1 (4%) MUSCULOSKELETAL SYSTEM Bone (3) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25)	INTEGUMENTARY SYSTEM						
Cyst Granuloma Inflammation, Suppurative Epithelium, Hyperplasia1 (4%)MUSCULOSKELETAL SYSTEMBone Bone, Femur(3)(1)(1)(1)(0)(0)Bone, Femur(25)(25)(25)(25)(25)(25)	Skin	(25)	(25)	(25)	(25)	(24)	(25)
Granuloma Inflammation, Suppurative Epithelium, Hyperplasia1 (4%)MUSCULOSKELETAL SYSTEMBone Bone, Femur(3)(1)(1)(1)(0)(0)(25)(25)(25)(25)(25)(25)(25)		(=0)		()	()	(= ·)	(=0)
Inflammation, Suppurative Epithelium, Hyperplasia MUSCULOSKELETAL SYSTEM Bone (3) (1) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25)							
Epithelium, Hyperplasia MUSCULOSKELETAL SYSTEM Bone (3) (1) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25) (25)			(
MUSCULOSKELETAL SYSTEM Bone (3) (1) (1) (0) (0) Bone, Femur (25) (25) (25) (25) (25) (25)							
Bone(3)(1)(1)(0)(0)Bone, Femur(25)(25)(25)(25)(25)(25)							
Bone, Femur (25) (25) (25) (25) (25)	MUSCULOSKELETAL SYSTEM						
Bone, Femur (25) (25) (25) (25) (25)	Bone	(3)	(1)	(1)	(1)	(0)	(0)
$\sqrt{1}$,		()	()	()	()	<u> </u>
Skeletal Muscle (3) (2) (1) (0) (0) (0)			(2)	(1)	(0)	(0)	(0)

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)	P03: INCIDENCE R	AZT+3TC of	LASTIC LESIONS BY a combination	ANATOMIC SITE(a)	Date Report Requ Time Report Requ First Dose M/F: 12 Lab: NCTR	ested: 12:30:53
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
NERVOUS SYSTEM						
Brain, Brain Stem Brain, Cerebellum Compression Hemorrhage	(25) (25)	(24) (24) 1 (4%)	(25) (25) 1 (4%)	(25) (25)	(24) (24)	(24) (24)
Brain, Cerebrum Mineralization Spinal Cord, Thoracic Compression	(25) 2 (8%) (1) 1 (100%)	(24) 3 (13%) (0)	(25) 4 (16%) (0)	(25) 4 (16%) (0)	(24) 2 (8%) (0)	(25) 1 (4%) (0)
RESPIRATORY SYSTEM						
Lung Hemorrhage Infiltration Cellular, Histiocyte Inflammation, Chronic Mineralization	(25)	(24) 1 (4%) 1 (4%) 1 (4%)	(25) 1 (4%)	(25) 1 (4%) 1 (4%)	(24) 1 (4%)	(25) 1 (4%)
Alveolar Epithelium, Hyperplasia Nose Hyaline Droplet	(25)	(25)	(25) 1 (4%)	1 (4%) (25)	(25) 2 (8%)	1 (4%) (25) 3 (12%)
SPECIAL SENSES SYSTEM						
Eye Inflammation, Chronic Active Cornea, Ulcer	(22)	(22) 1 (5%) 1 (5%)	(23)	(23)	(24)	(24)
Harderian Gland Infiltration Cellular, Lymphocyte	(25) 1 (4%)	(22)	(25)	(25)	(24)	(25) 1 (4%)

URINARY SYSTEM

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)	P03: INCIDENCE R	AZT+3TC	LASTIC LESIONS BY A combination AZT3TCCOMBO	ANATOMIC SITE(a)	Date Report Requ Time Report Requ First Dose M/F: 12 Lab: NCTR	lested: 12:30:53
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Kidney	(25)	(24)	(25)	(25)	(24)	(25)
Casts Protein	3 (12%)	5 (21%)	6 (24%)	7 (28%)	8 (33%)	7 (28%)
Cyst						
Hemorrhage				1 (4%)		
Hydronephrosis	1 (4%)	8 (33%)	7 (28%)	5 (20%)	9 (38%)	13 (52%)
Infarct						
Infiltration Cellular, Lymphocyte	8 (32%)	2 (8%)	10 (40%)	6 (24%)	2 (8%)	9 (36%)
Metaplasia, Osseous			1 (4%)		1 (4%)	
Nephropathy	1 (4%)	1 (4%)	2 (8%)			
Renal Tubule, Regeneration			1 (4%)			
Transitional Epithelium, Hyperplasia			1 (4%)			
Urinary Bladder	(25)	(24)	(25)	(25)	(24)	(25)
Hemorrhage					1 (4%)	
Infiltration Cellular, Histiocyte				1 (4%)		
Infiltration Cellular, Lymphocyte	2 (8%)			2 (8%)	1 (4%)	1 (4%)
Lumen, Dilatation	1 (4%)	1 (4%)	1 (4%)	1 (4%)		

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

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

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Disposition Summary		
Animals Initially In Study Early Deaths Moribund Sacrifice	25	25
Natural Death		1
Survivors		_
Moribund Sacrifice Natural Death	1	1
Terminal Sacrifice	24	23
Animals Examined Microscopically	23	24
ALIMENTARY SYSTEM		
Intestine Large, Cecum	(23)	(23)
Intestine Large, Colon	(23)	(23)
Intestine Large, Rectum	(23)	(23)
Intestine Small, Duodenum	(23)	(23)
Ectopic Pancreas		1 (4%)
Intestine Small, Jejunum	(23)	(23)
Liver	(23)	(23)
Basophilic Focus	2 (9%)	2 (9%)
Hematopoietic Cell Proliferation		
Infiltration Cellular, Lymphocyte	1 (4%)	
Inflammation, Suppurative	1 (4%)	
Inflammation, Chronic Active	1 (4%)	1 (4%)
Mixed Cell Focus		
Necrosis	1 (4%)	2 (9%)
Tension Lipidosis	2 (9%)	1 (4%)
Vacuolization Cytoplasmic	19 (83%)	20 (87%)
Centrilobular, Degeneration	18 (78%)	17 (74%)
Mesentery	(2)	(0)
Inflammation, Chronic Active		
Fat, Necrosis	2 (100%)	
Pancreas	(23)	(23)
Cyst		

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

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

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Hemorrhage		
Infiltration Cellular, Lymphocyte		
Acinus, Degeneration	1 (4%)	
Salivary Glands	(23)	(23)
Infiltration Cellular, Lymphocyte	16 (70%)	16 (70%)
Stomach, Forestomach	(23)	(23)
Hyperkeratosis	1 (4%)	
Ulcer		
Epithelium, Hyperplasia		
Stomach, Glandular	(23)	(23)
CARDIOVASCULAR SYSTEM		
Blood Vessel	(23)	(24)
Heart	(23)	(24)
Mineralization		()
ENDOCRINE SYSTEM		
Adrenal Cortex	(23)	(23)
Accessory Adrenal Cortical Nodule		1 (4%)
Cyst		
Hypertrophy	1 (4%)	2 (9%)
Subcapsular, Hyperplasia	11 (48%)	12 (52%)
Adrenal Medulla	(23)	(22)
Islets, Pancreatic	(23)	(23)
Hyperplasia	13 (57%)	6 (26%)
Parathyroid Gland	(23)	(23)
Cyst	x - /	x - /
Pituitary Gland	(23)	(23)
Thyroid Gland	(23)	(23)
Ectopic Thymus	(==)	(==)
		1 (4%)
Follicle, Degeneration		1 (4%)

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)	P03: INCIDENCE R/	ATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) AZT+3TC combination CAS Number: AZT3TCCOMBO	Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5	
GENERAL BODY SYSTEM			
Tissue NOS Abscess Abdominal, Fat, Necrosis	(0)	(0)	
GENITAL SYSTEM			
Epididymis Exfoliated Germ Cell Hypospermia Inflammation, Chronic Active Preputial Gland Cyst Infiltration Cellular, Lymphocyte Infiltration Cellular, Plasma Cell Inflammation, Suppurative Inflammation, Chronic Active Keratin Cyst Acinus, Degeneration Duct, Ectasia Prostate Infiltration Cellular, Lymphocyte Inflammation, Suppurative Seminal Vesicle Testes Seminiferous Tubule, Degeneration	 (23) 1 (4%) (23) 1 (4%) 1 (4%) 5 (22%) (23) 1 (4%) (23) (23) 1 (4%) 	$(23) \\ 1 (4\%) \\ 1 (4\%) \\ (23) \\ 5 (22\%) \\ 5 (22\%) \\ (23) \\ (23) \\ (23) \\ 1 (4\%) \\ (23) \\ 1 (4\%) \\ (23) \\ $	
HEMATOPOIETIC SYSTEM			
Bone Marrow Hyperplasia Lymph Node Axillary, Hyperplasia, Lymphoid	(23) 4 (17%) (1)	(23) (1)	

TDMS No. 20310 - 03
Test Type: 26-39 WEEKS
Route: GAVAGE
Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

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

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Lumbar, Hyperplasia, Lymphoid		
Mediastinal, Hyperplasia, Lymphoid		
Mediastinal, Infiltration Cellular, Plasma Cell		
Renal, Hyperplasia, Lymphoid	()	()
Lymph Node, Mandibular	(23)	(23)
Hyperplasia, Lymphoid	4 (17%)	5 (22%)
Infiltration Cellular, Plasma Cell	1 (4%)	
Lymph Node, Mesenteric	(23)	(23)
Congestion		
Hyperplasia, Lymphoid	5 (22%)	9 (39%)
Infiltration Cellular, Plasma Cell	1 (4%)	
Infiltration Cellular, Polymorphonuclear	1 (4%)	
Spleen	(23)	(23)
Congestion	(),	
Hematopoietic Cell Proliferation	6 (26%)	6 (26%)
Hyperplasia, Lymphoid	13 (57%)	12 (52%)
Thymus	(20)	(20)
Atrophy	(=0)	1 (5%)
Cyst		1 (070)
Hyperplasia, Lymphoid	1 (5%)	1 (5%)
	1 (370)	1 (070)
INTEGUMENTARY SYSTEM		
Skin	(23)	(24)
Cyst	(/	()
Granuloma		
Inflammation, Suppurative		1 (4%)
Epithelium, Hyperplasia		1 (4%)
		1 (770)
MUSCULOSKELETAL SYSTEM		
Bone	(1)	(1)
Bone, Femur	(23)	(24)
Fibro-Osseous Lesion	1 (4%)	. /
Skeletal Muscle	(0)	(0)
a - Number of animals examined microscopica		

TDMS No. 20310 - 03 Test Type: 26-39 WEEKS Route: GAVAGE Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)	P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) AZT+3TC combination CAS Number: AZT3TCCOMBO		Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR
C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5	
NERVOUS SYSTEM			
Brain, Brain Stem Brain, Cerebellum Compression Hemorrhage	(23) (23)	(23) (23)	
Brain, Cerebrum Mineralization Spinal Cord, Thoracic Compression	(23) 3 (13%) (0)	(23) 1 (4%) (0)	
RESPIRATORY SYSTEM			
Lung Hemorrhage Infiltration Cellular, Histiocyte Inflammation, Chronic Mineralization	(23)	(23)	
Alveolar Epithelium, Hyperplasia Nose Hyaline Droplet	(23) 2 (9%)	1 (4%) (24)	
SPECIAL SENSES SYSTEM			
Eye Inflammation, Chronic Active Cornea, Ulcer	(23)	(23)	
Harderian Gland Infiltration Cellular, Lymphocyte	(23) 1 (4%)	(23)	

URINARY SYSTEM

TDMS No. 20310 - 03
Test Type: 26-39 WEEKS
Route: GAVAGE
Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

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

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010 Time Report Requested: 12:30:53 First Dose M/F: 12/22/06 / NA Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Kidney	(23)	(23)
Casts Protein	7 (30%)	10 (43%)
Cyst	1 (4%)	
Hemorrhage		
Hydronephrosis	5 (22%)	12 (52%)
Infarct	1 (4%)	
Infiltration Cellular, Lymphocyte	9 (39%)	7 (30%)
Metaplasia, Osseous		
Nephropathy		1 (4%)
Renal Tubule, Regeneration		
Transitional Epithelium, Hyperplasia		
Urinary Bladder	(23)	(23)
Hemorrhage		
Infiltration Cellular, Histiocyte		
Infiltration Cellular, Lymphocyte	1 (4%)	1 (4%)
Lumen, Dilatation		

*** END OF REPORT ***