

|                                       |                                                                                                                                           |                                          |
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| <b>TDMS No.</b> 20537 - 02            | <b>P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]</b><br>Adenoviral Vector (AdhAQP1) | <b>Date Report Requested:</b> 09/10/2009 |
| <b>Test Type:</b> 90-DAY              | <b>CAS Number:</b> ADN VIRVECAQP                                                                                                          | <b>Time Report Requested:</b> 11:33:57   |
| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

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| <b>Test Type:</b> 90-DAY              | <b>CAS Number:</b> ADN VIRVECAQP                                                                                                          | <b>Time Report Requested:</b> 11:33:57   |
| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

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| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

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| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

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| <b>Test Type:</b> 90-DAY              | <b>CAS Number:</b> ADN VIRVECAQP                                                                                                          | <b>Time Report Requested:</b> 11:33:57   |
| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

|                                       |                                                                                                                                           |                                          |
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| <b>Test Type:</b> 90-DAY              | <b>CAS Number:</b> ADN VIRVECAQP                                                                                                          | <b>Time Report Requested:</b> 11:33:57   |
| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

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| <b>Test Type:</b> 90-DAY              | <b>CAS Number:</b> ADN VIRVECAQP                                                                                                          | <b>Time Report Requested:</b> 11:33:57   |
| <b>Route:</b> INTRADUCTAL CANNULATION |                                                                                                                                           | <b>First Dose M/F:</b> NA / 07/25/05     |
| <b>Species/Strain:</b> RATS/F 344/N   | F1_R2_3Wk_SSAC                                                                                                                            | <b>Lab:</b> MBA                          |

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|----------------------|-----------------------------------------------------------|-----------------------------|------------------------------|
| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
| Treatment Groups:    | Include 007 2-8ADHAQP1COHTB<br>Include 021 VEHCONTRCOHRTB | Include 012 8-9ADHAQP1COHTB | Include 017 2-11ADHAQP1COHTB |
| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
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| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
| Date Range:          | ALL                                                       |                             |                              |
| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
| Removal Date Range:  | ALL                                                       |                             |                              |
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| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

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| C Number:            | C20537                                                    |                             |                              |
| Lock Date:           | 11/19/2007                                                |                             |                              |
| Cage Range:          | ALL                                                       |                             |                              |
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| Reasons For Removal: | 25017 SSAC                                                |                             |                              |
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| Study Gender:        | Female                                                    |                             |                              |
| TDMSE Version:       | 2.1.0                                                     |                             |                              |

Test Type: 90-DAY

Time Report Requested: 11:33:57

Route: INTRADUCTAL CANNULATION

First Dose M/F: NA / 07/25/05

Species/Strain: RATS/F 344/N

Lab: MBA

| FISCHER 344 RATS FEMALE                                          | 2-8ADHAQP1COHTB | 8-9ADHAQP1COHTB | 2-11ADHAQP1COHTB | VEHCONTRCOHRTB |
|------------------------------------------------------------------|-----------------|-----------------|------------------|----------------|
| <b>Disposition Summary</b>                                       |                 |                 |                  |                |
| Animals Initially in Study                                       | 5               | 5               | 5                | 5              |
| Scheduled Sacrifice                                              | 5               | 5               | 5                | 5              |
| Early Deaths                                                     |                 |                 |                  |                |
| Survivors                                                        |                 |                 |                  |                |
| Animals Examined Microscopically                                 | 5               | 5               | 5                | 5              |
| <b>ALIMENTARY SYSTEM</b>                                         |                 |                 |                  |                |
| Liver                                                            | (5)             | (5)             | (5)              | (5)            |
| Inflammation                                                     |                 | 1 [1.0]         |                  |                |
| Salivary Glands                                                  | (5)             | (5)             | (4)              | (5)            |
| Left, Submandibular Gland,<br>Regeneration                       |                 |                 |                  | 1 [2.0]        |
| Parotid Gland, Right, Necrosis                                   |                 | 1 [1.0]         |                  |                |
| Right, Submandibular Gland,<br>Degeneration                      |                 | 1 [1.0]         |                  |                |
| Right, Submandibular Gland, Infiltration<br>Cellular, Lymphocyte |                 |                 | 2 [2.0]          |                |
| Right, Submandibular Gland,<br>Inflammation                      | 2 [1.0]         | 5 [1.8]         | 4 [2.3]          | 1 [2.0]        |
| Right, Submandibular Gland,<br>Regeneration                      | 5 [2.2]         | 5 [2.0]         | 4 [2.8]          | 4 [2.3]        |
| Stomach, Glandular<br>Mineralization                             | (5)             | (5)             | (5)              | (5)            |
|                                                                  |                 | 1 [1.0]         |                  | 2 [1.5]        |
| <b>CARDIOVASCULAR SYSTEM</b>                                     |                 |                 |                  |                |
| Heart                                                            | (5)             | (5)             | (5)              | (5)            |
| Cardiomyopathy                                                   |                 |                 | 2 [1.0]          |                |
| <b>ENDOCRINE SYSTEM</b>                                          |                 |                 |                  |                |
| None                                                             |                 |                 |                  |                |

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)

| FISCHER 344 RATS FEMALE | 2-8ADHAQP1COHTB | 8-9ADHAQP1COHTB | 2-11ADHAQP1COHTB | VEHCONTRCOHRTB |
|-------------------------|-----------------|-----------------|------------------|----------------|
| GENERAL BODY SYSTEM     |                 |                 |                  |                |
| None                    |                 |                 |                  |                |
| GENITAL SYSTEM          |                 |                 |                  |                |
| Uterus                  | (5)             | (5)             | (5)              | (5)            |
| Dilatation              |                 |                 |                  | 1 [3.0]        |
| HEMATOPOIETIC SYSTEM    |                 |                 |                  |                |
| Spleen                  | (5)             | (5)             | (5)              | (5)            |
| Depletion Lymphoid      |                 |                 | 1 [2.0]          |                |
| INTEGUMENTARY SYSTEM    |                 |                 |                  |                |
| None                    |                 |                 |                  |                |
| MUSCULOSKELETAL SYSTEM  |                 |                 |                  |                |
| None                    |                 |                 |                  |                |
| NERVOUS SYSTEM          |                 |                 |                  |                |
| None                    |                 |                 |                  |                |
| RESPIRATORY SYSTEM      |                 |                 |                  |                |
| Trachea                 | (5)             | (5)             | (5)              | (5)            |
| Inflammation            | 1 [2.0]         |                 |                  |                |
| SPECIAL SENSES SYSTEM   |                 |                 |                  |                |
| None                    |                 |                 |                  |                |

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)

| FISCHER 344 RATS FEMALE       | 2-8ADHAQP1COHTB | 8-9ADHAQP1COHTB | 2-11ADHAQP1COHTB | VEHCONTRCOHRTB |
|-------------------------------|-----------------|-----------------|------------------|----------------|
| URINARY SYSTEM                |                 |                 |                  |                |
| Kidney                        | (5)             | (5)             | (5)              | (5)            |
| Nephropathy, Diffuse, Chronic | 1 [2.0]         |                 |                  |                |

\*\*\* 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)