

**TDMS No.** 20310 - 04

**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:** 12:30:59

**Route:** GAVAGE

**CAS Number:** AZT3TCCOMBO

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

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

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

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

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
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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)
Intestine Small, Duodenum	(25)	(23)	(23)	(22)	(23)	(24)
Sarcoma						
Intestine Small, Ileum	(25)	(23)	(23)	(22)	(23)	(24)
Liver	(25)	(25)	(23)	(24)	(23)	(25)
Carcinoma Nos, Metastatic, Pancreas		1 (4%)				
Hepatocellular Carcinoma					1 (4%)	
Mesentery	(0)	(1)	(0)	(0)	(0)	(0)
Carcinoma Nos, Metastatic, Pancreas		1 (100%)				
Pancreas	(25)	(25)	(25)	(22)	(23)	(25)
Carcinoma Nos		1 (4%)				
Salivary Glands	(25)	(25)	(25)	(24)	(23)	(25)
Stomach, Forestomach	(25)	(24)	(24)	(24)	(23)	(25)
Stomach, Glandular	(25)	(23)	(23)	(22)	(23)	(25)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(25)	(25)	(25)	(25)	(23)	(25)
Heart	(25)	(25)	(25)	(25)	(24)	(25)

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 FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(25)	(24)	(24)	(25)	(23)	(25)
Islets, Pancreatic	(25)	(24)	(25)	(25)	(23)	(25)
Parathyroid Gland	(20)	(23)	(21)	(20)	(18)	(21)
Pituitary Gland	(25)	(25)	(24)	(25)	(23)	(24)
Pars Intermedia, Adenoma						
Thyroid Gland	(23)	(24)	(25)	(23)	(22)	(25)
C-cell, Adenoma				1 (4%)		
<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)
Ovary	(25)	(24)	(25)	(24)	(23)	(25)
Uterus	(25)	(25)	(25)	(23)	(23)	(25)
Polyp Stromal						
Vagina	(25)	(24)	(24)	(24)	(23)	(25)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(25)	(24)	(24)	(23)	(23)	(25)
Lymph Node	(1)	(3)	(1)	(3)	(4)	(3)
Mediastinal, Carcinoma Nos, Metastatic, Pancreas		1 (33%)				
Renal, Carcinoma Nos, Metastatic, Pancreas		1 (33%)				
Lymph Node, Mandibular	(25)	(25)	(24)	(24)	(23)	(25)
Lymph Node, Mesenteric	(25)	(24)	(23)	(24)	(23)	(25)
Carcinoma Nos, Metastatic, Pancreas		1 (4%)				
Spleen	(25)	(25)	(24)	(24)	(23)	(25)
Thymus	(25)	(21)	(22)	(22)	(24)	(25)

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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
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(25)	(25)	(25)	(23)	(23)	(25)
Adenoacanthoma		1 (4%)	1 (4%)			
Adenocarcinoma	1 (4%)		3 (12%)		2 (9%)	
Skin	(25)	(25)	(25)	(25)	(23)	(25)
Hemangiosarcoma				1 (4%)		
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(0)	(0)	(2)	(0)	(0)	(2)
Cranium, Osteosarcoma						
Mandible, Osteosarcoma			1 (50%)			
Pelvis, Osteosarcoma			1 (50%)			
Vertebra, Osteosarcoma						1 (50%)
Bone, Femur	(25)	(25)	(25)	(25)	(24)	(25)
Skeletal Muscle	(0)	(1)	(2)	(0)	(0)	(0)
Rhabdomyosarcoma			1 (50%)			
Sarcoma		1 (100%)				
<b>NERVOUS SYSTEM</b>						
Brain, Brain Stem	(25)	(24)	(25)	(24)	(23)	(25)
Brain, Cerebellum	(25)	(24)	(25)	(24)	(23)	(25)
Brain, Cerebrum	(25)	(24)	(25)	(24)	(23)	(25)
Peripheral Nerve	(0)	(0)	(1)	(0)	(0)	(0)
<b>RESPIRATORY SYSTEM</b>						
Lung	(25)	(24)	(24)	(24)	(24)	(25)
Adenocarcinoma, Metastatic, Mammary Gland	1 (4%)				1 (4%)	
Alveolar/Bronchiolar Adenoma	1 (4%)					

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 FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Osteosarcoma, Metastatic, Bone			1 (4%)			
Nose	(25)	(25)	(25)	(24)	(24)	(25)
Neuroblastoma				1 (4%)		
Trachea	(25)	(24)	(24)	(24)	(23)	(25)
SPECIAL SENSES SYSTEM						
Eye	(25)	(23)	(23)	(22)	(23)	(24)
Harderian Gland	(25)	(24)	(25)	(25)	(23)	(25)
Adenoma		1 (4%)		2 (8%)		
URINARY SYSTEM						
Kidney	(25)	(24)	(24)	(24)	(23)	(25)
Urinary Bladder	(25)	(24)	(24)	(23)	(23)	(25)
SYSTEMIC LESIONS						
Multiple Organ	*(25)	*(25)	*(25)	*(25)	*(24)	*(25)
Histiocytic Sarcoma				1 (4%)	1 (4%)	
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant	2 (8%)	2 (8%)	1 (4%)	5 (20%)	4 (17%)	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

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)
Intestine Small, Duodenum	(21)	(24)
Sarcoma		1 (4%)
Intestine Small, Ileum	(21)	(23)
Liver	(22)	(25)
Carcinoma Nos, Metastatic, Pancreas		
Hepatocellular Carcinoma		
Mesentery	(0)	(2)
Carcinoma Nos, Metastatic, Pancreas		
Pancreas	(21)	(24)
Carcinoma Nos		
Salivary Glands	(22)	(25)
Stomach, Forestomach	(21)	(24)
Stomach, Glandular	(21)	(23)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(22)	(25)
Heart	(22)	(25)

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

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

## ENDOCRINE SYSTEM

Adrenal Cortex	(22)	(25)
Islets, Pancreatic	(22)	(25)
Parathyroid Gland	(21)	(23)
Pituitary Gland	(22)	(23)
Pars Intermedia, Adenoma		1 (4%)
Thyroid Gland	(22)	(25)
C-cell, Adenoma		

## GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)
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## GENITAL SYSTEM

Clitoral Gland	(22)	(22)
Ovary	(22)	(25)
Uterus	(22)	(25)
Polyp Stromal	1 (5%)	1 (4%)
Vagina	(22)	(23)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(22)	(24)
Lymph Node	(1)	(4)
Mediastinal, Carcinoma Nos, Metastatic, Pancreas		
Renal, Carcinoma Nos, Metastatic, Pancreas		
Lymph Node, Mandibular	(22)	(25)
Lymph Node, Mesenteric	(21)	(24)
Carcinoma Nos, Metastatic, Pancreas		
Spleen	(22)	(25)
Thymus	(21)	(24)

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AZT40,3TC25,NVP7

A60,3T37.5,N10.5

## INTEGUMENTARY SYSTEM

Mammary Gland	(22)	(25)
Adenoacanthoma		1 (4%)
Adenocarcinoma		
Skin	(22)	(25)
Hemangiosarcoma		

## MUSCULOSKELETAL SYSTEM

Bone	(1)	(0)
Cranium, Osteosarcoma	1 (100%)	
Mandible, Osteosarcoma		
Pelvis, Osteosarcoma		
Vertebra, Osteosarcoma		
Bone, Femur	(22)	(25)
Skeletal Muscle	(0)	(0)
Rhabdomyosarcoma		
Sarcoma		

## NERVOUS SYSTEM

Brain, Brain Stem	(21)	(25)
Brain, Cerebellum	(21)	(25)
Brain, Cerebrum	(21)	(25)
Peripheral Nerve	(0)	(0)

## RESPIRATORY SYSTEM

Lung	(22)	(25)
Adenocarcinoma, Metastatic, Mammary Gland		
Alveolar/Bronchiolar Adenoma	1 (5%)	1 (4%)

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

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

Nose	(22)	(25)
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Neuroblastoma

Trachea	(21)	(25)
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## SPECIAL SENSES SYSTEM

Eye	(21)	(23)
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Harderian Gland	(22)	(24)
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Adenoma		1 (4%)
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## URINARY SYSTEM

Kidney	(22)	(25)
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Urinary Bladder	(22)	(25)
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## SYSTEMIC LESIONS

Multiple Organ	*(22)	*(25)
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Histiocytic Sarcoma	1 (5%)	1 (4%)
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Leukemia Granulocytic		
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Lymphoma Malignant	4 (18%)	4 (16%)
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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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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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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	4	6	8	12	8	3
Total Primary Neoplasms	4	6	8	12	8	3
Total Animals with Benign Neoplasms	1	1		3		
Total Benign Neoplasms	1	1		3		
Total Animals with Malignant Neoplasms	3	4	8	9	8	3
Total Malignant Neoplasms	3	4	8	9	8	3
Total Animals with Metastatic Neoplasms	1	1	1		1	
Total Metastatic Neoplasms	1	5	1		1	
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain- Benign or Malignant		1				
Total Uncertain Neoplasms		1				

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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

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	7	9
Total Primary Neoplasms	8	11
Total Animals with Benign Neoplasms	2	4
Total Benign Neoplasms	2	4
Total Animals with Malignant Neoplasms	6	6
Total Malignant Neoplasms	6	7
Total Animals with Metastatic Neoplasms		
Total Metastatic Neoplasms		
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