

Experiment Number: 20305-01
Test Type: 18-33 DAYS
Route: INTRADUCTAL CANNULATION
Species/Strain: Mouse/BALB/C

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA
Test Compound: Adeno-associated viral vector (hEPO)
CAS Number: HEPO

Date Report Requested: 10/15/2014
Time Report Requested: 15:20:45
First Dose M/F: NA / NA
Lab: MBA

C Number: C20305
Lock Date: 08/29/2005
Cage Range: All
Date Range: All
Reasons For Removal: All
Removal Date Range: All
Treatment Groups: All
Study Gender: Both
PWG Approval Date: NONE

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Male MOUSE
FIRST TERMINAL SACRIFICE AT 92 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = ISORMCONSALINE												
TOTAL 21			UNCENSORED DEATHS 4			CENSORED DEATHS 13			TERMINAL 4			
UNCENSORED DEATH DAYS												
2	2	17	91									
CENSORED DEATH DAYS												
3	3	3	30	30	30	30	30	55	55	55	55	55
DOSE = TRTRMCONSALINE												
TOTAL 12			UNCENSORED DEATHS 1			CENSORED DEATHS 9			TERMINAL 2			
UNCENSORED DEATH DAYS												
91												
CENSORED DEATH DAYS												
3	3	3	30	30	30	55	55	55				
DOSE = 1-7 SALINE												
TOTAL 21			UNCENSORED DEATHS 4			CENSORED DEATHS 11			TERMINAL 6			
UNCENSORED DEATH DAYS												
2	2	2	29									
CENSORED DEATH DAYS												
3	3	30	30	30	30	55	55	55	55	55		
DOSE = 1-8 SALINE												
TOTAL 21			UNCENSORED DEATHS 2			CENSORED DEATHS 13			TERMINAL 6			
UNCENSORED DEATH DAYS												
2												
CENSORED DEATH DAYS												
3	3	3	30	30	30	30	30	55	55	55	55	55

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 1-9 SALINE												
TOTAL 21			UNCENSORED DEATHS 3				CENSORED DEATHS 13				TERMINAL 5	
UNCENSORED DEATH DAYS												
29	54	76										
CENSORED DEATH DAYS												
3	3	3	3	3	30	30	30	30	55	55	55	55
DOSE = 1-10 SALINE												
TOTAL 21			UNCENSORED DEATHS 4				CENSORED DEATHS 11				TERMINAL 6	
UNCENSORED DEATH DAYS												
2	2	29	50									
CENSORED DEATH DAYS												
3	3	3	30	30	30	30	55	55	55	55		

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Male MOUSE
FIRST TERMINAL SACRIFICE AT 92 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE	TIME (DAYS)									
	10	20	30	40	50	60	70	80	90	92(A)
ISORMCONSALINE	90.5	84.8	84.8	84.8	84.8	84.8	84.8	84.8	84.8	67.9
TRTRMCONSALINE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	66.7
1-7 SALINE	85.7	85.7	80.4	80.4	80.4	80.4	80.4	80.4	80.4	80.4
1-8 SALINE	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5
1-9 SALINE	100.0	100.0	93.8	93.8	93.8	85.2	85.2	71.0	71.0	71.0
1-10 SALINE	90.5	90.5	84.8	84.8	77.1	77.1	77.1	77.1	77.1	77.1

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Male MOUSE
FIRST TERMINAL SACRIFICE AT 92 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	67.9%	66.7%	80.4%	90.5%
SIGNIFICANCE (B) (LIFE TABLE)	P=1.000N	-----	P=1.000N	P=0.648N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	28.0 (21.3)	91.0 (.)	8.8 (6.8)	2.0 (.)
MEAN LIFE SPAN (D) (STANDARD ERROR)	43.5 (7.3)	44.9 (9.8)	47.0 (7.5)	47.1 (7.5)

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Male MOUSE
FIRST TERMINAL SACRIFICE AT 92 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	1-9 SALINE	1-10 SALINE
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	71.0%	77.1%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.948N	P=1.000N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	53.0 (13.6)	20.8 (11.6)
MEAN LIFE SPAN (D) (STANDARD ERROR)	46.4 (7.3)	46.9 (7.5)

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First Dose M/F: NA / NA
Lab: MBA

Female MOUSE
FIRST TERMINAL SACRIFICE AT 92 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = ISORMCONSALINE													
TOTAL 21			UNCENSORED DEATHS 0				CENSORED DEATHS 15				TERMINAL 6		
UNCENSORED DEATH DAYS													
none													
CENSORED DEATH DAYS													
3	3	3	3	3	30	30	30	30	30	55	55	55	55
55													
DOSE = TRTRMCONSALINE													
TOTAL 12			UNCENSORED DEATHS 0				CENSORED DEATHS 9				TERMINAL 3		
UNCENSORED DEATH DAYS													
none													
CENSORED DEATH DAYS													
3	3	3	30	30	30	55	55	55					
55													
DOSE = 1-7 SALINE													
TOTAL 21			UNCENSORED DEATHS 2				CENSORED DEATHS 13				TERMINAL 6		
UNCENSORED DEATH DAYS													
2	2												
CENSORED DEATH DAYS													
3	3	3	30	30	30	30	30	55	55	55	55	55	55
55													
DOSE = 1-8 SALINE													
TOTAL 21			UNCENSORED DEATHS 0				CENSORED DEATHS 15				TERMINAL 6		
UNCENSORED DEATH DAYS													
none													
CENSORED DEATH DAYS													
3	3	3	3	3	30	30	30	30	30	55	55	55	55
55													

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INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 1-9 SALINE													
TOTAL 21			UNCENSORED DEATHS 1				CENSORED DEATHS 14				TERMINAL 6		
UNCENSORED DEATH DAYS													
1													
CENSORED DEATH DAYS													
3	3	3	3	3	30	30	30	30	30	55	55	55	55
DOSE = 1-10 SALINE													
TOTAL 21			UNCENSORED DEATHS 2				CENSORED DEATHS 15				TERMINAL 4		
UNCENSORED DEATH DAYS													
62 69													
CENSORED DEATH DAYS													
3	3	3	3	3	30	30	30	30	30	55	55	55	55
55													

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DOSE	TIME (DAYS)										
	10	20	30	40	50	60	70	80	90	92(A)	
ISORMCONSALINE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
TRTRMCONSALINE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1-7 SALINE	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5	90.5
1-8 SALINE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1-9 SALINE	95.2	95.2	95.2	95.2	95.2	95.2	95.2	95.2	95.2	95.2	95.2
1-10 SALINE	100.0	100.0	100.0	100.0	100.0	100.0	66.7	66.7	66.7	66.7	66.7

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 FIRST TERMINAL SACRIFICE AT 92 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	100.0%	100.0%	90.5%	100.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.367	-----	P=0.474	-----
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	.	.	2.0	.
	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D) (STANDARD ERROR)	47.2	45.0	47.1	47.2
	(7.5)	(9.9)	(7.5)	(7.5)

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SURVIVAL SUMMARY STATISTICS

DOSE	1-9 SALINE	1-10 SALINE
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	95.2%	66.7%
SIGNIFICANCE (B) (LIFE TABLE)	P=1.000	P=0.440
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	1.0 (.)	65.5 (3.5)
MEAN LIFE SPAN (D) (STANDARD ERROR)	44.7 (7.8)	44.7 (6.9)

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