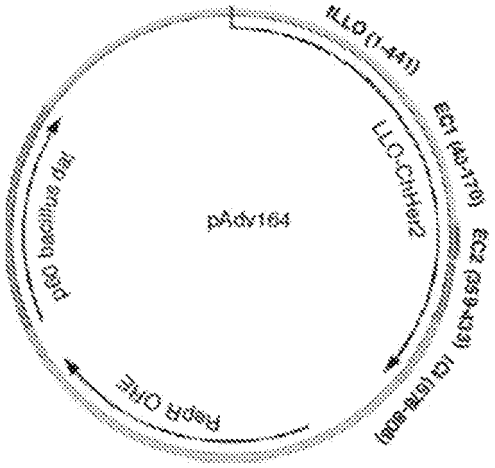
A.


pAdv164
LLO-ChHer2
PrfA dependent pro
PrfA OFF

B.

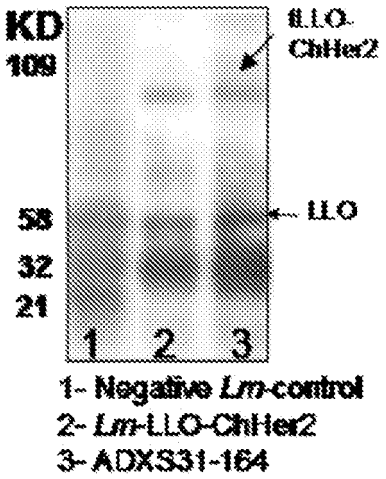

KD
109
58
32
21
fLLO-ChHer2
LLO
1 2 3
1- Negative Lm-control
2- Lm-LLO-ChHer2
3- ADXS31-164

Figure 1

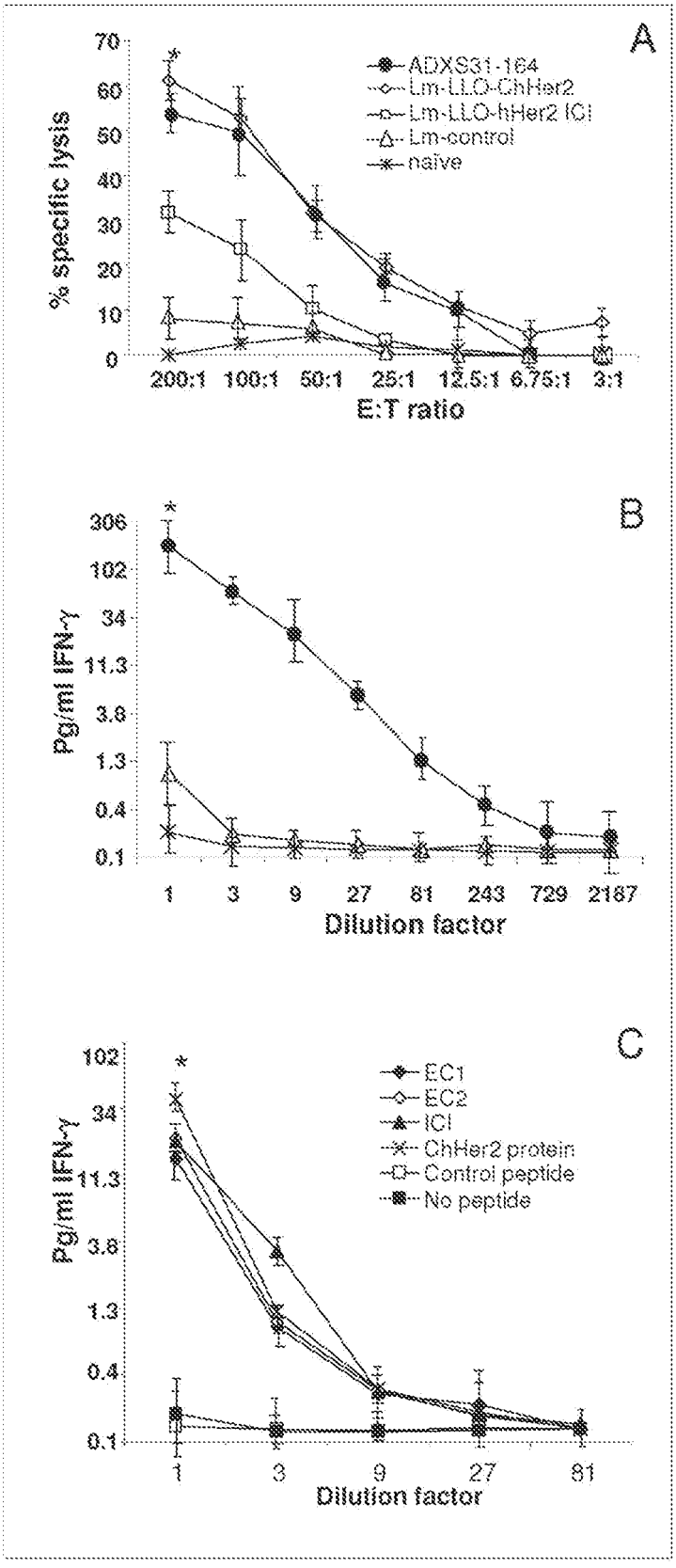

A
% specific lysis
70
60
50
40
30
20
10
0
ADXS31-164
Lm-LLO-ChHer2
Lm-LLO-hHer2 ICI
Lm-control
naïve
200:1 100:1 50:1 25:1 12.5:1 6.75:1 3:1
E:T ratio
B
Pg/ml IFN-γ
306
102
34
11.3
3.8
1.3
0.4
0.1
1 3 9 27 81 243 729 2187
Dilution factor
C
Pg/ml IFN-γ
102
34
11.3
3.8
1.3
0.4
0.1
EC1
EC2
ICI
ChHer2 protein
Control peptide
No peptide
1 3 9 27 81
Dilution factor

Figure 2

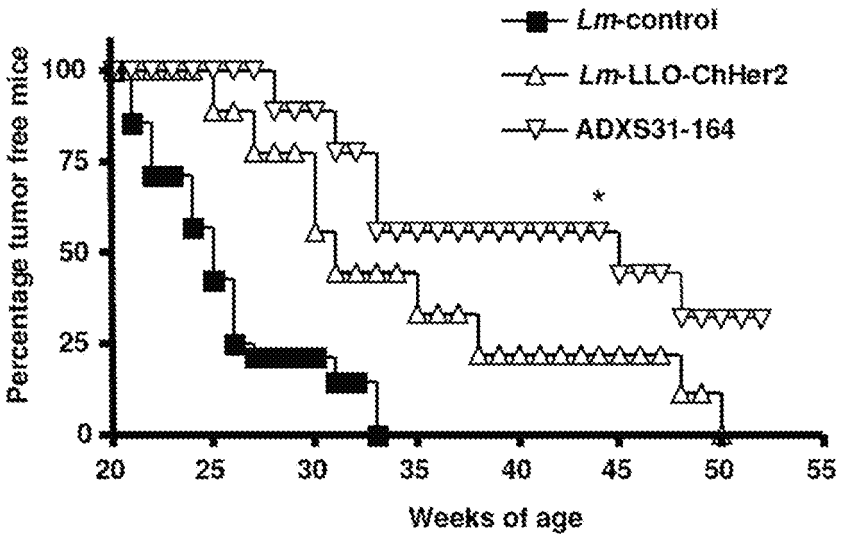


Figure 3

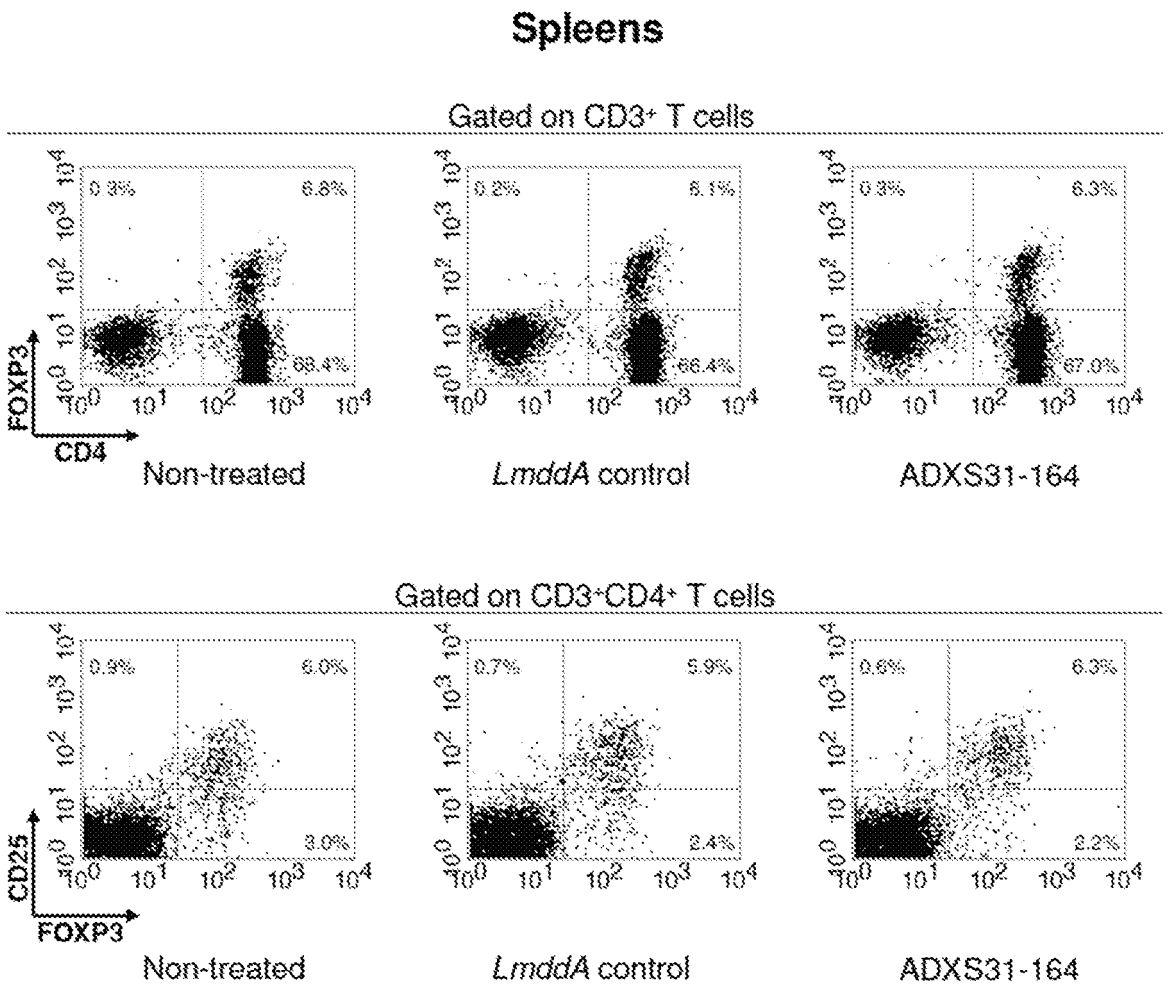
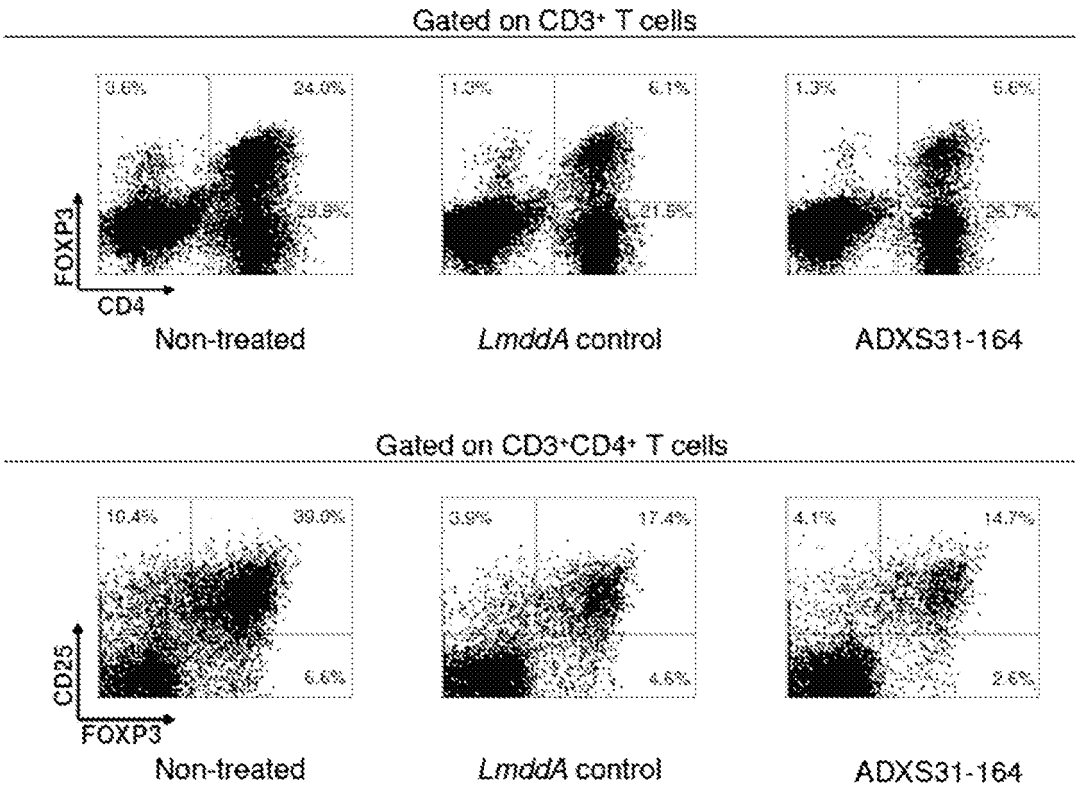


Figure 4

A.


Gated on CD3+ T cells
FOXP3
CD4
Non-treated
LmddA control
ADXS31-164
Gated on CD3+CD4+ T cells
CD25
FOXP3
Non-treated
LmddA control
ADXS31-164

B.

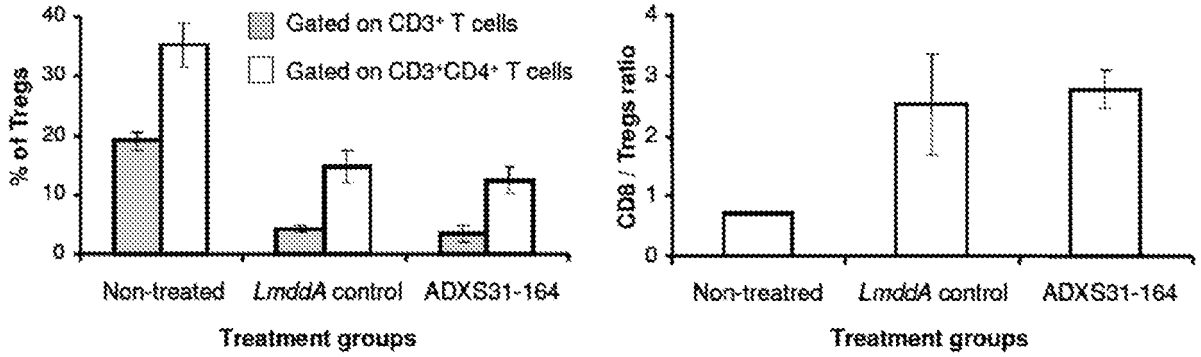
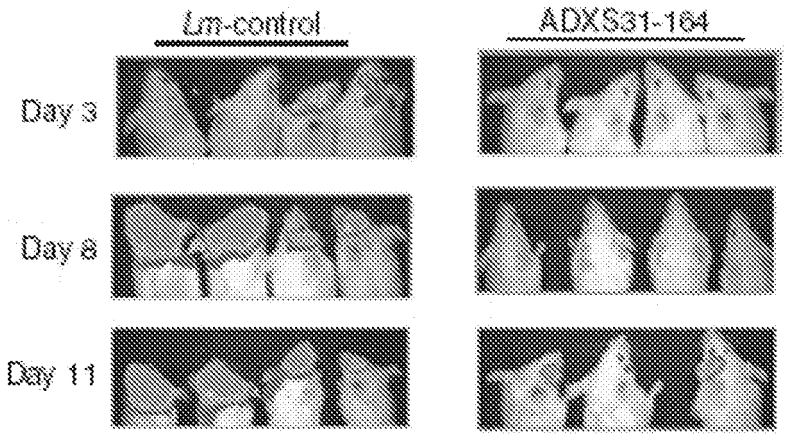
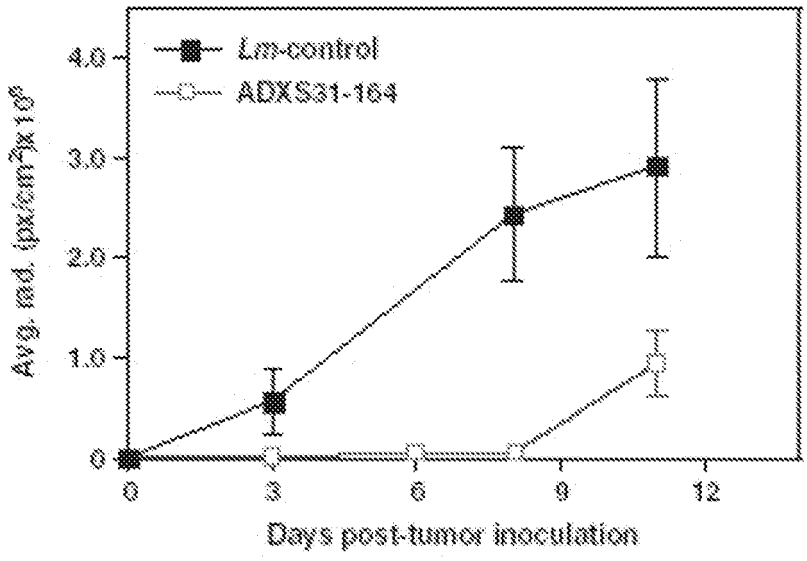

% of Tregs
Gated on CD3+ T cells
Gated on CD3+CD4+ T cells
Non-treated
LmddA control
ADXS31-164
Treatment groups
CD8 / Tregs ratio
Non-treatred
LmddA control
ADXS31-164
Treatment groups

Figure 5

A.


Lm-control
ADXS31-164
Day 3
Day 8
Day 11

B.


Lm-control
ADXS31-164
Avg. rad. (px/cm²)x10⁶
4.0
3.0
2.0
1.0
0
0
3
6
9
12
Days post-tumor inoculation

C.

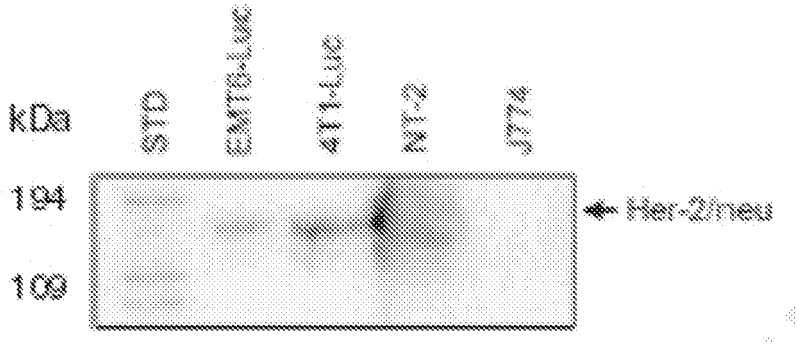
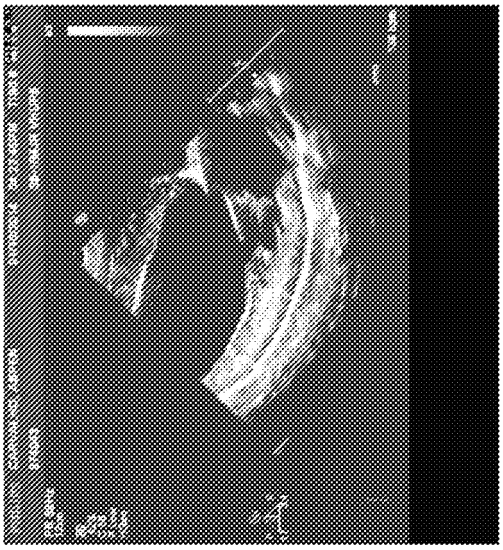

kDa
STD
EMT6-Luc
4T1-Luc
NT-2
J774
194
100
Her-2/neu

Figure 6

AGE	BREED	SEX	TUMOR LOCATION	SUBTYPE	GRADE	HER2 SCORE	DOSE	OVERALL SURVIVAL (days)
Group 1								
12.5	American Pit Bull	FS	Proximal humerus	Osteoblastic	II	2	2 x 10^8	738
11.5	Mixbreed	FS	Distal radius	Osteoblastic	I	5	2 x 10^8	267
9	Labrador	MC	Proximal humerus	Fibroblastic	II	7.5	2 x 10^8	1007+
Group 2								
6	Mixbreed	FS	Distal tibia	Osteoblastic	I	4.5	5 x 10^8	973+
7	Rottweiler	MC	Distal ulnar	Osteoblastic	III	2.25	5 x 10^8	955+
4.5	English Bulldog	MC	Proximal humerus	Osteoblastic	I	4	5 x 10^8	346
Group 3								
6	OES	MC	Distal femur	Osteoblastic	II	1.5	1 x 10^9	774+
9	Greyhound	MC	Proximal humerus	Osteoblastic	II	5	1 x 10^9	444
8	Golden Retriever	MC	Distal ulnar	Fibroblastic	I	3	1 x 10^9	518+
2	Labrador	FS	Proximal tibia	Fibroblastic	I	4.5	1 x 10^9	468+
7.5	Cavalier King Charles	FS	Proximal tibia	Osteoblastic	II	7.5	1 x 10^9	469+
6.5	Golden Retriever	FS	Distal radius	Osteoblastic	I	4.5	1 x 10^9	460+
10	Greyhound	MC	Distal femur	Osteoblastic	II	2	1 x 10^9	276
5.5	Labrador	MC	Distal femur	Osteoblastic	I	9	1 x 10^9	342+
9	Golden Retriever	FS	Distal femur	Osteoblastic	I	6	1 x 10^9	366+
Group 4								
6.6	Great Dane	MC	Distal radius	Osteoblastic	II	7.5	3 x 10^9	259
7	Mixbreed	MC	Proximal humerus	Osteoblastic	II	9	3 x 10^9	375+
6.5	Rottweiler	FS	Proximal humerus	Osteoblastic	II	6	3 x 10^9	362+

Figure 7

A



B

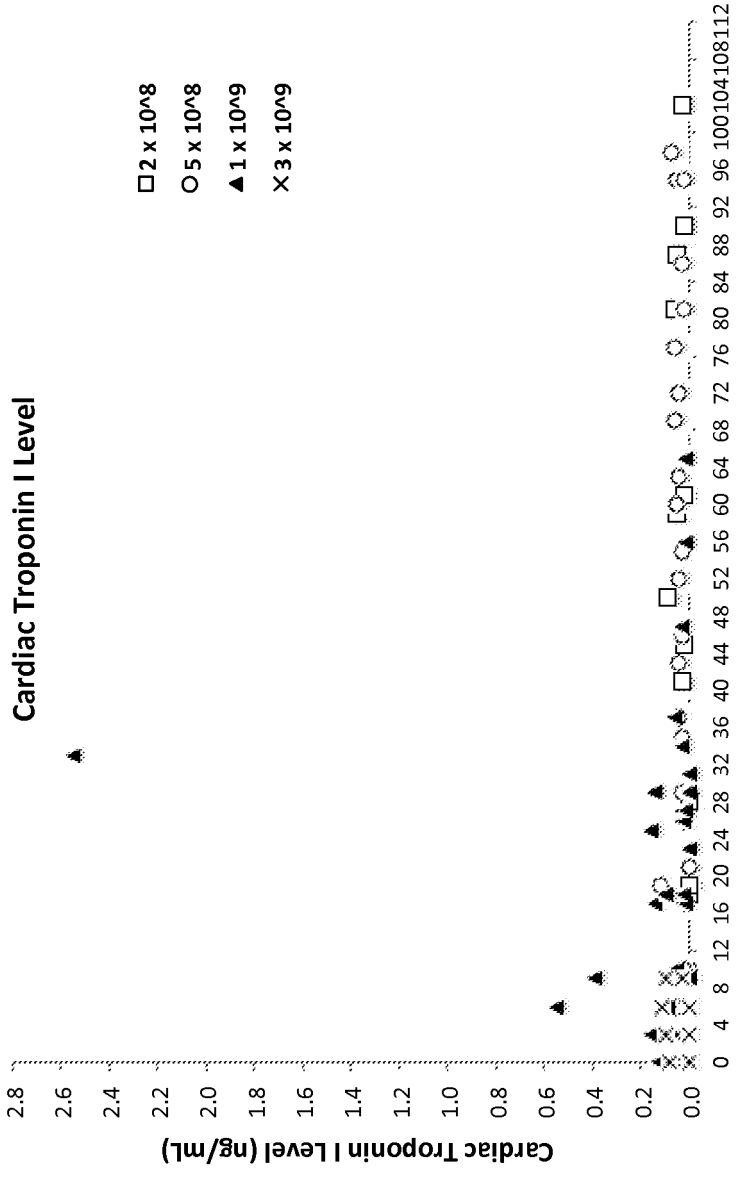

Cardiac Troponin I Level
2 x 10^8
5 x 10^8
1 x 10^9
3 x 10^9
Cardiac Troponin I Level (ng/mL)
0.0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100104108112
Weeks post first vaccination

Figure 8

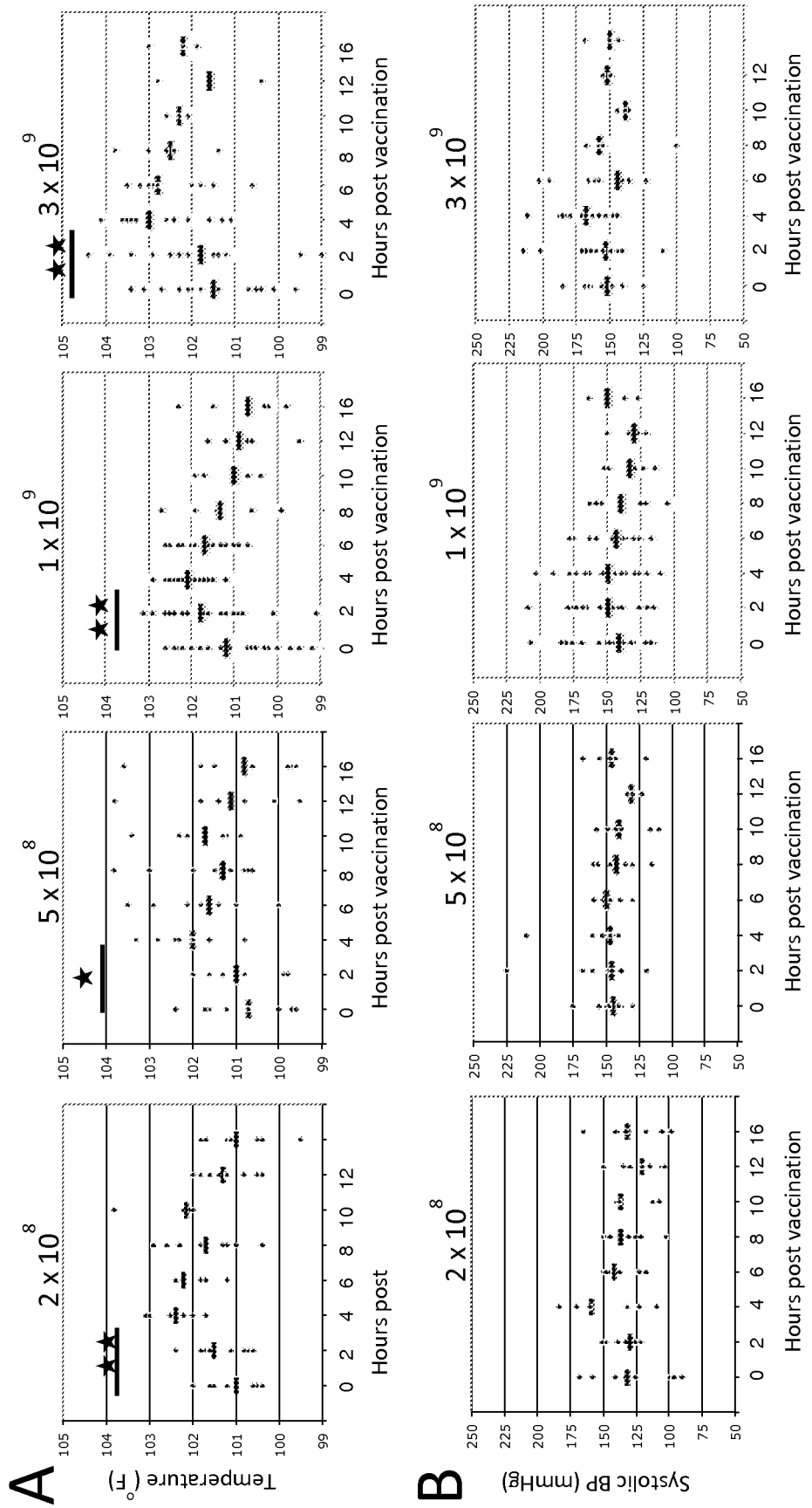

A
B
Temperature (°F)
Systolic BP (mmHg)
2 x 10^8
5 x 10^8
1 x 10^9
3 x 10^9
Hours post
Hours post vaccination

Figure 9

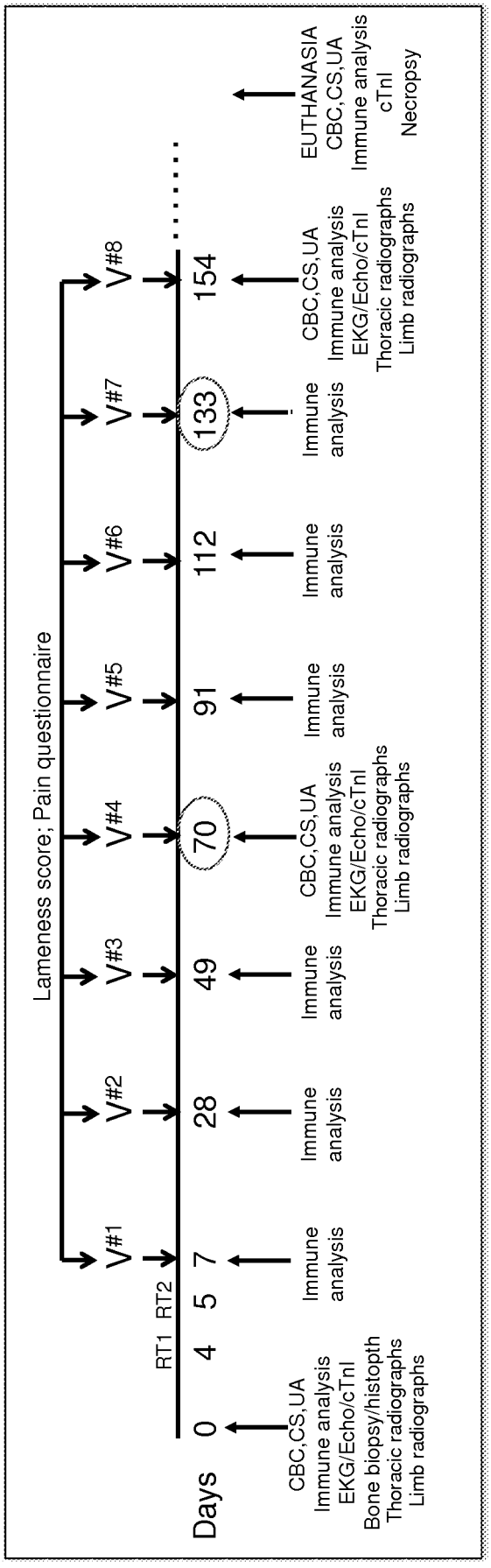

Lameness score; Pain questionnaire
Days
0
4
5
7
28
49
70
91
112
133
154
RT1
RT2
V#1
V#2
V#3
V#4
V#5
V#6
V#7
V#8
CBC,CS,UA
Immune analysis
EKG/Echo/cTnI
Bone biopsy/histopth
Thoracic radiographs
Limb radiographs
Immune analysis
Immune analysis
CBC,CS,UA
Immune analysis
EKG/Echo/cTnI
Thoracic radiographs
Limb radiographs
Immune analysis
Immune analysis
Immune analysis
CBC,CS,UA
Immune analysis
EKG/Echo/cTnI
Thoracic radiographs
Limb radiographs
EUTHANASIA
CBC,CS,UA
Immune analysis
cTnI
Necropsy

Figure 10

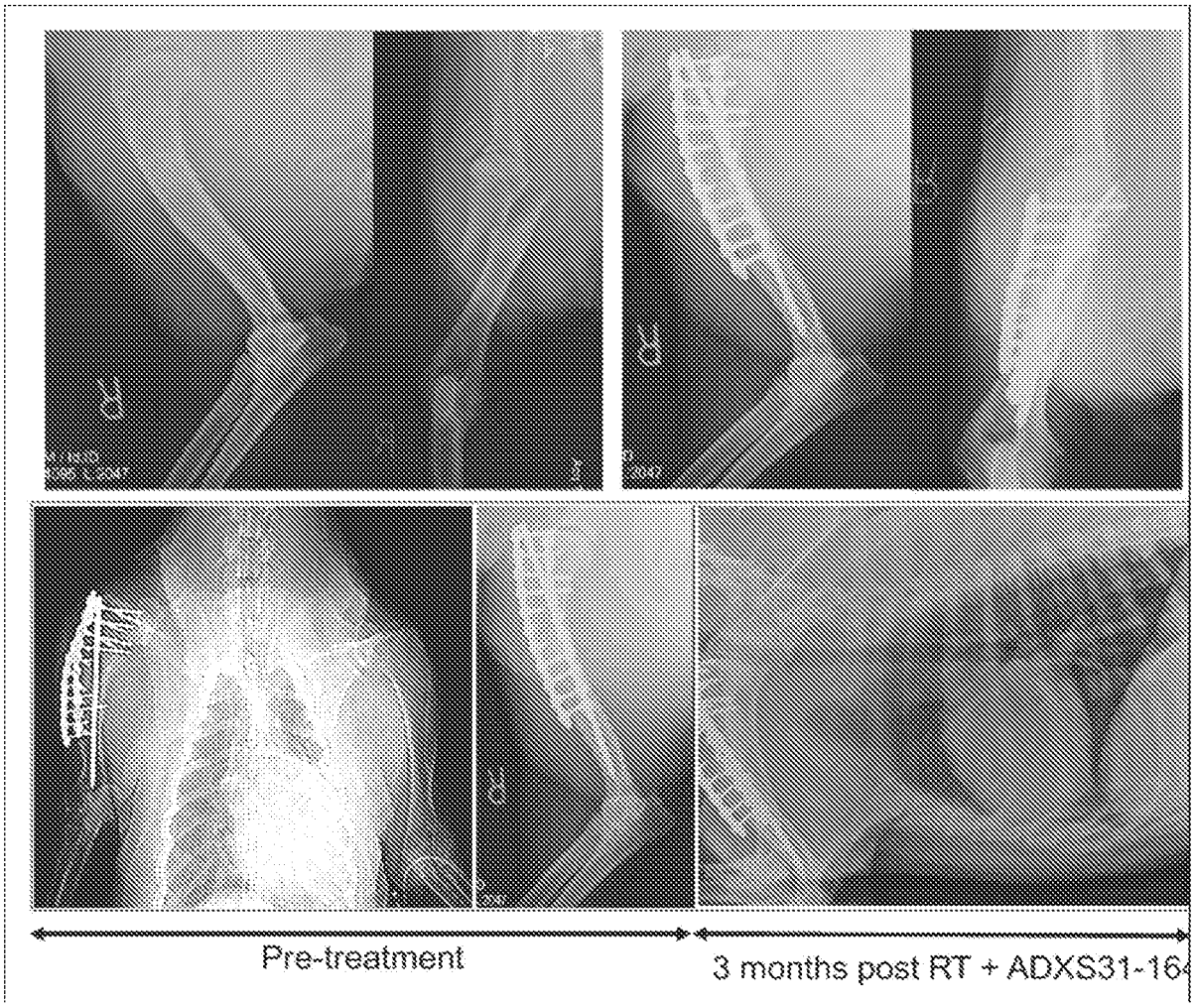


Figure 11

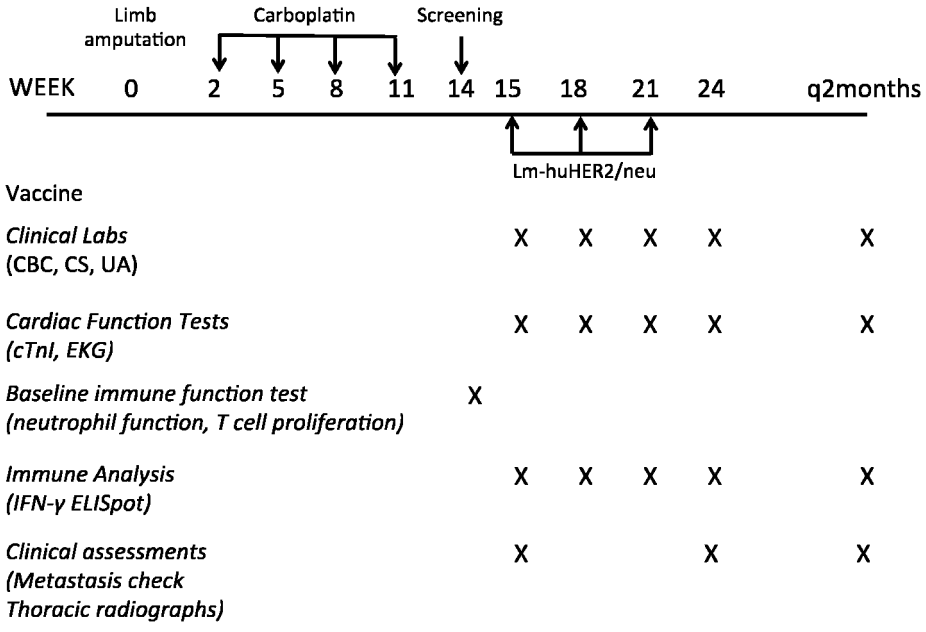


Figure 12

A.

Number of dogs with Treatment Related Adverse Events						
ADXS31-164 dose		$2x10^8$	$5x10^8$	$1x10^9$	$3x10^9$	Total
Number of dogs recruited		3	3	12	5	23
General Disorders						
Pyrexia (T>103)		2	1	4	4	11
Fatigue		1	0	7	2	10
Nausea	Grade 1	1	2	10	2	15
	Grade 2	1	0	0	0	1
Vomiting	Grade 1	1	2	9	3	15
	Grade 2	2	0	0	0	2
Cardiovascular abnormalities						
Arrhythmias	Grade 1	0	1	0	0	1
	Grade 2	0	0	1	1	2
Tachycardia	Grade 1	0	0	2	1	3
	Grade 2	0	0	0	1	1
Hypotension		0	0	0	0	0
Hypertension	Grade 1	2	3	8	5	18
Hematological parameters						
Thrombocytopenia	Grade 1	2	2	6	3	13
	Grade 2	0	0	2	1	3
Biochemical parameters (increased)						
γ-GT		0	2	1	0	3
ALKP	Grade 1	0	1	6	1	8
	Grade 2	0	0	0	1	1
	Grade 3	1	0	0	0	1
ALT	Grade 1	1	1	3	0	5
	Grade 2	0	0	0	1	1
	Grade 3	1	0	0	0	1
AST	Grade 1	1	1	4	2	8
	Grade 2	0	0	2	0	2
	Grade 3	0	0	1	0	1
BUN		0	0	0	0	0
CREA		0	0	0	0	0
Cardiac Troponin I (>0.2)		0	0	1	0	1

B.

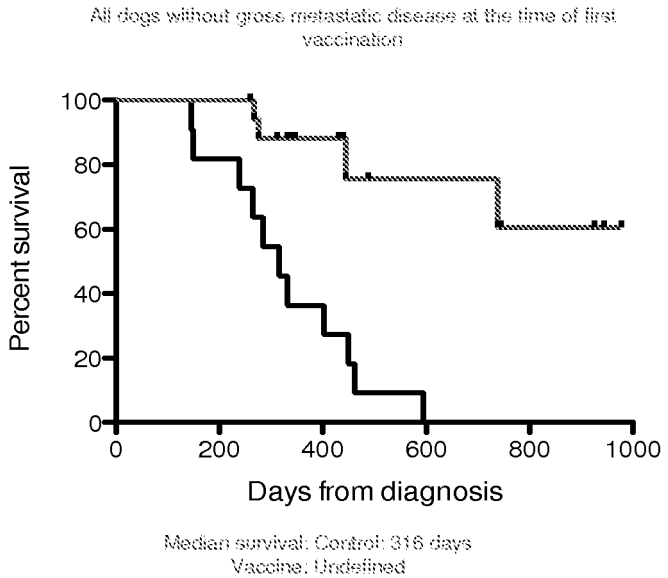


Figure 13

A.

B.

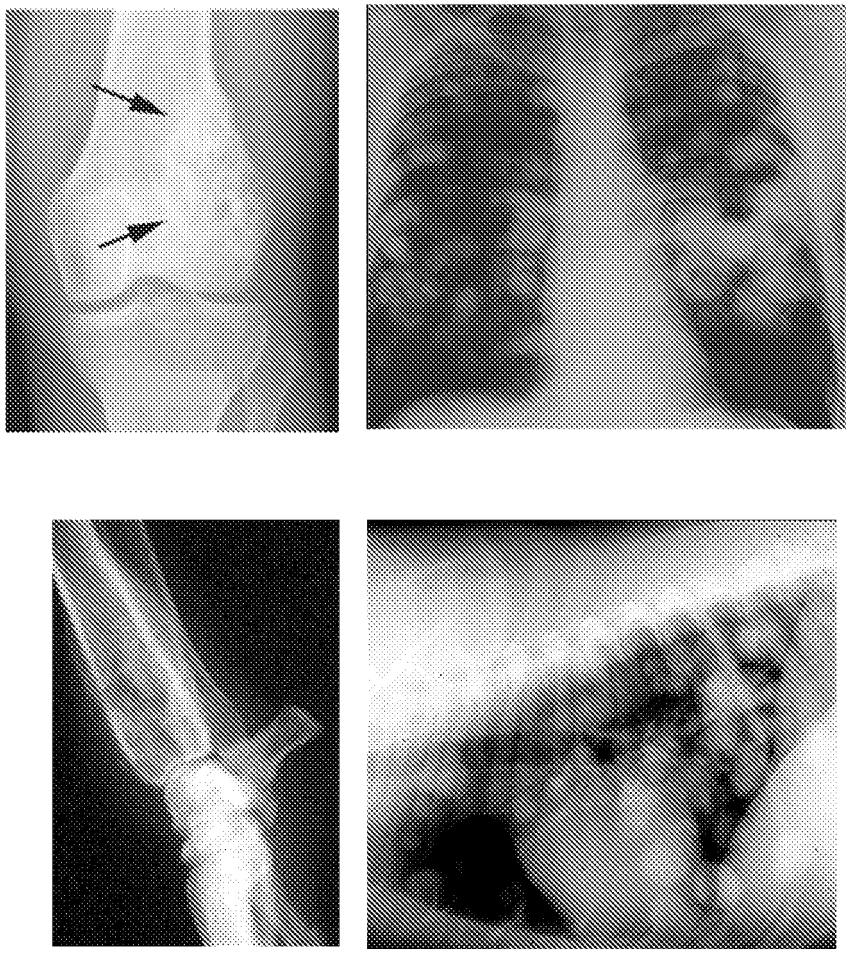


Figure 14

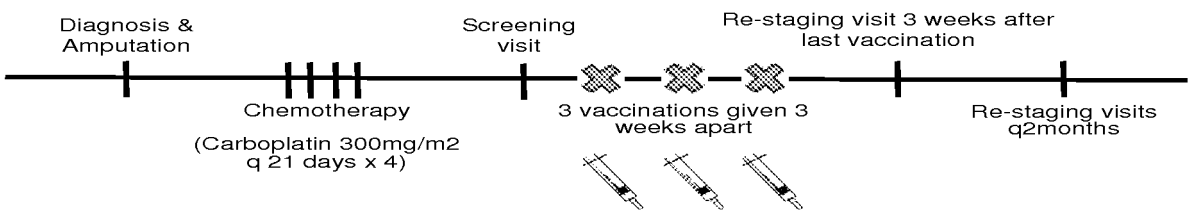


Figure 15

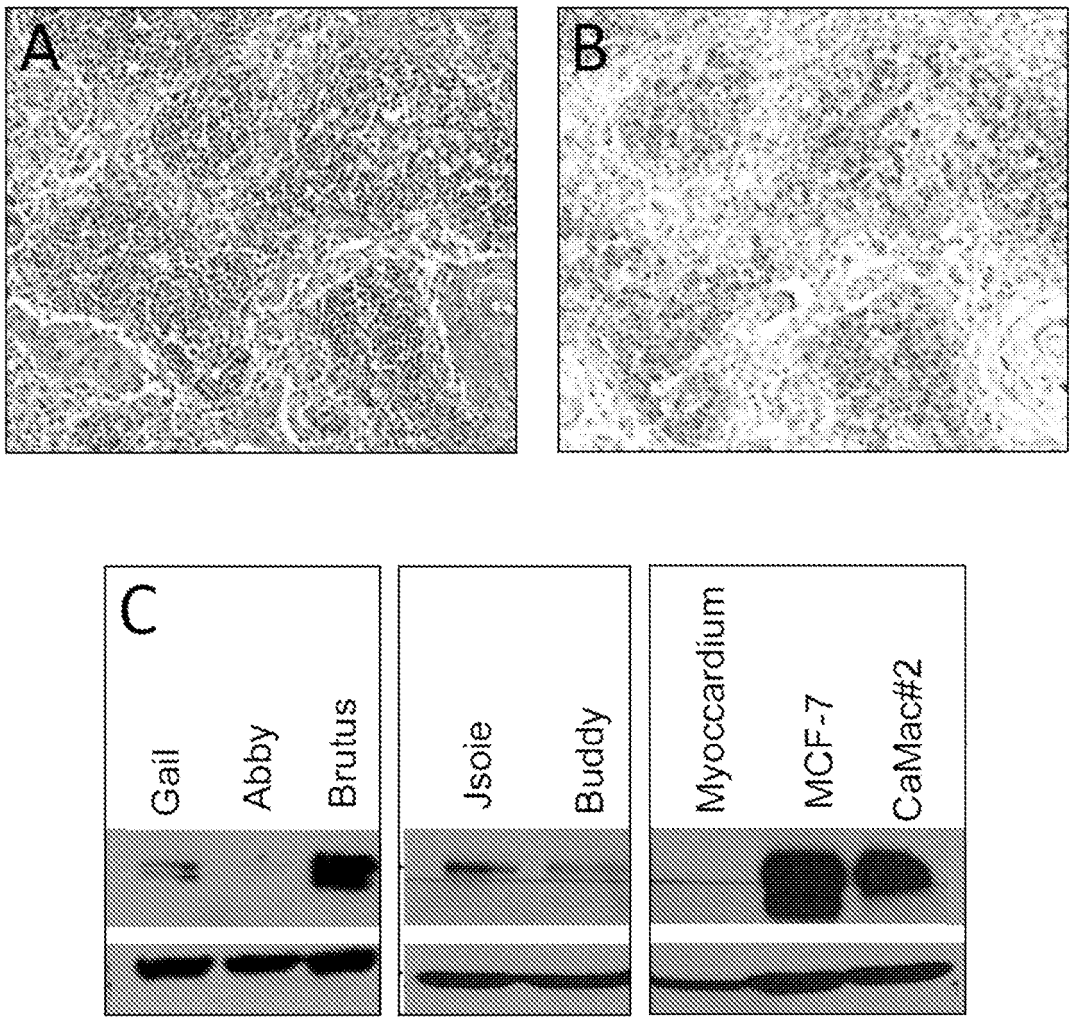


Figure 16

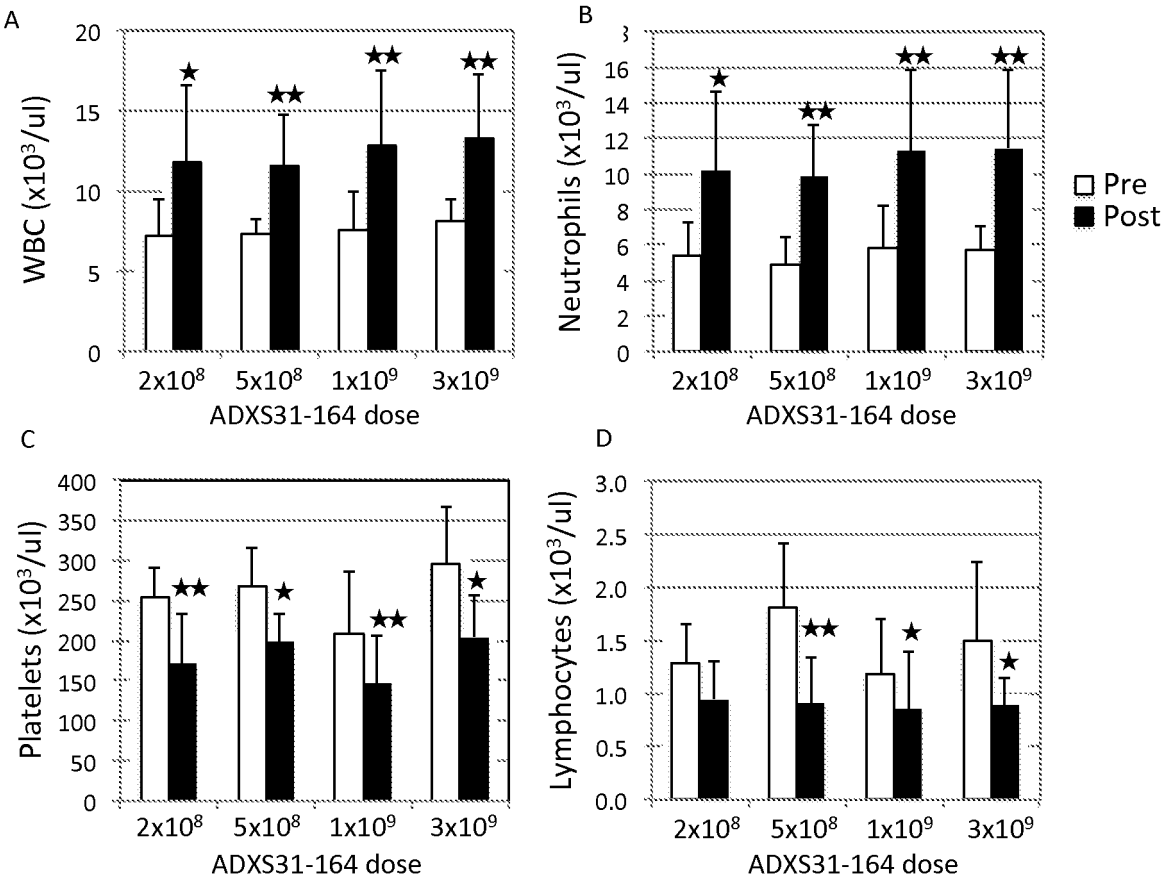

A
WBC (x10³/ul)
20
15
10
5
0
2x10⁸
5x10⁸
1x10⁹
3x10⁹
ADXS31-164 dose
B
Neutrophils (x10³/ul)
16
14
12
10
8
6
4
2
0
2x10⁸
5x10⁸
1x10⁹
3x10⁹
ADXS31-164 dose
Pre
Post
C
Platelets (x10³/ul)
400
350
300
250
200
150
100
50
0
2x10⁸
5x10⁸
1x10⁹
3x10⁹
ADXS31-164 dose
D
Lymphocytes (x10³/ul)
3.0
2.5
2.0
1.5
1.0
0.5
0.0
2x10⁸
5x10⁸
1x10⁹
3x10⁹
ADXS31-164 dose

Figure 17

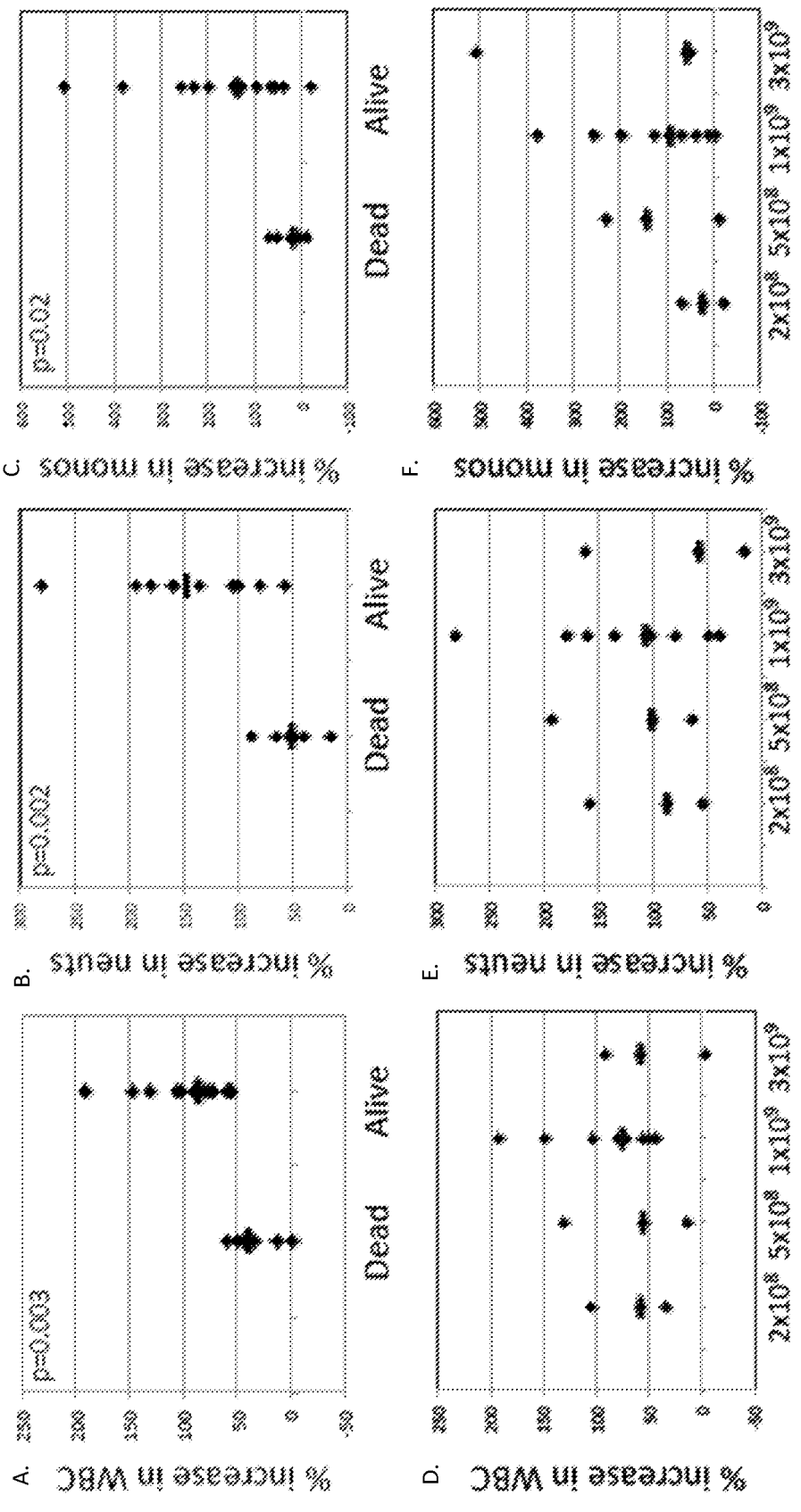

A.
% increase in WBC
p=0.003
Dead
Alive
B.
% increase in neuts
p=0.002
Dead
Alive
C.
% increase in monos
p=0.02
Dead
Alive
D.
% increase in WBC
2x10^8 5x10^8 1x10^9 3x10^9
E.
% increase in neuts
2x10^8 5x10^8 1x10^9 3x10^9
F.
% increase in monos
2x10^8 5x10^8 1x10^9 3x10^9

Figure 18

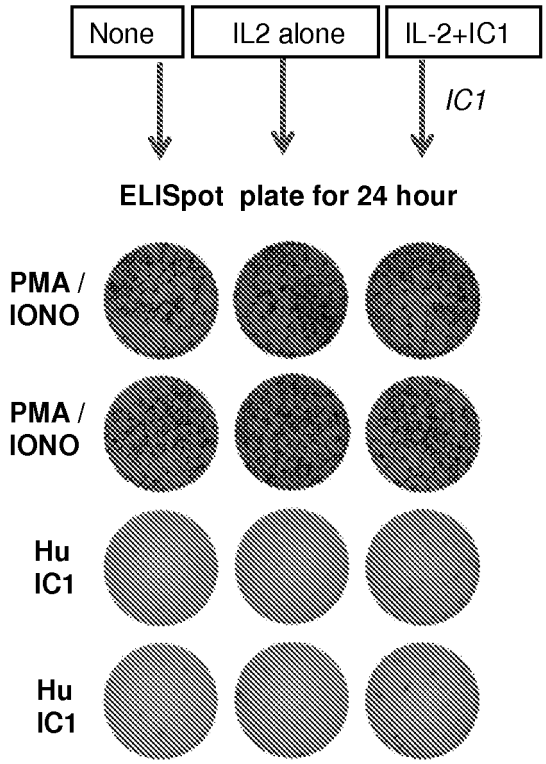


Figure 19

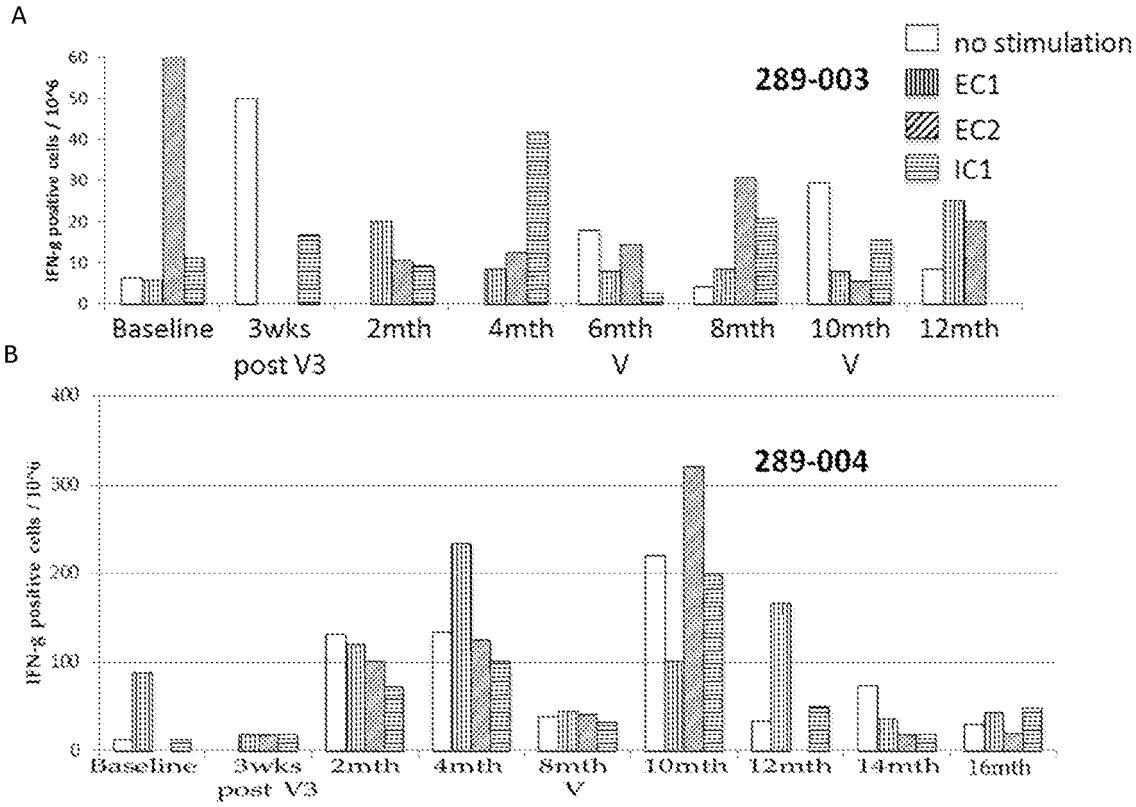
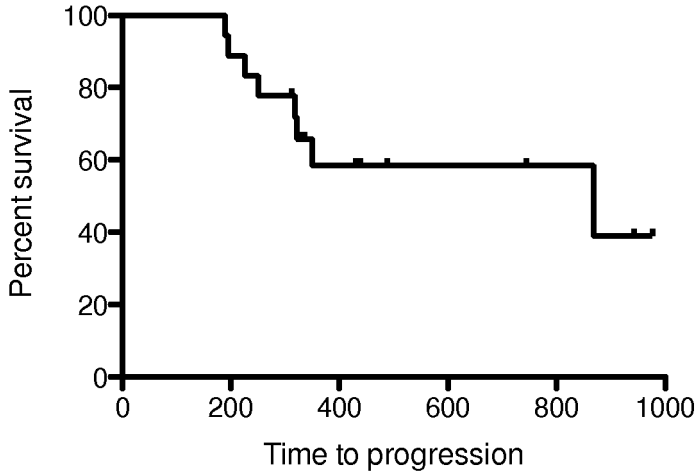


Figure 20

A


Time To Metastasis
Percent survival
100
80
60
40
20
0
0
200
400
600
800
1000
Time to progression

B

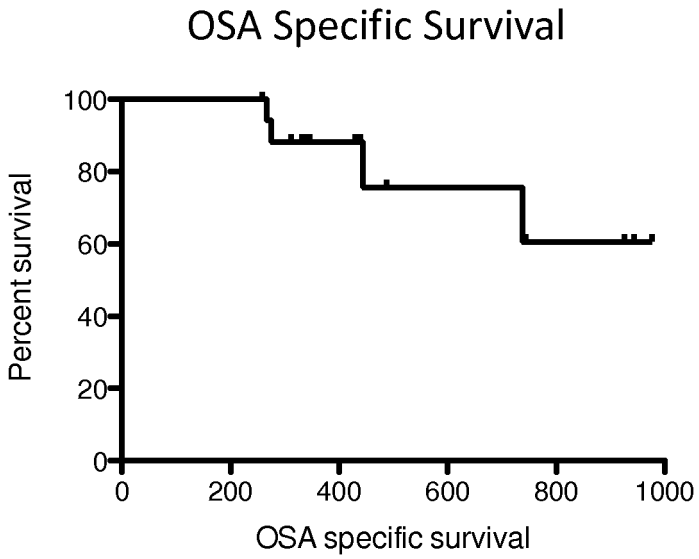

OSA Specific Survival
Percent survival
100
80
60
40
20
0
0
200
400
600
800
1000
OSA specific survival

Figure 21

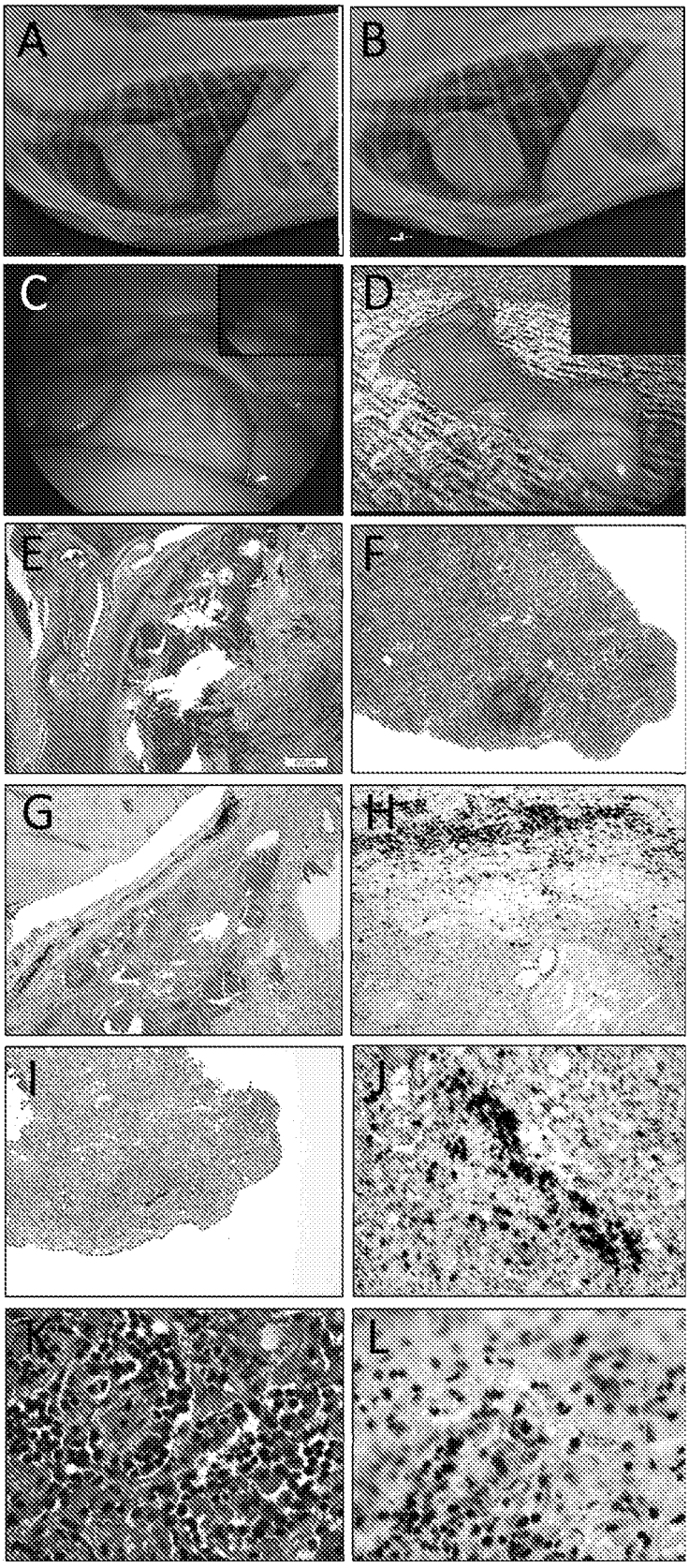


Figure 22

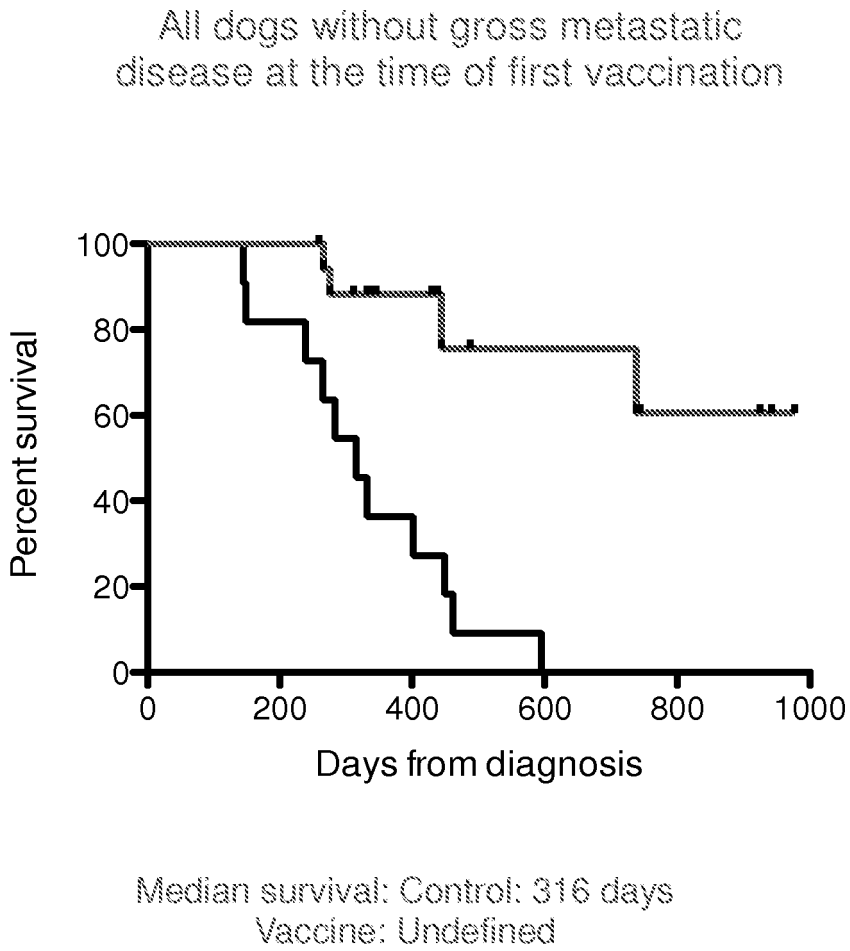

All dogs without gross metastatic disease at the time of first vaccination
Percent survival
100
80
60
40
20
0
0
200
400
600
800
1000
Days from diagnosis
Median survival: Control: 316 days
Vaccine: Undefined

Figure 23

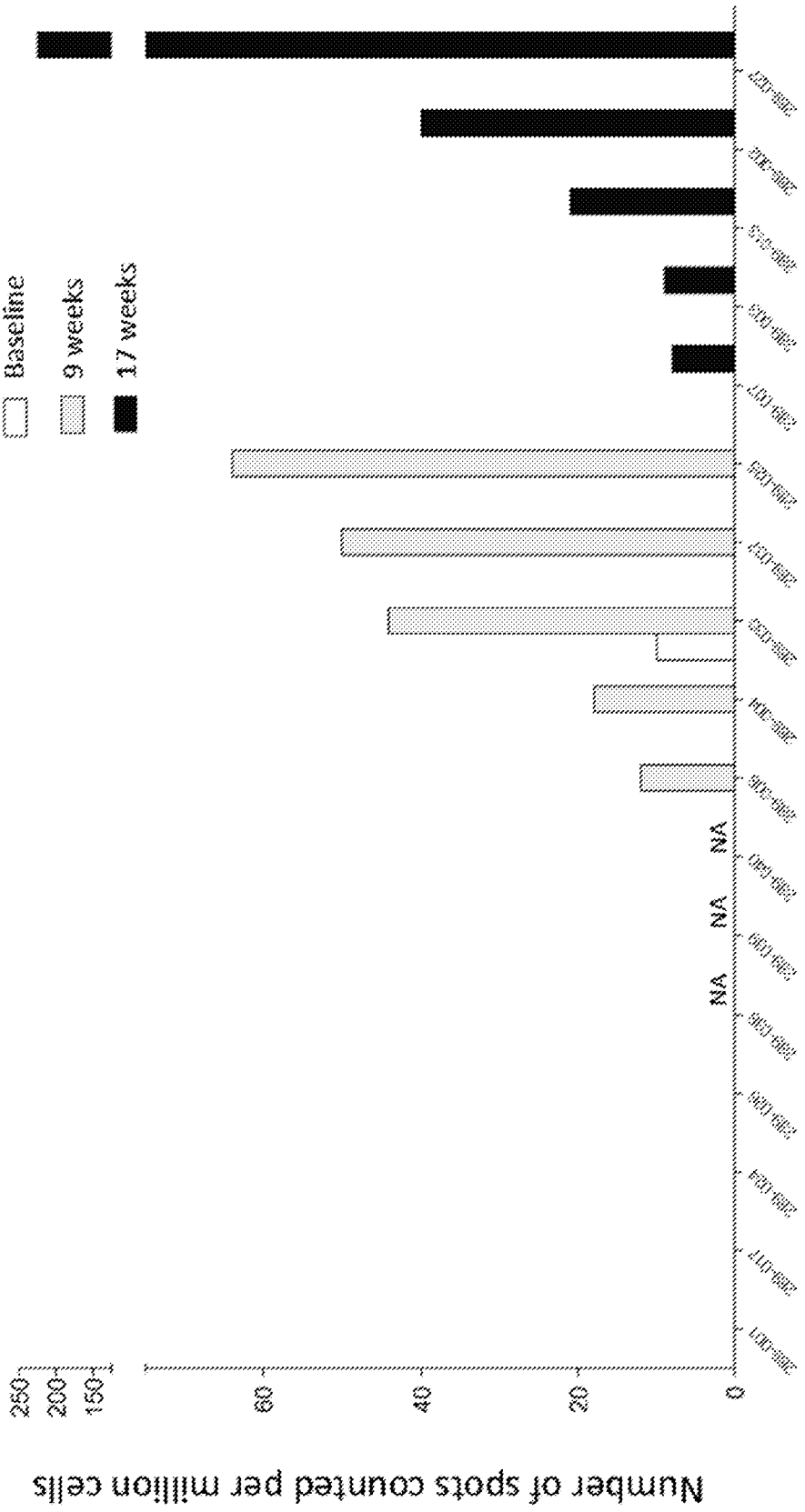

Baseline
9 weeks
17 weeks
Number of spots counted per million cells
250
200
150
60
40
20
0
NA
NA
NA
Dog number

Figure 24

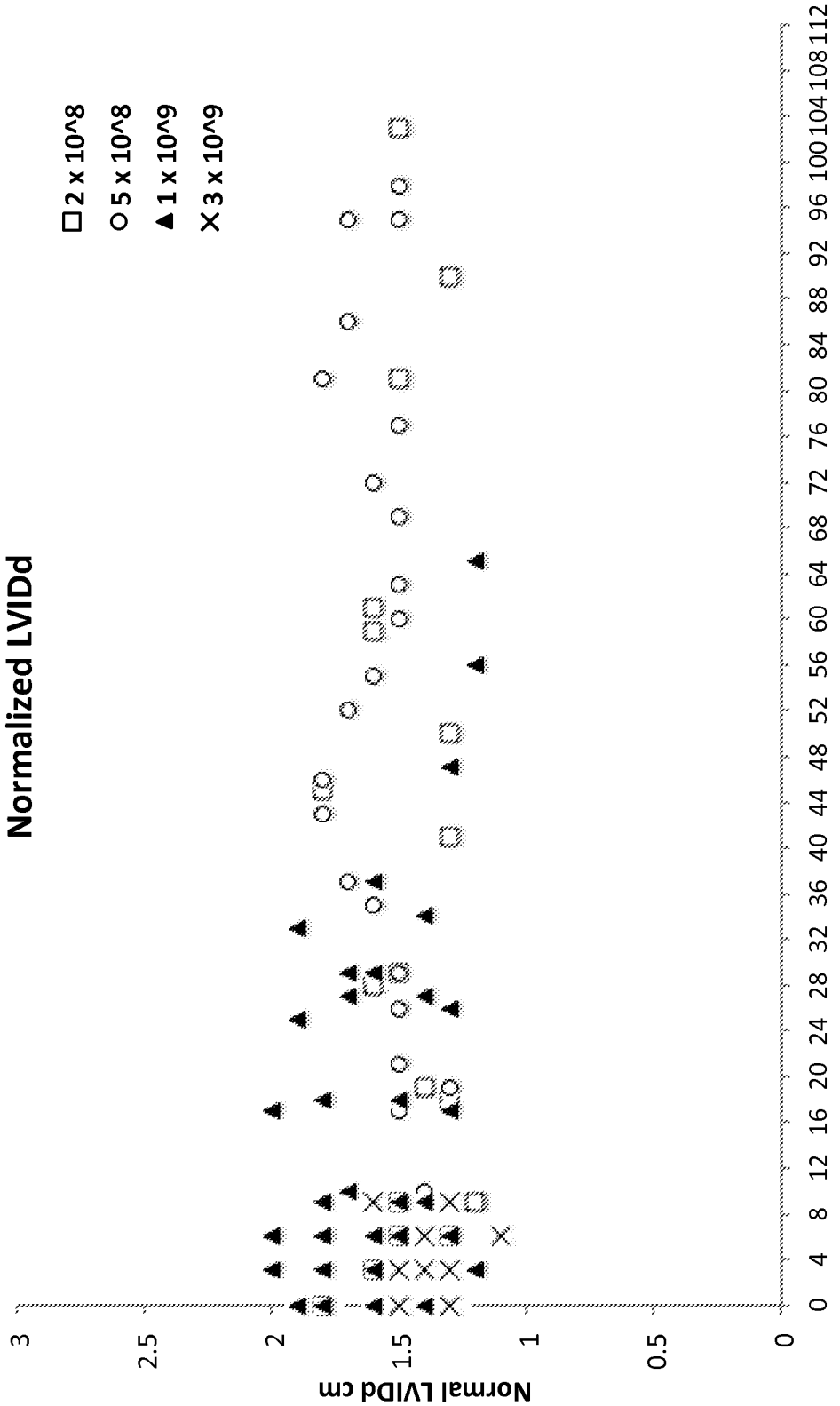

Normalized LVIDd
2 x 10^8
5 x 10^8
1 x 10^9
3 x 10^9
Normal LVIDd cm
3
2.5
2
1.5
1
0.5
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100 104 108 112
Weeks post first vaccination

Figure 25A

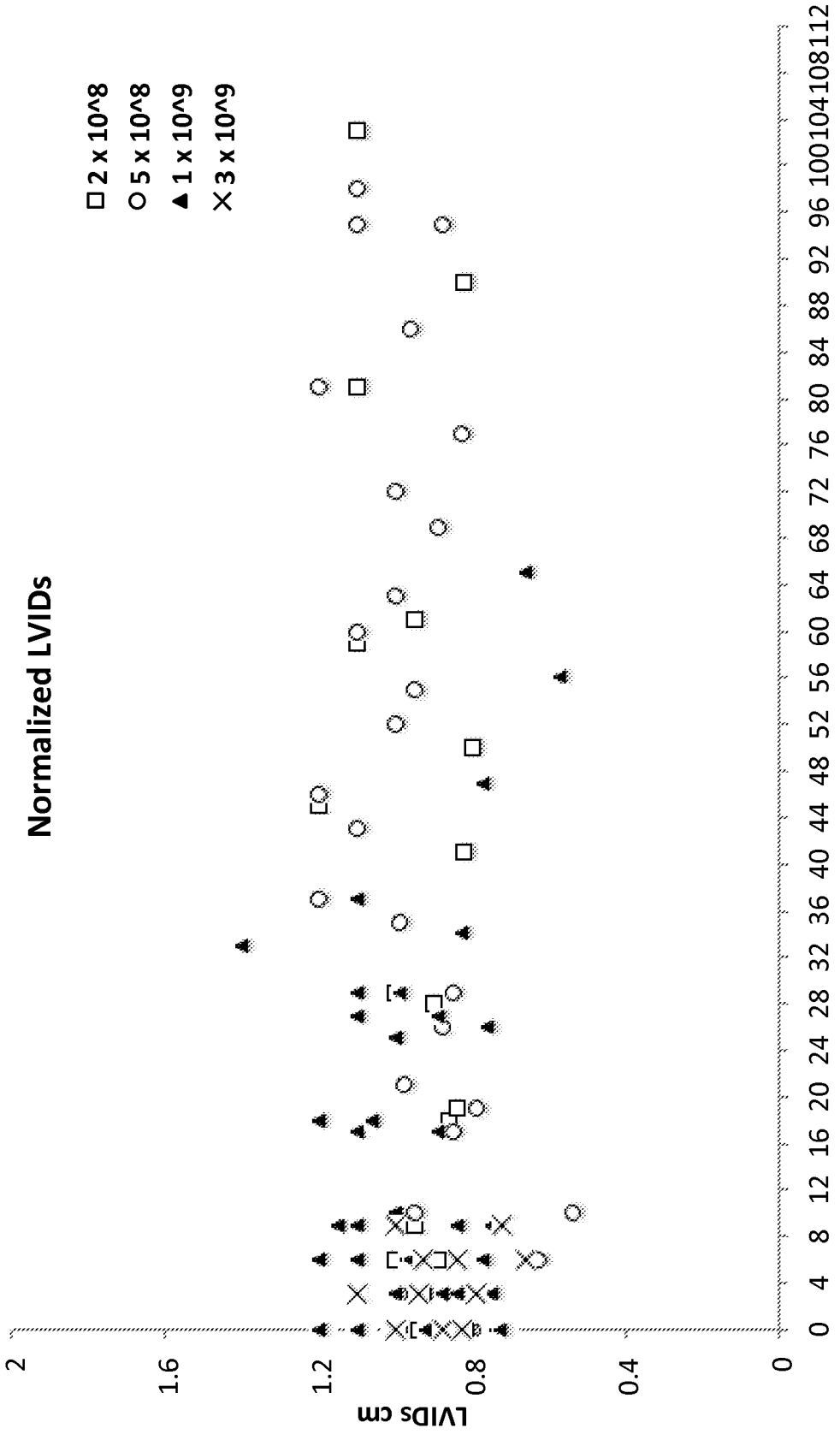

Normalized LVIDs
2 x 10^8
5 x 10^8
1 x 10^9
3 x 10^9
LVIDs cm
2
1.6
1.2
0.8
0.4
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100104108112
Weeks post first vaccination

Figure 25B

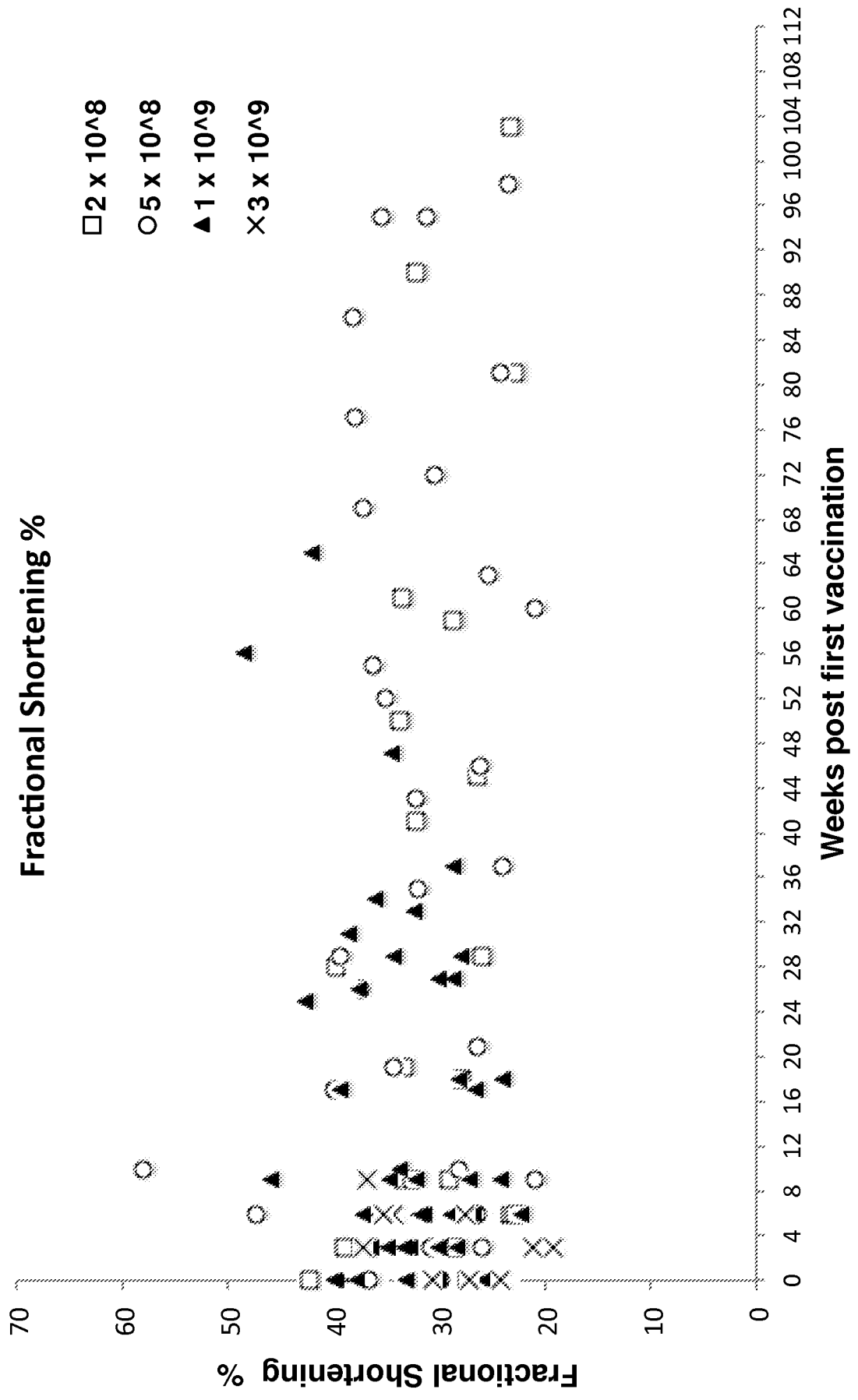

Fractional Shortening %
□2 x 10^8
○5 x 10^8
▲1 x 10^9
×3 x 10^9
Fractional Shortening %
0
10
20
30
40
50
60
70
Weeks post first vaccination
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100 104 108 112

Figure 25C

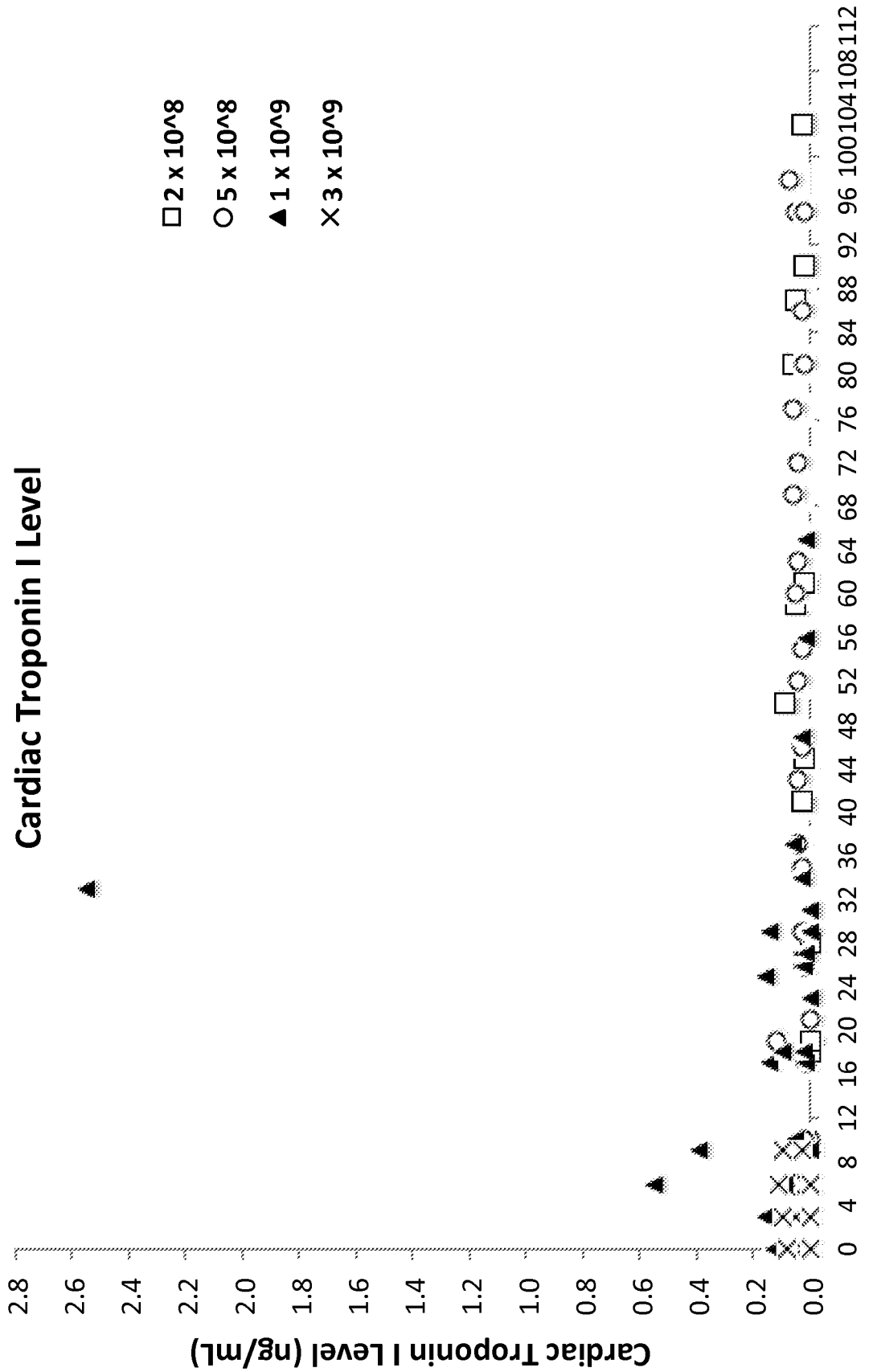

Cardiac Troponin I Level
□ 2 x 10^8
○ 5 x 10^8
◀ 1 x 10^9
✕ 3 x 10^9
Cardiac Troponin I Level (ng/mL)
0.0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72 76 80 84 88 92 96 100104108112
Weeks post first vaccination

Figure 25D

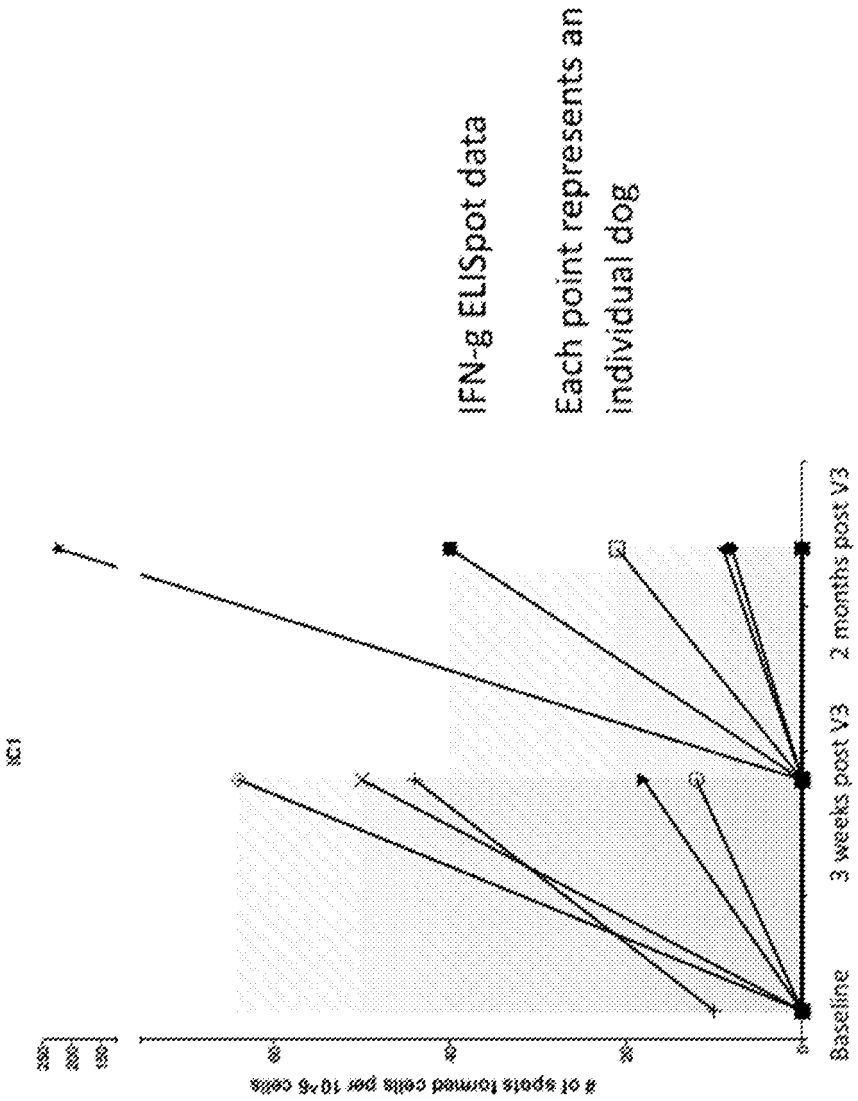

IFN-g ELISpot data
Each point represents an individual dog
# of spots formed cells per 10^6 cells
Baseline
3 weeks post V3
2 months post V3

Figure 26