Test Type: 18-33 DAYS

**Route: INTRADUCTAL CANNULATION** 

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014 Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

C Number: C20212

**Lock Date:** 06/16/2004

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range: All

Treatment Groups: All

Study Gender: Male

PWG Approval Date NONE

**Route: INTRADUCTAL CANNULATION** 

Test Type: 18-33 DAYS

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014
Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 29 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

			IND	IVIDUAL SURVIVAL TIMES (DAY	o)	
DOSE =	VEHICLE	SALINE				
TOTAL	12		UNCENSORED DEATHS 0	CENSORED DEATHS 4	TERMINAL 8	
UNCEN	SORED DI	EATH DAYS				
none						
CENSO	RED DEAT	TH DAYS				
3	3	3	3			
DOSE =	VEHICLE	HCQ				
TOTAL	12		UNCENSORED DEATHS 0	CENSORED DEATHS 4	TERMINAL 8	
UNCEN	SORED DI	EATH DAYS				
none						
CENSO	RED DEAT	TH DAYS				
3	3	3	3			
DOSE =	: 1.5 E11 H	ICQ				
TOTAL	12		UNCENSORED DEATHS 0	CENSORED DEATHS 4	TERMINAL 8	
UNCEN	SORED DI	EATH DAYS				
none						
CENSO	RED DEAT	TH DAYS				
3	3	3	3			
DOSE =	2.4 E8 H	CQ				
TOTAL	12		UNCENSORED DEATHS 0	CENSORED DEATHS 4	TERMINAL 8	
UNCEN	SORED DI	EATH DAYS				
none						
CENSO	RED DEAT	TH DAYS				
2	3	3	3			

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Route: INTRADUCTAL CANNULATION** 

Test Type: 18-33 DAYS

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014
Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 29 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

			2		-,	
DOSE =	6.0 E9 SA	LINE				
TOTAL	12		UNCENSORED DEATHS 0	CENSORED DEATHS 4	TERMINAL 8	
UNCEN	SORED DE	ATH DAYS	<b>i</b>			
none						
CENSO	RED DEAT	H DAYS				
3	3	3	3			
DOSE =	6.0 E9 HC	Q				
TOTAL	12		UNCENSORED DEATHS 0	CENSORED DEATHS 4	TERMINAL 8	
UNCEN	SORED DE	ATH DAYS	<b>i</b>			
none						
CENSO	RED DEAT	H DAYS				
3	3	3	3			

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Route: INTRADUCTAL CANNULATION** 

Test Type: 18-33 DAYS

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014 Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

### Male RAT FIRST TERMINAL SACRIFICE AT 29 DAYS

# KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE					TIME	(DAYS)				
	3	6	9	12	15	18	21	24	27	29(A)
VEHICLE SALINE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
VEHICLE HCQ	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1.5 E11 HCQ	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2.4 E8 HCQ	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
6.0 E9 SALINE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
6.0 E9 HCQ	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Route: INTRADUCTAL CANNULATION** 

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Type: 18-33 DAYS

Test Compound: Adenoviral vector (hGH)

Species/Strain: Rat/F 344/N

CAS Number: HGH

Date Report Requested: 10/23/2014 Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

### Male RAT FIRST TERMINAL SACRIFICE AT 29 DAYS

## SURVIVAL SUMMARY STATISTICS

DOSE	VEHICLE SALINE	VEHICLE HCQ	1.5 E11 HCQ	2.4 E8 HCQ	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)					
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)					
(STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	20.3	20.3	20.3	20.3	
(STANDARD ERROR)	(3.7)	(3.7)	(3.7)	(3.7)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Route: INTRADUCTAL CANNULATION** 

Test Type: 18-33 DAYS

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014 Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

### Male RAT FIRST TERMINAL SACRIFICE AT 29 DAYS

## **SURVIVAL SUMMARY STATISTICS**

DOSE	6.0 E9 SALINE	6.0 E9 HCQ
SURVIVAL AT END OF STUDY	100.0%	100.0%
(KAPLAN-MEIER)		
SIGNIFICANCE (B)		
(LIFE TABLE)		
MEAN DAY OF NATURAL DEATHS (C)		
(STANDARD ERROR)	(.)	(.)
MEAN LIFE SPAN (D)	20.3	20.3
(STANDARD ERROR)	(3.7)	(3.7)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 18-33 DAYS

**Route: INTRADUCTAL CANNULATION** 

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014 Time Report Requested: 07:20:17

First Dose M/F: NA / NA

Lab: MBA

\*\* END OF REPORT \*\*

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)