

**TDMs No.** 20310 - 03

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

**Date Report Requested:** 05/04/2010

**Test Type:** 26-39 WEEKS

AZT+3TC combination

**Time Report Requested:** 12:30:53

**Route:** GAVAGE

**CAS Number:** AZT3TCCOMBO

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

**Species/Strain:** MICE/C3B6F1-+/Trp53(tm1Brd)

**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

Test Type: 26-39 WEEKS

AZT+3TC combination

Time Report Requested: 12:30:53

Route: GAVAGE

CAS Number: AZT3TCCOMBO

First Dose M/F: 12/22/06 / 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
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**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	1	1	
Hematopoietic Cell Proliferation	1 [2.0]					1 [3.0]
Infiltration Cellular, Lymphocyte				1 [1.0]		1 [3.0]
Inflammation, Suppurative						
Inflammation, Chronic Active			1 [3.0]		1 [1.0]	1 [1.0]
Mixed Cell Focus			1		1	
Necrosis	1 [1.0]		1 [4.0]			1 [4.0]
Tension Lipidosis		1 [1.0]		1 [2.0]	1 [2.0]	2 [1.5]
Vacuolization Cytoplasmic	19 [1.9]	18 [2.5]	20 [2.4]	20 [2.3]	21 [2.3]	21 [2.1]
Centrilobular, Degeneration	15 [2.0]	16 [2.4]	18 [2.4]	17 [2.4]	17 [2.4]	20 [2.1]
Mesentery	(3)	(0)	(0)	(1)	(2)	(1)
Inflammation, Chronic Active					1 [4.0]	
Fat, Necrosis	1 [4.0]				1 [4.0]	
Pancreas	(24)	(23)	(25)	(25)	(24)	(25)
Cyst	1 [4.0]	1 [4.0]				

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)

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AZT+3TC combination

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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
Hemorrhage					1 [3.0]	
Infiltration Cellular, Lymphocyte Acinus, Degeneration		1 [4.0]	1 [4.0]		1 [2.0]	2 [1.0]
Salivary Glands	(25)	(23)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte	18 [1.2]	12 [1.1]	13 [1.2]	18 [1.2]	11 [1.2]	14 [1.6]
Stomach, Forestomach	(25)	(23)	(25)	(23)	(24)	(25)
Hyperkeratosis		1 [3.0]				
Ulcer					1 [2.0]	
Epithelium, Hyperplasia	1 [1.0]				1 [2.0]	
Stomach, Glandular	(23)	(22)	(24)	(22)	(24)	(24)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(25)	(24)	(25)	(25)	(24)	(25)
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Mineralization						1 [3.0]
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(25)	(24)	(25)	(25)	(23)	(25)
Accessory Adrenal Cortical Nodule	1					
Cyst					1 [2.0]	
Hypertrophy		1 [4.0]				
Subcapsular, Hyperplasia	13 [1.0]	12 [1.0]	13 [1.0]	7 [1.0]	11 [1.1]	14 [1.0]
Adrenal Medulla	(25)	(23)	(25)	(23)	(21)	(25)
Islets, Pancreatic	(24)	(24)	(25)	(25)	(24)	(25)
Hyperplasia	13 [1.5]	10 [1.7]	15 [1.7]	10 [1.3]	14 [1.6]	9 [1.4]
Parathyroid Gland	(23)	(21)	(24)	(18)	(19)	(23)
Cyst			1 [1.0]			
Pituitary Gland	(24)	(22)	(25)	(25)	(24)	(25)
Thyroid Gland	(25)	(23)	(25)	(23)	(23)	(25)
Ectopic Thymus	2		1			
Follicle, Degeneration						

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

Test Type: 26-39 WEEKS

AZT+3TC combination

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First Dose M/F: 12/22/06 / 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
<b>GENERAL BODY SYSTEM</b>						
Tissue NOS	(1)	(0)	(1)	(3)	(0)	(0)
Abscess				1 [4.0]		
Abdominal, Fat, Necrosis			1 [4.0]			
<b>GENITAL SYSTEM</b>						
Epididymis	(25)	(23)	(25)	(25)	(24)	(25)
Exfoliated Germ Cell		1 [3.0]				
Hypospermia						
Inflammation, Chronic Active						
Preputial Gland	(25)	(24)	(25)	(25)	(24)	(25)
Cyst						1 [3.0]
Infiltration Cellular, Lymphocyte			1 [2.0]			1 [3.0]
Infiltration Cellular, Plasma Cell		1 [3.0]				
Inflammation, Suppurative		1 [4.0]				
Inflammation, Chronic Active	1 [2.0]	1 [2.0]				
Keratin Cyst						1
Acinus, Degeneration	3 [3.7]	2 [3.0]	3 [3.0]	3 [2.0]	1 [3.0]	4 [2.0]
Duct, Ectasia	3 [3.3]	2 [3.0]	2 [3.5]	4 [2.0]	1 [2.0]	3 [2.0]
Prostate	(25)	(23)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte			1 [3.0]			
Inflammation, Suppurative			1 [3.0]			
Seminal Vesicle	(25)	(23)	(24)	(25)	(24)	(25)
Testes	(25)	(24)	(24)	(25)	(24)	(25)
Seminiferous Tubule, Degeneration		1 [2.0]	1 [4.0]	2 [2.0]		
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(23)	(24)	(24)	(25)	(24)	(25)
Hyperplasia	3 [3.3]	3 [3.3]	1 [3.0]	2 [3.0]	2 [2.0]	2 [3.5]
Lymph Node	(2)	(2)	(1)	(1)	(2)	(3)
Axillary, Hyperplasia, Lymphoid						1 [4.0]

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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
Lumbar, Hyperplasia, Lymphoid						1 [3.0]
Mediastinal, Hyperplasia, Lymphoid	1 [1.0]			1 [4.0]		2 [2.0]
Mediastinal, Infiltration Cellular, Plasma Cell						1 [2.0]
Renal, Hyperplasia, Lymphoid						1 [1.0]
Lymph Node, Mandibular	(25)	(23)	(25)	(25)	(24)	(25)
Hyperplasia, Lymphoid	2 [1.5]	1 [1.0]	2 [1.0]	2 [1.0]	2 [2.0]	2 [2.5]
Infiltration Cellular, Plasma Cell						
Lymph Node, Mesenteric	(24)	(23)	(25)	(25)	(24)	(25)
Congestion		1 [4.0]				
Hyperplasia, Lymphoid	9 [2.0]	5 [1.6]	12 [1.7]	11 [2.4]	11 [1.9]	10 [2.1]
Infiltration Cellular, Plasma Cell			1 [3.0]	2 [3.0]	1 [3.0]	1 [2.0]
Infiltration Cellular, Polymorphonuclear						
Spleen	(25)	(23)	(24)	(25)	(24)	(25)
Congestion					1 [3.0]	
Hematopoietic Cell Proliferation	7 [2.7]	11 [2.5]	4 [3.3]	5 [2.8]	11 [2.4]	9 [2.4]
Hyperplasia, Lymphoid	12 [2.4]	14 [2.3]	16 [2.1]	18 [2.3]	14 [2.5]	15 [2.2]
Thymus	(24)	(22)	(24)	(23)	(22)	(25)
Atrophy	2 [3.5]	1 [4.0]		1 [4.0]	1 [2.0]	1 [4.0]
Cyst		1 [2.0]				
Hyperplasia, Lymphoid	2 [2.5]			1 [2.0]	3 [2.0]	3 [1.3]

**INTEGUMENTARY SYSTEM**

Skin	(25)	(25)	(25)	(25)	(24)	(25)
Cyst		1 [4.0]				
Granuloma		1 [4.0]				
Inflammation, Suppurative						
Epithelium, Hyperplasia						

**MUSCULOSKELETAL SYSTEM**

Bone	(3)	(1)	(1)	(1)	(0)	(0)
Bone, Femur	(25)	(25)	(25)	(25)	(25)	(25)
Fibro-Osseous Lesion	1 [4.0]					
Skeletal Muscle	(3)	(2)	(1)	(0)	(0)	(0)

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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
<b>NERVOUS SYSTEM</b>						
Brain, Brain Stem	(25)	(24)	(25)	(25)	(24)	(24)
Brain, Cerebellum	(25)	(24)	(25)	(25)	(24)	(24)
Compression			1 [4.0]			
Hemorrhage		1 [2.0]				
Brain, Cerebrum	(25)	(24)	(25)	(25)	(24)	(25)
Mineralization	2 [1.0]	3 [1.0]	4 [1.0]	4 [1.0]	2 [1.0]	1 [1.0]
Spinal Cord, Thoracic	(1)	(0)	(0)	(0)	(0)	(0)
Compression	1 [4.0]					
<b>RESPIRATORY SYSTEM</b>						
Lung	(25)	(24)	(25)	(25)	(24)	(25)
Hemorrhage		1 [3.0]			1 [4.0]	1 [3.0]
Infiltration Cellular, Histiocyte		1 [3.0]	1 [2.0]			
Inflammation, Chronic				1 [3.0]		
Mineralization		1 [3.0]		1 [2.0]		
Alveolar Epithelium, Hyperplasia				1 [3.0]		1 [4.0]
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Hyaline Droplet			1 [2.0]		2 [1.5]	3 [1.3]
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(22)	(22)	(23)	(23)	(24)	(24)
Inflammation, Chronic Active		1 [3.0]				
Cornea, Ulcer		1 [4.0]				
Harderian Gland	(25)	(22)	(25)	(25)	(24)	(25)
Infiltration Cellular, Lymphocyte	1 [1.0]					1 [1.0]
<b>URINARY SYSTEM</b>						

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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
Kidney	(25)	(24)	(25)	(25)	(24)	(25)
Casts Protein	3 [1.0]	5 [1.2]	6 [1.0]	7 [1.1]	8 [1.0]	7 [1.0]
Cyst						
Hemorrhage				1 [4.0]		
Hydronephrosis	1 [2.0]	8 [1.8]	7 [1.4]	5 [1.6]	9 [1.4]	13 [1.2]
Infarct						
Infiltration Cellular, Lymphocyte	8 [1.1]	2 [1.0]	10 [1.1]	6 [1.0]	2 [1.0]	9 [1.4]
Metaplasia, Osseous			1 [1.0]		1 [1.0]	
Nephropathy	1 [1.0]	1 [2.0]	2 [1.0]			
Renal Tubule, Regeneration			1 [1.0]			
Transitional Epithelium, Hyperplasia			1 [2.0]			
Urinary Bladder	(25)	(24)	(25)	(25)	(24)	(25)
Hemorrhage					1 [3.0]	
Infiltration Cellular, Histiocyte				1 [4.0]		
Infiltration Cellular, Lymphocyte	2 [1.0]			2 [1.0]	1 [1.0]	1 [1.0]
Lumen, Dilatation	1 [4.0]	1 [4.0]	1 [4.0]	1 [4.0]		

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

**Disposition Summary**

Animals Initially In Study	25	25
Early Deaths		
Moribund Sacrifice		
Natural Death		1
Survivors		
Moribund Sacrifice	1	1
Natural Death		
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
Intestine Small, Jejunum	(23)	(23)
Liver	(23)	(23)
Basophilic Focus	2	2
Hematopoietic Cell Proliferation		
Infiltration Cellular, Lymphocyte	1 [2.0]	
Inflammation, Suppurative	1 [2.0]	
Inflammation, Chronic Active	1 [1.0]	1 [2.0]
Mixed Cell Focus		
Necrosis	1 [2.0]	2 [3.0]
Tension Lipidosis	2 [2.0]	1 [1.0]
Vacuolization Cytoplasmic	19 [2.4]	20 [2.8]
Centrilobular, Degeneration	18 [2.3]	17 [2.9]
Mesentery	(2)	(0)
Inflammation, Chronic Active		
Fat, Necrosis	2 [4.0]	
Pancreas	(23)	(23)
Cyst		

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

Hemorrhage		
Infiltration Cellular, Lymphocyte		
Acinus, Degeneration	1 [3.0]	
Salivary Glands	(23)	(23)
Infiltration Cellular, Lymphocyte	16 [1.2]	16 [1.4]
Stomach, Forestomach	(23)	(23)
Hyperkeratosis	1 [2.0]	
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
Cyst		
Hypertrophy	1 [2.0]	2 [1.5]
Subcapsular, Hyperplasia	11 [1.1]	12 [1.1]
Adrenal Medulla	(23)	(22)
Islets, Pancreatic	(23)	(23)
Hyperplasia	13 [1.3]	6 [1.8]
Parathyroid Gland	(23)	(23)
Cyst		
Pituitary Gland	(23)	(23)
Thyroid Gland	(23)	(23)
Ectopic Thymus		
Follicle, Degeneration		1 [2.0]

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)
Abscess		
Abdominal, Fat, Necrosis		

GENITAL SYSTEM

Epididymis	(23)	(23)
Exfoliated Germ Cell		1 [3.0]
Hypospermia		1 [3.0]
Inflammation, Chronic Active	1 [2.0]	
Preputial Gland	(23)	(23)
Cyst		
Infiltration Cellular, Lymphocyte		
Infiltration Cellular, Plasma Cell		
Inflammation, Suppurative	1 [4.0]	
Inflammation, Chronic Active	1 [2.0]	
Keratin Cyst		
Acinus, Degeneration	7 [3.0]	5 [2.4]
Duct, Ectasia	5 [3.0]	5 [2.4]
Prostate	(23)	(23)
Infiltration Cellular, Lymphocyte		
Inflammation, Suppurative	1 [3.0]	
Seminal Vesicle	(23)	(23)
Testes	(23)	(23)
Seminiferous Tubule, Degeneration	1 [1.0]	1 [4.0]

HEMATOPOIETIC SYSTEM

Bone Marrow	(23)	(23)
Hyperplasia	4 [3.0]	
Lymph Node	(1)	(1)
Axillary, Hyperplasia, Lymphoid		

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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 [1.5]	5 [2.2]
Infiltration Cellular, Plasma Cell	1 [2.0]	
Lymph Node, Mesenteric	(23)	(23)
Congestion		
Hyperplasia, Lymphoid	5 [2.0]	9 [1.6]
Infiltration Cellular, Plasma Cell	1 [4.0]	
Infiltration Cellular, Polymorphonuclear	1 [2.0]	
Spleen	(23)	(23)
Congestion		
Hematopoietic Cell Proliferation	6 [1.8]	6 [2.0]
Hyperplasia, Lymphoid	13 [2.2]	12 [2.4]
Thymus	(20)	(20)
Atrophy		1 [3.0]
Cyst		
Hyperplasia, Lymphoid	1 [2.0]	1 [1.0]

**INTEGUMENTARY SYSTEM**

Skin	(23)	(24)
Cyst		
Granuloma		
Inflammation, Suppurative		1 [3.0]
Epithelium, Hyperplasia		1 [2.0]

**MUSCULOSKELETAL SYSTEM**

Bone	(1)	(1)
Bone, Femur	(23)	(24)
Fibro-Osseous Lesion	1 [3.0]	
Skeletal Muscle	(0)	(0)

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

NERVOUS SYSTEM

Brain, Brain Stem	(23)	(23)
Brain, Cerebellum	(23)	(23)
Compression		
Hemorrhage		
Brain, Cerebrum	(23)	(23)
Mineralization	3 [1.0]	1 [1.0]
Spinal Cord, Thoracic	(0)	(0)
Compression		

RESPIRATORY SYSTEM

Lung	(23)	(23)
Hemorrhage		
Infiltration Cellular, Histiocyte		
Inflammation, Chronic		
Mineralization		
Alveolar Epithelium, Hyperplasia		1 [1.0]
Nose	(23)	(24)
Hyaline Droplet	2 [1.5]	

SPECIAL SENSES SYSTEM

Eye	(23)	(23)
Inflammation, Chronic Active		
Cornea, Ulcer		
Harderian Gland	(23)	(23)
Infiltration Cellular, Lymphocyte	1 [1.0]	

URINARY SYSTEM

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: 26-39 WEEKS

AZT+3TC combination

Time Report Requested: 12:30:53

Route: GAVAGE

CAS Number: AZT3TCCOMBO

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

Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

Lab: NCTR

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

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Kidney	(23)	(23)
Casts Protein	7 [1.3]	10 [1.0]
Cyst	1 [3.0]	
Hemorrhage		
Hydronephrosis	5 [1.2]	12 [2.0]
Infarct	1 [1.0]	
Infiltration Cellular, Lymphocyte	9 [1.0]	7 [1.7]
Metaplasia, Osseous		
Nephropathy		1 [1.0]
Renal Tubule, Regeneration		
Transitional Epithelium, Hyperplasia		
Urinary Bladder	(23)	(23)
Hemorrhage		
Infiltration Cellular, Histiocyte		
Infiltration Cellular, Lymphocyte	1 [1.0]	1 [1.0]
Lumen, Dilatation		

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\*\*\* 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)