

TDMS No. 20310 - 04

Test Type: 26-39 WEEKS

Route: GAVAGE

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

P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010

Time Report Requested: 13:35:38

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
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)
Histiocytic Sarcoma						
Lymphoma Malignant				1 (5%)		
Intestine Large, Cecum	(25)	(23)	(23)	(22)	(23)	(24)
Intestine Small, Duodenum	(25)	(23)	(23)	(22)	(23)	(24)
Histiocytic Sarcoma						
Sarcoma						
Intestine Small, Ileum	(25)	(23)	(23)	(22)	(23)	(24)
Histiocytic Sarcoma					1 (4%)	
Liver	(25)	(25)	(23)	(24)	(23)	(25)
Carcinoma Nos, Metastatic, Pancreas		1 (4%)				
Hepatocellular Carcinoma					1 (4%)	
Histiocytic Sarcoma					1 (4%)	
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant	1 (4%)		1 (4%)	2 (8%)	2 (9%)	2 (8%)
Mesentery	(0)	(1)	(0)	(0)	(0)	(0)
Carcinoma Nos, Metastatic, Pancreas		1 (100%)				
Pancreas	(25)	(25)	(25)	(22)	(23)	(25)
Carcinoma Nos		1 (4%)				
Histiocytic Sarcoma						
Leukemia Granulocytic				1 (5%)		
Lymphoma Malignant	1 (4%)		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
Salivary Glands	(25)	(25)	(25)	(24)	(23)	(25)
Histiocytic Sarcoma					1 (4%)	
Lymphoma Malignant	1 (4%)					
Stomach, Forestomach	(25)	(24)	(24)	(24)	(23)	(25)
Stomach, Glandular	(25)	(23)	(23)	(22)	(23)	(25)
Lymphoma Malignant						
CARDIOVASCULAR SYSTEM						
Blood Vessel	(25)	(25)	(25)	(25)	(23)	(25)
Lymphoma Malignant		1 (4%)	1 (4%)		3 (13%)	1 (4%)
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Lymphoma Malignant		1 (4%)			4 (17%)	2 (8%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(25)	(24)	(24)	(25)	(23)	(25)
Histiocytic Sarcoma						
Lymphoma Malignant						
Islets, Pancreatic	(25)	(24)	(25)	(25)	(23)	(25)
Parathyroid Gland	(20)	(23)	(21)	(20)	(18)	(21)
Pituitary Gland	(25)	(25)	(24)	(25)	(23)	(24)
Lymphoma Malignant					2 (9%)	
Pars Intermedia, Adenoma						
Thyroid Gland	(23)	(24)	(25)	(23)	(22)	(25)
C-cell, Adenoma				1 (4%)		
GENERAL BODY SYSTEM						
Tissue NOS	(0)	(0)	(0)	(1)	(0)	(0)
Thoracic, Histiocytic Sarcoma				1 (100%)		

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

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
GENITAL SYSTEM						
Clitoral Gland	(24)	(24)	(23)	(21)	(21)	(24)
Ovary	(25)	(24)	(25)	(24)	(23)	(25)
Histiocytic Sarcoma						
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant	1 (4%)			1 (4%)	2 (9%)	
Uterus	(25)	(25)	(25)	(23)	(23)	(25)
Histiocytic Sarcoma						
Polyp Stromal						
Vagina	(25)	(24)	(24)	(24)	(23)	(25)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(25)	(24)	(24)	(23)	(23)	(25)
Histiocytic Sarcoma					1 (4%)	
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant						
Lymph Node	(1)	(3)	(1)	(3)	(4)	(3)
Axillary, Histiocytic Sarcoma					1 (25%)	
Axillary, Lymphoma Malignant	1 (100%)			1 (33%)	1 (25%)	
Iliac, Histiocytic Sarcoma						
Inguinal, Lymphoma Malignant						
Lumbar, Histiocytic Sarcoma						
Lumbar, Lymphoma Malignant	1 (100%)			1 (33%)	1 (25%)	
Mediastinal, Carcinoma Nos, Metastatic, Pancreas		1 (33%)				
Mediastinal, Histiocytic Sarcoma					1 (25%)	
Mediastinal, Lymphoma Malignant	1 (100%)	1 (33%)	1 (100%)	1 (33%)	3 (75%)	2 (67%)
Pancreatic, Leukemia Granulocytic				1 (33%)		
Pancreatic, Lymphoma Malignant	1 (100%)					
Renal, Carcinoma Nos, Metastatic, Pancreas		1 (33%)				
Renal, Histiocytic Sarcoma					1 (25%)	
Renal, Lymphoma Malignant	1 (100%)		1 (100%)	1 (33%)		
Thoracic, Histiocytic Sarcoma					1 (25%)	

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

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 Histiocytic Sarcoma	(25)	(25)	(24)	(24)	(23)	(25)
Lymphoma Malignant	1 (4%)			1 (4%)	2 (9%)	1 (4%)
Lymph Node, Mesenteric Carcinoma Nos, Metastatic, Pancreas	(25)	(24) 1 (4%)	(23)	(24)	(23)	(25)
Histiocytic Sarcoma					1 (4%)	
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant	1 (4%)		1 (4%)	4 (17%)	1 (4%)	
Spleen Histiocytic Sarcoma	(25)	(25)	(24)	(24)	(23) 1 (4%)	(25)
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant	1 (4%)		1 (4%)	3 (13%)	2 (9%)	2 (8%)
Thymus Histiocytic Sarcoma	(25)	(21)	(22)	(22)	(24)	(25)
Leukemia Granulocytic				1 (5%)		
Lymphoma Malignant	1 (4%)	2 (10%)		2 (9%)	4 (17%)	2 (8%)
INTEGUMENTARY SYSTEM						
Mammary Gland Adenoacanthoma	(25)	(25) 1 (4%)	(25) 1 (4%)	(23)	(23)	(25)
Adenocarcinoma	1 (4%)		3 (12%)		2 (9%)	
Skin Hemangiosarcoma	(25)	(25)	(25)	(25) 1 (4%)	(23)	(25)
Histiocytic Sarcoma					1 (4%)	
MUSCULOSKELETAL SYSTEM						
Bone Cranium, Osteosarcoma	(0)	(0)	(2)	(0)	(0)	(2)
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)

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

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
Rhabdomyosarcoma Sarcoma		1 (100%)	1 (50%)			
NERVOUS SYSTEM						
Brain, Brain Stem	(25)	(24)	(25)	(24)	(23)	(25)
Histiocytic Sarcoma						
Lymphoma Malignant					1 (4%)	
Brain, Cerebellum	(25)	(24)	(25)	(24)	(23)	(25)
Histiocytic Sarcoma						
Lymphoma Malignant	1 (4%)		1 (4%)			
Brain, Cerebrum	(25)	(24)	(25)	(24)	(23)	(25)
Histiocytic Sarcoma						
Lymphoma Malignant			1 (4%)		1 (4%)	
Peripheral Nerve	(0)	(0)	(1)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Lung	(25)	(24)	(24)	(24)	(24)	(25)
Adenocarcinoma, Metastatic, Mammary Gland	1 (4%)				1 (4%)	
Alveolar/Bronchiolar Adenoma	1 (4%)					
Histiocytic Sarcoma				1 (4%)		
Lymphoma Malignant	1 (4%)	2 (8%)	1 (4%)	3 (13%)	3 (13%)	2 (8%)
Osteosarcoma, Metastatic, Bone			1 (4%)			
Nose	(25)	(25)	(25)	(24)	(24)	(25)
Neuroblastoma				1 (4%)		
Trachea	(25)	(24)	(24)	(24)	(23)	(25)
Lymphoma Malignant					1 (4%)	
SPECIAL SENSES SYSTEM						
Eye	(25)	(23)	(23)	(22)	(23)	(24)
Lymphoma Malignant					1 (4%)	
Harderian Gland	(25)	(24)	(25)	(25)	(23)	(25)

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

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Route: GAVAGE

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

P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010

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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
Adenoma		1 (4%)		2 (8%)		
Lymphoma Malignant					1 (4%)	
URINARY SYSTEM						
Kidney	(25)	(24)	(24)	(24)	(23)	(25)
Histiocytic Sarcoma						
Leukemia Granulocytic				1 (4%)		
Lymphoma Malignant	1 (4%)		1 (4%)	1 (4%)	3 (13%)	
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

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

Disposition Summary

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

ALIMENTARY SYSTEM

Gallbladder	(21)	(24)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant		
Intestine Large, Cecum	(21)	(23)
Intestine Small, Duodenum	(21)	(24)
Histiocytic Sarcoma		1 (4%)
Sarcoma		1 (4%)
Intestine Small, Ileum	(21)	(23)
Histiocytic Sarcoma		
Liver	(22)	(25)
Carcinoma Nos, Metastatic, Pancreas		
Hepatocellular Carcinoma		
Histiocytic Sarcoma	1 (5%)	1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant	1 (5%)	3 (12%)
Mesentery	(0)	(2)
Carcinoma Nos, Metastatic, Pancreas		
Pancreas	(21)	(24)
Carcinoma Nos		
Histiocytic Sarcoma		1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant		

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

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Route: GAVAGE

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

P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010

Time Report Requested: 13:35:38

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

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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Salivary Glands	(22)	(25)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant		2 (8%)
Stomach, Forestomach	(21)	(24)
Stomach, Glandular	(21)	(23)
Lymphoma Malignant		1 (4%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(22)	(25)
Lymphoma Malignant	2 (9%)	2 (8%)
Heart	(22)	(25)
Lymphoma Malignant	2 (9%)	2 (8%)

ENDOCRINE SYSTEM

Adrenal Cortex	(22)	(25)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant		1 (4%)
Islets, Pancreatic	(22)	(25)
Parathyroid Gland	(21)	(23)
Pituitary Gland	(22)	(23)
Lymphoma Malignant	1 (5%)	1 (4%)
Pars Intermedia, Adenoma		1 (4%)
Thyroid Gland	(22)	(25)
C-cell, Adenoma		

GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)
Thoracic, Histiocytic Sarcoma		

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

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

GENITAL SYSTEM

Clitoral Gland	(22)	(22)
Ovary	(22)	(25)
Histiocytic Sarcoma		1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant	1 (5%)	1 (4%)
Uterus	(22)	(25)
Histiocytic Sarcoma		1 (4%)
Polyp Stromal	1 (5%)	1 (4%)
Vagina	(22)	(23)

HEMATOPOIETIC SYSTEM

Bone Marrow	(22)	(24)
Histiocytic Sarcoma		1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant		1 (4%)
Lymph Node	(1)	(4)
Axillary, Histiocytic Sarcoma		
Axillary, Lymphoma Malignant		2 (50%)
Iliac, Histiocytic Sarcoma		1 (25%)
Inguinal, Lymphoma Malignant		1 (25%)
Lumbar, Histiocytic Sarcoma		1 (25%)
Lumbar, Lymphoma Malignant		1 (25%)
Mediastinal, Carcinoma Nos, Metastatic, Pancreas		
Mediastinal, Histiocytic Sarcoma		
Mediastinal, Lymphoma Malignant	1 (100%)	3 (75%)
Pancreatic, Leukemia Granulocytic		
Pancreatic, Lymphoma Malignant		
Renal, Carcinoma Nos, Metastatic, Pancreas		
Renal, Histiocytic Sarcoma		
Renal, Lymphoma Malignant	1 (100%)	1 (25%)
Thoracic, Histiocytic Sarcoma		

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

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Route: GAVAGE

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

P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010

Time Report Requested: 13:35:38

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

Lab: NCTR

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

Lymph Node, Mandibular	(22)	(25)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant	2 (9%)	3 (12%)
Lymph Node, Mesenteric	(21)	(24)
Carcinoma Nos, Metastatic, Pancreas		
Histiocytic Sarcoma		1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant		3 (13%)
Spleen	(22)	(25)
Histiocytic Sarcoma	1 (5%)	1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant		3 (12%)
Thymus	(21)	(24)
Histiocytic Sarcoma		1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant	4 (19%)	4 (17%)

INTEGUMENTARY SYSTEM

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

MUSCULOSKELETAL SYSTEM

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

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

Rhabdomyosarcoma
Sarcoma

NERVOUS SYSTEM

Brain, Brain Stem	(21)	(25)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant		1 (4%)
Brain, Cerebellum	(21)	(25)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant		1 (4%)
Brain, Cerebrum	(21)	(25)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant		1 (4%)
Peripheral Nerve	(0)	(0)

RESPIRATORY SYSTEM

Lung	(22)	(25)
Adenocarcinoma, Metastatic, Mammary Gland		
Alveolar/Bronchiolar Adenoma	1 (5%)	1 (4%)
Histiocytic Sarcoma		1 (4%)
Lymphoma Malignant	2 (9%)	4 (16%)
Osteosarcoma, Metastatic, Bone		
Nose	(22)	(25)
Neuroblastoma		
Trachea	(21)	(25)
Lymphoma Malignant		

SPECIAL SENSES SYSTEM

Eye	(21)	(23)
Lymphoma Malignant		
Harderian Gland	(22)	(24)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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Adenoma		1 (4%)
Lymphoma Malignant		

URINARY SYSTEM

Kidney	(22)	(25)
Histiocytic Sarcoma	1 (5%)	1 (4%)
Leukemia Granulocytic		
Lymphoma Malignant	1 (5%)	2 (8%)
Urinary Bladder	(22)	(25)

SYSTEMIC LESIONS

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

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* Number of animals with any tissue examined microscopically

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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
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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				

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

b - Primary tumors: all tumors except metastatic tumors

TDMS No. 20310 - 04

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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