Number of Animals Died by Dose and Time

Animal: Mouse
Sex: Male
2ND CONTROL GROUP

Number of Animals Died	Dose				
	Ctrl	Low	Med	High	Total
Time (weeks)					
0-52	1	2	2	9	14
53-78	3	7	5	14	29
79-93	7	4	5	7	23
94-103	7	6	10	5	28
FNL KILL	32	31	28	15	106
Total	50	50	50	50	200

	Dose											
	Ctrl			Low			Med			High		
	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died
Time(wks)												
0-52	1	50	2.0	2	50	4.0	2	50	4.0	9	50	18.0
53-78	3	49	8.0	7	48	18.0	5	48	14.0	14	41	46.0
79-93	7	46	22.0	4	41	26.0	5	43	24.0	7	27	60.0
94-103	7	39	36.0	6	37	38.0	10	38	44.0	5	20	70.0
FNL KILL	32	50	64.0	31	50	62.0	28	50	56.0	15	50	30.0

Source: AXCAN PHARMA, INC STUDY [redacted]
Survival Rates

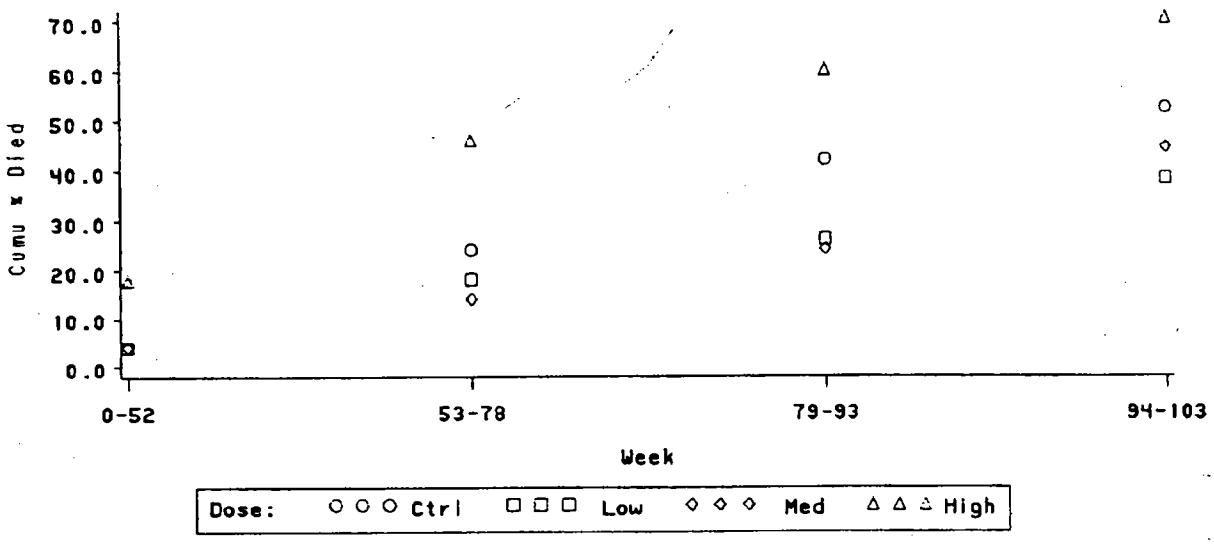
Animal: Mouse
Sex: Male

	Time(wks)							
	0-52		53-78		79-93		94-103	
Dose	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival
Ctrl	49	98.0	46	92.0	39	78.0	32	64.0
Low	48	96.0	41	82.0	37	74.0	31	62.0
Med	48	96.0	43	86.0	38	76.0	28	56.0
High	41	82.0	27	54.0	20	40.0	15	30.0

	Time(wks)			
	0-52	53-78	79-93	94-103
Dose	Mortality Rate	Mortality Rate	Mortality Rate	Mortality Rate
Ctrl	2.0	8.0	22.0	36.0
Low	4.0	18.0	26.0	38.0
Med	4.0	14.0	24.0	44.0
High	18.0	46.0	60.0	70.0

Cumulative Percentages of Death

Animal: Mouse
Sex: Male

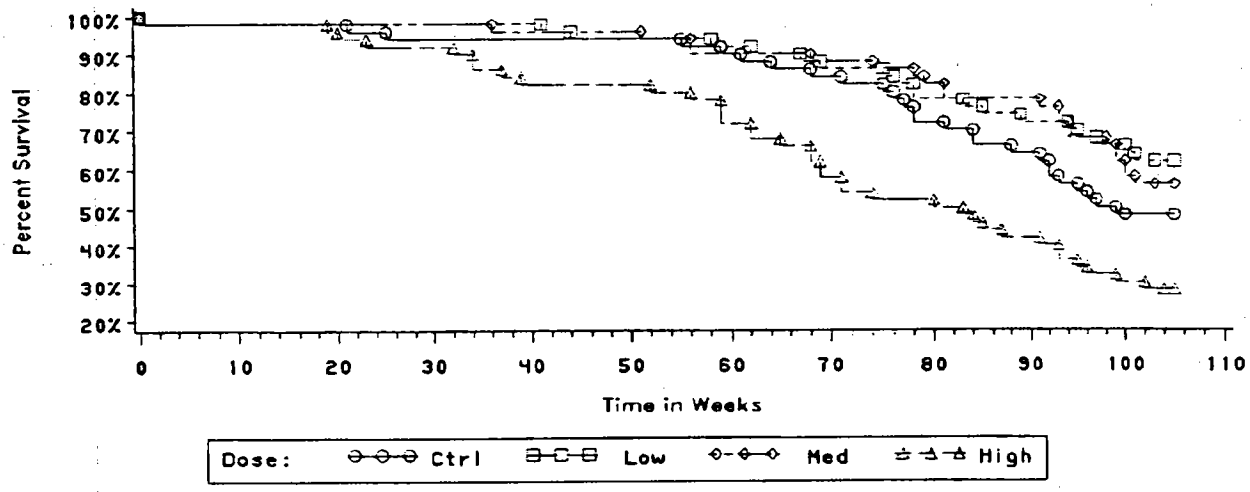


Source: AXCAN PHARMA. INC. STUDY [redacted]

Kaplan–Meier Survival Function

Animal: Mouse

Sex: Male



Source: AXCAN PHARMA. INC. STUDY [redacted]

ADJUSTED ANALYSES DSNAME: C:\animal\S_RATS_M.MMS

GR.	0	1	2	3	
DOSE	.00	25.00	150.00	1000.00	
OBS	19.	19.	22.	36.	
EXP	27.25	25.81	26.01	16.93	
OBS/EXP	.70	.74	.85	2.13	
	N	50	50	50	50

COX'S TEST FOR LIFE TABLE DATA

TEST STATISTICS:	EXACT INVERSE	CONSERVATIVE	D.F.
VALUES OF CHI-SQUARE	26.9123	26.7017	3
PROBABILITIES	.0000**	.0000**	

TEST STATISTICS FOR ADJUSTED TRENDS:

	CHI-SQUARE	D.F.	LOWER BOUND Z	UPPER BOUND Z
JYG TREND ------- 1	26.8259	1	5.1758	5.0591
JYG PROBABILITIES 2	.0000**		.0000**	.0000**
JYG DEPT FR TREND 3	.0863			
JYG PROBABILITY 4	.9577			
JYG TOT COX CHISQ 5	26.9123			
JYG PROBABILITY 6	.0000			

NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)= 18301.857
SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND= 12486360.000

GENERALIZED K/W ANALYSIS (GEHAN-BRESLOW) DSNAME: C:\animal\S_RATS_M.MMS

This analysis gives more weight to early differences in death rates between groups than the previous Cox analysis.

VECTOR SCORE STATISTIC W

-1444 -1037 -785 3266

TEST STATISTICS:	EXACT INVERSE	CONSERVATIVE	D.F.
VALUES OF CHI-SQUARE	30.8611	30.6209	3
PROBABILITIES	.0000**	.0000**	

TEST STATISTICS FOR ADJUSTED TRENDS:

	CHI-SQUARE	D.F.	LOWER BOUND Z	UPPER BOUND Z
JYG TREND ------- 1	30.6561	1	5.5368	5.5360
JYG PROBABILITIES 2	.0000**		.0000**	.0000**
JYG DEPT FR TREND-3	.2050			
JYG PROBABILITY -4	.9026			
JYG TOTAL --------5	30.8611			
JYG PROBABILITY -6	.0000			

NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)= 3122325.000
SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND= 318009211533.320

Source: AXCAN PHARMA, INC STUDY [redacted]
List of Organ Names and Tumor Names

Animal: Mouse
Sex: Male
2ND CONTROL GROUP

No.	Organ Name	Tumor Name
1	ADRENAL	CORTICAL ADENOMA
2	ADRENAL	PHEOCHROMOCYTOMA
3	LUNG	ADENOMA
4	LUNG	ADENOCARCINOMA
5	LYMPHORETICULAR SYSTEM	MALLGNANT LYMPHOMA
6	PITUITARY	ADENOMA
7	SPLEEN	HEMANGLOSARCOMA
8	SPLEEN	HEMANGLOMA
9	TESTIS	SERTOLL CELL TUMOR
10	TESTIS	LEYDIG CELL TUMOR
11	TESTIS	HEMANGLOMA
12	DUODENUM	ADENOCARCINOMA
13	EYE	HARDERLAN GLAND ADENOMA
14	INTEGUMENT	FIBROSARCOMA
15	INTEGUMENT	HEMANGLOMA
16	INTEGUMENT	CHONDROSARCOMA
17	JEJUNUM	ADENOCARCINOMA
18	KIDNEY	ADENOCARCINOMA
19	LIVER	HEPATOCELLULAR CARCINOMA
20	LIVER	HEPATOCELLULAR ADENOMA
21	LIVER	HEMANGLOSARCOMA

Source: AXCAN PHARMA, INC STUDY [redacted]
Test of Trend Based on the Tumor Data

Animal Type: Mouse

Sex: Male

Organ Code	Tumor Code	Organ Name	Tumor Name	Tumor Type	Exact p	Asymp p	#Incid /Ctrls	Dose 25	Dose 150	Dose 1000
1	1	ADRENAL	CORTICAL ADENO	S-	0.5560	(0.3040)	1/50	0	0	1
1	2	ADRENAL	PHEOCHROMOCYTO	S-	1.0000	(0.7136)	1/50	0	0	0
10	4	LUNG	ADENOCARCINOMA	M+	(0.0205)	0.0049	1/50	0	1	3
10	13	LUNG	ADENOMA	M-	(0.4480)	0.4551	11/50	4	6	4
11	14	LYMPHORET	MALLGNANT LYMP	M-	(0.0707)	0.0659	2/50	4	8	8
12	13	PITUITARY	ADENOMA	S-	1.0000	(0.7136)	1/50	0	0	0
13	8	SPLEEN	HEMANGLOMA	S-	0.3043	(0.0670)	0/50	0	0	1
13	12	SPLEEN	HEMANGLOSARCOM	M-	(0.9192)	0.8496	1/50	3	0	0
14	8	TESTIS	HEMANGLOMA	S-	0.1455	(0.0085)	0/50	0	0	1
14	16	TESTIS	LEYDIG CELL TU	S-	1.0000	(0.7136)	1/50	0	0	0
14	15	TESTIS	SERTOLL CELL T	S-	0.1415	(0.0077)	0/50	0	0	1
3	4	DUODENUM	ADENOCARCINOMA	S-	0.1415	(0.0077)	0/50	0	0	1
5	6	EYE	HARDERLAN GLAN	S-	0.6982	(0.6877)	0/50	1	0	0
6	9	INTEGUMENT	CHONDROSARCOMA	S-	0.4828	(0.1517)	0/50	0	0	1
6	7	INTEGUMENT	FIBROSARCOMA	S-	1.0000	(0.7133)	1/50	0	0	0
6	8	INTEGUMENT	HEMANGLOMA	S-	1.0000	(0.7136)	1/50	0	0	0
7	4	JEJUNUM	ADENOCARCINOMA	S-	0.1786	(0.0174)	0/50	0	0	1
8	4	KIDNEY	ADENOCARCINOMA	M+	(0.0202)	0.0049	1/50	0	1	3
9	12	LIVER	HEMANGLOSARCOM	M-	(0.9735)	0.9473	2/50	5	1	0
9	11	LIVER	HEPATOCELLULAR	M-	(0.6552)	0.7524	2/50	0	2	0
9	10	LIVER	HEPATOCELLULAR	M-	(0.9413)	0.9296	5/50	10	5	1

Note: Tumor Type=M indicates that the tumor is fatal to some but not all animals.
Tumor Type=S indicates that the tumor is fatal or non-fatal to all animals.

Symbol '+' indicates a significant positive linear dose-tumor trend.
Symbol '-' indicates a non-significant positive linear dose-tumor trend.

Source: AXCAN PHARMA, INC STUDY [redacted]

Pairwise Comparisons
Dosage Pair: 0 vs 1000

Species: Mouse
Sex: Male
2ND CONTROL GROUP

Organ Code	Tumor Code	Organ	Tumor	Strata	Row	_0	_1E3	Exact p	Asmp p
1	1	ADRENAL	CORTICAL ADENO	53-78	1	0	1	0.5833	(0.1993)
1	1	ADRENAL	CORTICAL ADENO	53-78	2	10	13	0.5833	(0.1993)
10	13	LUNG	ADENOMA	53-78	1	1	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	53-78	2	8	13	(0.9321)	0.8828
10	13	LUNG	ADENOMA	79-93	1	1	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	79-93	2	7	6	(0.9321)	0.8828
10	13	LUNG	ADENOMA	94-103	1	1	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	94-103	2	4	4	(0.9321)	0.8828
10	13	LUNG	ADENOMA	FNL KILL	1	6	1	(0.9321)	0.8828
10	13	LUNG	ADENOMA	FNL KILL	2	18	14	(0.9321)	0.8828
10	13	LUNG	ADENOMA	74	1	0	1	(0.9321)	0.8828
10	13	LUNG	ADENOMA	74	2	42	28	(0.9321)	0.8828
10	13	LUNG	ADENOMA	78	1	1	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	78	2	38	27	(0.9321)	0.8828
10	13	LUNG	ADENOMA	87	1	0	1	(0.9321)	0.8828
10	13	LUNG	ADENOMA	87	2	35	22	(0.9321)	0.8828
10	13	LUNG	ADENOMA	91	1	1	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	91	2	32	22	(0.9321)	0.8828
10	13	LUNG	ADENOMA	94	1	0	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	94	2	29	20	(0.9321)	0.8828
10	13	LUNG	ADENOMA	100	1	0	0	(0.9321)	0.8828
10	13	LUNG	ADENOMA	100	2	25	16	(0.9321)	0.8828
10	13	LUNG	ADENOMA	102	1	0	1	(0.9321)	0.8828
10	13	LUNG	ADENOMA	102	2	24	15	(0.9321)	0.8828
	4	LUNG	ADENOCARCINOMA	79-93	1	0	0	(0.2891)	0.1590
	4	LUNG	ADENOCARCINOMA	79-93	2	9	7	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	94-103	1	0	0	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	94-103	2	4	4	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	FNL KILL	1	1	1	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	FNL KILL	2	23	13	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	95	1	0	1	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	95	2	29	19	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	100	1	1	0	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	100	2	24	16	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	104	1	0	1	(0.2891)	0.1590
10	4	LUNG	ADENOCARCINOMA	104	2	24	14	(0.2891)	0.1590
11	14	LYMPHORETICU	MALLGNANT LYMP	0-52	1	0	1	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	0-52	2	2	7	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	53-78	1	2	3	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	53-78	2	8	10	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	79-93	1	1	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	79-93	2	8	6	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	94-103	1	0	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	94-103	2	4	5	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	FNL KILL	1	2	1	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	FNL KILL	2	22	14	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	37	1	0	1	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	37	2	48	44	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	41	1	0	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	41	2	48	42	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	44	1	0	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	44	2	48	42	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	69	1	0	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	69	2	43	33	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	74	1	0	1	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	74	2	42	28	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	83	1	0	1	(0.3612)	0.2621
11		LYMPHORETICU	MALLGNANT LYMP	83	2	36	25	(0.3612)	0.2621

11	14	LYMPHORETICU	MALLGNANT LYMP	91	1	0	0	(0.3612)	0.2621
	14	LYMPHORETICU	MALLGNANT LYMP	91	2	33	22	(0.3612)	0.2621
	14	LYMPHORETICU	MALLGNANT LYMP	94	1	0	0	(0.3612)	0.2621
	14	LYMPHORETICU	MALLGNANT LYMP	94	2	29	20	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	98	1	0	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	98	2	26	17	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	99	1	1	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	99	2	25	17	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	103	1	0	0	(0.3612)	0.2621
11	14	LYMPHORETICU	MALLGNANT LYMP	103	2	24	15	(0.3612)	0.2621
12	13	PITUITARY	ADENOMA	FNL KILL	1	1	0	1.0000	(0.7857)
12	13	PITUITARY	ADENOMA	FNL KILL	2	23	15	1.0000	(0.7857)
13	12	SPLEEN	HEMANGLOSARCOM	94-103	1	0	0		
13	12	SPLEEN	HEMANGLOSARCOM	94-103	2	5	5		
13	12	SPLEEN	HEMANGLOSARCOM	94	1	0	0		
13	12	SPLEEN	HEMANGLOSARCOM	94	2	29	20		
13	12	SPLEEN	HEMANGLOSARCOM	95	1	0	0		
13	12	SPLEEN	HEMANGLOSARCOM	95	2	29	20		
13	12	SPLEEN	HEMANGLOSARCOM	101	1	0	0		
13	12	SPLEEN	HEMANGLOSARCOM	101	2	24	16		
13	8	SPLEEN	HEMANGLOMA	79-93	1	0	1	0.4375	(0.1286)
13	8	SPLEEN	HEMANGLOMA	79-93	2	9	6	0.4375	(0.1286)
14	15	TESTIS	SERTOLL CELL T	FNL KILL	1	0	1	0.3846	(0.1031)
14	15	TESTIS	SERTOLL CELL T	FNL KILL	2	24	14	0.3846	(0.1031)
14	8	TESTIS	HEMANGLOMA	94-103	1	0	0	0.4000	(0.1105)
14	8	TESTIS	HEMANGLOMA	94-103	2	5	4	0.4000	(0.1105)
14	8	TESTIS	HEMANGLOMA	102	1	0	1	0.4000	(0.1105)
14	8	TESTIS	HEMANGLOMA	102	2	24	15	0.4000	(0.1105)
15	17	THYROID	FOLLICULAR ADE	FNL KILL	1	1	0	1.0000	(0.7857)
15	17	THYROID	FOLLICULAR ADE	FNL KILL	2	23	15	1.0000	(0.7857)
15	18	THYROID	PARAFOLLICULAR	FNL KILL	1	1	0	1.0000	(0.7857)
15	18	THYROID	PARAFOLLICULAR	FNL KILL	2	23	15	1.0000	(0.7857)
2	3	BRAIN	EPENDYMOMA	53-78	1	1	0	1.0000	(0.8818)
2	3	BRAIN	EPENDYMOMA	53-78	2	9	14	1.0000	(0.8818)
	4	DUODENUM	ADENOCARCINOMA	FNL KILL	1	0	1	0.3846	(0.1031)
	4	DUODENUM	ADENOCARCINOMA	FNL KILL	2	24	14	0.3846	(0.1031)
	5	EPIDIDYMIS	LELOMYOMA	FNL KILL	1	1	0	1.0000	(0.7857)
4	5	EPIDIDYMIS	LELOMYOMA	FNL KILL	2	23	15	1.0000	(0.7857)
5	6	EYE	HARDERLAN GLAN	FNL KILL	1	0	0		
5	6	EYE	HARDERLAN GLAN	FNL KILL	2	24	15		
6	9	INTEGUMENT	CHONDROSARCOMA	53-78	1	0	1	0.5833	(0.1993)
6	9	INTEGUMENT	CHONDROSARCOMA	53-78	2	10	13	0.5833	(0.1993)
7	4	JEJUNUM	ADENOCARCINOMA	94-103	1	0	1	0.5000	(0.1589)
7	4	JEJUNUM	ADENOCARCINOMA	94-103	2	5	4	0.5000	(0.1589)
8	4	KIDNEY	ADENOCARCINOMA	79-93	1	0	1	0.0620	(0.0165)
8	4	KIDNEY	ADENOCARCINOMA	79-93	2	9	6	0.0620	(0.0165)
8	4	KIDNEY	ADENOCARCINOMA	FNL KILL	1	0	2	0.0620	(0.0165)
8	4	KIDNEY	ADENOCARCINOMA	FNL KILL	2	24	13	0.0620	(0.0165)
9	10	LIVER	HEPATOCELLULAR	0-52	1	0	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	0-52	2	2	9	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	53-78	1	1	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	53-78	2	9	14	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	79-93	1	0	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	79-93	2	8	7	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	94-103	1	1	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	94-103	2	4	5	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	FNL KILL	1	4	1	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	FNL KILL	2	20	14	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	51	1	0	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	51	2	48	42	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	76	1	0	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	76	2	41	27	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	88	1	1	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	88	2	34	22	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	94	1	0	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	94	2	29	20	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	98	1	0	0	(0.9905)	0.9631
9	10	LIVER	HEPATOCELLULAR	98	2	26	17	(0.9905)	0.9631

9	11	LIVER	HEPATOCELLULAR	94-103	1	0	0	(1.0000)	0.8688
	11	LIVER	HEPATOCELLULAR	94-103	2	4	5	(1.0000)	0.8688
	11	LIVER	HEPATOCELLULAR	FNL KILL	1	1	0	(1.0000)	0.8688
	11	LIVER	HEPATOCELLULAR	FNL KILL	2	23	15	(1.0000)	0.8688
9	11	LIVER	HEPATOCELLULAR	97	1	1	0	(1.0000)	0.8688
9	11	LIVER	HEPATOCELLULAR	97	2	26	17	(1.0000)	0.8688
9	11	LIVER	HEPATOCELLULAR	101	1	0	0	(1.0000)	0.8688
9	11	LIVER	HEPATOCELLULAR	101	2	24	16	(1.0000)	0.8688
9	12	LIVER	HEMANGLOSARCOM	53-78	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	53-78	2	10	14	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	79-93	1	1	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	79-93	2	8	7	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	94-103	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	94-103	2	5	5	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	FNL KILL	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	FNL KILL	2	24	15	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	76	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	76	2	41	27	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	83	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	83	2	36	26	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	94	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	94	2	29	20	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	95	1	0	0	(1.0000)	0.8114
9	12	LIVER	HEMANGLOSARCOM	95	2	29	20	(1.0000)	0.8114

Note: An '*' indicates that the dose-tumor association may be significant ($p<0.05$).

Number of Animals Died by Dose and Time

Animal: Rat

Sex: Male

Number of Animals Died	Dose				
	Ctrl	Low	Med	High	Total
Time (weeks)					
0-52	3	2	2	9	16
53-78	13	7	5	14	39
79-91	13	4	4	6	27
92-103	15	6	11	6	38
FNL KILL	56	31	28	15	130
Total	100	50	50	50	250

Source: AXCAN PHARMA,INC. [redacted] 2CNTL
Intercurrent Mortality Rates

Animal Type: Rat

Sex: Male

	Dose											
	Ctrl			Low			Med			High		
	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died
Time(wks)												
0-52	3	100	3.0	2	50	4.0	2	50	4.0	9	50	18.0
53-78	13	97	16.0	7	48	18.0	5	48	14.0	14	41	46.0
79-91	13	84	29.0	4	41	26.0	4	43	22.0	6	27	58.0
92-103	15	71	44.0	6	37	38.0	11	39	44.0	6	21	70.0
FNL KILL	56	100	56.0	31	50	62.0	28	50	56.0	15	50	30.0

Source: AXCAN PHARMA,INC. [redacted] 2CNTL
Survival Rates

Animal: Rat

Sex: Male

	Time(wks) 0-52		53-78		79-91		92-103	
Dose	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival
Ctrl	97	97.0	84	84.0	71	71.0	56	56.0
Low	48	96.0	41	82.0	37	74.0	31	62.0
Med	48	96.0	43	86.0	39	78.0	28	56.0
High	41	82.0	27	54.0	21	42.0	15	30.0

Source: AXCAN PHARMA,INC. [redacted] 2CNTL
Mortality Rates

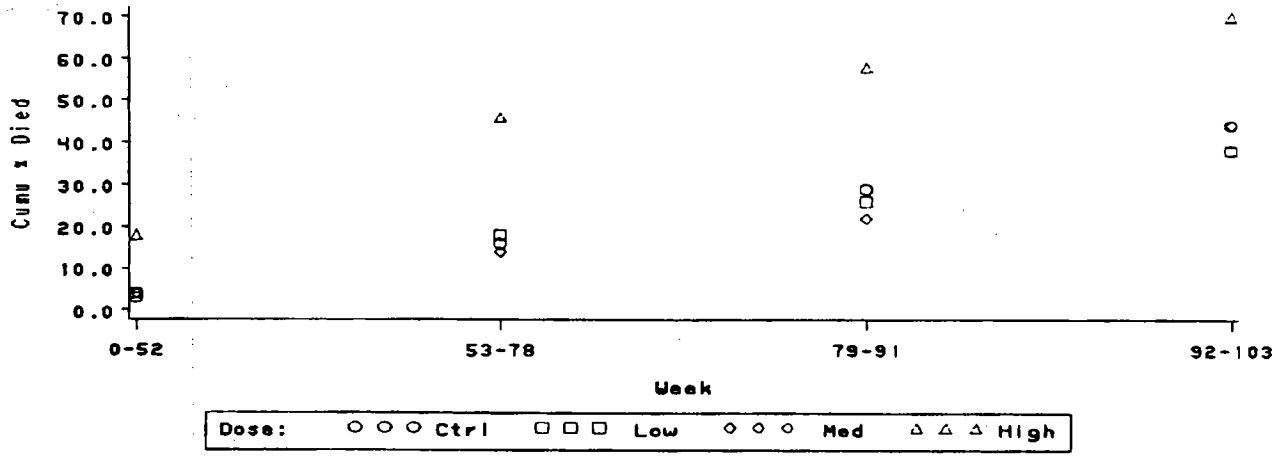
Animal Type: Rat

Sex: Male

	Time(wks) 0-52	53-78	79-91	92-103
Dose	Mortality Rate	Mortality Rate	Mortality Rate	Mortality Rate
Ctrl	3.0	16.0	29.0	44.0
Low	4.0	18.0	26.0	38.0
Med	4.0	14.0	22.0	44.0
High	18.0	46.0	58.0	70.0

Cumulative Percentages of Death

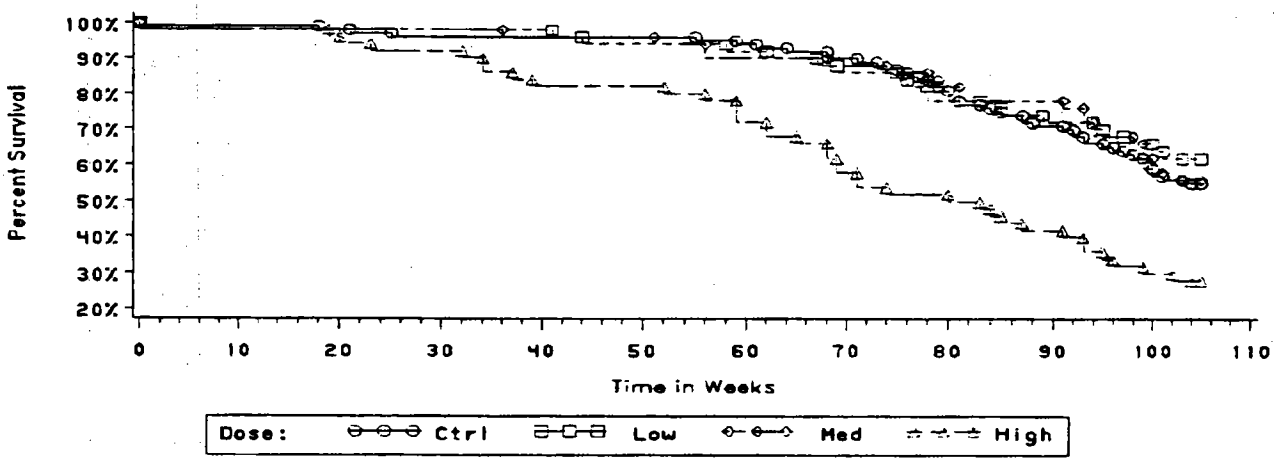
Animal: Rat
Sex: Male



Source: AXCAN PHARMA, INC. [redacted] 2CNTL

Kaplan – Meier Survival Function

Animal: Rat
Sex: Male



Source: AXCAN PHARMA, INC. [redacted] 2CNTL

ADJU ANALYSES DSNAME: C:\animal\S_RATS_M.MMS

GRC	0	1	2	3
DOSE	.00	25.00	150.00	1000.00
OBS	45.	19.	22.	36.
EXP	51.44	26.47	26.79	17.31
OBS/EXP	.87	.72	.82	2.08
N	100	50	50	50

COX'S TEST FOR LIFE TABLE DATA

TEST STATISTICS:	EXACT INVERSE	CONSERVATIVE	D.F.
VALUES OF CHI-SQUARE	24.3459	24.2161	3
PROBABILITIES	.0000**	.0000**	

TEST STATISTICS FOR ADJUSTED TRENDS:

	CHI-SQUARE	D.F.	LOWER BOUND Z	UPPER BOUND Z
JYG TREND ------- 1	23.0156	1	4.7941	4.6828
JYG PROBABILITIES 2	.0000**		.0000**	.0000**
JYG DEPT FR TREND 3	1.3303			
JYG PROBABILITY 4	.5142			
JYG TOT COX CHISQ 5	24.3459			
JYG PROBABILITY 6	.0000			

NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)= 17788.604
SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND= 13748690.000

GEN D K/W ANALYSIS (GEHAN-BRESLOW) DSNAME: C:\animal\S_RATS_M.MMS

This analysis gives more weight to early differences in death rates between groups than the previous Cox analysis.

VECTOR SCORE STATISTIC W

-1458 -1409 -1139 4006

TEST STATISTICS:	EXACT INVERSE	CONSERVATIVE	D.F.
VALUES OF CHI-SQUARE	28.1539	28.0017	3
PROBABILITIES	.0000**	.0000**	

TEST STATISTICS FOR ADJUSTED TRENDS:

	CHI-SQUARE	D.F.	LOWER BOUND Z	UPPER BOUND Z
JYG TREND ------- 1	26.6547	1	5.1628	5.1622
JYG PROBABILITIES 2	.0000**		.0000**	.0000**
JYG DEPT FR TREND-3	1.4992			
JYG PROBABILITY -4	.4726			
JYG TOTAL --------5	28.1539			
JYG PROBABILITY -6	.0000			

NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)= 3799925.000
SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND= 541722161718.809

Source: AXCAN PHARMA,INC. [redacted] 2CNTL
List of Organ Names and Tumor Names

Animal: Rat

Sex: Male

No.	Organ Name	Tumor Name
1	ADRENAL	CORTICAL ADENOMA
2	ADRENAL	PHEOCHROMOCYTOMA
3	LUNG	ADENOMA
4	LUNG	ADENOCARCINOMA
5	LYMPHORETICULAR SYSTEM	MALLGNANT LYMPHOMA
6	PITUITARY	ADENOMA
7	SPLEEN	HEMANGLOSARCOMA
8	SPLEEN	HEMANGLOMA
9	TESTIS	SERTOLL CELL TUMOR
10	TESTIS	LEYDIG CELL TUMOR
11	TESTIS	HEMANGLOMA
12	THYROID	FOLLICULAR ADENOMA
13	THYROID	PARAFOLLICULAR ADENOMA
14	BRAIN	EPENDYMOMA
15	DUODENUM	ADENOCARCINOMA
16	EPIDIDYMIS	LELOMYOMA
17	EYE	HARDERLAN GLAND ADENOMA
18	INTEGUMENT	FIBROSARCOMA
19	INTEGUMENT	HEMANGLOMA
20	INTEGUMENT	CHONDROSARCOMA
21	JEJUNUM	ADENOCARCINOMA
22	KIDNEY	ADENOCARCINOMA
23	LIVER	HEPATOCELLULAR CARCINOMA
24	LIVER	HEPATOCELLULAR ADENOMA
25	LIVER	HEMANGLOSARCOMA

Source:· AXCAN PHARMA,INC. [redacted]2CNTL
Test of Trend Based on the Tumor Data

Animal Type: Rat

Sex: Male

Organ Code	Tumor Code	Organ Name	Tumor Name	Tumor Type	Exact p	Asymp p	#Incid /Ctrls	Dose 25	Dose 150	Dose 1000
1	1	ADRENAL	CORTICAL ADENO	S-	0.4329	(0.2036)	1/100	0	0	1
1	2	ADRENAL	PHEOCHROMOCYTO	S-	1.0000	(0.6899)	1/100	0	0	0
10	4	LUNG	ADENOCARCINOMA	M-	(0.0340)	0.0098	3/100	0	1	3
10	13	LUNG	ADENOMA	M-	(0.7014)	0.7086	22/100	4	6	4
11	14	LYMPHORETICU	MALLGNANT LYMP	M-	(0.0857)	0.0813	8/100	4	8	8
12	13	PITUITARY	ADENOMA	S-	1.0000	(0.7588)	2/100	0	0	0
13	8	SPLEEN	HEMANGLOMA	S-	0.2222	(0.0318)	0/100	0	0	1
13	12	SPLEEN	HEMANGLOSARCOM	M-	(0.8386)	0.8133	1/100	3	0	0
14	8	TESTIS	HEMANGLOMA	S-	0.1194	(0.0038)	0/100	0	0	1
14	16	TESTIS	LEYDIG CELL TU	S-	1.0000	(0.6899)	1/100	0	0	0
14	15	TESTIS	SERTOLL CELL T	S-	0.1154	(0.0033)	0/100	0	0	1
15	17	THYROID	FOLLICULAR ADE	S-	1.0000	(0.6899)	1/100	0	0	0
15	18	THYROID	PARAFOLLICULAR	S-	1.0000	(0.6899)	1/100	0	0	0
2	3	BRAIN	EPENDYMOMA	S-	1.0000	(0.7955)	1/100	0	0	0
3	4	DUODENUM	ADENOCARCINOMA	S-	0.1154	(0.0033)	0/100	0	0	1
4	5	EPIDIDYMIS	LELOMYOMA	S-	1.0000	(0.6899)	1/100	0	0	0
5	6	EYE	HARDERLAN GLAN	S-	0.5693	(0.6610)	0/100	1	0	0
6	9	INTEGUMENT	CHONDROSARCOMA	S-	0.3590	(0.0920)	0/100	0	0	1
6	7	INTEGUMENT	FIBROSARCOMA	S-	1.0000	(0.6912)	1/100	0	0	0
6	8	INTEGUMENT	HEMANGLOMA	S-	1.0000	(0.6899)	1/100	0	0	0
7	4	JEJUNUM	ADENOCARCINOMA	S-	0.1579	(0.0116)	0/100	0	0	1
8	4	KIDNEY	ADENOCARCINOMA	M+	(0.0074)	0.0005	1/100	0	1	3
9	12	LIVER	HEMANGLOSARCOM	M-	(0.9419)	0.9252	3/100	5	1	0
	11	LIVER	HEPATOCELLULAR	M-	(0.7431)	0.7953	4/100	0	2	0
	10	LIVER	HEPATOCELLULAR	M-	(0.9695)	0.9567	12/100	10	5	1

Note: Tumor Type=M indicates that the tumor is fatal to some but not all animals.
Tumor Type=S indicates that the tumor is fatal or non-fatal to all animals.

Symbol '+' indicates a significant positive linear dose-tumor trend.
Symbol '-' indicates a non-significant positive linear dose-tumor trend.

Source: AXCAN PHARMA,INC. [redacted] 2CNTL
Pairwise Comparisons
Dosage Pair: 0 vs 1000

Species: Rat
Sex: Male

Organ	Organ Code	Tumor	Tumor Code	Strata	Row	_0	_1E3	Exact p	Asmp p
ADRENAL	1	CORTICAL ADENOMA	1	2	1	0	1	0.6202	(0.3380)
ADRENAL	1	CORTICAL ADENOMA	1	2	2	13	13	0.6202	(0.3380)
ADRENAL	1	CORTICAL ADENOMA	1	9	1	1	0	0.6202	(0.3380)
ADRENAL	1	CORTICAL ADENOMA	1	9	2	55	15	0.6202	(0.3380)
ADRENAL	1	PHEOCHROMOCYTOMA	2	9	1	1	0	1.0000	(0.6981)
ADRENAL	1	PHEOCHROMOCYTOMA	2	9	2	55	15	1.0000	(0.6981)
LUNG	10	ADENOMA	13	2	1	1	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	2	2	11	13	(0.9092)	0.8546
LUNG	10	ADENOMA	13	3	1	1	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	3	2	9	5	(0.9092)	0.8546
LUNG	10	ADENOMA	13	4	1	1	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	4	2	12	5	(0.9092)	0.8546
LUNG	10	ADENOMA	13	9	1	13	1	(0.9092)	0.8546
LUNG	10	ADENOMA	13	9	2	43	14	(0.9092)	0.8546
LUNG	10	ADENOMA	13	74	1	0	1	(0.9092)	0.8546
LUNG	10	ADENOMA	13	74	2	89	28	(0.9092)	0.8546
LUNG	10	ADENOMA	13	78	1	1	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	78	2	84	27	(0.9092)	0.8546
LUNG	10	ADENOMA	13	79	1	1	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	79	2	83	27	(0.9092)	0.8546
LUNG	10	ADENOMA	13	87	1	1	1	(0.9092)	0.8546
LUNG	10	ADENOMA	13	87	2	74	22	(0.9092)	0.8546
LUNG	10	ADENOMA	13	91	1	1	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	91	2	71	22	(0.9092)	0.8546
LUN	10	ADENOMA	13	94	1	0	0	(0.9092)	0.8546
LUI	10	ADENOMA	13	94	2	68	20	(0.9092)	0.8546
LUNL	10	ADENOMA	13	100	1	2	0	(0.9092)	0.8546
LUNG	10	ADENOMA	13	100	2	60	16	(0.9092)	0.8546
LUNG	10	ADENOMA	13	102	1	0	1	(0.9092)	0.8546
LUNG	10	ADENOMA	13	102	2	57	15	(0.9092)	0.8546
LUNG	10	ADENOCARCINOMA	4	3	1	0	0	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	3	2	13	6	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	4	1	0	0	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	4	2	14	5	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	9	1	2	1	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	9	2	54	13	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	95	1	0	1	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	95	2	68	19	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	100	1	1	0	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	100	2	61	16	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	104	1	0	1	(0.1062)	*0.0374
LUNG	10	ADENOCARCINOMA	4	104	2	56	14	(0.1062)	*0.0374
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	1	0	1	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	2	3	7	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	1	2	3	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	2	11	10	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	1	1	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	2	11	5	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	1	0	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	2	13	6	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	1	2	1	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	2	54	14	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	37	1	0	1	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	37	2	97	44	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	41	1	0	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	41	2	97	42	(0.1397)	0.0862
LYMP[illegible]TICULAR SYST	11	MALLGNANT LYMPHOMA	14	44	1	0	0	(0.1397)	0.0862

LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	44	2	97	42	(0.1397)	0.0862
LY ETICULAR SYST	11	MALLGNANT LYMPHOMA	14	69	1	0	0	(0.1397)	0.0862
L TICULAR SYST	11	MALLGNANT LYMPHOMA	14	69	2	92	33	(0.1397)	0.0862
LY. ETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	1	0	1	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	2	89	28	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	83	1	0	1	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	83	2	78	25	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	87	1	1	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	87	2	74	23	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	91	1	0	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	91	2	72	22	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	1	0	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	2	68	20	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	1	0	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	2	64	17	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	99	1	1	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	99	2	62	17	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	100	1	1	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	100	2	61	16	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	103	1	0	0	(0.1397)	0.0862
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	103	2	57	15	(0.1397)	0.0862
PITUITARY	12	ADENOMA	13	9	1	2	0	1.0000	(0.7697)
PITUITARY	12	ADENOMA	13	9	2	54	15	1.0000	(0.7697)
SPLEEN	13	HEMANGLOSARCOMA	12	4	1	0	0	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	4	2	15	6	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	9	1	1	0	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	9	2	55	15	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	94	1	0	0	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	94	2	68	20	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	95	1	0	0	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	95	2	68	20	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	101	1	0	0	(1.0000)	0.6981
SPLEEN	13	HEMANGLOSARCOMA	12	101	2	59	16	(1.0000)	0.6981
SPLEEN	13	HEMANGLOMA	8	3	1	0	1	0.3158	(0.0707)
SPI	13	HEMANGLOMA	8	3	2	13	5	0.3158	(0.0707)
TE:	14	SERTOLL CELL TUMOR	15	9	1	0	1	0.2113	(0.0267)
TES.	14	SERTOLL CELL TUMOR	15	9	2	56	14	0.2113	(0.0267)
TESTIS	14	LEYDIG CELL TUMOR	16	9	1	1	0	1.0000	(0.6981)
TESTIS	14	LEYDIG CELL TUMOR	16	9	2	55	15	1.0000	(0.6981)
TESTIS	14	HEMANGLOMA	8	4	1	0	0	0.2192	(0.0296)
TESTIS	14	HEMANGLOMA	8	4	2	15	5	0.2192	(0.0296)
TESTIS	14	HEMANGLOMA	8	102	1	0	1	0.2192	(0.0296)
TESTIS	14	HEMANGLOMA	8	102	2	57	15	0.2192	(0.0296)
THYROID	15	FOLLICULAR ADENOMA	17	9	1	1	0	1.0000	(0.6981)
THYROID	15	FOLLICULAR ADENOMA	17	9	2	55	15	1.0000	(0.6981)
THYROID	15	PARAFOLLICULAR ADENO	18	9	1	1	0	1.0000	(0.6981)
THYROID	15	PARAFOLLICULAR ADENO	18	9	2	55	15	1.0000	(0.6981)
BRAIN	2	EPENDYMOMA	3	2	1	1	0	1.0000	(0.8505)
BRAIN	2	EPENDYMOMA	3	2	2	12	14	1.0000	(0.8505)
DUODENUM	3	ADENOCARCINOMA	4	9	1	0	1	0.2113	(0.0267)
DUODENUM	3	ADENOCARCINOMA	4	9	2	56	14	0.2113	(0.0267)
EPIDIDYMIS	4	LELOMYOMA	5	9	1	1	0	1.0000	(0.6981)
EPIDIDYMIS	4	LELOMYOMA	5	9	2	55	15	1.0000	(0.6981)
EYE	5	HARDERLAN GLAND ADEN	6	9	1	0	0		
EYE	5	HARDERLAN GLAND ADEN	6	9	2	56	15		
INTEGUMENT	6	FIBROSARCOMA	7	4	1	0	0	1.0000	(0.6991)
INTEGUMENT	6	FIBROSARCOMA	7	4	2	14	6	1.0000	(0.6991)
INTEGUMENT	6	FIBROSARCOMA	7	101	1	1	0	1.0000	(0.6991)
INTEGUMENT	6	FIBROSARCOMA	7	101	2	58	16	1.0000	(0.6991)
INTEGUMENT	6	HEMANGLOMA	8	9	1	1	0	1.0000	(0.6981)
INTEGUMENT	6	HEMANGLOMA	8	9	2	55	15	1.0000	(0.6981)
INTEGUMENT	6	CHONDROSARCOMA	9	2	1	0	1	0.5185	(0.1679)
INTEGUMENT	6	CHONDROSARCOMA	9	2	2	13	13	0.5185	(0.1679)
JEJUNUM	7	ADENOCARCINOMA	4	4	1	0	1	0.2857	(0.0571)
JEJUNUM	7	ADENOCARCINOMA	4	4	2	15	5	0.2857	(0.0571)
KIDNEY	8	ADENOCARCINOMA	4	4	1	0	1	(0.0406)	*0.0070
KIDNEY	8	ADENOCARCINOMA	4	4	2	14	5	(0.0406)	*0.0070
KIDN	8	ADENOCARCINOMA	4	9	1	0	2	(0.0406)	*0.0070

KIDNEY	8	ADENOCARCINOMA	4	9	2	56	13	(0.0406)	*0.0070
KID	8	ADENOCARCINOMA	4	101	1	1	0	(0.0406)	*0.0070
KI	8	ADENOCARCINOMA	4	101	2	58	16	(0.0406)	*0.0070
LIV.	9	HEPATOCELLULAR CARCI	10	1	1	0	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	1	2	3	9	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	2	1	1	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	2	2	11	14	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	3	1	0	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	3	2	12	6	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	4	1	1	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	4	2	13	6	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	9	1	7	1	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	9	2	49	14	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	51	1	0	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	51	2	97	42	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	75	1	1	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	75	2	88	27	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	76	1	0	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	76	2	87	27	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	88	1	1	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	88	2	73	22	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	94	1	0	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	94	2	68	20	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	95	1	1	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	95	2	67	20	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	98	1	0	0	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR CARCI	10	98	2	64	17	(0.9803)	0.9331
LIVER	9	HEPATOCELLULAR ADENO	11	4	1	0	0	(1.0000)	0.8517
LIVER	9	HEPATOCELLULAR ADENO	11	4	2	14	6	(1.0000)	0.8517
LIVER	9	HEPATOCELLULAR ADENO	11	9	1	3	0	(1.0000)	0.8517
LIVER	9	HEPATOCELLULAR ADENO	11	9	2	53	15	(1.0000)	0.8517
LIVER	9	HEPATOCELLULAR ADENO	11	97	1	1	0	(1.0000)	0.8517
LIVER	9	HEPATOCELLULAR ADENO	11	97	2	64	17	(1.0000)	0.8517
LIVER	9	HEPATOCELLULAR ADENO	11	101	1	0	0	(1.0000)	0.8517
LIV	9	HEPATOCELLULAR ADENO	11	101	2	59	16	(1.0000)	0.8517
LI	9	HEMANGLOSARCOMA	12	2	1	0	0	(1.0000)	0.8400
LIVE.	9	HEMANGLOSARCOMA	12	2	2	13	14	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	3	1	1	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	3	2	12	6	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	4	1	0	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	4	2	14	6	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	9	1	1	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	9	2	55	15	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	76	1	0	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	76	2	87	27	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	83	1	0	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	83	2	78	26	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	94	1	0	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	94	2	68	20	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	95	1	0	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	95	2	68	20	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	103	1	1	0	(1.0000)	0.8400
LIVER	9	HEMANGLOSARCOMA	12	103	2	56	15	(1.0000)	0.8400

Note: An '*' indicates that the dose-tumor association may be significant ($p<0.05$).

Number of Animals Died by Dose and Time

Animal: MOUSE
CIONTROL GROUP 1
Sex: FEMALE

Number of Animals Died	Dose				
	CTRL	LOW	MED	HIGH	Total
Time (weeks)					
0-52	2	1	4	1	8
53-78	3	6	7	6	22
79-93	8	9	6	12	35
94-103	10	6	6	8	30
FNL KILL	27	28	27	23	105
Total	50	50	50	50	200

Source: AXCAN PHARMA, INC. [redacted]
Intercurrent Mortality Rates

Animal Type: MOUSE

Sex: FEMALE

	Dose											
	CTRL			LOW			MED			HIGH		
	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died
Time(wks)												
0-52	2	50	4.0	1	50	2.0	4	50	8.0	1	50	2.0
53-78	3	48	10.0	6	49	14.0	7	46	22.0	6	49	14.0
79-93	8	45	26.0	9	43	32.0	6	39	34.0	12	43	38.0
94-103	10	37	46.0	6	34	44.0	6	33	46.0	8	31	54.0
FNL KILL	27	50	54.0	28	50	56.0	27	50	54.0	23	50	46.0

Source: AXCAN PHARMA, INC. [redacted]
Survival Rates

Animal: MOUSE
CONTROL GROUP 1
Sex: FEMALE

	Time(wks) 0-52		53-78		79-93		94-103	
Dose	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival
CTRL	48	96.0	45	90.0	37	74.0	27	54.0
LOW	49	98.0	43	86.0	34	68.0	28	56.0
MED	46	92.0	39	78.0	33	66.0	27	54.0
HIGH	49	98.0	43	86.0	31	62.0	23	46.0

Source: AXCAN PHARMA, INC. [redacted]
Mortality Rates

Animal Type: MOUSE

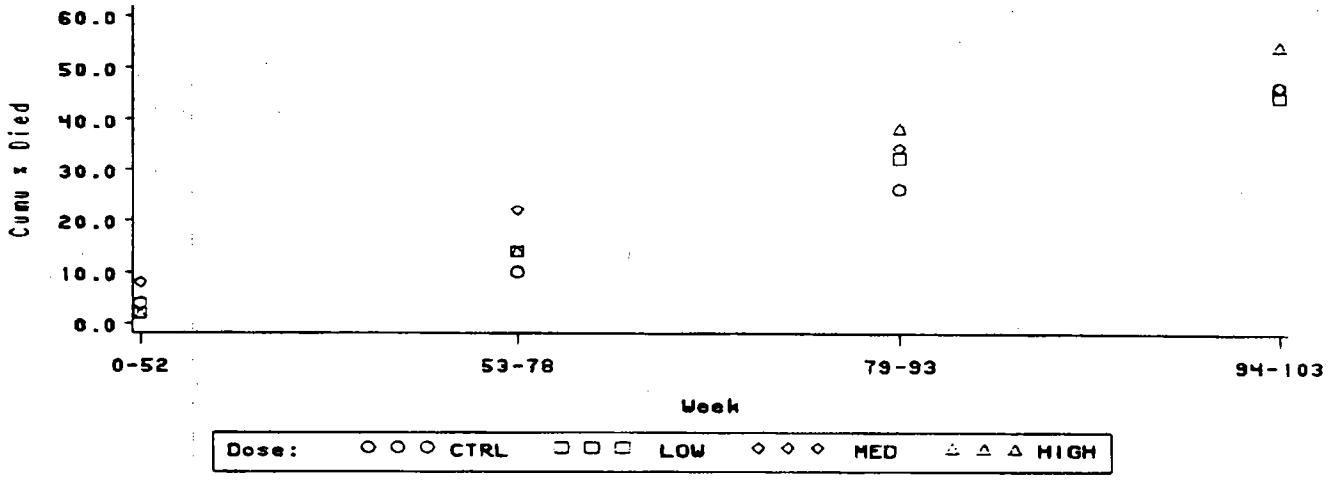
Sex: FEMALE

	Time(wks) 0-52	53-78	79-93	94-103
Dose	Mortality Rate	Mortality Rate	Mortality Rate	Mortality Rate
CTRL	4.0	10.0	26.0	46.0
LOW	2.0	14.0	32.0	44.0
MED	8.0	22.0	34.0	46.0
HIGH	2.0	14.0	38.0	54.0

CONTROL GROUP 1

Cumulative Percentages of Death

Animal: MOUSE
Sex: FEMALE

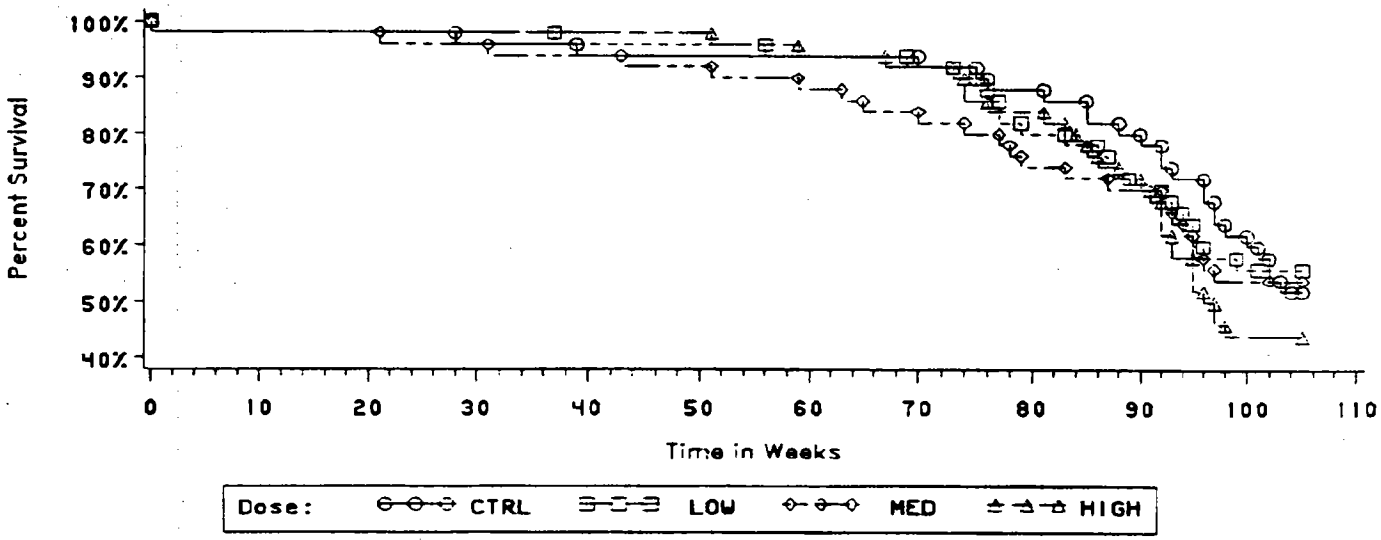


Source: AXCAN PHARMA, INC. [redacted]

Kaplan–Meier Survival Function

Animal: MOUSE

Sex: FEMALE



Source: AXCAN PHARMA, INC. [redacted]

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CONTROL GROUP 1
COX'S TEST FOR LIFE TABLE DATA
 T'     'ATISTICS:                EXACT INVERSE  CONSERVATIVE     D.F.

      .LUES OF CHI-SQUARE            1.0462        1.0449          3
    PROBABILITIES                     .7901         .7904

 TEST STATISTICS FOR ADJUSTED TRENDS:
                                                LOWER BOUND  UPPER BOUND
                              CHI-SQUARE  D.F.      Z            Z
JYG TREND ------- 1           1.0037        1     .9987        .8943
JYG PROBABILITIES 2            .3164                              .1590        .1856
JYG DEPT FR TREND 3            .0425
JYG PROBABILITY   4            .9790
JYG TOT COX CHISQ 5           1.0462
JYG PROBABILITY   6            .7901

                  NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)=      3960.224
       SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND=                       15625300.000


GENERALIZED K/W ANALYSIS (GEHAN-BRESLOW)                                    DSNAME:  C:\ANIMAL\S_MICE_F.MMS

This analysis gives more weight to early differences in death rates between groups than the previous Cox analysis.

 VECTOR SCORE STATISTIC W

    -546    -251     228     569


'EST STATISTICS:                EXACT INVERSE  CONSERVATIVE     D.F.

     VALUES OF CHI-SQUARE           1.2643        1.2631          3
     PROBABILITIES                   .7376         .7379

 TE      (ISTICS FOR ADJUSTED TRENDS:
                                                LOWER BOUND  UPPER BOUND
                              CHI-SQUARE  D.F.      Z            Z
:YG TREND ------- 1            .9209        1     .9596        .9590
:YG PROBABILITIES 2            .3372              .1686        .1688
:YG DEPT FR TREND-3            .3434
:YG PROBABILITY  -4            .8423
:YG TOTAL --------5           1.2643
:YG PROBABILITY  -6            .7376

                  NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)=    596925.000
       SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND=                    386904665678.506
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Source: AXCAN PHARMA, INC. [redacted]
List of Organ Names and Tumor Names

Animal: MOUSE
CONTROL GROUP 1
Sex: FEMALE

No.	Organ Name	Tumor Name
1	LUNG	ADENOMA
2	LUNG	ADENOCARCINOMA
3	LYMPHORETICULAR SYSTEM	MALLGNANT LYMPHOMA
4	PITUITARY	ADENOMA
5	SPLEEN	HEMANGLOSARCOMA
6	SPLEEN	HEMANGLOMA
7	THYROID	FOLLICULAR ADENOMA
8	THYROID	PARAFOLLICULAR ADENOMA
9	MAMMARY GLAND	ADENOCARCINOMA
10	STOMACH	LELOMYOMA
11	STOMACH	FIBROSARCOMA
12	OVARY	TUBULAR ADENOMA
13	OVARY	PAPILLARY CYSTADENOMA
14	UTERUS	HEMANGLOSARCOMA
15	UTERUS	ENDOMETRIAL POLYP
16	UTERUS	OSTEOSAROMA
17	UTERUS	LEIOMYOSARCOMA
18	UTERUS	LELOMYOMA
19	VAGINA	POLYP
20	MISC.	ADENOCARCINOMA PRIMARY SITE UN
21	DUODENUM	FIBROSARCOMA
22	INTEGUMENT	TRICHOEPITHELLOMA
23	INTEGUMENT	FIBROSARCOMA
24	LIVER	HEPATOCELLULAR CARCINOMA
25	LIVER	HEPATOCELLULAR ADENOMA
26	LIVER	HEMANGLOSARCOMA

Source: AXCAN PHARMA, INC. [redacted]
Test of Trend Based on the Tumor Data

Animal Type: MOUSE
CONTROL GROUP 1
Sex: FEMALE

Organ Code	Tumor Code	Organ Name	Tumor Name	Tumor Type	Exact p	Asymp p	#Incid /Ctrls	Dose 25	Dose 150	Dose 1000
10	4	LUNG	ADENOCARCINOMA	M-	(0.9926)	0.9290	3/50	2	0	0
10	13	LUNG	ADENOMA	M-	(0.6327)	0.6378	13/50	3	4	6
11	14	LYMPHORETICU	MALLGNANT LYMP	M-	(0.1762)	0.1747	13/50	9	16	15
12	13	PITUITARY	ADENOMA	M-	(0.6056)	0.6804	1/50	2	2	1
13	8	SPLEEN	HEMANGLOMA	S-	0.2137	(0.0289)	0/50	0	0	1
13	12	SPLEEN	HEMANGLOSARCOM	M-	(0.5140)	0.5099	1/50	1	1	1
15	17	THYROID	FOLLICULAR ADE	S-	0.0463	(0.0040)	0/50	0	0	2
15	18	THYROID	PARAFOLLICULAR	S-	0.2190	(0.0310)	0/50	0	0	1
16	4	MAMMARY GLAN	ADENOCARCINOMA	S-	0.5409	(0.5161)	3/50	4	1	3
17	7	STOMACH	FIBROSARCOMA	S-	0.7429	(0.7287)	0/50	1	0	0
17	5	STOMACH	LELOMYOMA	S-	1.0000	(0.7617)	1/50	0	0	0
18	22	OVARY	PAPILLARY CYST	M-	(0.5096)	0.4059	1/50	1	0	1
18	21	OVARY	TUBULAR ADENOM	S-	0.2190	(0.0310)	0/50	0	0	1
20	24	UTERUS	ENDOMETRIAL PO	S-	0.8370	(0.7919)	3/50	3	0	1
20	12	UTERUS	HEMANGLOSARCOM	S-	0.5309	(0.7140)	0/50	0	2	0
20	26	UTERUS	LEIOMYOSARCOMA	S-	0.4761	(0.6146)	0/50	0	1	0
20	5	UTERUS	LELOMYOMA	M-	(0.9514)	0.9427	3/50	2	2	0
20	25	UTERUS	OSTEOSAROMA	S-	1.0000	(0.7489)	1/50	0	0	0
21	27	VAGINA	POLYP	S-	0.7429	(0.7287)	0/50	1	0	0
22	28	MISC.	ADENOCARCINOMA	S-	1.0000	(0.7493)	1/50	0	0	0
3	7	DUODENUM	FIBROSARCOMA	S-	0.7429	(0.7287)	0/50	1	0	0
6	7	INTEGUMENT	FIBROSARCOMA	S-	0.2667	(0.0501)	0/50	0	0	1
6	19	INTEGUMENT	TRICHOEPITHELL	M-	(0.8082)	0.8387	0/50	2	0	0
9	12	LIVER	HEMANGLOSARCOM	M-	(0.4057)	0.3723	0/50	2	0	1
9	11	LIVER	HEPATOCELLULAR	S-	0.3600	(0.4358)	1/50	0	2	1
9	10	LIVER	HEPATOCELLULAR	S-	0.7990	(0.8582)	0/50	3	1	0

Pairwise Comparisons
Dosage Pair: 0 vs 1000

Species: Mouse
CONTROL GROUP 1
Sex: Female

Organ	Organ Code	Tumor	Tumor Code	Strata	Row	_0	_1E3	Exact p	Asmp p
LUNG	10	ADENOMA	13	2	1	0	0	(0.9573)	0.9270
LUNG	10	ADENOMA	13	2	2	3	5	(0.9573)	0.9270
LUNG	10	ADENOMA	13	3	1	2	0	(0.9573)	0.9270
LUNG	10	ADENOMA	13	3	2	5	11	(0.9573)	0.9270
LUNG	10	ADENOMA	13	4	1	2	2	(0.9573)	0.9270
LUNG	10	ADENOMA	13	4	2	7	5	(0.9573)	0.9270
LUNG	10	ADENOMA	13	9	1	7	1	(0.9573)	0.9270
LUNG	10	ADENOMA	13	9	2	20	22	(0.9573)	0.9270
LUNG	10	ADENOMA	13	74	1	0	1	(0.9573)	0.9270
LUNG	10	ADENOMA	13	74	2	47	45	(0.9573)	0.9270
LUNG	10	ADENOMA	13	86	1	0	1	(0.9573)	0.9270
LUNG	10	ADENOMA	13	86	2	43	38	(0.9573)	0.9270
LUNG	10	ADENOMA	13	92	1	1	0	(0.9573)	0.9270
LUNG	10	ADENOMA	13	92	2	39	35	(0.9573)	0.9270
LUNG	10	ADENOMA	13	96	1	1	1	(0.9573)	0.9270
LUNG	10	ADENOMA	13	96	2	36	28	(0.9573)	0.9270
LUNG	10	ADENOCARCINOMA	4	2	1	0	0	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	2	2	3	6	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	3	1	0	0	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	3	2	8	12	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	4	1	0	0	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	4	2	9	8	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	9	1	2	0	(1.0000)	0.9442
LUN	10	ADENOCARCINOMA	4	9	2	25	23	(1.0000)	0.9442
LUN	10	ADENOCARCINOMA	4	77	1	0	0	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	77	2	45	43	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	92	1	0	0	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	92	2	40	35	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	103	1	1	0	(1.0000)	0.9442
LUNG	10	ADENOCARCINOMA	4	103	2	28	23	(1.0000)	0.9442
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	2	2	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	1	1	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	2	1	3	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	1	4	2	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	2	3	6	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	1	2	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	2	8	5	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	1	4	3	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	2	23	20	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	51	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	51	2	48	50	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	59	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	59	2	48	49	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	73	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	73	2	47	46	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	2	47	46	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	76	1	1	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	76	2	45	44	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	84	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	84	2	44	40	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	86	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	86	2	43	38	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	90	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	90	2	41	36	(0.3542)	0.2828
LYMP ICULAR SYST	11	MALLGNANT LYMPHOMA	14	92	1	1	0	(0.3542)	0.2828

LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	92	2	39	35	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	93	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	93	2	39	33	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	2	37	31	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	95	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	95	2	37	31	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	96	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	96	2	37	28	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	97	1	0	0	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	97	2	36	26	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	1	0	1	(0.3542)	0.2828
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	2	34	24	(0.3542)	0.2828
PITUITARY	12	ADENOMA	13	3	1	0	0	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	3	2	8	11	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	4	1	1	0	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	4	2	9	8	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	9	1	0	0	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	9	2	27	23	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	85	1	0	1	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	85	2	44	39	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	102	1	0	0	(0.7090)	0.4554
PITUITARY	12	ADENOMA	13	102	2	30	23	(0.7090)	0.4554
SPLEEN	13	HEMANGLOSARCOMA	12	2	1	0	0	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	2	2	3	6	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	3	1	0	1	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	3	2	8	11	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	4	1	0	0	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	4	2	9	8	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	9	1	0	0	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	9	2	27	23	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	63	1	0	0	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	63	2	48	48	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	103	1	1	0	(0.7769)	0.5243
SPLEEN	13	HEMANGLOSARCOMA	12	103	2	28	23	(0.7769)	0.5243
SPLEEN	13	HEMANGLOMA	8	4	1	0	0	0.4237	(0.1219)
SPLEEN	13	HEMANGLOMA	8	4	2	10	7	0.4237	(0.1219)
SPLEEN	13	HEMANGLOMA	8	98	1	0	1	0.4237	(0.1219)
SPLEEN	13	HEMANGLOMA	8	98	2	34	24	0.4237	(0.1219)
THYROID	15	FOLLICULAR ADENOMA	17	9	1	0	2	0.2065	(0.0609)
THYROID	15	FOLLICULAR ADENOMA	17	9	2	27	21	0.2065	(0.0609)
THYROID	15	PARAFOLLICULAR ADENO	18	9	1	0	1	0.4600	(0.1395)
THYROID	15	PARAFOLLICULAR ADENO	18	9	2	27	22	0.4600	(0.1395)
MAMMARY GLAND	16	ADENOCARCINOMA	4	2	1	0	0	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	2	2	3	6	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	3	1	0	1	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	3	2	8	11	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	4	1	1	1	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	4	2	9	7	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	9	1	2	1	0.6189	(0.4564)
MAMMARY GLAND	16	ADENOCARCINOMA	4	9	2	25	22	0.6189	(0.4564)
STOMACH	17	LELOMYOMA	5	4	1	1	0	1.0000	(0.8147)
STOMACH	17	LELOMYOMA	5	4	2	9	8	1.0000	(0.8147)
STOMACH	17	FIBROSARCOMA	7	9	1	0	0		
STOMACH	17	FIBROSARCOMA	7	9	2	27	23		
OVARY	18	TUBULAR ADENOMA	21	9	1	0	1	0.4600	(0.1395)
OVARY	18	TUBULAR ADENOMA	21	9	2	27	22	0.4600	(0.1395)
OVARY	18	PAPILLARY CYSTADENOM	22	3	1	0	0	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	3	2	8	11	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	4	1	1	0	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	4	2	9	8	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	9	1	0	0	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	9	2	27	23	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	85	1	0	1	(0.7090)	0.4554
OVARY	18	PAPILLARY CYSTADENOM	22	85	2	44	39	(0.7090)	0.4554
UTERUS	20	HEMANGLOSARCOMA	12	3	1	0	0		
UTERUS	20	HEMANGLOSARCOMA	12	3	2	8	12		
UTERUS	20	HEMANGLOSARCOMA	12	9	1	0	0		

UTERUS	20	HEMANGLOSARCOMA	12	9	2	27	23		
UT[illegible]	20	ENDOMETRIAL POLYP	24	4	1	0	1	0.9171	(0.7997)
U1	20	ENDOMETRIAL POLYP	24	4	2	10	7	0.9171	(0.7997)
UT[illegible]	20	ENDOMETRIAL POLYP	24	9	1	3	0	0.9171	(0.7997)
UTERUS	20	ENDOMETRIAL POLYP	24	9	2	24	23	0.9171	(0.7997)
UTERUS	20	OSTEOSAROMA	25	4	1	0	0	1.0000	(0.8123)
UTERUS	20	OSTEOSAROMA	25	4	2	9	8	1.0000	(0.8123)
UTERUS	20	OSTEOSAROMA	25	96	1	1	0	1.0000	(0.8123)
UTERUS	20	OSTEOSAROMA	25	96	2	36	29	1.0000	(0.8123)
UTERUS	20	LEIOMYOSARCOMA	26	9	1	0	0		
UTERUS	20	LEIOMYOSARCOMA	26	9	2	27	23		
UTERUS	20	LELOMYOMA	5	2	1	0	0	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	2	2	3	6	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	3	1	0	0	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	3	2	8	12	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	4	1	2	0	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	4	2	8	8	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	9	1	1	0	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	9	2	26	23	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	70	1	0	0	(1.0000)	0.9450
UTERUS	20	LELOMYOMA	5	70	2	48	47	(1.0000)	0.9450
VAGINA	21	POLYP	27	9	1	0	0		
VAGINA	21	POLYP	27	9	2	27	23		
MISC.	22	ADENOCARCINOMA PRIMA	28	9	1	1	0	1.0000	(0.8222)
MISC.	22	ADENOCARCINOMA PRIMA	28	9	2	26	23	1.0000	(0.8222)
DUODENUM	3	FIBROSARCOMA	7	9	1	0	0		
DUODENUM	3	FIBROSARCOMA	7	9	2	27	23		
INTEGUMENT	6	TRICHOEPITHELLOMA	19	3	1	0	0		
INTEGUMENT	6	TRICHOEPITHELLOMA	19	3	2	8	12		
INTEGUMENT	6	TRICHOEPITHELLOMA	19	4	1	0	0		
INTEGUMENT	6	TRICHOEPITHELLOMA	19	4	2	10	8		
INTEGUMENT	6	TRICHOEPITHELLOMA	19	95	1	0	0		
INTEGUMENT	6	TRICHOEPITHELLOMA	19	95	2	37	31		
INTEG[illegible]MENT	6	FIBROSARCOMA	7	4	1	0	1	0.4444	(0.1320)
INT[illegible]IT	6	FIBROSARCOMA	7	4	2	10	7	0.4444	(0.1320)
LI[illegible]	9	HEPATOCELLULAR CARCI	10	9	1	0	0		
LIV[illegible]	9	HEPATOCELLULAR CARCI	10	9	2	27	23		
LIVER	9	HEPATOCELLULAR ADENO	11	3	1	0	1	0.7840	(0.5345)
LIVER	9	HEPATOCELLULAR ADENO	11	3	2	8	11	0.7840	(0.5345)
LIVER	9	HEPATOCELLULAR ADENO	11	9	1	1	0	0.7840	(0.5345)
LIVER	9	HEPATOCELLULAR ADENO	11	9	2	26	23	0.7840	(0.5345)
LIVER	9	HEMANGLOSARCOMA	12	2	1	0	0	(0.4946)	0.1563
LIVER	9	HEMANGLOSARCOMA	12	2	2	3	5	(0.4946)	0.1563
LIVER	9	HEMANGLOSARCOMA	12	9	1	0	0	(0.4946)	0.1563
LIVER	9	HEMANGLOSARCOMA	12	9	2	27	23	(0.4946)	0.1563
LIVER	9	HEMANGLOSARCOMA	12	74	1	0	1	(0.4946)	0.1563
LIVER	9	HEMANGLOSARCOMA	12	74	2	47	45	(0.4946)	0.1563

Note: An '*' indicates that the dose-tumor association may be significant ($p<0.05$).

Number of Animals Died by Dose and Time

Animal: MOUSE
2ND CONTROL GROUP
Sex: FEMALE

Number of Animals Died	Dose				
	CTRL	LOW	MED	HIGH	Total
Time (weeks)					
0-52	1	1	4	1	7
53-78	4	6	7	6	23
79-93	8	9	6	12	35
94-103	4	6	6	8	24
FNL KILL	31	28	27	23	109
Total	48	50	50	50	198

Source: AXCAN PHARMA, INC., [redacted]

Intercurrent Mortality Rates

Animal Type: MOUSE
2ND CONTROL GROUP
Sex: FEMALE

	Dose											
	CTRL			LOW			MED			HIGH		
	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died
Time(wks)												
0-52	1	48	2.1	1	50	2.0	4	50	8.0	1	50	2.0
53-78	4	47	10.4	6	49	14.0	7	46	22.0	6	49	14.0
79-93	8	43	27.1	9	43	32.0	6	39	34.0	12	43	38.0
94-103	4	35	35.4	6	34	44.0	6	33	46.0	8	31	54.0
FNL KILL	31	48	64.6	28	50	56.0	27	50	54.0	23	50	46.0

Source: AXCAN PHARMA,. INC., [redacted]

Survival Rates

Animal: MOUSE

Sex: FEMALE

Dose	Time(wks) 0-52 No. Still Alive	0-52 Pct Survival	53-78 No. Still Alive	53-78 Pct Survival	79-93 No. Still Alive	79-93 Pct Survival	94-103 No. Still Alive	94-103 Pct Survival
CTRL	47	97.9	43	89.6	35	72.9	31	64.6
LOW	49	98.0	43	86.0	34	68.0	28	56.0
MED	46	92.0	39	78.0	33	66.0	27	54.0
HIGH	49	98.0	43	86.0	31	62.0	23	46.0

Source: AXCAN PHARMA, INC., [redacted]
Mortality Rates

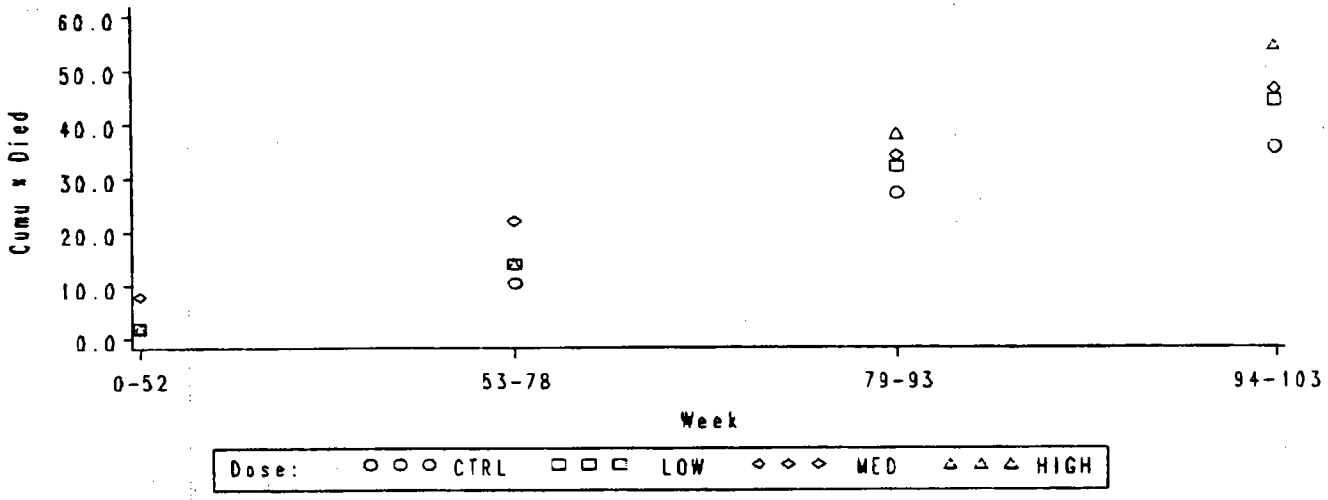
Animal Type: MOUSE

Sex: FEMALE

Dose	Time(wks) 0-52 Mortality Rate	53-78 Mortality Rate	79-93 Mortality Rate	94-103 Mortality Rate
CTRL	2.1	10.4	27.1	35.4
LOW	2.0	14.0	32.0	44.0
MED	8.0	22.0	34.0	46.0
HIGH	2.0	14.0	38.0	54.0

Cumulative Percentages of Death

Animal: MOUSE
Sex: FEMALE

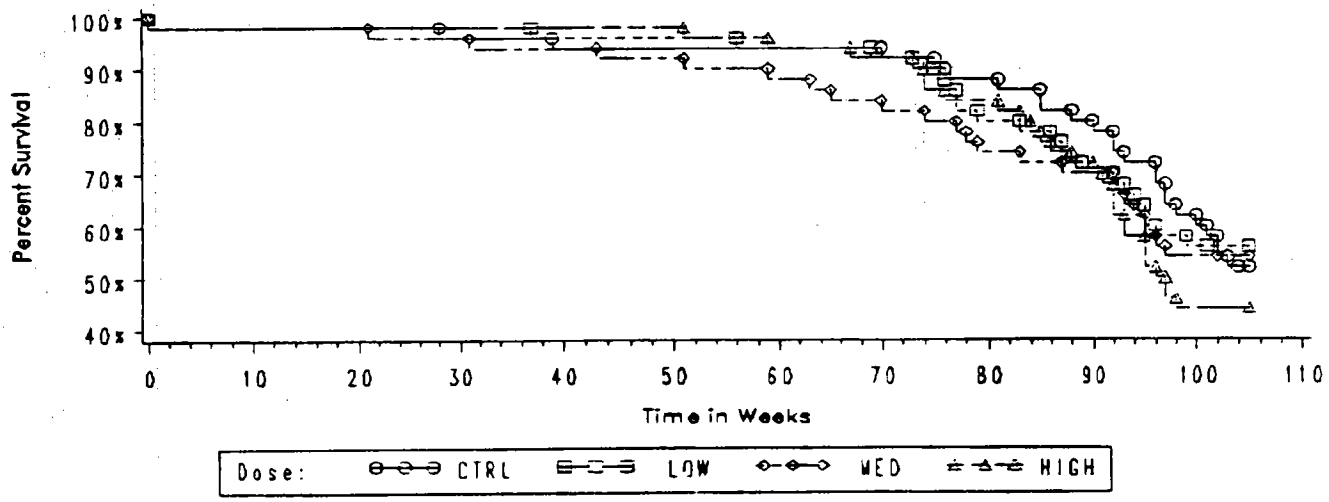


Source: AXCAN PHARMA. INC.. [redacted]

Kaplan – Meier Survival Function

Animal: MOUSE

Sex: FEMALE



Source: AXCAN PHARMA. INC. [redacted]

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)JI'     ANALYSES                                                                    DSNAME:  C:\ANIMAL\S_MICE_F.MMS

ROU.        0       1       2       3

)OSE       .00   25.00  150.00 1000.00

)BS       17.     22.     23.     27.
EXP       23.19   22.58   21.46   21.77

)BS/EXP    .73     .97    1.07    1.24
  N       48      50      50      50


)X'S TEST FOR LIFE TABLE DATA
TEST STATISTICS:                EXACT INVERSE  CONSERVATIVE     D.F.

    VALUES OF CHI-SQUARE           3.0818        3.0771          3
    PROBABILITIES                   .3792         .3799

TEST STATISTICS FOR ADJUSTED TRENDS:
                                          LOWER BOUND  UPPER BOUND
                                CHI-SQUARE  D.F.      Z            Z
YG TREND ------- 1                 2.0176   1    1.4172       1.3096
YG PROBABILITIES 2                  .1555         .0782        .0952
YG DEPT FR TREND 3                 1.0641
YG PROBABILITY   4                  .5874
YG TOT COX CHISQ 5                 3.0818
YG PROBABILITY   6                  .3792

                 NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)=      5445.869
      SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND=                        14699170.000


ENL      .D K/W ANALYSIS (GEHAN-BRESLOW)                                             DSNAME:  C:\ANIMAL\S_MICE_F.MMS

his analysis gives more weight to early differences in death rates between groups than the previous Cox analysis.

VECTOR SCORE STATISTIC W

   -967     -93     385     675


EST STATISTICS:                 EXACT INVERSE  CONSERVATIVE     D.F.

    VALUES OF CHI-SQUARE           2.8256        2.8229          3
    PROBABILITIES                   .4193         .4197

TEST STATISTICS FOR ADJUSTED TRENDS:
                                          LOWER BOUND  UPPER BOUND
                                CHI-SQUARE  D.F.      Z            Z
YG TREND ------- 1                 1.4518   1    1.2049       1.2042
YG PROBABILITIES 2                  .2282         .1141        .1143
YG DEPT FR TREND-3                 1.3738
YG PROBABILITY  -4                  .5031
YG TOTAL --------5                 2.8256
YG PROBABILITY  -6                  .4193

                 NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)=     730425.000
      SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND=                       367480671816.401
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Source: AXCAN PHARMA, INC., [redacted]
List of Organ Names and Tumor Names

Animal: MOUSE

Sex: FEMALE

No.	Organ Name	Tumor Name
1	LUNG	ADENOMA
2	LUNG	ADENOCARCINOMA
3	LYMPHORETICULAR SYSTEM	MALLGNANT LYMPHOMA
4	PITUITARY	ADENOMA
5	SPLEEN	HEMANGLOSARCOMA
6	SPLEEN	HEMANGLOMA
7	THYROID	FOLLICULAR ADENOMA
8	THYROID	PARAFOLLICULAR ADENOMA
9	MAMMARY GLAND	ADENOCARCINOMA
10	STOMACH	FIBROSARCOMA
11	OVARY	TUBULAR ADENOMA
12	OVARY	PAPILLARY CYSTADENOMA
13	PANCREAS	ISLET ADENOMA
14	UTERUS	HEMANGLOSARCOMA
15	UTERUS	ENDOMETRIAL POLYP
16	UTERUS	LEIOMYOSARCOMA
17	UTERUS	ADENOCARCINOMA
18	UTERUS	LELOMYOMA
19	UTERUS	FIBROSARCOMA
20	VAGINA	POLYP
21	DUODENUM	FIBROSARCOMA
22	INTEGUMENT	TRICHOEPITHELLOMA
23	INTEGUMENT	FIBROSARCOMA
24	LIVER	HEPATOCELLULAR CARCINOMA
25	LIVER	HEPATOCELLULAR ADENOMA
26	LIVER	HEMANGLOSARCOMA
27	LIVER	HEMANGLOMA

Source: AXCAN PHARMA, INC., [redacted]
Test of Trend Based on the Tumor Data

Animal Type: MOUSE

Sex: FEMALE

Organ Code	Tumor Code	Organ Name	Tumor Name	Tumor Type	Exact p	Asymp p	#Incid /Ctrls	Dose 25	Dose 150	Dose 1000
10	4	LUNG	ADENOCARCINOMA	M-	(0.9293)	0.8699	1/48	2	0	0
10	13	LUNG	ADENOMA	M-	(0.2592)	0.2493	6/48	3	4	6
11	14	LYMPHORETICU	MALLGNANT LYMP	M-	(0.0393)	0.0351	4/48	9	16	15
12	13	PITUITARY	ADENOMA	M-	(0.8034)	0.8020	3/48	2	2	1
13	8	SPLEEN	HEMANGLOMA	S-	0.2155	(0.0296)	0/48	0	0	1
13	12	SPLEEN	HEMANGLOSARCOM	M-	(0.6765)	0.6383	2/48	1	1	1
15	17	THYROID	FOLLICULAR ADE	S-	0.0430	(0.0033)	0/48	0	0	2
15	18	THYROID	PARAFOLLICULAR	S-	0.2110	(0.0280)	0/48	0	0	1
16	4	MAMMARY GLAN	ADENOCARCINOMA	S-	0.5544	(0.5282)	3/48	4	1	3
17	7	STOMACH	FIBROSARCOMA	S-	0.7156	(0.7225)	0/48	1	0	0
18	22	OVARY	PAPILLARY CYST	M-	(0.5218)	0.4076	1/48	1	0	1
18	21	OVARY	TUBULAR ADENOM	S-	0.2110	(0.0280)	0/48	0	0	1
19	23	PANCREAS	ISLET ADENOMA	S-	1.0000	(0.7765)	1/48	0	0	0
20	4	UTERUS	ADENOCARCINOMA	S-	1.0000	(0.7608)	1/48	0	0	0
20	24	UTERUS	ENDOMETRIAL PO	S-	0.8122	(0.7612)	2/48	3	0	1
20	7	UTERUS	FIBROSARCOMA	S-	1.0000	(0.7436)	1/48	0	0	0
20	12	UTERUS	HEMANGLOSARCOM	S-	0.5240	(0.7094)	0/48	0	2	0
20	26	UTERUS	LEIOMYOSARCOMA	S-	0.4587	(0.6063)	0/48	0	1	0
20	5	UTERUS	LELOMYOMA	M-	(0.8640)	0.9019	1/48	2	2	0
21	27	VAGINA	POLYP	S-	0.7156	(0.7225)	0/48	1	0	0
3	7	DUODENUM	FIBROSARCOMA	S-	0.7156	(0.7225)	0/48	1	0	0
6	7	INTEGUMENT	FIBROSARCOMA	S-	0.6112	(0.4697)	2/48	0	0	1
6	19	INTEGUMENT	TRICHOEPITHELL	M-	(0.8127)	0.8399	0/48	2	0	0
9	8	LIVER	HEMANGLOMA	S-	1.0000	(0.7436)	1/48	0	0	0
9	12	LIVER	HEMANGLOSARCOM	M-	(0.3927)	0.3638	0/48	2	0	1
9	11	LIVER	HEPATOCELLULAR	S-	0.1967	(0.2799)	0/48	0	2	1
9	10	LIVER	HEPATOCELLULAR	S-	0.8802	(0.8899)	1/48	3	1	0

Note: Tumor Type=M indicates that the tumor is fatal to some but not all animals.
Tumor Type=S indicates that the tumor is fatal or non-fatal to all animals.

Symbol '+' indicates a significant positive linear dose-tumor trend.
Symbol '-' indicates a non-significant positive linear dose-tumor trend.

Source: AXCAN PHARMA, INC. (b)(4) CNTL2
Pairwise Comparisons
Dosage Pair: 0 vs 1000

Species: Mouse
Sex: Female

Organ	Organ Code	Tumor	Tumor Code	Strata	Row	_0	_1E3	Exact p	Asmp p
LUNG	10	ADENOMA	13	2	1	1	0	(0.6578)	0.5425
LUNG	10	ADENOMA	13	2	2	3	5	(0.6578)	0.5425
LUNG	10	ADENOMA	13	3	1	1	0	(0.6578)	0.5425
LUNG	10	ADENOMA	13	3	2	7	8	(0.6578)	0.5425
LUNG	10	ADENOMA	13	4	1	0	2	(0.6578)	0.5425
LUNG	10	ADENOMA	13	4	2	3	8	(0.6578)	0.5425
LUNG	10	ADENOMA	13	9	1	3	1	(0.6578)	0.5425
LUNG	10	ADENOMA	13	9	2	28	22	(0.6578)	0.5425
LUNG	10	ADENOMA	13	74	1	0	1	(0.6578)	0.5425
LUNG	10	ADENOMA	13	74	2	44	45	(0.6578)	0.5425
LUNG	10	ADENOMA	13	86	1	0	1	(0.6578)	0.5425
LUNG	10	ADENOMA	13	86	2	41	38	(0.6578)	0.5425
LUNG	10	ADENOMA	13	96	1	0	1	(0.6578)	0.5425
LUNG	10	ADENOMA	13	96	2	35	28	(0.6578)	0.5425
LUNG	10	ADENOMA	13	97	1	1	0	(0.6578)	0.5425
LUNG	10	ADENOMA	13	97	2	34	26	(0.6578)	0.5425
LUNG	10	ADENOCARCINOMA	4	2	1	0	0	(1.0000)	0.8057
LUNG	10	ADENOCARCINOMA	4	2	2	4	6	(1.0000)	0.8057
LUNG	10	ADENOCARCINOMA	4	3	1	0	0	(1.0000)	0.8057
LUNG	10	ADENOCARCINOMA	4	3	2	8	9	(1.0000)	0.8057
LUNG	10	ADENOCARCINOMA	4	9	1	1	0	(1.0000)	0.8057
LUNG	10	ADENOCARCINOMA	4	9	2	30	23	(1.0000)	0.8057
LUNG	10	ADENOCARCINOMA	4	77	1	0	0	(1.0000)	0.8057
LUN	10	ADENOCARCINOMA	4	77	2	43	43	(1.0000)	0.8057
LU	10	ADENOCARCINOMA	4	92	1	0	0	(1.0000)	0.8057
LUN	10	ADENOCARCINOMA	4	92	2	36	35	(1.0000)	0.8057
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	1	0	0	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	2	1	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	2	4	3	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	1	1	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	2	7	5	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	1	2	2	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	2	1	6	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	1	0	3	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	2	31	20	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	51	1	0	0	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	51	2	47	50	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	59	1	0	0	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	59	2	47	49	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	73	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	73	2	45	46	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	1	0	0	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	2	44	46	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	76	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	76	2	44	44	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	84	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	84	2	42	40	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	86	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	86	2	41	38	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	90	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	90	2	38	36	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	93	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	93	2	35	33	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	1	0	0	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	2	35	31	(0.0105)	*0.0059
YMP TICULAR SYST	11	MALLGNANT LYMPHOMA	14	95	1	0	0	(0.0105)	*0.0059

LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	95	2	35	31	(0.0105)	*0.0059
LY TICULAR SYST	11	MALLGNANT LYMPHOMA	14	96	1	0	1	(0.0105)	*0.0059
LY TICULAR SYST	11	MALLGNANT LYMPHOMA	14	96	2	35	28	(0.0105)	*0.0059
LYM ETICULAR SYST	11	MALLGNANT LYMPHOMA	14	97	1	1	0	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	97	2	34	26	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	1	0	1	(0.0105)	*0.0059
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	2	33	24	(0.0105)	*0.0059
PITUITARY	12	ADENOMA	13	3	1	0	0	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	3	2	7	8	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	4	1	0	0	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	4	2	4	11	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	9	1	2	0	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	9	2	29	23	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	85	1	0	1	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	85	2	42	39	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	87	1	1	0	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	87	2	40	38	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	102	1	0	0	(0.9137)	0.7968
PITUITARY	12	ADENOMA	13	102	2	33	23	(0.9137)	0.7968
SPLEEN	13	HEMANGLOSARCOMA	12	2	1	1	0	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	2	2	3	6	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	3	1	0	1	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	3	2	8	8	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	9	1	1	0	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	9	2	30	23	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	63	1	0	0	(0.8919)	0.7417
SPLEEN	13	HEMANGLOSARCOMA	12	63	2	47	48	(0.8919)	0.7417
SPLEEN	13	HEMANGLOMA	8	4	1	0	0	0.4310	(0.1255)
SPLEEN	13	HEMANGLOMA	8	4	2	4	10	0.4310	(0.1255)
SPLEEN	13	HEMANGLOMA	8	98	1	0	1	0.4310	(0.1255)
SPLEEN	13	HEMANGLOMA	8	98	2	33	24	0.4310	(0.1255)
THYROID	15	FOLLICULAR ADENOMA	17	9	1	0	2	0.1768	(0.0488)
THYROID	15	FOLLICULAR ADENOMA	17	9	2	31	21	0.1768	(0.0488)
THYR	15	PARAFOLLICULAR ADENO	18	9	1	0	1	0.4259	(0.1230)
TH	15	PARAFOLLICULAR ADENO	18	9	2	31	22	0.4259	(0.1230)
MA GLAND	16	ADENOCARCINOMA	4	2	1	0	0	0.7235	(0.5598)
MAMMA GLAND	16	ADENOCARCINOMA	4	2	2	4	6	0.7235	(0.5598)
MAMMARY GLAND	16	ADENOCARCINOMA	4	3	1	0	0	0.7235	(0.5598)
MAMMARY GLAND	16	ADENOCARCINOMA	4	3	2	8	9	0.7235	(0.5598)
MAMMARY GLAND	16	ADENOCARCINOMA	4	4	1	0	2	0.7235	(0.5598)
MAMMARY GLAND	16	ADENOCARCINOMA	4	4	2	4	9	0.7235	(0.5598)
MAMMARY GLAND	16	ADENOCARCINOMA	4	9	1	3	1	0.7235	(0.5598)
MAMMARY GLAND	16	ADENOCARCINOMA	4	9	2	28	22	0.7235	(0.5598)
STOMACH	17	FIBROSARCOMA	7	9	1	0	0		
STOMACH	17	FIBROSARCOMA	7	9	2	31	23		
OVARY	18	TUBULAR ADENOMA	21	9	1	0	1	0.4259	(0.1230)
OVARY	18	TUBULAR ADENOMA	21	9	2	31	22	0.4259	(0.1230)
OVARY	18	PAPILLARY CYSTADENOM	22	2	1	1	0	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	2	2	3	6	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	3	1	0	0	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	3	2	8	8	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	9	1	0	0	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	9	2	31	23	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	85	1	0	1	(0.7951)	0.5503
OVARY	18	PAPILLARY CYSTADENOM	22	85	2	42	39	(0.7951)	0.5503
PANCREAS	19	ISLET ADENOMA	23	2	1	1	0	1.0000	(0.8899)
PANCREAS	19	ISLET ADENOMA	23	2	2	3	6	1.0000	(0.8899)
UTERUS	20	HEMANGLOSARCOMA	12	3	1	0	0		
UTERUS	20	HEMANGLOSARCOMA	12	3	2	8	9		
UTERUS	20	HEMANGLOSARCOMA	12	9	1	0	0		
UTERUS	20	HEMANGLOSARCOMA	12	9	2	31	23		
UTERUS	20	ENDOMETRIAL POLYP	24	4	1	0	1	0.9134	(0.7619)
UTERUS	20	ENDOMETRIAL POLYP	24	4	2	4	10	0.9134	(0.7619)
UTERUS	20	ENDOMETRIAL POLYP	24	9	1	2	0	0.9134	(0.7619)
UTERUS	20	ENDOMETRIAL POLYP	24	9	2	29	23	0.9134	(0.7619)
UTERUS	20	LEIOMYOSARCOMA	26	9	1	0	0		
UTERUS	20	LEIOMYOSARCOMA	26	9	2	31	23		
UTE	20	ADENOCARCINOMA	4	3	1	0	0	1.0000	(0.8357)

JTERUS	20	ADENOCARCINOMA	4	3	2	7	9	1.0000	(0.8357)
JTEP	20	ADENOCARCINOMA	4	85	1	1	0	1.0000	(0.8357)
JT	20	ADENOCARCINOMA	4	85	2	41	40	1.0000	(0.8357)
JTL	20	LELOMYOMA	5	2	1	0	0	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	2	2	4	6	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	3	1	1	0	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	3	2	7	9	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	9	1	0	0	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	9	2	31	23	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	70	1	0	0	(1.0000)	0.8558
JTERUS	20	LELOMYOMA	5	70	2	46	47	(1.0000)	0.8558
JTERUS	20	FIBROSARCOMA	7	9	1	1	0	1.0000	(0.8057)
JTERUS	20	FIBROSARCOMA	7	9	2	30	23	1.0000	(0.8057)
/AGINA	21	POLYP	27	9	1	0	0		
/AGINA	21	POLYP	27	9	2	31	23		
)UODENUM	3	FIBROSARCOMA	7	9	1	0	0		
)UODENUM	3	FIBROSARCOMA	7	9	2	31	23		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	3	1	0	0		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	3	2	8	9		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	4	1	0	0		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	4	2	4	11		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	95	1	0	0		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	95	2	35	31		
NTEGUMENT	6	FIBROSARCOMA	7	2	1	1	0	0.9388	(0.8215)
NTEGUMENT	6	FIBROSARCOMA	7	2	2	3	6	0.9388	(0.8215)
NTEGUMENT	6	FIBROSARCOMA	7	4	1	0	1	0.9388	(0.8215)
NTEGUMENT	6	FIBROSARCOMA	7	4	2	4	10	0.9388	(0.8215)
NTEGUMENT	6	FIBROSARCOMA	7	9	1	1	0	0.9388	(0.8215)
NTEGUMENT	6	FIBROSARCOMA	7	9	2	30	23	0.9388	(0.8215)
IVER	9	HEPATOCELLULAR CARCI	10	9	1	1	0	1.0000	(0.8057)
IVER	9	HEPATOCELLULAR CARCI	10	9	2	30	23	1.0000	(0.8057)
IVER	9	HEPATOCELLULAR ADENO	11	4	1	0	1	0.7333	(0.2736)
IVER	9	HEPATOCELLULAR ADENO	11	4	2	4	10	0.7333	(0.2736)
IVER	9	HEPATOCELLULAR ADENO	11	9	1	0	0	0.7333	(0.2736)
IVF	9	HEPATOCELLULAR ADENO	11	9	2	31	23	0.7333	(0.2736)
IV	9	HEMANGLOSARCOMA	12	2	1	0	0	(0.5111)	0.1643
IVL	9	HEMANGLOSARCOMA	12	2	2	4	5	(0.5111)	0.1643
IVER	9	HEMANGLOSARCOMA	12	9	1	0	0	(0.5111)	0.1643
IVER	9	HEMANGLOSARCOMA	12	9	2	31	23	(0.5111)	0.1643
IVER	9	HEMANGLOSARCOMA	12	74	1	0	1	(0.5111)	0.1643
IVER	9	HEMANGLOSARCOMA	12	74	2	44	45	(0.5111)	0.1643
IVER	9	HEMANGLOMA	8	9	1	1	0	1.0000	(0.8057)
IVER	9	HEMANGLOMA	8	9	2	30	23	1.0000	(0.8057)

Note: An '*' indicates that the dose-tumor association may be significant ($p<0.05$).

Number of Animals Died by Dose and Time

Animal: Mouse

Sex: Female

Number of Animals Died	Dose				
	Ctrl	Low	Med	High	Total
Time (weeks)					
0-52	3	1	4	1	9
53-78	7	6	7	6	26
79-93	16	9	6	12	43
94-103	14	6	6	8	34
FNL KILL	58	28	27	23	136
Total	98	50	50	50	248

Source: AXCAN PHARMA, INC. [redacted] 2CNTL
Intercurrent Mortality Rates

Animal Type: Mouse

Sex: Female

	Dose											
	Ctrl			Low			Med			High		
	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died	No. Died	No. Risk	Cumu Pct. Died
Time(wks)												
0-52	3	98	3.1	1	50	2.0	4	50	8.0	1	50	2.0
53-78	7	95	10.2	6	49	14.0	7	46	22.0	6	49	14.0
79-93	16	88	26.5	9	43	32.0	6	39	34.0	12	43	38.0
94-103	14	72	40.8	6	34	44.0	6	33	46.0	8	31	54.0
FNL KILL	58	98	59.2	28	50	56.0	27	50	54.0	23	50	46.0

Source: AXCAN PHARMA, INC. [redacted] 2CNTL
Survival Rates

Animal: Mouse

Sex: Female

	Time(wks) 0-52		53-78		79-93		94-103	
Dose	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival	No. Still Alive	Pct Survival
Ctrl	95	96.9	88	89.8	72	73.5	58	59.2
Low	49	98.0	43	86.0	34	68.0	28	56.0
Med	46	92.0	39	78.0	33	66.0	27	54.0
High	49	98.0	43	86.0	31	62.0	23	46.0

Source: AXCAN PHARMA, INC. [redacted] 2CNTL
Mortality Rates

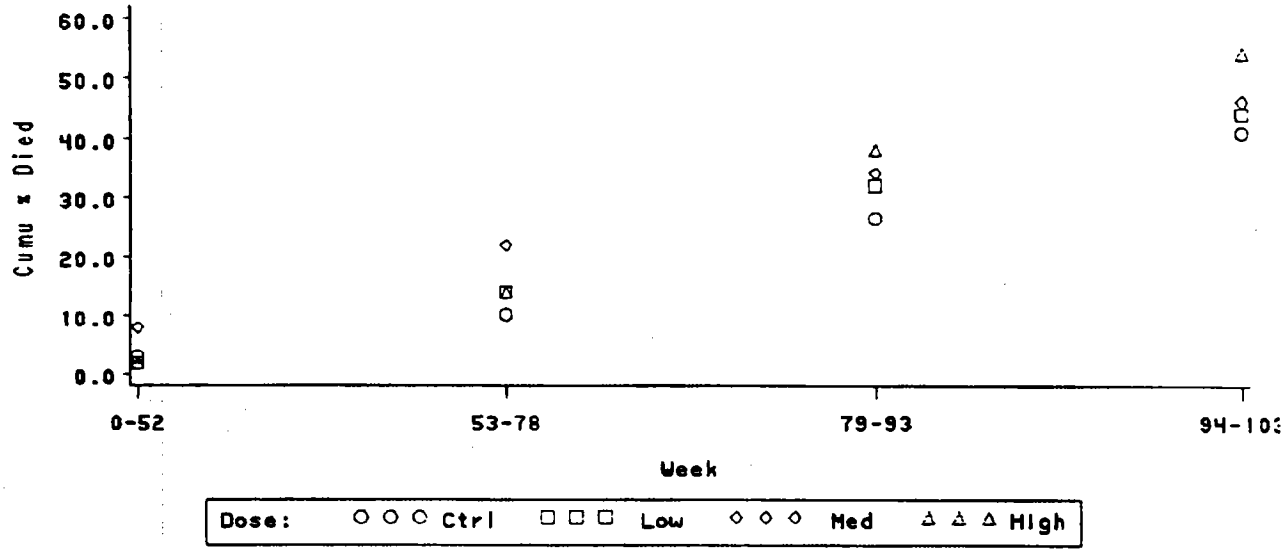
Animal Type: Mouse

Sex: Female

	Time(wks) 0-52	53-78	79-93	94-103
Dose	Mortality Rate	Mortality Rate	Mortality Rate	Mortality Rate
Ctrl	3.1	10.2	26.5	40.8
Low	2.0	14.0	32.0	44.0
Med	8.0	22.0	34.0	46.0
High	2.0	14.0	38.0	54.0

Cumulative Percentages of Death

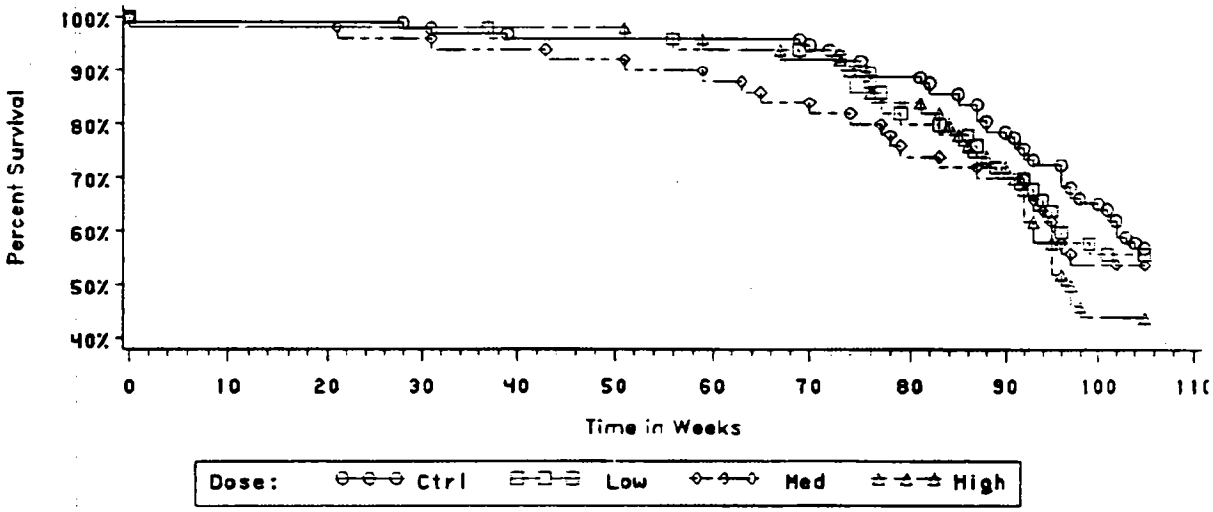
Animal: Mouse
Sex: Female



Kaplan-Meier Survival Function

Animal: Mouse

Sex: Female



AD.'' ''D ANALYSES DSNAME: C:\animal\S_MICE_F.MMS

GR	0	1	2	3
DOSE	.00	25.00	150.00	1000.00
OBS	41.	22.	23.	27.
EXP	47.53	22.51	21.44	21.52
OBS/EXP	.86	.98	1.07	1.25
N	98	50	50	50

COX'S TEST FOR LIFE TABLE DATA

TEST STATISTICS:	EXACT INVERSE	CONSERVATIVE	D.F.
VALUES OF CHI-SQUARE	2.4585	2.4546	3
PROBABILITIES	.4828	.4836	

TEST STATISTICS FOR ADJUSTED TRENDS:

	CHI-SQUARE	D.F.	LOWER BOUND Z	UPPER BOUND Z
JYG TREND ------- 1	2.0208	1	1.4184	1.3156
JYG PROBABILITIES 2	.1552		.0780	.0942
JYG DEPT FR TREND 3	.4377			
JYG PROBABILITY 4	.8034			
JYG TOT COX CHISQ 5	2.4585			
JYG PROBABILITY 6	.4828			

NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)= 5701.885
SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND= 16088250.000

GE' ''ZED K/W ANALYSIS (GEHAN-BRESLOW) DSNAME: C:\animal\S_MICE_F.MMS

Th: ..lysis gives more weight to early differences in death rates between groups than the previous Cox analysis.

VECTOR SCORE STATISTIC W

-1513 -29 552 990

TEST STATISTICS:	EXACT INVERSE	CONSERVATIVE	D.F.
VALUES OF CHI-SQUARE	2.8389	2.8355	3
PROBABILITIES	.4171	.4177	

TEST STATISTICS FOR ADJUSTED TRENDS:

	CHI-SQUARE	D.F.	LOWER BOUND Z	UPPER BOUND Z
JYG TREND ------- 1	1.8252	1	1.3510	1.3504
JYG PROBABILITIES 2	.1767		.0884	.0884
JYG DEPT FR TREND-3	1.0137			
JYG PROBABILITY -4	.6024			
JYG TOTAL --------5	2.8389			
JYG PROBABILITY -6	.4171			

NUMERATOR OF Z-STATISTIC FOR ADJUSTED TREND (WITHOUT CONT. CORR.)= 1072075.000
SQUARE OF DENOMINATOR OF Z-STATISTIC FOR ADJUSTED TREND= 629725120667.188

Source: AXCAN PHARMA, INC. [redacted] 2CNTL
List of Organ Names and Tumor Names

Animal: Mouse

Sex: Female

No.	Organ Name	Tumor Name
1	LUNG	ADENOMA
2	LUNG	ADENOCARCINOMA
3	LYMPHORETICULAR SYSTEM	MALLGNANT LYMPHOMA
4	PITUITARY	ADENOMA
5	SPLEEN	HEMANGLOSARCOMA
6	SPLEEN	HEMANGLOMA
7	THYROID	FOLLICULAR ADENOMA
8	THYROID	PARAFOLLICULAR ADENOMA
9	MAMMARY GLAND	ADENOCARCINOMA
10	STOMACH	LELOMYOMA
11	STOMACH	FIBROSARCOMA
12	OVARY	TUBULAR ADENOMA
13	OVARY	PAPILLARY CYSTADENOMA
14	PANCREAS	ISLET ADENOMA
15	UTERUS	HEMANGLOSARCOMA
16	UTERUS	ENDOMETRIAL POLYP
17	UTERUS	OSTEOSAROMA
18	UTERUS	LEIOMYOSARCOMA
19	UTERUS	ADENOCARCINOMA
20	UTERUS	LELOMYOMA
21	UTERUS	FIBROSARCOMA
22	VAGINA	POLYP
23	MISC.	ADENOCARCINOMA PRIMARY SITE UN
24	DUODENUM	FIBROSARCOMA
25	INTEGUMENT	TRICHOEPITHELLOMA
26	INTEGUMENT	FIBROSARCOMA
27	LIVER	HEPATOCELLULAR CARCINOMA
28	LIVER	HEPATOCELLULAR ADENOMA
29	LIVER	HEMANGLOSARCOMA
30	LIVER	HEMANGLOMA

Source: AXCAN PHARMA, INC. [redacted] 2CNTL
Test of Trend Based on the Tumor Data

Animal Type: Mouse

Sex: Female

Organ Code	Tumor Code	Organ Name	Tumor Name	Tumor Type	Exact p	Asymp p	#Incid /Ctrls	Dose 25	Dose 150	Dose 1000
10	4	LUNG	ADENOCARCINOMA	M-	(0.9780)	0.9118	4/98	2	0	0
10	13	LUNG	ADENOMA	M-	(0.6129)	0.6198	19/98	3	4	6
11	14	LYMPHORETICU	MALLGNANT LYMP	M-	(0.0467)	0.0417	17/98	9	16	15
12	13	PITUITARY	ADENOMA	M-	(0.7138)	0.7478	4/98	2	2	1
13	8	SPLEEN	HEMANGLOMA	S-	0.1667	(0.0136)	0/98	0	0	1
13	12	SPLEEN	HEMANGLOSARCOM	M-	(0.6242)	0.6070	3/98	1	1	1
15	17	THYROID	FOLLICULAR ADE	S-	0.0276	(0.0009)	0/98	0	0	2
15	18	THYROID	PARAFOLLICULAR	S-	0.1691	(0.0143)	0/98	0	0	1
16	4	MAMMARY GLAN	ADENOCARCINOMA	S-	0.5341	(0.5193)	6/98	4	1	3
17	7	STOMACH	FIBROSARCOMA	S-	0.5735	(0.6893)	0/98	1	0	0
17	5	STOMACH	LELOMYOMA	S-	1.0000	(0.7421)	1/98	0	0	0
18	22	OVARY	PAPILLARY CYST	M-	(0.5617)	0.4755	2/98	1	0	1
18	21	OVARY	TUBULAR ADENOM	S-	0.1691	(0.0143)	0/98	0	0	1
19	23	PANCREAS	ISLET ADENOMA	S-	1.0000	(0.7558)	1/98	0	0	0
20	4	UTERUS	ADENOCARCINOMA	S-	1.0000	(0.7244)	1/98	0	0	0
20	24	UTERUS	ENDOMETRIAL PO	S-	0.8290	(0.7899)	5/98	3	0	1
20	7	UTERUS	FIBROSARCOMA	S-	1.0000	(0.7132)	1/98	0	0	0
20	12	UTERUS	HEMANGLOSARCOM	S-	0.4287	(0.6444)	0/98	0	2	0
20	26	UTERUS	LEIOMYOSARCOMA	S-	0.3676	(0.5596)	0/98	0	1	0
20	5	UTERUS	LELOMYOMA	M-	(0.9266)	0.9299	4/98	2	2	0
20	25	UTERUS	OSTEOSAROMA	S-	1.0000	(0.7153)	1/98	0	0	0
21	27	VAGINA	POLYP	S-	0.5735	(0.6893)	0/98	1	0	0
22	28	MISC.	ADENOCARCINOMA	S-	1.0000	(0.7132)	1/98	0	0	0
3	7	DUODENUM	FIBROSARCOMA	S-	0.5735	(0.6893)	0/98	1	0	0
6	7	INTEGUMENT	FIBROSARCOMA	S-	0.5112	(0.3550)	2/98	0	0	1
6	19	INTEGUMENT	TRICHOEPITHELL	M-	(0.6777)	0.7950	0/98	2	0	0
9	8	LIVER	HEMANGLOMA	S-	1.0000	(0.7132)	1/98	0	0	0
9	12	LIVER	HEMANGLOSARCOM	M-	(0.2618)	0.2652	0/98	2	0	1
9	11	LIVER	HEPATOCELLULAR	S-	0.2280	(0.3079)	1/98	0	2	1
9	10	LIVER	HEPATOCELLULAR	S-	0.7598	(0.8398)	1/98	3	1	0

Note: Tumor Type=M indicates that the tumor is fatal to some but not all animals.
Tumor Type=S indicates that the tumor is fatal or non-fatal to all animals.

Symbol '+' indicates a significant positive linear dose-tumor trend.
Symbol '-' indicates a non-significant positive linear dose-tumor trend.

Source: AXCAN PHARMA, INC. [redacted] 2CNTL

Pairwise Comparisons
Dosage Pair: 0 vs 1000

Species: Rat
Sex: Female

rgan	Organ Code	Tumor	Tumor Code	Strata	Row	_0	_1E3	Exact p	Asmp p
UNG	10	ADENOMA	13	2	1	1	0	(0.8914)	0.8398
UNG	10	ADENOMA	13	2	2	6	5	(0.8914)	0.8398
UNG	10	ADENOMA	13	3	1	2	0	(0.8914)	0.8398
UNG	10	ADENOMA	13	3	2	10	7	(0.8914)	0.8398
UNG	10	ADENOMA	13	4	1	3	2	(0.8914)	0.8398
UNG	10	ADENOMA	13	4	2	12	9	(0.8914)	0.8398
UNG	10	ADENOMA	13	9	1	10	1	(0.8914)	0.8398
UNG	10	ADENOMA	13	9	2	48	22	(0.8914)	0.8398
UNG	10	ADENOMA	13	74	1	0	1	(0.8914)	0.8398
UNG	10	ADENOMA	13	74	2	91	45	(0.8914)	0.8398
UNG	10	ADENOMA	13	86	1	0	1	(0.8914)	0.8398
UNG	10	ADENOMA	13	86	2	84	38	(0.8914)	0.8398
UNG	10	ADENOMA	13	92	1	1	0	(0.8914)	0.8398
UNG	10	ADENOMA	13	92	2	75	35	(0.8914)	0.8398
UNG	10	ADENOMA	13	96	1	1	1	(0.8914)	0.8398
UNG	10	ADENOMA	13	96	2	71	28	(0.8914)	0.8398
UNG	10	ADENOMA	13	97	1	1	0	(0.8914)	0.8398
UNG	10	ADENOMA	13	97	2	70	26	(0.8914)	0.8398
UNG	10	ADENOCARCINOMA	4	2	1	0	0	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	2	2	7	6	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	4	1	0	0	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	4	2	17	12	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	9	1	3	0	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	9	2	55	23	(1.0000)	0.8970
UN	10	ADENOCARCINOMA	4	77	1	0	0	(1.0000)	0.8970
UN	10	ADENOCARCINOMA	4	77	2	88	43	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	92	1	0	0	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	92	2	76	35	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	103	1	1	0	(1.0000)	0.8970
UNG	10	ADENOCARCINOMA	4	103	2	60	23	(1.0000)	0.8970
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	1	0	0	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	1	2	3	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	1	1	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	2	2	5	3	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	1	2	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	3	2	10	4	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	1	7	2	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	4	2	9	7	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	1	4	3	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	9	2	54	20	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	51	1	0	0	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	51	2	95	50	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	59	1	0	0	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	59	2	95	49	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	73	1	0	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	73	2	92	46	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	1	0	0	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	74	2	91	46	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	76	1	1	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	76	2	89	44	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	84	1	0	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	84	2	86	40	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	86	1	0	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	86	2	84	38	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	90	1	0	1	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	90	2	79	36	(0.0469)	*0.0285
YMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	92	1	1	0	(0.0469)	*0.0285
YMP TICULAR SYST	11	MALLGNANT LYMPHOMA	14	92	2	75	35	(0.0469)	*0.0285

LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	93	1	0	1	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	93	2	74	33	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	1	0	0	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	94	2	72	31	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	95	1	0	0	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	95	2	72	31	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	96	1	0	1	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	96	2	72	28	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	97	1	1	0	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	97	2	70	26	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	1	0	1	(0.0469)	*0.0285
LYMPHORETICULAR SYST	11	MALLGNANT LYMPHOMA	14	98	2	67	24	(0.0469)	*0.0285
PITUITARY	12	ADENOMA	13	3	1	0	0	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	3	2	11	7	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	4	1	1	0	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	4	2	17	12	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	9	1	2	0	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	9	2	56	23	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	85	1	0	1	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	85	2	86	39	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	87	1	1	0	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	87	2	83	38	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	102	1	0	0	(0.8562)	0.7179
PITUITARY	12	ADENOMA	13	102	2	63	23	(0.8562)	0.7179
SPLEEN	13	HEMANGLOSARCOMA	12	2	1	1	0	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	2	2	6	6	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	3	1	0	1	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	3	2	12	7	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	4	1	0	0	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	4	2	17	12	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	9	1	1	0	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	9	2	57	23	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	63	1	0	0	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	63	2	95	48	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	103	1	1	0	(0.8320)	0.6717
SPLEEN	13	HEMANGLOSARCOMA	12	103	2	60	23	(0.8320)	0.6717
SPLEEN	13	HEMANGLOMA	8	4	1	0	0	0.2717	(0.0509)
SPLEEN	13	HEMANGLOMA	8	4	2	18	11	0.2717	(0.0509)
SPLEEN	13	HEMANGLOMA	8	98	1	0	1	0.2717	(0.0509)
SPLEEN	13	HEMANGLOMA	8	98	2	67	24	0.2717	(0.0509)
THYROID	15	FOLLICULAR ADENOMA	17	9	1	0	2	0.0781	(0.0119)
THYROID	15	FOLLICULAR ADENOMA	17	9	2	58	21	0.0781	(0.0119)
THYROID	15	PARAFOLLICULAR ADENO	18	9	1	0	1	0.2840	(0.0563)
THYROID	15	PARAFOLLICULAR ADENO	18	9	2	58	22	0.2840	(0.0563)
MAMMARY GLAND	16	ADENOCARCINOMA	4	2	1	0	0	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	2	2	7	6	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	3	1	0	0	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	3	2	12	8	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	4	1	1	2	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	4	2	17	10	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	9	1	5	1	0.6035	(0.4717)
MAMMARY GLAND	16	ADENOCARCINOMA	4	9	2	53	22	0.6035	(0.4717)
STOMACH	17	LELOMYOMA	5	4	1	1	0	1.0000	(0.7932)
STOMACH	17	LELOMYOMA	5	4	2	17	12	1.0000	(0.7932)
STOMACH	17	FIBROSARCOMA	7	9	1	0	0		
STOMACH	17	FIBROSARCOMA	7	9	2	58	23		
OVARY	18	TUBULAR ADENOMA	21	9	1	0	1	0.2840	(0.0563)
OVARY	18	TUBULAR ADENOMA	21	9	2	58	22	0.2840	(0.0563)
OVARY	18	PAPILLARY CYSTADENOM	22	2	1	1	0	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	2	2	6	6	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	3	1	0	0	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	3	2	12	7	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	4	1	1	0	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	4	2	17	12	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	9	1	0	0	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	9	2	58	23	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	85	1	0	1	(0.7795)	0.5846
OVARY	18	PAPILLARY CYSTADENOM	22	85	2	86	39	(0.7795)	0.5846

PANCREAS	19	ISLET ADENOMA	23	2	1	1	0	1.0000	(0.8230)
PANCREAS	19	ISLET ADENOMA	23	2	2	6	6	1.0000	(0.8230)
U	20	HEMANGLOSARCOMA	12	3	1	0	0		
U	20	HEMANGLOSARCOMA	12	3	2	12	8		
UTERUS	20	HEMANGLOSARCOMA	12	9	1	0	0		
UTERUS	20	HEMANGLOSARCOMA	12	9	2	58	23		
UTERUS	20	ENDOMETRIAL POLYP	24	4	1	0	1	0.8927	(0.7725)
UTERUS	20	ENDOMETRIAL POLYP	24	4	2	18	11	0.8927	(0.7725)
UTERUS	20	ENDOMETRIAL POLYP	24	9	1	5	0	0.8927	(0.7725)
UTERUS	20	ENDOMETRIAL POLYP	24	9	2	53	23	0.8927	(0.7725)
UTERUS	20	OSTEOSAROMA	25	4	1	0	0	1.0000	(0.7375)
UTERUS	20	OSTEOSAROMA	25	4	2	17	12	1.0000	(0.7375)
UTERUS	20	OSTEOSAROMA	25	96	1	1	0	1.0000	(0.7375)
UTERUS	20	OSTEOSAROMA	25	96	2	71	29	1.0000	(0.7375)
UTERUS	20	LEIOMYOSARCOMA	26	9	1	0	0		
UTERUS	20	LEIOMYOSARCOMA	26	9	2	58	23		
UTERUS	20	ADENOCARCINOMA	4	3	1	0	0	1.0000	(0.7527)
UTERUS	20	ADENOCARCINOMA	4	3	2	11	8	1.0000	(0.7527)
UTERUS	20	ADENOCARCINOMA	4	85	1	1	0	1.0000	(0.7527)
UTERUS	20	ADENOCARCINOMA	4	85	2	85	40	1.0000	(0.7527)
UTERUS	20	LELOMYOMA	5	2	1	0	0	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	2	2	7	6	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	3	1	1	0	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	3	2	11	8	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	4	1	2	0	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	4	2	16	12	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	9	1	1	0	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	9	2	57	23	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	70	1	0	0	(1.0000)	0.9405
UTERUS	20	LELOMYOMA	5	70	2	94	47	(1.0000)	0.9405
UTERUS	20	FIBROSARCOMA	7	9	1	1	0	1.0000	(0.7360)
UTERUS	20	FIBROSARCOMA	7	9	2	57	23	1.0000	(0.7360)
VAGINA	21	POLYP	27	9	1	0	0		
VAGINA	21	POLYP	27	9	2	58	23		
HISC	22	ADENOCARCINOMA PRIMA	28	9	1	1	0	1.0000	(0.7360)
HIS	22	ADENOCARCINOMA PRIMA	28	9	2	57	23	1.0000	(0.7360)
DUO	3	FIBROSARCOMA	7	9	1	0	0		
DUODENUM	3	FIBROSARCOMA	7	9	2	58	23		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	3	1	0	0		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	3	2	12	8		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	4	1	0	0		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	4	2	18	12		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	95	1	0	0		
NTEGUMENT	6	TRICHOEPITHELLOMA	19	95	2	72	31		
NTEGUMENT	6	FIBROSARCOMA	7	2	1	1	0	0.7687	(0.5694)
NTEGUMENT	6	FIBROSARCOMA	7	2	2	6	6	0.7687	(0.5694)
NTEGUMENT	6	FIBROSARCOMA	7	4	1	0	1	0.7687	(0.5694)
NTEGUMENT	6	FIBROSARCOMA	7	4	2	18	11	0.7687	(0.5694)
NTEGUMENT	6	FIBROSARCOMA	7	9	1	1	0	0.7687	(0.5694)
NTEGUMENT	6	FIBROSARCOMA	7	9	2	57	23	0.7687	(0.5694)
IVER	9	HEPATOCELLULAR CARCI	10	9	1	1	0	1.0000	(0.7360)
IVER	9	HEPATOCELLULAR CARCI	10	9	2	57	23	1.0000	(0.7360)
IVER	9	HEPATOCELLULAR ADENO	11	4	1	0	1	0.5704	(0.3178)
IVER	9	HEPATOCELLULAR ADENO	11	4	2	18	11	0.5704	(0.3178)
IVER	9	HEPATOCELLULAR ADENO	11	9	1	1	0	0.5704	(0.3178)
IVER	9	HEPATOCELLULAR ADENO	11	9	2	57	23	0.5704	(0.3178)
VER	9	HEMANGLOSARCOMA	12	2	1	0	0	(0.3358)	0.0800
VER	9	HEMANGLOSARCOMA	12	2	2	7	5	(0.3358)	0.0800
VER	9	HEMANGLOSARCOMA	12	9	1	0	0	(0.3358)	0.0800
VER	9	HEMANGLOSARCOMA	12	9	2	58	23	(0.3358)	0.0800
VER	9	HEMANGLOSARCOMA	12	74	1	0	1	(0.3358)	0.0800
VER	9	HEMANGLOSARCOMA	12	74	2	91	45	(0.3358)	0.0800
VER	9	HEMANGLOMA	8	9	1	1	0	1.0000	(0.7360)
VER	9	HEMANGLOMA	8	9	2	57	23	1.0000	(0.7360)

Note: An '*' indicates that the dose-tumor association may be significant ($p<0.05$).