

**TDMS No.** 20310 - 04

**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:** 12:30:59

**First Dose M/F:** NA / 12/22/06

**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:** Female  
**TDMSE Version:** 2.2.0

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
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**Disposition Summary**

Animals Initially In Study	25	25	25	25	24	25
Early Deaths						
Moribund Sacrifice		1		1	2	1
Natural Death				1	1	
Survivors						
Moribund Sacrifice		2	3	1	2	1
Natural Death		2	2	2		1
Terminal Sacrifice	25	20	20	20	19	22
Animals Examined Microscopically	25	25	25	25	24	25

ALIMENTARY SYSTEM

Gallbladder	(25)	(23)	(23)	(22)	(23)	(23)
Intestine Large, Cecum	(25)	(23)	(23)	(22)	(23)	(24)
Hyperplasia, Lymphoid			1 (4%)			
Intestine Small, Duodenum	(25)	(23)	(23)	(22)	(23)	(24)
Intestine Small, Ileum	(25)	(23)	(23)	(22)	(23)	(24)
Liver	(25)	(25)	(23)	(24)	(23)	(25)
Basophilic Focus		1 (4%)				
Clear Cell Focus			1 (4%)			
Hematopoietic Cell Proliferation		1 (4%)		1 (4%)		
Hepatodiaphragmatic Nodule			1 (4%)			
Infiltration Cellular, Lymphocyte	1 (4%)	3 (12%)	2 (9%)	6 (25%)	3 (13%)	2 (8%)
Inflammation, Chronic Active	1 (4%)	2 (8%)	1 (4%)	2 (8%)	2 (9%)	1 (4%)
Necrosis						1 (4%)
Tension Lipidosis	2 (8%)		2 (9%)	3 (13%)	2 (9%)	
Vacuolization Cytoplasmic	14 (56%)	13 (52%)	14 (61%)	11 (46%)	13 (57%)	17 (68%)
Centrilobular, Degeneration				1 (4%)		
Mesentery	(0)	(1)	(0)	(0)	(0)	(0)
Fat, Necrosis						
Pancreas	(25)	(25)	(25)	(22)	(23)	(25)
Infiltration Cellular, Lymphocyte	2 (8%)	4 (16%)	2 (8%)	1 (5%)	3 (13%)	3 (12%)
Necrosis	1 (4%)					
Salivary Glands	(25)	(25)	(25)	(24)	(23)	(25)

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

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AZT+3TC combination  
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First Dose M/F: NA / 12/22/06

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Infiltration Cellular, Lymphocyte Stomach, Forestomach	22 (88%) (25)	17 (68%) (24)	18 (72%) (24)	19 (79%) (24)	16 (70%) (23)	18 (72%) (25)
Inflammation, Suppurative Inflammation, Chronic Active		1 (4%)			1 (4%)	
Ulcer	1 (4%)	1 (4%)			1 (4%)	
Epithelium, Hyperplasia Stomach, Glandular	2 (8%) (25)	1 (4%) (23)			1 (4%) (23)	
			(23)	(22)		(25)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(25)	(25)	(25)	(25)	(23)	(25)
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Inflammation, Chronic Active			1 (4%)			
Mineralization			1 (4%)	1 (4%)		
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(25)	(24)	(24)	(25)	(23)	(25)
Accessory Adrenal Cortical Nodule	1 (4%)			1 (4%)		
Hypertrophy	1 (4%)					
Infiltration Cellular, Polymorphonuclear						
Vacuolization Cytoplasmic	16 (64%)	14 (58%)	16 (67%)	16 (64%)	13 (57%)	15 (60%)
Subcapsular, Hyperplasia	25 (100%)	24 (100%)	24 (100%)	24 (96%)	22 (96%)	24 (96%)
Islets, Pancreatic	(25)	(24)	(25)	(25)	(23)	(25)
Hyperplasia		2 (8%)		1 (4%)		1 (4%)
Parathyroid Gland	(20)	(23)	(21)	(20)	(18)	(21)
Cyst						1 (5%)
Infiltration Cellular, Lymphocyte					1 (6%)	
Pituitary Gland	(25)	(25)	(24)	(25)	(23)	(24)
Fibrosis			1 (4%)			
Pars Distalis, Hyperplasia						
Thyroid Gland	(23)	(24)	(25)	(23)	(22)	(25)
Cyst				1 (4%)		
Ectopic Thymus	3 (13%)		1 (4%)		1 (5%)	1 (4%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
<b>GENERAL BODY SYSTEM</b>						
Tissue NOS	(0)	(0)	(0)	(1)	(0)	(0)
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(24)	(24)	(23)	(21)	(21)	(24)
Acinus, Degeneration	9 (38%)	12 (50%)	6 (26%)	5 (24%)	6 (29%)	6 (25%)
Duct, Ectasia						
Ovary	(25)	(24)	(25)	(24)	(23)	(25)
Atrophy	1 (4%)	1 (4%)	1 (4%)			
Cyst	1 (4%)	3 (13%)	1 (4%)	2 (8%)	3 (13%)	3 (12%)
Cyst Dermoid			1 (4%)			
Hemorrhage						
Uterus	(25)	(25)	(25)	(23)	(23)	(25)
Atrophy			1 (4%)			
Degeneration, Cystic		1 (4%)				
Endometrium, Hyperplasia, Cystic	22 (88%)	19 (76%)	19 (76%)	19 (83%)	17 (74%)	18 (72%)
Vagina	(25)	(24)	(24)	(24)	(23)	(25)
Infiltration Cellular, Polymorphonuclear		2 (8%)		2 (8%)		1 (4%)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(25)	(24)	(24)	(23)	(23)	(25)
Fibrosis			1 (4%)			
Hyperplasia	1 (4%)	2 (8%)	2 (8%)	1 (4%)	3 (13%)	
Lymph Node	(1)	(3)	(1)	(3)	(4)	(3)
Lumbar, Hyperplasia, Lymphoid						1 (33%)
Lumbar, Sinus, Dilatation		1 (33%)				
Pancreatic, Hyperplasia, Lymphoid						1 (33%)
Renal, Angiectasis		1 (33%)				
Renal, Hyperplasia, Lymphoid						1 (33%)
Renal, Thrombus		1 (33%)				

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Lymph Node, Mandibular Hyperplasia, Lymphoid	(25) 3 (12%)	(25)	(24)	(24)	(23)	(25)
Lymph Node, Mesenteric Angiectasis	(25)	(24)	(23)	(24)	(23)	(25)
Hyperplasia, Lymphoid	1 (4%)	3 (13%)	3 (13%)	4 (17%)	3 (13%)	3 (12%)
Spleen	(25)	(25)	(24)	(24)	(23)	(25)
Hematopoietic Cell Proliferation Hyperplasia, Lymphoid	2 (8%) 20 (80%)	8 (32%) 16 (64%)	7 (29%) 17 (71%)	6 (25%) 14 (58%)	6 (26%) 14 (61%)	2 (8%) 19 (76%)
Thymus	(25)	(21)	(22)	(22)	(24)	(25)
Atrophy	1 (4%)		2 (9%)			
Hyperplasia, Lymphoid	6 (24%)	2 (10%)	2 (9%)	8 (36%)	6 (25%)	9 (36%)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(25)	(25)	(25)	(23)	(23)	(25)
Skin	(25)	(25)	(25)	(25)	(23)	(25)
Inflammation, Suppurative		1 (4%)				
Ulcer		1 (4%)				
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(0)	(0)	(2)	(0)	(0)	(2)
Bone, Femur	(25)	(25)	(25)	(25)	(24)	(25)
Fibro-Osseous Lesion	1 (4%)					
Skeletal Muscle	(0)	(1)	(2)	(0)	(0)	(0)
Degeneration			1 (50%)			
<b>NERVOUS SYSTEM</b>						
Brain, Brain Stem	(25)	(24)	(25)	(24)	(23)	(25)
Brain, Cerebellum	(25)	(24)	(25)	(24)	(23)	(25)
Hemorrhage		1 (4%)				
Brain, Cerebrum	(25)	(24)	(25)	(24)	(23)	(25)
Mineralization	2 (8%)			3 (13%)		1 (4%)

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Peripheral Nerve Axon, Degeneration	(0)	(0)	(1) 1 (100%)	(0)	(0)	(0)
<b>RESPIRATORY SYSTEM</b>						
Lung	(25)	(24)	(24)	(24)	(24)	(25)
Hemorrhage				1 (4%)		1 (4%)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active		1 (4%)			1 (4%)	1 (4%)
Metaplasia, Osseous		1 (4%)				1 (4%)
Nose	(25)	(25)	(25)	(24)	(24)	(25)
Hyaline Droplet	1 (4%)	3 (12%)	4 (16%)	1 (4%)	6 (25%)	4 (16%)
Trachea	(25)	(24)	(24)	(24)	(23)	(25)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(25)	(23)	(23)	(22)	(23)	(24)
Cataract						
Harderian Gland	(25)	(24)	(25)	(25)	(23)	(25)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active	2 (8%)		1 (4%)		1 (4%)	1 (4%)
<b>URINARY SYSTEM</b>						
Kidney	(25)	(24)	(24)	(24)	(23)	(25)
Casts Protein	14 (56%)	14 (58%)	8 (33%)	10 (42%)	12 (52%)	15 (60%)
Hydronephrosis						
Infarct	1 (4%)					
Infiltration Cellular, Lymphocyte Metaplasia, Osseous	11 (44%)	10 (42%)	11 (46%)	15 (63%)	11 (48%)	13 (52%)
Mineralization			1 (4%)			
Renal Tubule, Regeneration			1 (4%)			
Urinary Bladder	(25)	(24)	(24)	(23)	(23)	(25)
Infiltration Cellular, Lymphocyte	8 (32%)	4 (17%)	8 (33%)	4 (17%)	8 (35%)	5 (20%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

**Disposition Summary**

<b>Animals Initially In Study</b>	<b>24</b>	<b>25</b>
<b>Early Deaths</b>		
<b>Moribund Sacrifice</b>	<b>1</b>	
<b>Natural Death</b>	<b>1</b>	
<b>Survivors</b>		
<b>Moribund Sacrifice</b>	<b>1</b>	<b>2</b>
<b>Natural Death</b>		<b>2</b>
<b>Terminal Sacrifice</b>	<b>21</b>	<b>21</b>
<b>Animals Examined Microscopically</b>	<b>22</b>	<b>25</b>

## ALIMENTARY SYSTEM

Gallbladder	(21)	(24)
Intestine Large, Cecum	(21)	(23)
Hyperplasia, Lymphoid		
Intestine Small, Duodenum	(21)	(24)
Intestine Small, Ileum	(21)	(23)
Liver	(22)	(25)
Basophilic Focus	1 (5%)	
Clear Cell Focus	1 (5%)	
Hematopoietic Cell Proliferation		
Hepatodiaphragmatic Nodule		
Infiltration Cellular, Lymphocyte	4 (18%)	4 (16%)
Inflammation, Chronic Active		3 (12%)
Necrosis		
Tension Lipidosis	4 (18%)	3 (12%)
Vacuolization Cytoplasmic	13 (59%)	15 (60%)
Centrilobular, Degeneration		3 (12%)
Mesentery	(0)	(2)
Fat, Necrosis		2 (100%)
Pancreas	(21)	(24)
Infiltration Cellular, Lymphocyte	5 (24%)	2 (8%)
Necrosis		
Salivary Glands	(22)	(25)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE                      AZT40,3TC25,NVP7                      A60,3T37.5,N10.5

Infiltration Cellular, Lymphocyte Stomach, Forestomach Inflammation, Suppurative Inflammation, Chronic Active Ulcer Epithelium, Hyperplasia Stomach, Glandular	12 (55%) (21)	20 (80%) (24)
		1 (4%) (23)

CARDIOVASCULAR SYSTEM

Blood Vessel	(22)	(25)
Heart Inflammation, Chronic Active Mineralization	(22)	(25)

ENDOCRINE SYSTEM

Adrenal Cortex Accessory Adrenal Cortical Nodule Hypertrophy Infiltration Cellular, Polymorphonuclear Vacuolization Cytoplasmic Subcapsular, Hyperplasia Islets, Pancreatic Hyperplasia Parathyroid Gland Cyst Infiltration Cellular, Lymphocyte Pituitary Gland Fibrosis Pars Distalis, Hyperplasia Thyroid Gland Cyst Ectopic Thymus	(22)	(25)
	16 (73%) 20 (91%)	18 (72%) 24 (96%)
	(22)	(25)
	(21)	(23)
	(22)	(23)
		1 (4%) (25)
	(22)	(25)
	1 (5%)	
	2 (9%)	2 (8%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

GENERAL BODY SYSTEM

Tissue NOS (0) (0)

GENITAL SYSTEM

Clitoral Gland (22) (22)  
  Acinus, Degeneration 5 (23%) 11 (50%)  
  Duct, Ectasia 1 (5%)  
Ovary (22) (25)  
  Atrophy 1 (5%)  
  Cyst 1 (5%)  
  Cyst Dermoid  
  Hemorrhage 1 (4%)  
Uterus (22) (25)  
  Atrophy  
  Degeneration, Cystic  
  Endometrium, Hyperplasia, Cystic 16 (73%) 17 (68%)  
Vagina (22) (23)  
  Infiltration Cellular, Polymorphonuclear 2 (9%)

HEMATOPOIETIC SYSTEM

Bone Marrow (22) (24)  
  Fibrosis  
  Hyperplasia 3 (13%)  
Lymph Node (1) (4)  
  Lumbar, Hyperplasia, Lymphoid  
  Lumbar, Sinus, Dilatation  
  Pancreatic, Hyperplasia, Lymphoid  
  Renal, Angiectasis  
  Renal, Hyperplasia, Lymphoid  
  Renal, Thrombus

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Lymph Node, Mandibular	(22)	(25)
Hyperplasia, Lymphoid	2 (9%)	1 (4%)
Lymph Node, Mesenteric	(21)	(24)
Angiectasis		
Hyperplasia, Lymphoid	2 (10%)	3 (13%)
Spleen	(22)	(25)
Hematopoietic Cell Proliferation	8 (36%)	7 (28%)
Hyperplasia, Lymphoid	16 (73%)	16 (64%)
Thymus	(21)	(24)
Atrophy		
Hyperplasia, Lymphoid	2 (10%)	5 (21%)

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INTEGUMENTARY SYSTEM

Mammary Gland	(22)	(25)
Skin	(22)	(25)
Inflammation, Suppurative		
Ulcer		

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MUSCULOSKELETAL SYSTEM

Bone	(1)	(0)
Bone, Femur	(22)	(25)
Fibro-Osseous Lesion		
Skeletal Muscle	(0)	(0)
Degeneration		

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NERVOUS SYSTEM

Brain, Brain Stem	(21)	(25)
Brain, Cerebellum	(21)	(25)
Hemorrhage		
Brain, Cerebrum	(21)	(25)
Mineralization	2 (10%)	

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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Peripheral Nerve Axon, Degeneration	(0)	(0)
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RESPIRATORY SYSTEM

Lung	(22)	(25)
Hemorrhage		
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Metaplasia, Osseous		3 (12%)
Nose	(22)	(25)
Hyaline Droplet	1 (5%)	6 (24%)
Trachea	(21)	(25)

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SPECIAL SENSES SYSTEM

Eye	(21)	(23)
Cataract		1 (4%)
Harderian Gland	(22)	(24)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active		

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URINARY SYSTEM

Kidney	(22)	(25)
Casts Protein	9 (41%)	15 (60%)
Hydronephrosis		3 (12%)
Infarct		
Infiltration Cellular, Lymphocyte	7 (32%)	11 (44%)
Metaplasia, Osseous		1 (4%)
Mineralization		
Renal Tubule, Regeneration		
Urinary Bladder	(22)	(25)
Infiltration Cellular, Lymphocyte	5 (23%)	3 (12%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

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\*\*\* END OF REPORT \*\*\*

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