

**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 |
|---|---------|--------|----------|----------|-----------------|------------------|
| <b>Disposition Summary</b>              |         |        |          |          |                 |                  |
| 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

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

| 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                      |         |        |          |          |                 |                  |
| <b>CARDIOVASCULAR SYSTEM</b>            |         |        |          |          |                 |                  |
| 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%)           |
| <b>ENDOCRINE SYSTEM</b>                 |         |        |          |          |                 |                  |
| 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%)   |                 |                  |
| <b>GENERAL BODY SYSTEM</b>              |         |        |          |          |                 |                  |
| 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 |
|--|----------|---------|----------|----------|-----------------|------------------|
| <b>GENITAL SYSTEM</b>                            |          |         |          |          |                 |                  |
| Clitoral Gland                                   | (24)     | (24)    | (23)     | (21)     | (21)            | (24)             |
| Ovary  | (25)     | (24)    | (25)     | (24)     | (23)            | (25)             |
| Histiocytic Sarcoma                              |          |         |          | 1 (4%)   |                 |                  |
| Leukemia Granulocytic                            |          |         |          | 1 (4%)   | 2 (9%)          |                  |
| Lymphoma Malignant                               | 1 (4%)   |         |          |          |                 |                  |
| Uterus   | (25)     | (25)    | (25)     | (23)     | (23)            | (25)             |
| Histiocytic Sarcoma                              |          |         |          |          |                 |                  |
| Polyp Stromal                                    |          |         |          |          |                 |                  |
| Vagina   | (25)     | (24)    | (24)     | (24)     | (23)            | (25)             |
| <b>HEMATOPOIETIC SYSTEM</b>                      |          |         |          |          |                 |                  |
| 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<br>Histiocytic Sarcoma                 | (25)    | (25)           | (24)           | (24)           | (23)            | (25)             |
| Lymphoma Malignant  | 1 (4%)  |                |                | 1 (4%)         | 2 (9%)          | 1 (4%)           |
| Lymph Node, Mesenteric<br>Carcinoma Nos, Metastatic, Pancreas | (25)    | (24)<br>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<br>Histiocytic Sarcoma                                 | (25)    | (25)           | (24)           | (24)           | (23)<br>1 (4%)  | (25)             |
| Leukemia Granulocytic   |         |                |                | 1 (4%)         |                 |                  |
| Lymphoma Malignant  | 1 (4%)  |                | 1 (4%)         | 3 (13%)        | 2 (9%)          | 2 (8%)           |
| Thymus<br>Histiocytic Sarcoma                                 | (25)    | (21)           | (22)           | (22)           | (24)            | (25)             |
| Leukemia Granulocytic   |         |                |                | 1 (5%)         |                 |                  |
| Lymphoma Malignant  | 1 (4%)  | 2 (10%)        |                | 2 (9%)         | 4 (17%)         | 2 (8%)           |
| <b>INTEGUMENTARY SYSTEM</b>                                   |         |                |                |                |                 |                  |
| Mammary Gland<br>Adenoacanthoma                               | (25)    | (25)<br>1 (4%) | (25)<br>1 (4%) | (23)           | (23)            | (25)             |
| Adenocarcinoma  | 1 (4%)  |                | 3 (12%)        |                | 2 (9%)          |                  |
| Skin<br>Hemangiosarcoma                                       | (25)    | (25)           | (25)           | (25)<br>1 (4%) | (23)            | (25)             |
| Histiocytic Sarcoma   |         |                |                |                | 1 (4%)          |                  |
| <b>MUSCULOSKELETAL SYSTEM</b>                                 |         |                |                |                |                 |                  |
| Bone<br>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

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

| 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<br>Sarcoma               |         | 1 (100%) | 1 (50%)  |          |                 |                  |
| <b>NERVOUS SYSTEM</b>                     |         |          |          |          |                 |                  |
| 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)              |
| <b>RESPIRATORY SYSTEM</b>                 |         |          |          |          |                 |                  |
| 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%)          |                  |
| <b>SPECIAL SENSES SYSTEM</b>              |         |          |          |          |                 |                  |
| 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

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

| 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%)          |                  |
| <b>URINARY SYSTEM</b>                   |         |        |          |          |                 |                  |
| 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)             |
| <b>SYSTEMIC LESIONS</b>                 |         |        |          |          |                 |                  |
| 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**

|   |           |           |
|---|-----------|-----------|
| <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)    |
| 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

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AZT+3TC combination

CAS Number: AZT3TCCOMBO

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

Lab: NCTR

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| 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%) |

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CARDIOVASCULAR SYSTEM

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

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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          |        |        |

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GENERAL BODY SYSTEM

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

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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,<br>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

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

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)  |

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

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) |

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

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

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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 |  |        |

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URINARY SYSTEM

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

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SYSTEMIC LESIONS

|                       |         |         |
|-----------------------|---------|---------|
| Multiple Organ        | *(22)   | *(25)   |
| Histiocytic Sarcoma   | 1 (5%)  | 1 (4%)  |
| Leukemia Granulocytic |         |         |
| 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

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

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

Lab: NCTR

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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<br>Uncertain Primary Site |   |   |   |    |   |   |
| Total Animals with Neoplasms Uncertain-<br>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

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

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

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**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<br>Uncertain Primary Site |   |    |
| Total Animals with Neoplasms Uncertain-<br>Benign or Malignant   |   |    |
| Total Uncertain Neoplasms  |   |    |

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\*\*\* 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