

**TDMSE No.** 20310 - 03

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS  
ABRIDGED) (a)**

**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

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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 Adenoma	(22)	(22)	(24)	(22) 1 (5%)	(24)	(24)
Intestine Large, Colon	(22)	(22)	(25)	(23)	(24)	(24)
Intestine Large, Rectum	(22)	(22)	(23)	(22)	(24)	(24)
Intestine Small, Duodenum Leiomyosarcoma	(23) 1 (4%)	(22)	(23)	(22)	(24)	(24)
Intestine Small, Jejunum Adenocarcinoma	(23) 1 (4%)	(22)	(23)	(22)	(24)	(24)
Liver Hemangiosarcoma	(25)	(24)	(25)	(25)	(25) 1 (4%)	(25)
Hepatocellular Adenoma	1 (4%)	4 (17%)	2 (8%)	2 (8%)	7 (28%)	4 (16%)
Hepatocellular Adenoma, Multiple		4 (17%)	1 (4%)		2 (8%)	3 (12%)
Hepatocellular Carcinoma		1 (4%)				2 (8%)
Hepatocellular Carcinoma, Multiple					1 (4%)	
Sarcoma, Metastatic, Uncertain Primary Site			1 (4%)			
Capsule, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (4%)			
Mesentery Fibrosarcoma	(3)	(0)	(0)	(1)	(2) 1 (50%)	(1)
Hemangiosarcoma						1 (100%)
Leiomyosarcoma, Metastatic, Intestine Small, Duodenum	1 (33%)					

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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Route: GAVAGE

CAS Number: AZT3TCCOMBO

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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
Sarcoma	1 (33%)			1 (100%)		
Pancreas	(24)	(23)	(25)	(25)	(24)	(25)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (4%)			
Leiomyosarcoma, Metastatic, Intestine Small, Duodenum	1 (4%)					
Sarcoma, Metastatic, Tissue Nos	1 (4%)					
Sarcoma, Metastatic, Uncertain Primary Site			1 (4%)			
Salivary Glands	(25)	(23)	(25)	(25)	(24)	(25)
Stomach, Forestomach	(25)	(23)	(25)	(23)	(24)	(25)
Stomach, Glandular	(23)	(22)	(24)	(22)	(24)	(24)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(25)	(24)	(25)	(25)	(24)	(25)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (4%)			
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (4%)			
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(25)	(24)	(25)	(25)	(23)	(25)
Adrenal Medulla	(25)	(23)	(25)	(23)	(21)	(25)
Pheochromocytoma Benign						
Islets, Pancreatic	(24)	(24)	(25)	(25)	(24)	(25)
Parathyroid Gland	(23)	(21)	(24)	(18)	(19)	(23)
Pituitary Gland	(24)	(22)	(25)	(25)	(24)	(25)
Thyroid Gland	(25)	(23)	(25)	(23)	(23)	(25)
<b>GENERAL BODY SYSTEM</b>						
Tissue NOS	(1)	(0)	(1)	(3)	(0)	(0)
Abdominal, Sarcoma	1 (100%)		1 (100%)	1 (33%)		

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

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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
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## GENITAL SYSTEM

Epididymis	(25)	(23)	(25)	(25)	(24)	(25)
Sarcoma, Metastatic, Uncertain Primary Site			1 (4%)			
Preputial Gland	(25)	(24)	(25)	(25)	(24)	(25)
Squamous Cell Carcinoma						
Squamous Cell Papilloma						
Prostate	(25)	(23)	(25)	(25)	(24)	(25)
Seminal Vesicle	(25)	(23)	(24)	(25)	(24)	(25)
Sarcoma, Metastatic, Uncertain Primary Site			1 (4%)			
Testes	(25)	(24)	(24)	(25)	(24)	(25)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(23)	(24)	(24)	(25)	(24)	(25)
Lymph Node	(2)	(2)	(1)	(1)	(2)	(3)
Sarcoma, Metastatic, Uncertain Primary Site			1 (100%)			
Mediastinal, Sarcoma, Metastatic, Tissue Nos	1 (50%)					
Mediastinal, Sarcoma, Metastatic, Uncertain Primary Site			1 (100%)			
Lymph Node, Mandibular	(25)	(23)	(25)	(25)	(24)	(25)
Lymph Node, Mesenteric	(24)	(23)	(25)	(25)	(24)	(25)
Sarcoma, Metastatic, Tissue Nos	1 (4%)					
Sarcoma, Metastatic, Uncertain Primary Site			1 (4%)			
Spleen	(25)	(23)	(24)	(25)	(24)	(25)
Hemangiosarcoma					1 (4%)	
Thymus	(24)	(22)	(24)	(23)	(22)	(25)
Sarcoma, Metastatic, Uncertain Primary Site			1 (4%)			

## INTEGUMENTARY SYSTEM

Skin	(25)	(25)	(25)	(25)	(24)	(25)
Osteosarcoma, Metastatic, Bone						

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

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CAS Number: AZT3TCCOMBO

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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
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Squamous Cell Papilloma

MUSCULOSKELETAL SYSTEM

Bone	(3)	(1)	(1)	(1)	(0)	(0)
Osteosarcoma	1 (33%)					
Cranium, Neuroblastoma, Metastatic, Nose						
Cranium, Osteosarcoma			1 (100%)			
Humerus, Osteosarcoma	1 (33%)					
Pelvis, Osteosarcoma		1 (100%)		1 (100%)		
Rib, Osteosarcoma						
Tibia, Osteosarcoma	1 (33%)					
Bone, Femur	(25)	(25)	(25)	(25)	(25)	(25)
Osteosarcoma			1 (4%)			
Skeletal Muscle	(3)	(2)	(1)	(0)	(0)	(0)
Leiomyosarcoma, Metastatic, Intestine Small, Duodenum	1 (33%)					
Rhabdomyosarcoma		1 (50%)				
Diaphragm, Sarcoma, Metastatic, Tissue Nos	1 (33%)					
Diaphragm, Sarcoma, Metastatic, Uncertain Primary Site			1 (100%)			

NERVOUS SYSTEM

Brain, Brain Stem	(25)	(24)	(25)	(25)	(24)	(24)
Brain, Cerebellum	(25)	(24)	(25)	(25)	(24)	(24)
Brain, Cerebrum	(25)	(24)	(25)	(25)	(24)	(25)
Olfactory Lobe, Neuroblastoma, Metastatic, Nose						
Spinal Cord, Thoracic	(1)	(0)	(0)	(0)	(0)	(0)

RESPIRATORY SYSTEM

Lung	(25)	(24)	(25)	(25)	(24)	(25)
Alveolar/Bronchiolar Adenoma			1 (4%)	1 (4%)		

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: 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
Alveolar/Bronchiolar Carcinoma		1 (4%)	1 (4%)			
Osteosarcoma, Metastatic, Bone	1 (4%)					
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Neuroblastoma						
Osteosarcoma		1 (4%)				
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(22)	(22)	(23)	(23)	(24)	(24)
Harderian Gland	(25)	(22)	(25)	(25)	(24)	(25)
Adenoma			1 (4%)	1 (4%)		1 (4%)
Carcinoma			1 (4%)			
Neuroblastoma, Metastatic, Nose						
<b>URINARY SYSTEM</b>						
Kidney	(25)	(24)	(25)	(25)	(24)	(25)
Capsule, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (4%)			
Urinary Bladder	(25)	(24)	(25)	(25)	(24)	(25)
Sarcoma				1 (4%)		
<b>SYSTEMIC LESIONS</b>						
Multiple Organ	*(25)	*(25)	*(25)	*(26)	*(25)	*(25)
Histiocytic Sarcoma				1 (4%)	1 (4%)	
Leukemia Granulocytic						1 (4%)
Lymphoma Malignant	1 (4%)	3 (12%)			3 (12%)	

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

\* Number of animals with any tissue examined microscopically

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

**Disposition Summary**

<b>Animals Initially In Study</b>	<b>25</b>	<b>25</b>
<b>Early Deaths</b>		
<b>Moribund Sacrifice</b>		
<b>Natural Death</b>		<b>1</b>
<b>Survivors</b>		
<b>Moribund Sacrifice</b>	<b>1</b>	<b>1</b>
<b>Natural Death</b>		
<b>Terminal Sacrifice</b>	<b>24</b>	<b>23</b>
<b>Animals Examined Microscopically</b>	<b>23</b>	<b>24</b>

## ALIMENTARY SYSTEM

Intestine Large, Cecum	(23)	(23)
Adenoma		
Intestine Large, Colon	(23)	(23)
Intestine Large, Rectum	(23)	(23)
Intestine Small, Duodenum	(23)	(23)
Leiomyosarcoma		
Intestine Small, Jejunum	(23)	(23)
Adenocarcinoma		
Liver	(23)	(23)
Hemangiosarcoma		
Hepatocellular Adenoma	5 (22%)	7 (30%)
Hepatocellular Adenoma, Multiple	2 (9%)	2 (9%)
Hepatocellular Carcinoma	2 (9%)	
Hepatocellular Carcinoma, Multiple		1 (4%)
Sarcoma, Metastatic, Uncertain Primary Site		
Capsule, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		
Mesentery	(2)	(0)
Fibrosarcoma		
Hemangiosarcoma		
Leiomyosarcoma, Metastatic, Intestine Small, Duodenum		

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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Sarcoma		
Pancreas	(23)	(23)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		
Leiomyosarcoma, Metastatic, Intestine Small, Duodenum		
Sarcoma, Metastatic, Tissue Nos		
Sarcoma, Metastatic, Uncertain Primary Site		
Salivary Glands	(23)	(23)
Stomach, Forestomach	(23)	(23)
Stomach, Glandular	(23)	(23)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(23)	(24)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		
Heart	(23)	(24)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		

## ENDOCRINE SYSTEM

Adrenal Cortex	(23)	(23)
Adrenal Medulla	(23)	(22)
Pheochromocytoma Benign	1 (4%)	
Islets, Pancreatic	(23)	(23)
Parathyroid Gland	(23)	(23)
Pituitary Gland	(23)	(23)
Thyroid Gland	(23)	(23)

## GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)
Abdominal, Sarcoma		

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



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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

GENITAL SYSTEM

Epididymis	(23)	(23)
Sarcoma, Metastatic, Uncertain Primary Site		
Preputial Gland	(23)	(23)
Squamous Cell Carcinoma	1 (4%)	
Squamous Cell Papilloma		1 (4%)
Prostate	(23)	(23)
Seminal Vesicle	(23)	(23)
Sarcoma, Metastatic, Uncertain Primary Site		
Testes	(23)	(23)

HEMATOPOIETIC SYSTEM

Bone Marrow	(23)	(23)
Lymph Node	(1)	(1)
Sarcoma, Metastatic, Uncertain Primary Site		
Mediastinal, Sarcoma, Metastatic, Tissue Nos		
Mediastinal, Sarcoma, Metastatic, Uncertain Primary Site		
Lymph Node, Mandibular	(23)	(23)
Lymph Node, Mesenteric	(23)	(23)
Sarcoma, Metastatic, Tissue Nos		
Sarcoma, Metastatic, Uncertain Primary Site		
Spleen	(23)	(23)
Hemangiosarcoma		
Thymus	(20)	(20)
Sarcoma, Metastatic, Uncertain Primary Site		

INTEGUMENTARY SYSTEM

Skin	(23)	(24)
Osteosarcoma, Metastatic, Bone		1 (4%)

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

Squamous Cell Papilloma

1 (4%)

MUSCULOSKELETAL SYSTEM

Bone	(1)	(1)
Osteosarcoma		
Cranium, Neuroblastoma, Metastatic, Nose	1 (100%)	
Cranium, Osteosarcoma		
Humerus, Osteosarcoma		
Pelvis, Osteosarcoma		
Rib, Osteosarcoma		1 (100%)
Tibia, Osteosarcoma		
Bone, Femur	(23)	(24)
Osteosarcoma		
Skeletal Muscle	(0)	(0)
Leiomyosarcoma, Metastatic, Intestine Small, Duodenum		
Rhabdomyosarcoma		
Diaphragm, Sarcoma, Metastatic, Tissue Nos		
Diaphragm, Sarcoma, Metastatic, Uncertain Primary Site		

NERVOUS SYSTEM

Brain, Brain Stem	(23)	(23)
Brain, Cerebellum	(23)	(23)
Brain, Cerebrum	(23)	(23)
Olfactory Lobe, Neuroblastoma, Metastatic, Nose	1 (4%)	
Spinal Cord, Thoracic	(0)	(0)

RESPIRATORY SYSTEM

Lung	(23)	(23)
Alveolar/Bronchiolar Adenoma	2 (9%)	

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

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Lab: NCTR

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

Alveolar/Bronchiolar Carcinoma		
Osteosarcoma, Metastatic, Bone		
Nose	(23)	(24)
Neuroblastoma	1 (4%)	
Osteosarcoma		

SPECIAL SENSES SYSTEM

Eye	(23)	(23)
Harderian Gland	(23)	(23)
Adenoma		
Carcinoma		
Neuroblastoma, Metastatic, Nose	1 (4%)	

URINARY SYSTEM

Kidney	(23)	(23)
Capsule, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		
Urinary Bladder	(23)	(23)
Sarcoma		

SYSTEMIC LESIONS

Multiple Organ	*(23)	*(24)
Histiocytic Sarcoma		
Leukemia Granulocytic		
Lymphoma Malignant	1 (4%)	2 (8%)

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

\* Number of animals with any tissue examined microscopically

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Lab: NCTR

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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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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	7	13	9	9	17	11
Total Primary Neoplasms	9	16	10	10	17	12
 Total Animals with Benign Neoplasms	 1	 8	 5	 5	 9	 7
Total Benign Neoplasms	1	8	5	5	9	8
 Total Animals with Malignant Neoplasms	 7	 7	 5	 5	 8	 4
Total Malignant Neoplasms	8	8	5	5	8	4
 Total Animals with Metastatic Neoplasms	 3		 2			
Total Metastatic Neoplasms	8		14			
 Total Animals with Malignant Neoplasms Uncertain Primary Site			 1			
 Total Animals with Neoplasms Uncertain- Benign or Malignant						
Total Uncertain Neoplasms						

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

b - Primary tumors: all tumors except metastatic tumors

Test Type: 26-39 WEEKS

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE MALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	13	14
Total Primary Neoplasms	16	14
Total Animals with Benign Neoplasms	11	10
Total Benign Neoplasms	11	10
Total Animals with Malignant Neoplasms	5	4
Total Malignant Neoplasms	5	4
Total Animals with Metastatic Neoplasms	1	1
Total Metastatic Neoplasms	3	1
Total Animals with Malignant Neoplasms Uncertain Primary Site		
Total Animals with Neoplasms Uncertain- Benign or Malignant		
Total Uncertain Neoplasms		

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

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

b - Primary tumors: all tumors except metastatic tumors