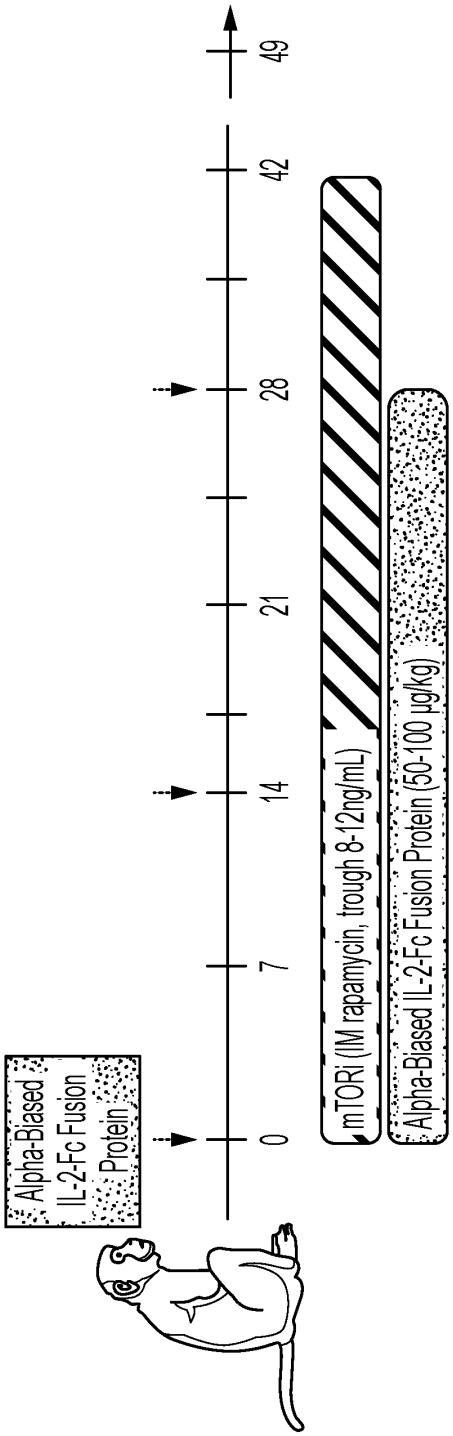

Alpha-Biased IL-2-Fc Fusion Protein
0
7
14
21
28
42
49
mTORi (IM rapamycin, trough 8-12ng/mL)
Alpha-Biased IL-2-Fc Fusion Protein (50-100 µg/kg)

FIG. 1A

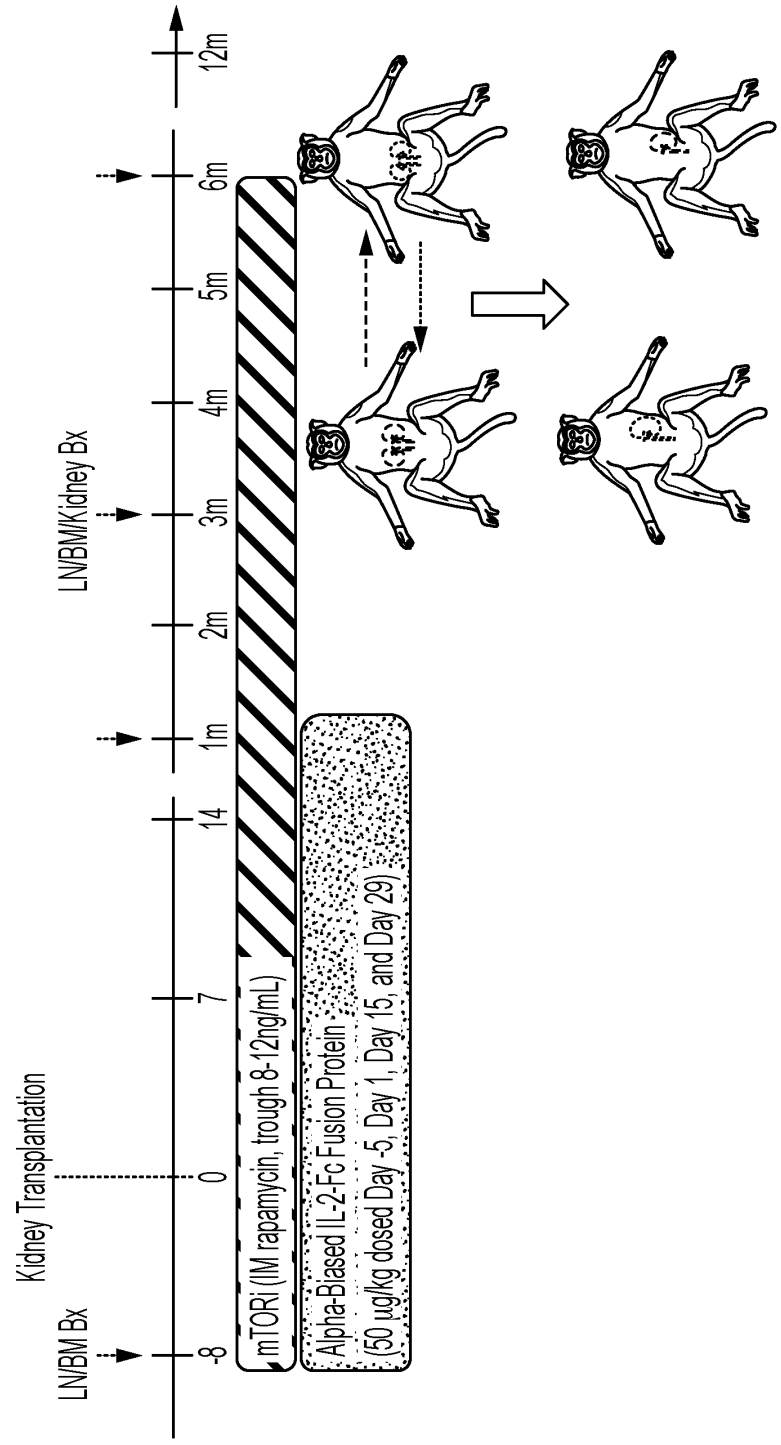

LN/BM Bx
Kidney Transplantation
LN/BM/Kidney Bx
-8
0
7
14
1m
2m
3m
4m
5m
6m
12m
mTORi (IM rapamycin, trough 8-12ng/mL)
Alpha-Biased IL-2-Fc Fusion Protein
(50 µg/kg dosed Day -5, Day 1, Day 15, and Day 29)

FIG. 1B

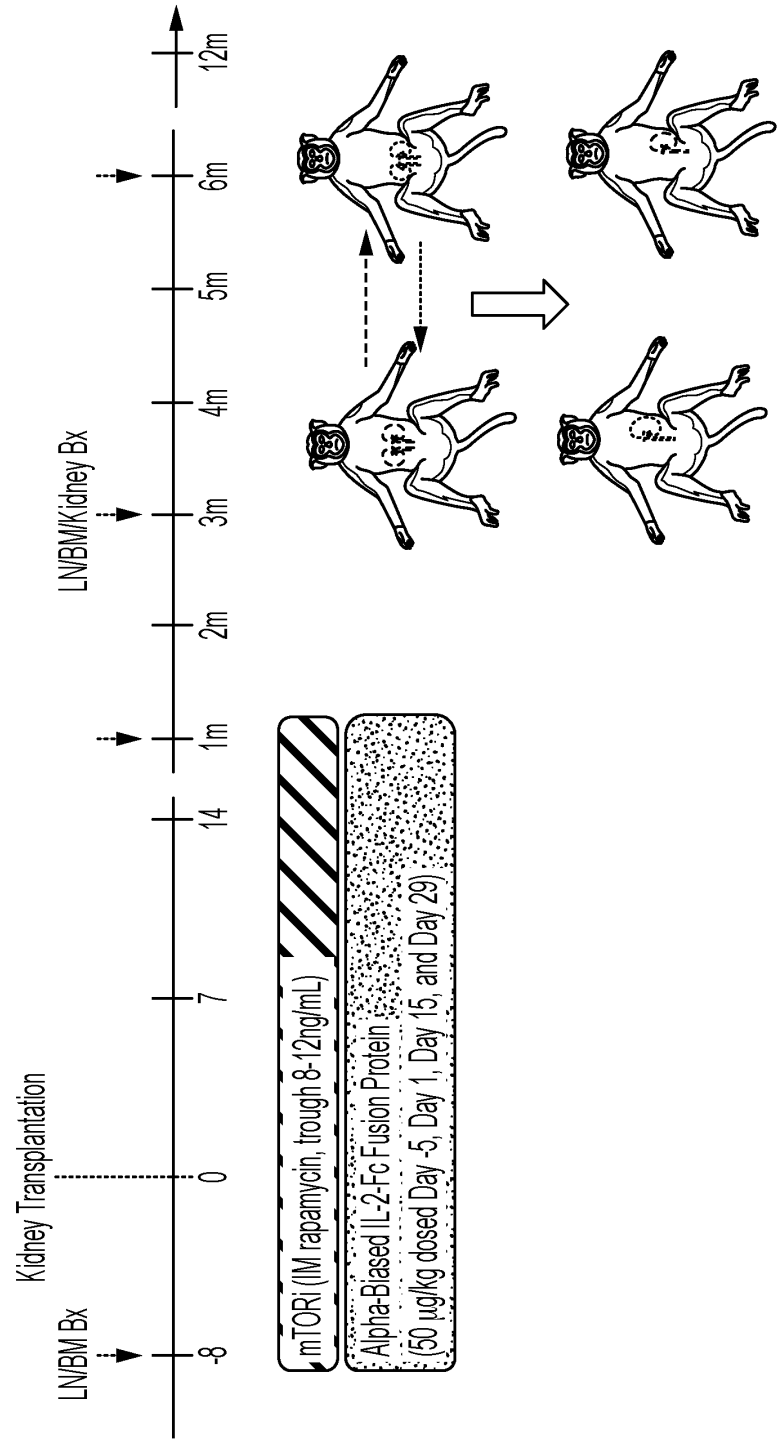

LN/BM Bx
Kidney Transplantation
LN/BM/Kidney Bx
-8
0
7
14
1m
2m
3m
4m
5m
6m
12m
mTORi (IM rapamycin, trough 8-12ng/mL)
Alpha-Biased IL-2-Fc Fusion Protein
(50 µg/kg dosed Day -5, Day 1, Day 15, and Day 29)

FIG. 1C

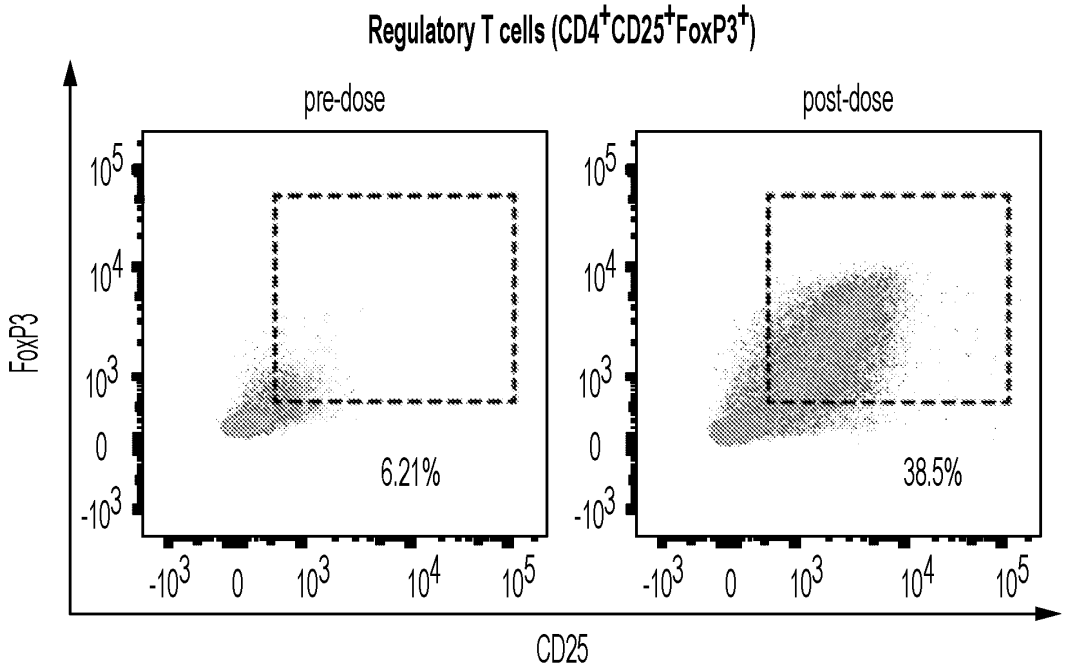

Regulatory T cells (CD4+CD25+FoxP3+)
pre-dose
post-dose
FoxP3
CD25
6.21%
38.5%
10^5
10^4
10^3
0
-10^3

FIG. 2A

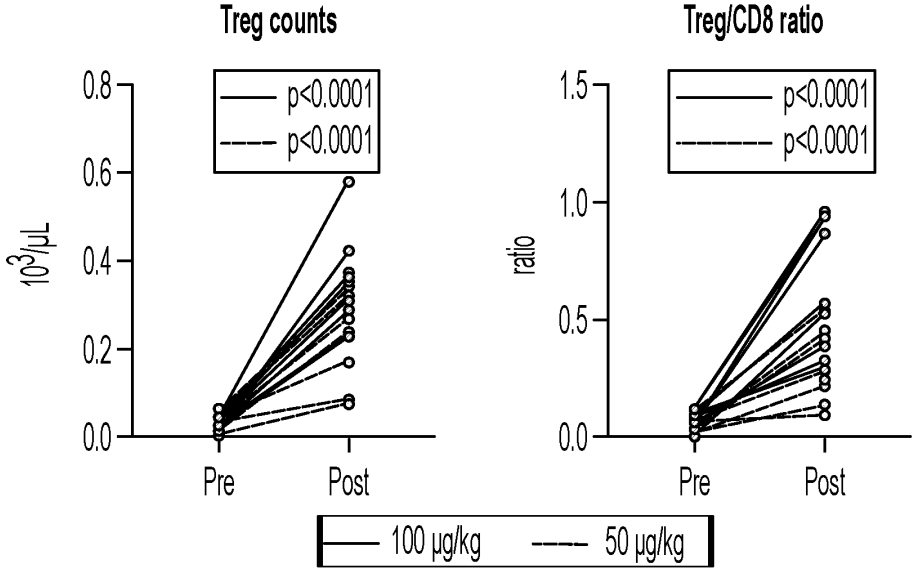

Treg counts
Treg/CD8 ratio
p<0.0001
p<0.0001
p<0.0001
p<0.0001
10^3/µL
ratio
Pre
Post
100 µg/kg
50 µg/kg

FIG. 2B

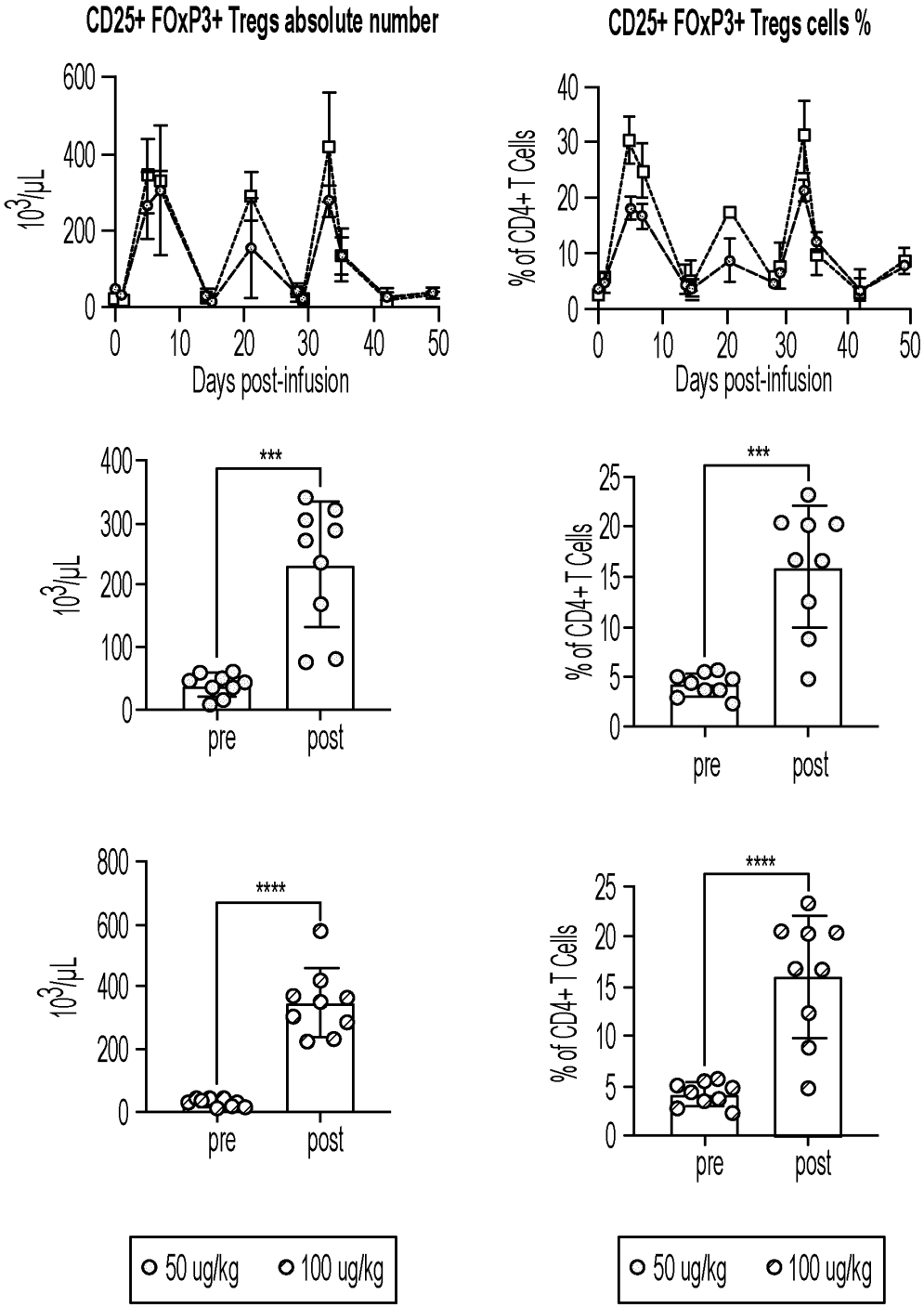

CD25+ FOxP3+ Tregs absolute number
10^3/µL
Days post-infusion
***
pre
post
****
50 ug/kg
100 ug/kg

FIG. 3A

CD25+ FOxP3+ Tregs cells %
% of CD4+ T Cells
Days post-infusion
***
pre
post
****
50 ug/kg
100 ug/kg

FIG. 3B

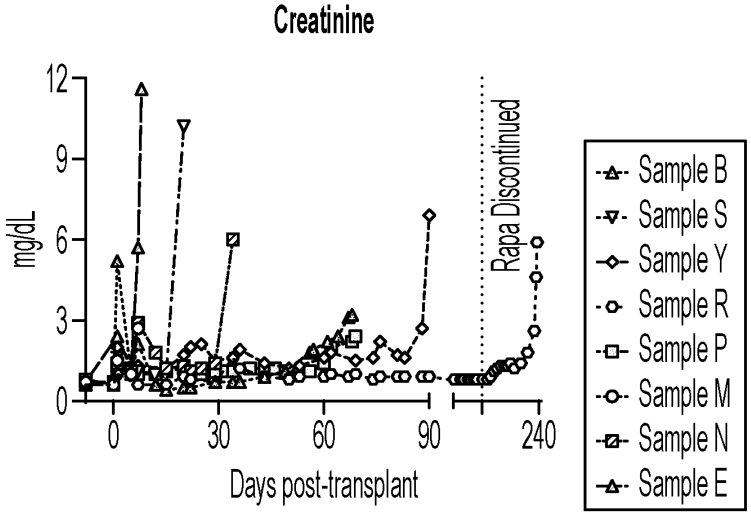

Creatinine
12
9
6
3
0
mg/dL
0
30
60
90
240
Days post-transplant
Rapa Discontinued
Sample B
Sample S
Sample Y
Sample R
Sample P
Sample M
Sample N
Sample E

FIG. 4A

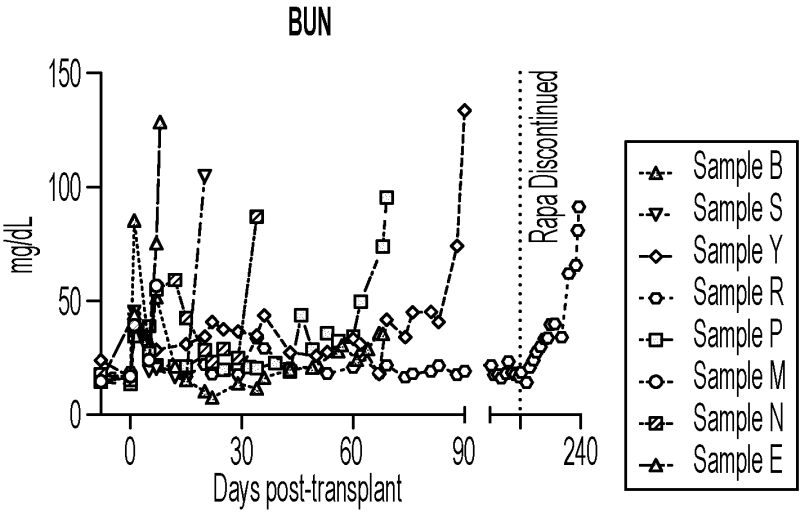

BUN
150
100
50
0
mg/dL
0
30
60
90
240
Days post-transplant
Rapa Discontinued
Sample B
Sample S
Sample Y
Sample R
Sample P
Sample M
Sample N
Sample E

FIG. 4B

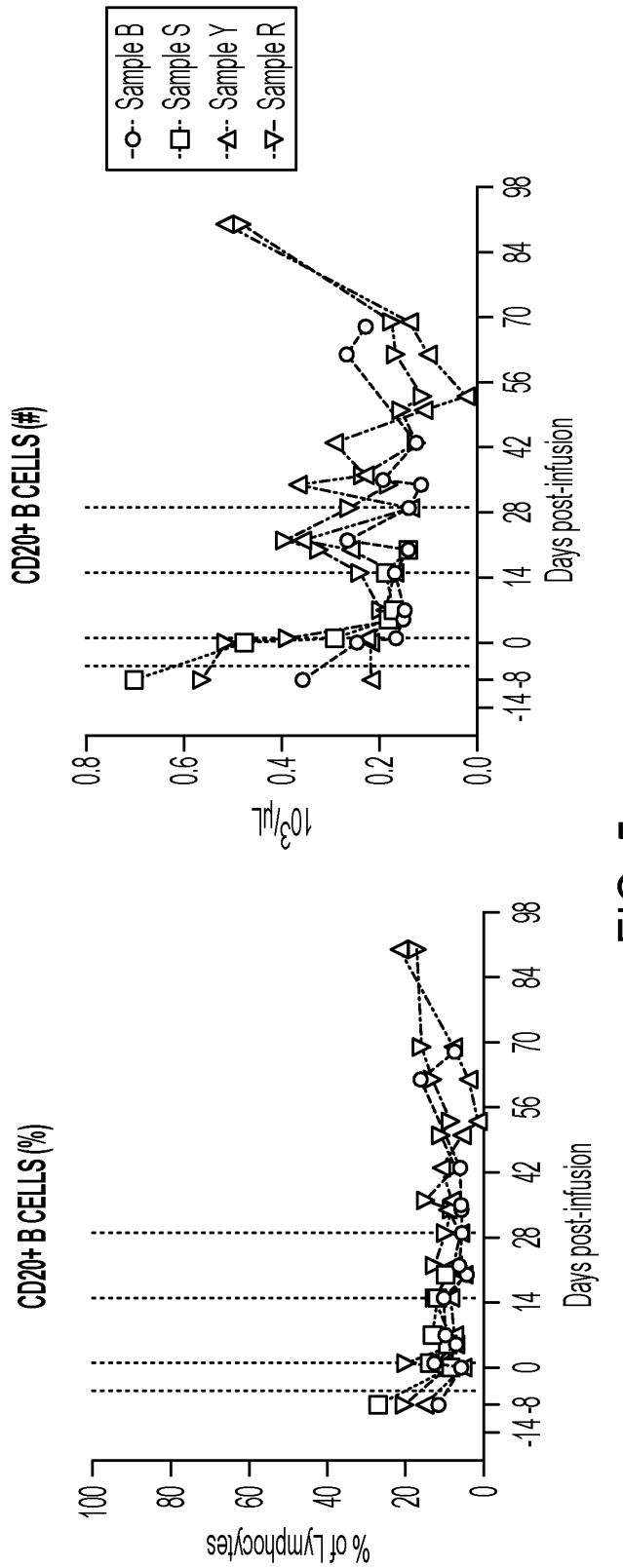

CD20+ B CELLS (%)
% of Lymphocytes
100
80
60
40
20
0
-14 -8 0 14 28 42 56 70 84 98
Days post-infusion
CD20+ B CELLS (#)
$10^3/\mu L$
0.8
0.6
0.4
0.2
0.0
-14 -8 0 14 28 42 56 70 84 98
Days post-infusion
Sample B
Sample S
Sample Y
Sample R

FIG. 5

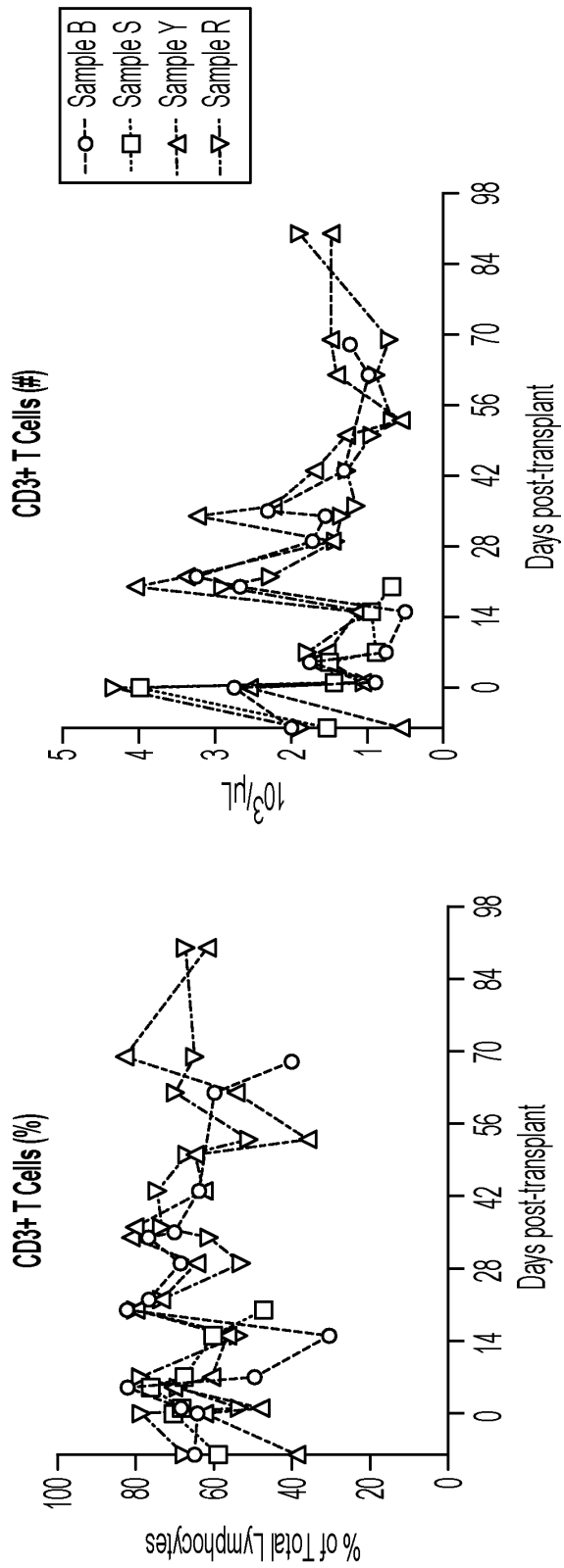

Sample B
Sample S
Sample Y
Sample R
CD3+ T Cells (#)
10^3/µL
Days post-transplant
CD3+ T Cells (%)
% of Total Lymphocytes
Days post-transplant

FIG. 6

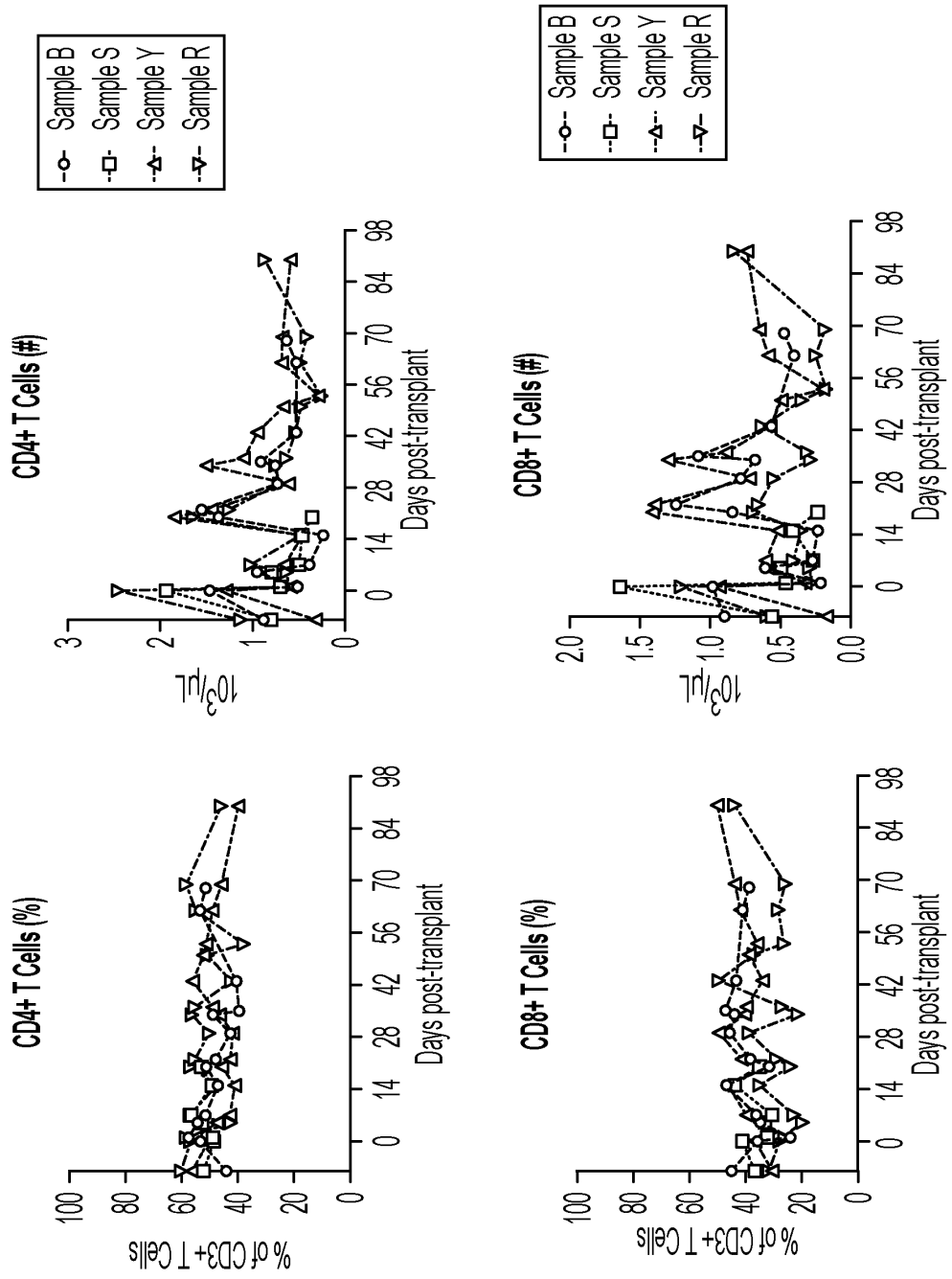

Sample B
Sample S
Sample Y
Sample R
CD4+ T Cells (#)
10^3/µL
Days post-transplant
CD8+ T Cells (#)
10^3/µL
Days post-transplant
CD4+ T Cells (%)
% of CD3+ T Cells
Days post-transplant
CD8+ T Cells (%)
% of CD3+ T Cells
Days post-transplant

FIG. 7

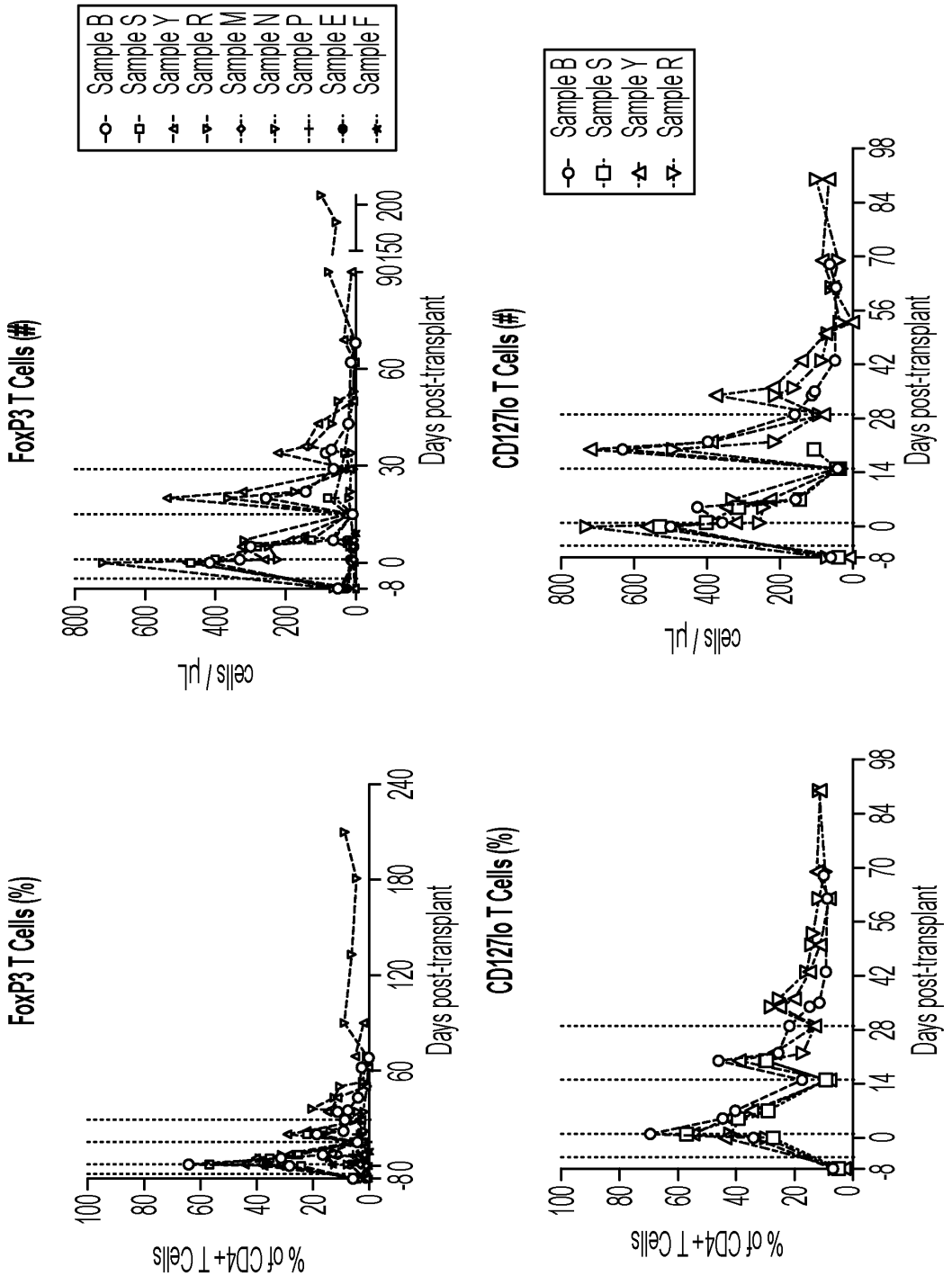

FoxP3 T Cells (#)
cells / µL
Days post-transplant
Sample B
Sample S
Sample Y
Sample R
Sample M
Sample N
Sample P
Sample E
Sample F
CD127lo T Cells (#)
cells / µL
Days post-transplant
Sample B
Sample S
Sample Y
Sample R
FoxP3 T Cells (%)
% of CD4+ T Cells
Days post-transplant
CD127lo T Cells (%)
% of CD4+ T Cells
Days post-transplant

FIG. 8

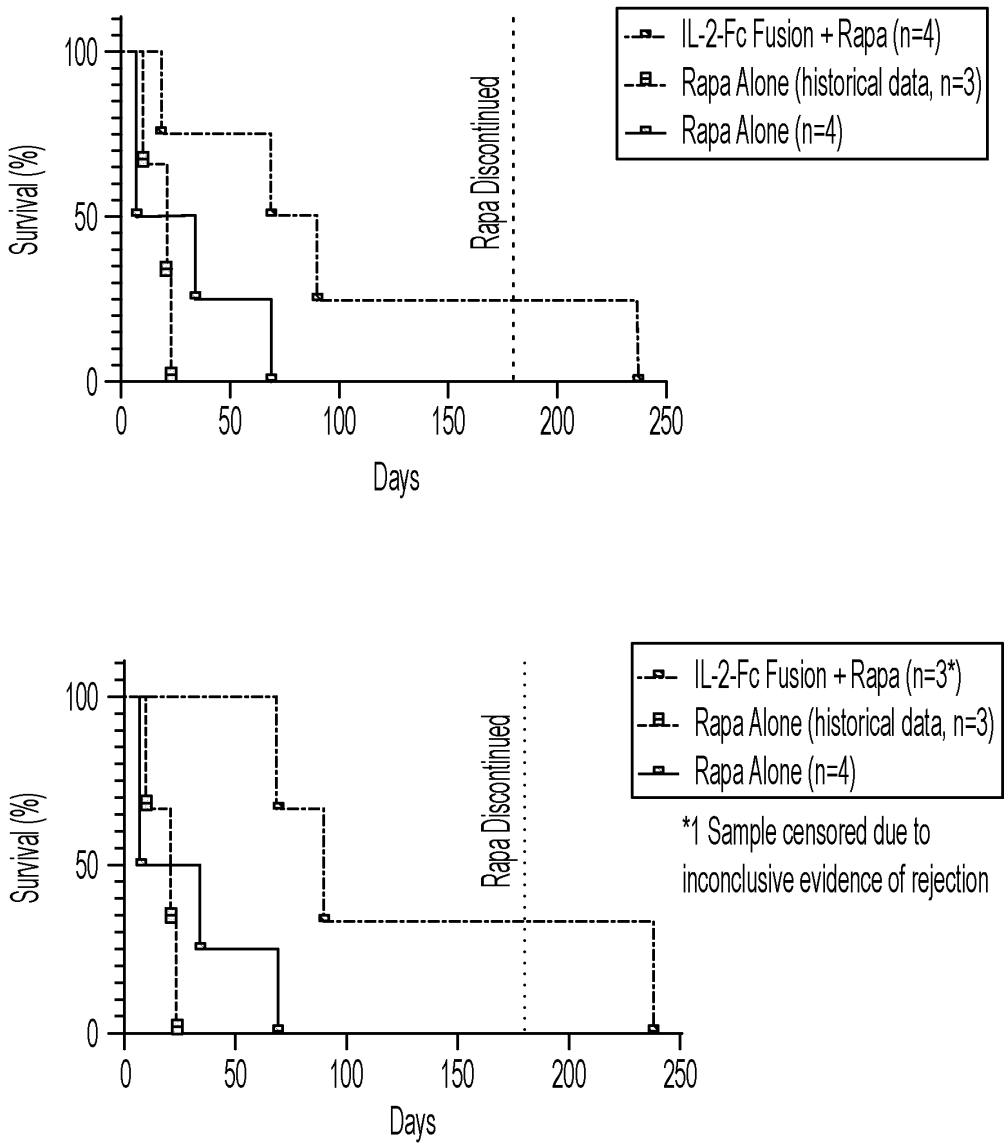

IL-2-Fc Fusion + Rapa (n=4)
Rapa Alone (historical data, n=3)
Rapa Alone (n=4)
Rapa Discontinued
Survival (%)
Days
0
50
100
150
200
250
IL-2-Fc Fusion + Rapa (n=3*)
Rapa Alone (historical data, n=3)
Rapa Alone (n=4)
*1 Sample censored due to inconclusive evidence of rejection

FIG. 9

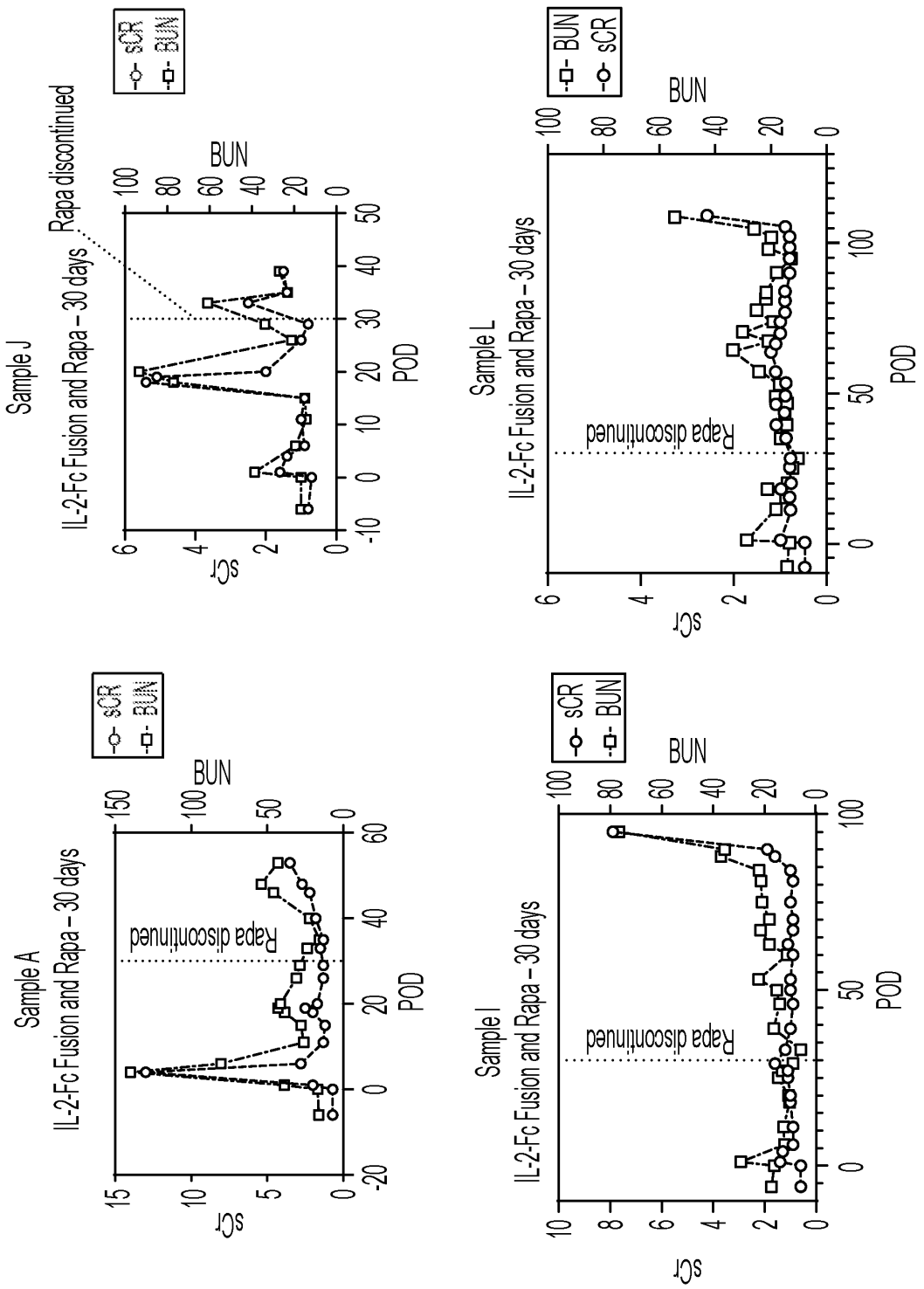

Sample J
IL-2-Fc Fusion and Rapa – 30 days
Rapa discontinued
sCR
BUN
POD
Sample L
IL-2-Fc Fusion and Rapa – 30 days
Rapa discontinued
sCR
BUN
POD
Sample A
IL-2-Fc Fusion and Rapa – 30 days
Rapa discontinued
sCR
BUN
POD
Sample I
IL-2-Fc Fusion and Rapa – 30 days
Rapa discontinued
sCR
BUN
POD

FIG. 10A

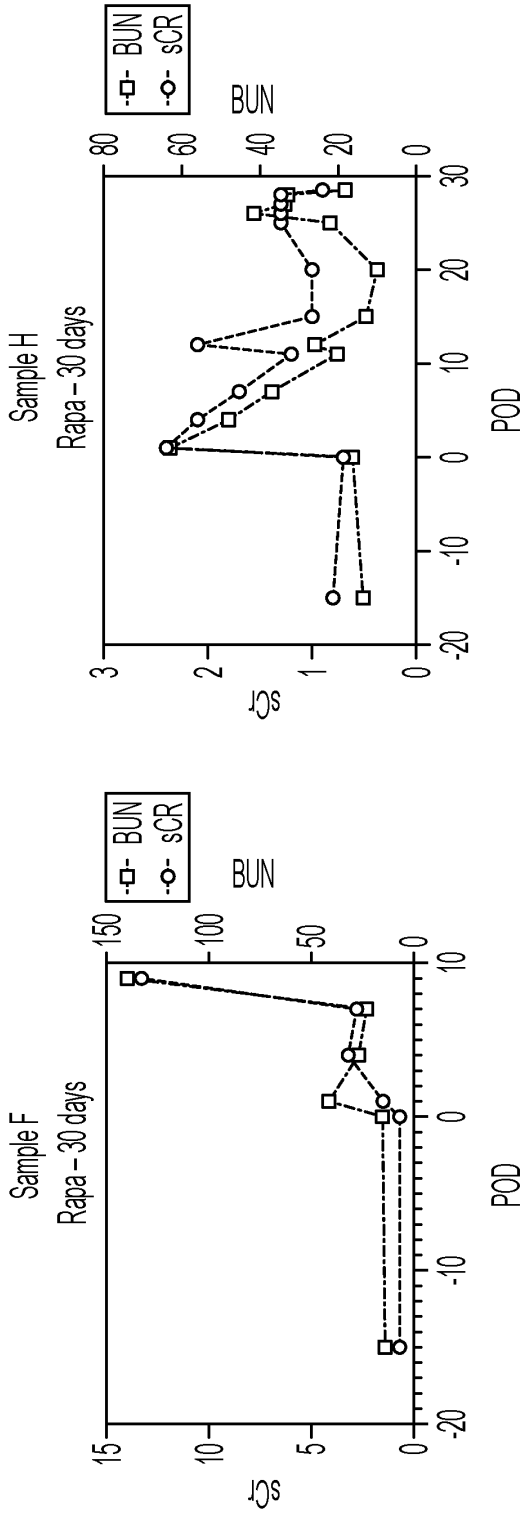

Sample H
Rapa – 30 days
BUN
sCR
POD
Sample F
Rapa – 30 days
BUN
sCR
POD

FIG. 10B

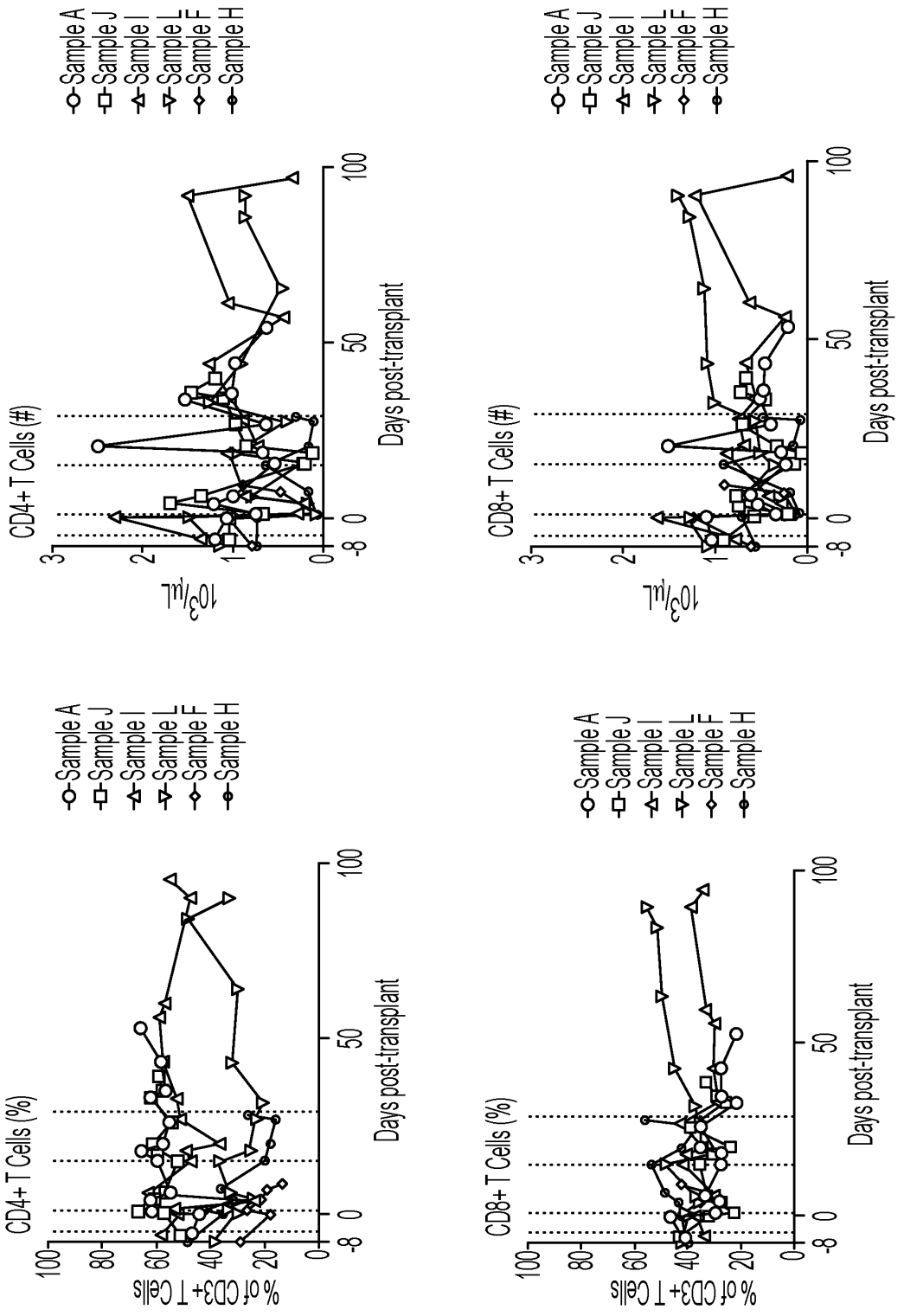
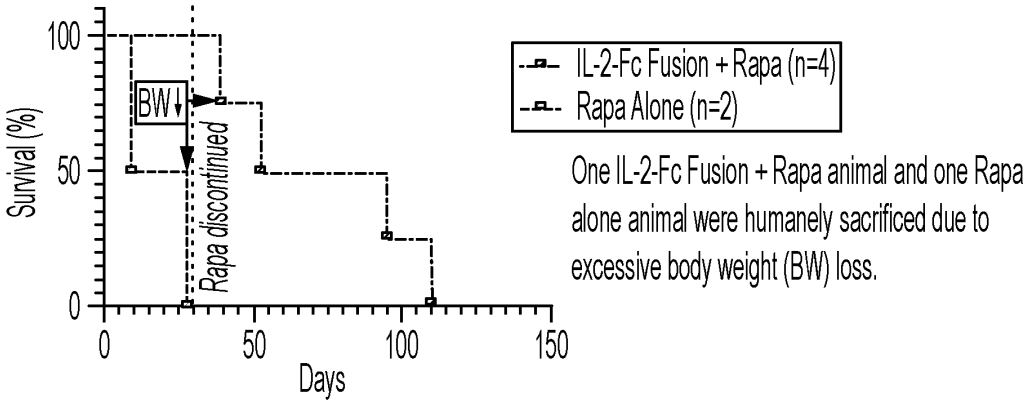

CD4+ T Cells (%)
% of CD3+ T Cells
Days post-transplant
CD4+ T Cells (#)
$10^3/\mu L$
CD8+ T Cells (%)
CD8+ T Cells (#)
Sample A
Sample J
Sample I
Sample L
Sample F
Sample H

FIG. 11


100
50
0
Survival (%)
BW↓
Rapa discontinued
0
50
100
150
Days
IL-2-Fc Fusion + Rapa (n=4)
Rapa Alone (n=2)
One IL-2-Fc Fusion + Rapa animal and one Rapa alone animal were humanely sacrificed due to excessive body weight (BW) loss.

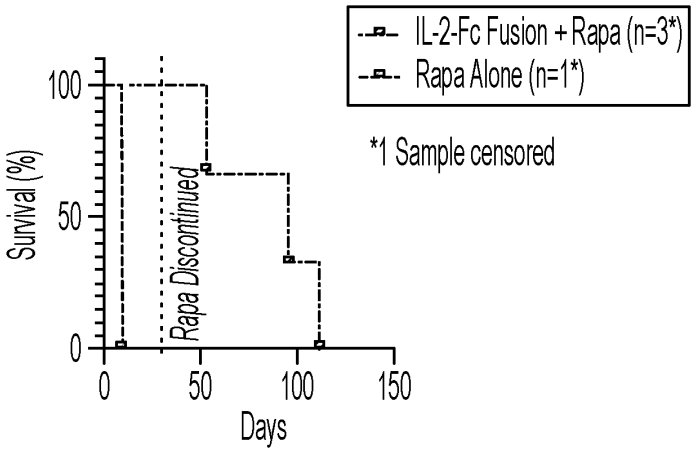

IL-2-Fc Fusion + Rapa (n=3*)
Rapa Alone (n=1*)
*1 Sample censored
100
50
0
Survival (%)
Rapa Discontinued
0
50
100
150
Days

FIG. 12