

TDMS No. 20537 - 02
Test Type: 90-DAY
Route: INTRADUCTAL CANNULATION
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Adenoviral Vector (AdhAQP1)
CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
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First Dose M/F: NA / 07/25/05
Lab: MBA

F1_R2_1Wk_SSAC

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 001 VEHCONTRCOHRTA Include 006 2-8ADHAQP1COHTA Include 011 8-9ADHAQP1COHTA
Include 016 2-11ADHAQP1COHTA
Study Gender: Female
TDMSE Version: 2.1.0

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF ADENOVIRAL VECTOR (ADHAQP1)

FEMALE RATS

Organ

Eye: Retina

Salivary Glands: Parotid Gland, Left

Morphology

Dysplasia

Mitosis

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 1 WEEKS

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Eye: Retina Dysplasia			
LESION RATES			
OVERALL (a)	2/5 (40%)	0/10 (0%)	0/5 (0%)
POLY-3 RATE (b)	2/5.00	0/10.00	0/5.00
POLY-3 PERCENT (g)	40%	0%	0%
INT SACRIFICE 1	2/5 (40%	0/10 (0%	0/5 (0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	---	---
STATISTICAL TESTS			
POLY 3	P=0.200N	P=0.067N	P=0.207N
POLY 1.5	P=0.200N	P=0.067N	P=0.207N
POLY 6	P=0.200N	P=0.067N	P=0.207N
COCH-ARM / FISHERS	P=0.228N	P=0.095N	P=0.222N
MAX-ISO-POLY-3	P=0.013N*	P=0.019N*	P=0.051N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 1 WEEKS**

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Parotid Gland, Left Degeneration			
LESION RATES			
OVERALL (a)	1/5 (20%)	2/10 (20%)	2/5 (40%)
POLY-3 RATE (b)	1/5.00	2/10.00	2/5.00
POLY-3 PERCENT (g)	20%	20%	40%
INT SACRIFICE 1	1/5 (20%)	2/10 (20%)	2/5 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.373	P=0.738	P=0.500
POLY 1.5	P=0.373	P=0.738	P=0.500
POLY 6	P=0.373	P=0.738	P=0.500
COCH-ARM / FISHERS	P=0.365	P=0.736N	P=0.500
MAX-ISO-POLY-3	P=0.346	P=1.000	P=0.264

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 1 WEEKS**

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Parotid Gland, Left Mitosis			
LESION RATES			
OVERALL (a)	0/5 (0%)	4/10 (40%)	3/5 (60%)
POLY-3 RATE (b)	0/5.00	4/10.00	3/5.00
POLY-3 PERCENT (g)	0%	40%	60%
INT SACRIFICE 1	0/5 (0%)	4/10 (40%)	3/5 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.098	P=0.144	P=0.051
POLY 1.5	P=0.098	P=0.144	P=0.051
POLY 6	P=0.098	P=0.144	P=0.051
COCH-ARM / FISHERS	P=0.106	P=0.154	P=0.083
MAX-ISO-POLY-3	P=0.028*	P=0.070	P=0.007**

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 1 WEEKS**

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Parotid Gland, Right Degeneration			
LESION RATES			
OVERALL (a)	3/5 (60%)	4/10 (40%)	1/5 (20%)
POLY-3 RATE (b)	3/5.00	4/10.00	1/5.00
POLY-3 PERCENT (g)	60%	40%	20%
INT SACRIFICE 1	3/5 (60%)	4/10 (40%)	1/5 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.232N	P=0.431N	P=0.264N
POLY 1.5	P=0.232N	P=0.431N	P=0.264N
POLY 6	P=0.232N	P=0.431N	P=0.264N
COCH-ARM / FISHERS	P=0.223N	P=0.427N	P=0.262N
MAX-ISO-POLY-3	P=0.152N	P=0.274N	P=0.103N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 1 WEEKS**

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Parotid Gland, Right			
Mitosis			
LESION RATES			
OVERALL (a)	0/5 (0%)	4/10 (40%)	2/5 (40%)
POLY-3 RATE (b)	0/5.00	4/10.00	2/5.00
POLY-3 PERCENT (g)	0%	40%	40%
INT SACRIFICE 1	0/5 (0%)	4/10 (40%)	2/5 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.314	P=0.144	P=0.207
POLY 1.5	P=0.314	P=0.144	P=0.207
POLY 6	P=0.314	P=0.144	P=0.207
COCH-ARM / FISHERS	P=0.313	P=0.154	P=0.222
MAX-ISO-POLY-3	P=0.120	P=0.070	P=0.051

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LAST REMOVAL AT 1 WEEKS**

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Parotid Gland, Right Necrosis			
LESION RATES			
OVERALL (a)	0/5 (0%)	2/10 (20%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	2/10.00	0/5.00
POLY-3 PERCENT (g)	0%	20%	0%
INT SACRIFICE 1	0/5 (0%)	2/10 (20%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	3 (I)	---
STATISTICAL TESTS			
POLY 3	P=0.596N	P=0.397	(e)
POLY 1.5	P=0.596N	P=0.397	(e)
POLY 6	P=0.596N	P=0.397	(e)
COCH-ARM / FISHERS	P=0.598N	P=0.429	(e)
MAX-ISO-POLY-3	P=0.346	P=0.184	(e)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 1 WEEKS

Females				
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA	
Salivary Glands: Parotid Gland, Right Regeneration				
LESION RATES				
OVERALL (a)	2/5 (40%)	1/10 (10%)	0/5 (0%)	
POLY-3 RATE (b)	2/5.00	1/10.00	0/5.00	
POLY-3 PERCENT (g)	40%	10%	0%	
INT SACRIFICE 1	2/5 (40%)	1/10 (10%)	0/5 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	3 (I)	3 (I)	---	
STATISTICAL TESTS				
POLY 3	P=0.198N	P=0.248N	P=0.207N	
POLY 1.5	P=0.198N	P=0.248N	P=0.207N	
POLY 6	P=0.198N	P=0.248N	P=0.207N	
COCH-ARM / FISHERS	P=0.202N	P=0.242N	P=0.222N	
MAX-ISO-POLY-3	P=0.051N	P=0.119N	P=0.051N	

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Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Submandibular Gland, Right Degeneration			
LESION RATES			
OVERALL (a)	4/5 (80%)	8/10 (80%)	5/5 (100%)
POLY-3 RATE (b)	4/5.00	8/10.00	5/5.00
POLY-3 PERCENT (g)	80%	80%	100%
INT SACRIFICE 1	4/5 (80%)	8/10 (80%)	5/5 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.346	P=0.738	P=0.500
POLY 1.5	P=0.346	P=0.738	P=0.500
POLY 6	P=0.346	P=0.738	P=0.500
COCH-ARM / FISHERS	P=0.338	P=0.736	P=0.500
MAX-ISO-POLY-3	P=0.283	P=1.000	P=0.159

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 1 WEEKS

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	2/5 (40%)	8/10 (80%)	4/5 (80%)
POLY-3 RATE (b)	2/5.00	8/10.00	4/5.00
POLY-3 PERCENT (g)	40%	80%	80%
INT SACRIFICE 1	2/5 (40%)	8/10 (80%)	4/5 (80%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.314	P=0.163	P=0.264
POLY 1.5	P=0.314	P=0.163	P=0.264
POLY 6	P=0.314	P=0.163	P=0.264
COCH-ARM / FISHERS	P=0.313	P=0.167	P=0.262
MAX-ISO-POLY-3	P=0.120	P=0.087	P=0.103

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Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Submandibular Gland, Right Necrosis			
LESION RATES			
OVERALL (a)	1/5 (20%)	4/10 (40%)	0/5 (0%)
POLY-3 RATE (b)	1/5.00	4/10.00	0/5.00
POLY-3 PERCENT (g)	20%	40%	0%
INT SACRIFICE 1	1/5 (20%)	4/10 (40%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	---
STATISTICAL TESTS			
POLY 3	P=0.246N	P=0.427	P=0.500N
POLY 1.5	P=0.246N	P=0.427	P=0.500N
POLY 6	P=0.246N	P=0.427	P=0.500N
COCH-ARM / FISHERS	P=0.246N	P=0.434	P=0.500N
MAX-ISO-POLY-3	P=0.160N	P=0.262	P=0.159N

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LAST REMOVAL AT 1 WEEKS**

Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	4/5 (80%)	8/10 (80%)	5/5 (100%)
POLY-3 RATE (b)	4/5.00	8/10.00	5/5.00
POLY-3 PERCENT (g)	80%	80%	100%
INT SACRIFICE 1	4/5 (80%)	8/10 (80%)	5/5 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	3 (I)
STATISTICAL TESTS			
POLY 3	P=0.346	P=0.738	P=0.500
POLY 1.5	P=0.346	P=0.738	P=0.500
POLY 6	P=0.346	P=0.738	P=0.500
COCH-ARM / FISHERS	P=0.338	P=0.736	P=0.500
MAX-ISO-POLY-3	P=0.283	P=1.000	P=0.159

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Females			
DOSE	VEHCONTRCOHRTA	2-11ADHAQP1COHTA	8-9ADHAQP1COHTA
Stomach, Glandular Mineralization			
LESION RATES			
OVERALL (a)	2/5 (40%)	1/10 (10%)	0/5 (0%)
POLY-3 RATE (b)	2/5.00	1/10.00	0/5.00
POLY-3 PERCENT (g)	40%	10%	0%
INT SACRIFICE 1	2/5 (40%)	1/10 (10%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	3 (I)	3 (I)	---
STATISTICAL TESTS			
POLY 3	P=0.198N	P=0.248N	P=0.207N
POLY 1.5	P=0.198N	P=0.248N	P=0.207N
POLY 6	P=0.198N	P=0.248N	P=0.207N
COCH-ARM / FISHERS	P=0.202N	P=0.242N	P=0.222N
MAX-ISO-POLY-3	P=0.051N	P=0.119N	P=0.051N

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (e) Value of Statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***