FIG. 1

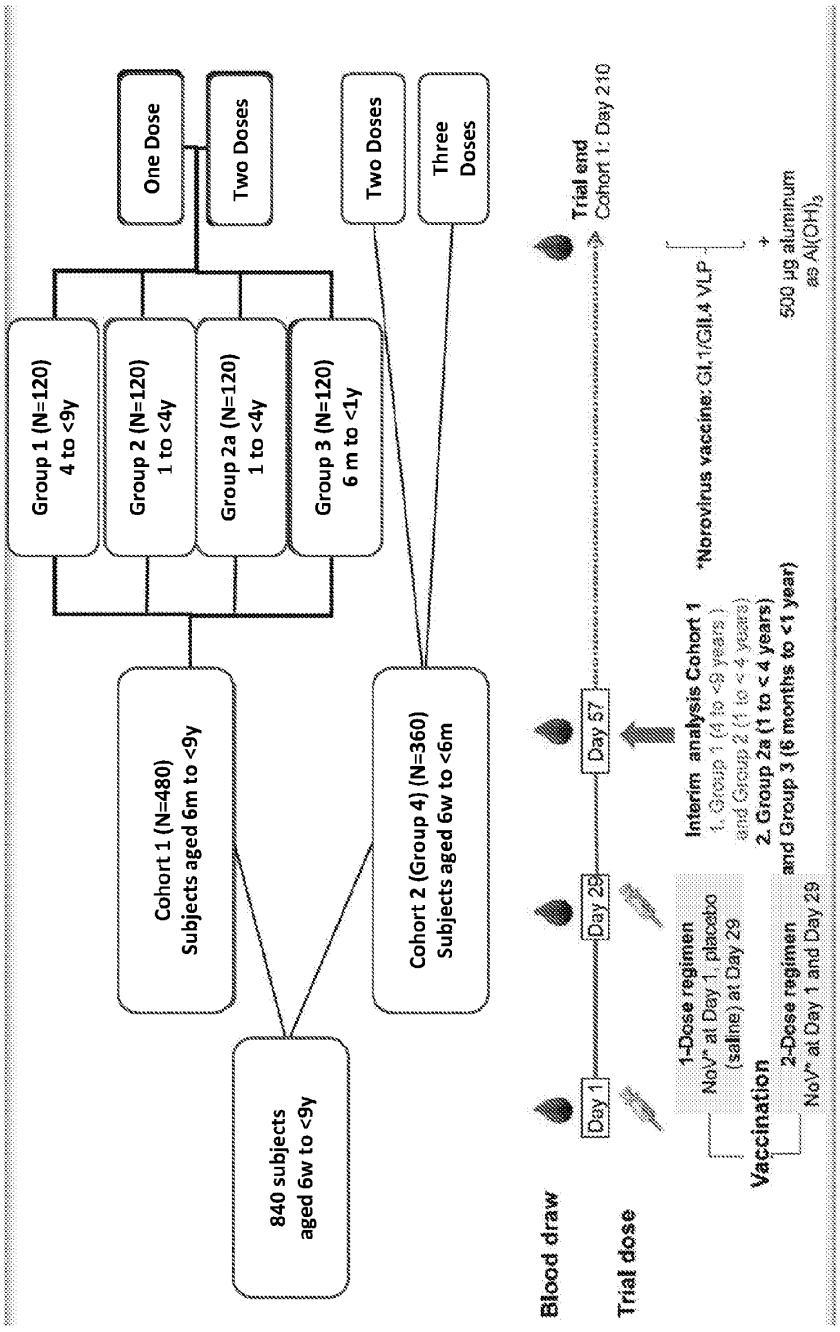

840 subjects aged 6w to <9y
Cohort 1 (N=480) Subjects aged 6m to <9y
Cohort 2 (Group 4) (N=360) Subjects aged 6w to <6m
Group 1 (N=120) 4 to <9y
Group 2 (N=120) 1 to <4y
Group 2a (N=120) 1 to <4y
Group 3 (N=120) 6 m to <1y
One Dose
Two Doses
Two Doses
Three Doses
Blood draw
Trial dose
Day 1
Day 29
Day 57
Trial end Cohort 1: Day 210
Vaccination
1-Dose regimen NoV* at Day 1, placebo (saline) at Day 29
2-Dose regimen NoV* at Day 1 and Day 29
Interim analysis Cohort 1 1. Group 1 (4 to <9 years) and Group 2 (1 to < 4 years) 2. Group 2a (1 to < 4 years) and Group 3 (6 months to <1 year)
*Norovirus vaccine: GI.1/GII.4 VLP
+
500 µg aluminum as Al(OH)3

FIG. 2A-D

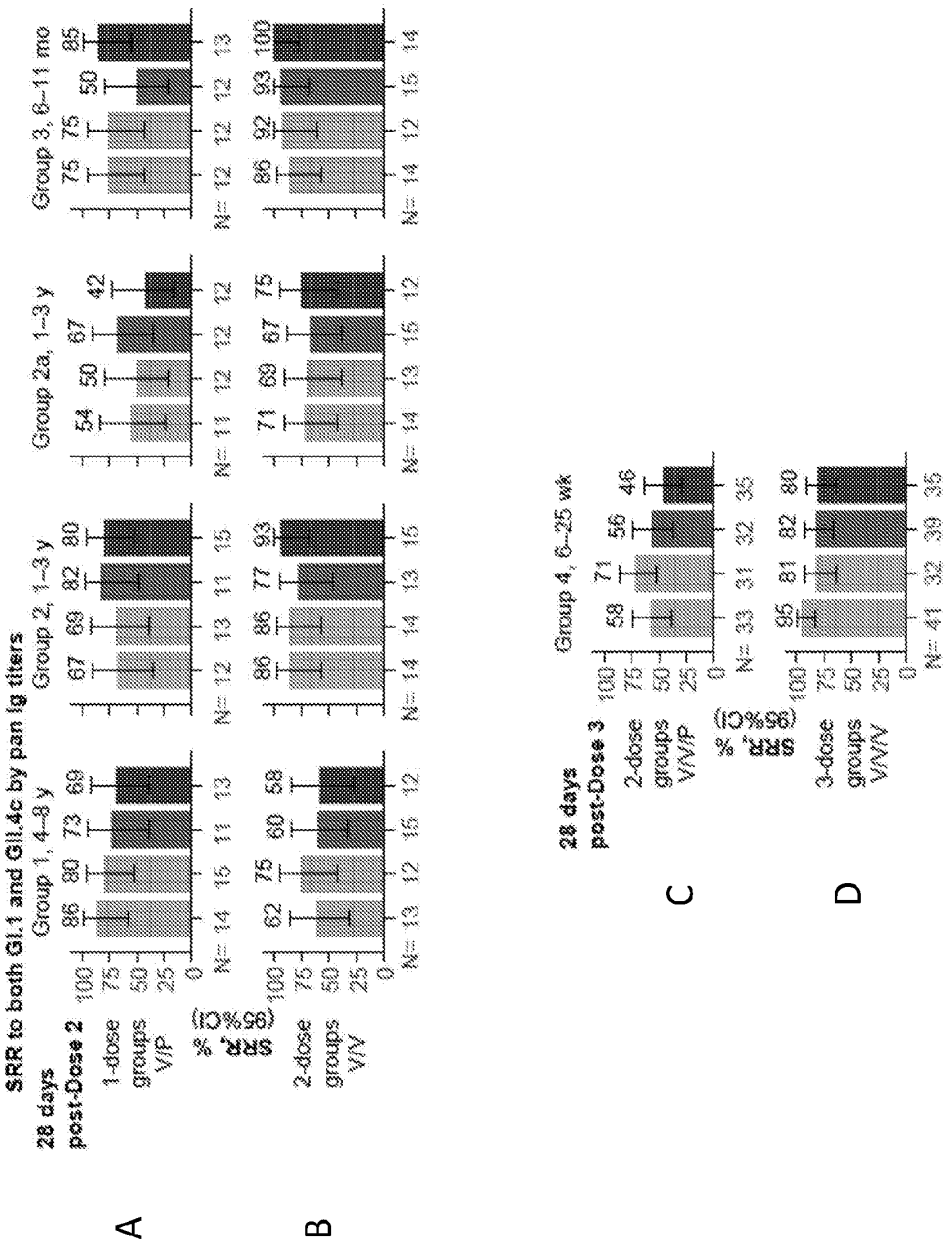

SRR to both GI.1 and GII.4c by pan Ig titers
28 days post-Dose 2
1-dose groups V/P
2-dose groups V/V
SRR, % (95%CI)
Group 1, 4–8 y
Group 2, 1–3 y
Group 2a, 1–3 y
Group 3, 6–11 mo
A
B
28 days post-Dose 3
2-dose groups V/V/P
3-dose groups V/V/V
Group 4, 6–25 wk
C
D

FIG. 3A-D

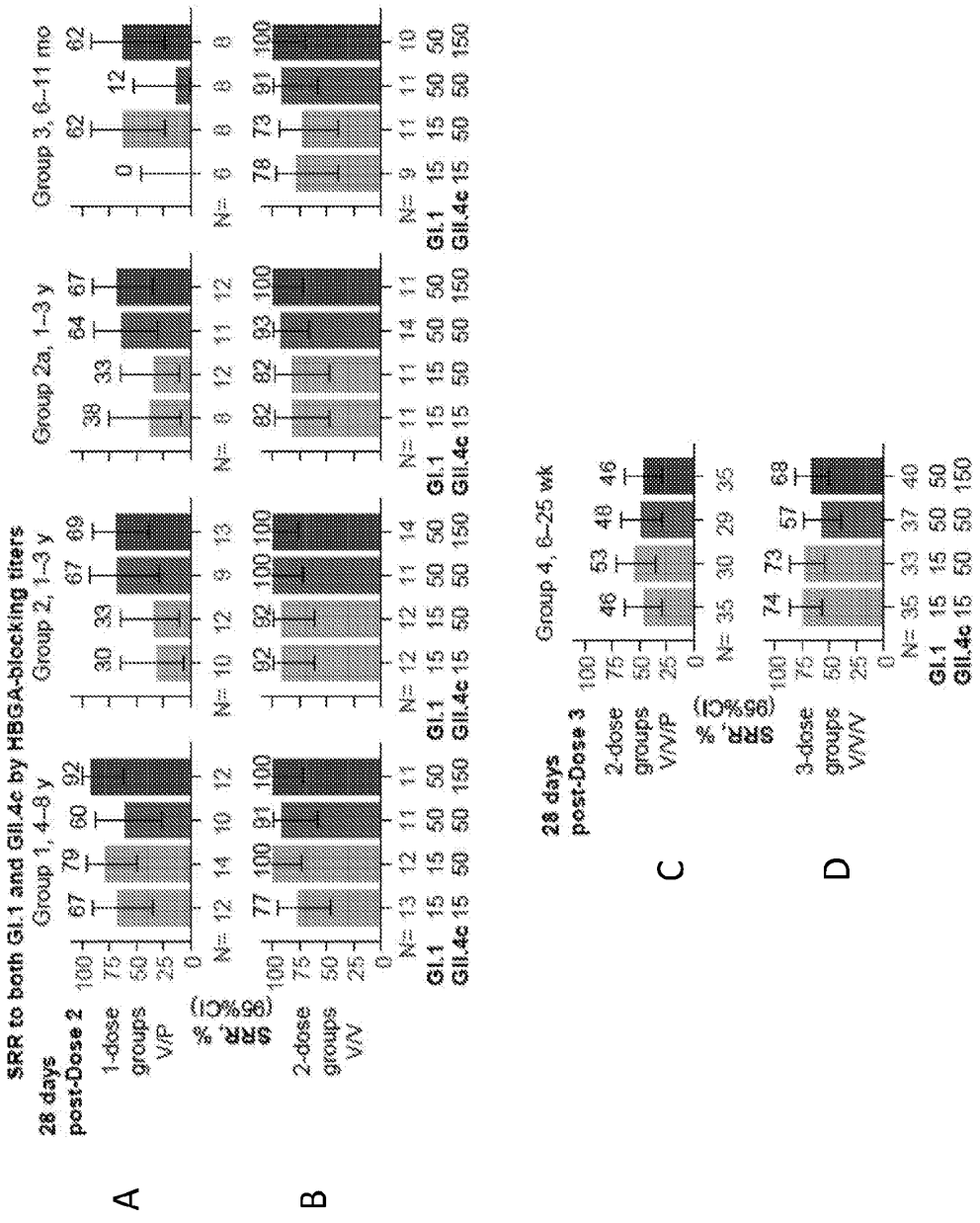

SRR to both GI.1 and GII.4c by HBGA-blocking titers
28 days post-Dose 2
Group 1, 4–8 y
Group 2, 1–3 y
Group 2a, 1–3 y
Group 3, 6–11 mo
1-dose groups V/P
2-dose groups V/V
SRR, % (95%CI)
N= 12 14 10 12
N= 10 12 9 13
N= 6 12 11 12
N= 6 6 8 8
N= 13 12 11 11
N= 12 12 11 14
N= 11 11 14 11
N= 9 11 11 10
GI.1 15 15 50 50
GII.4c 15 50 50 150
GI.1 15 15 50 50
GII.4c 15 50 50 150
GI.1 15 15 50 50
GII.4c 15 50 50 150
GI.1 15 15 50 50
GII.4c 15 50 50 150
A
B
Group 4, 6–25 wk
28 days post-Dose 3
2-dose groups V/V/P
3-dose groups V/V/V
N= 35 30 29 35
N= 35 33 37 40
GI.1 15 15 50 50
GII.4c 15 50 50 150
C
D

FIG. 4A-D

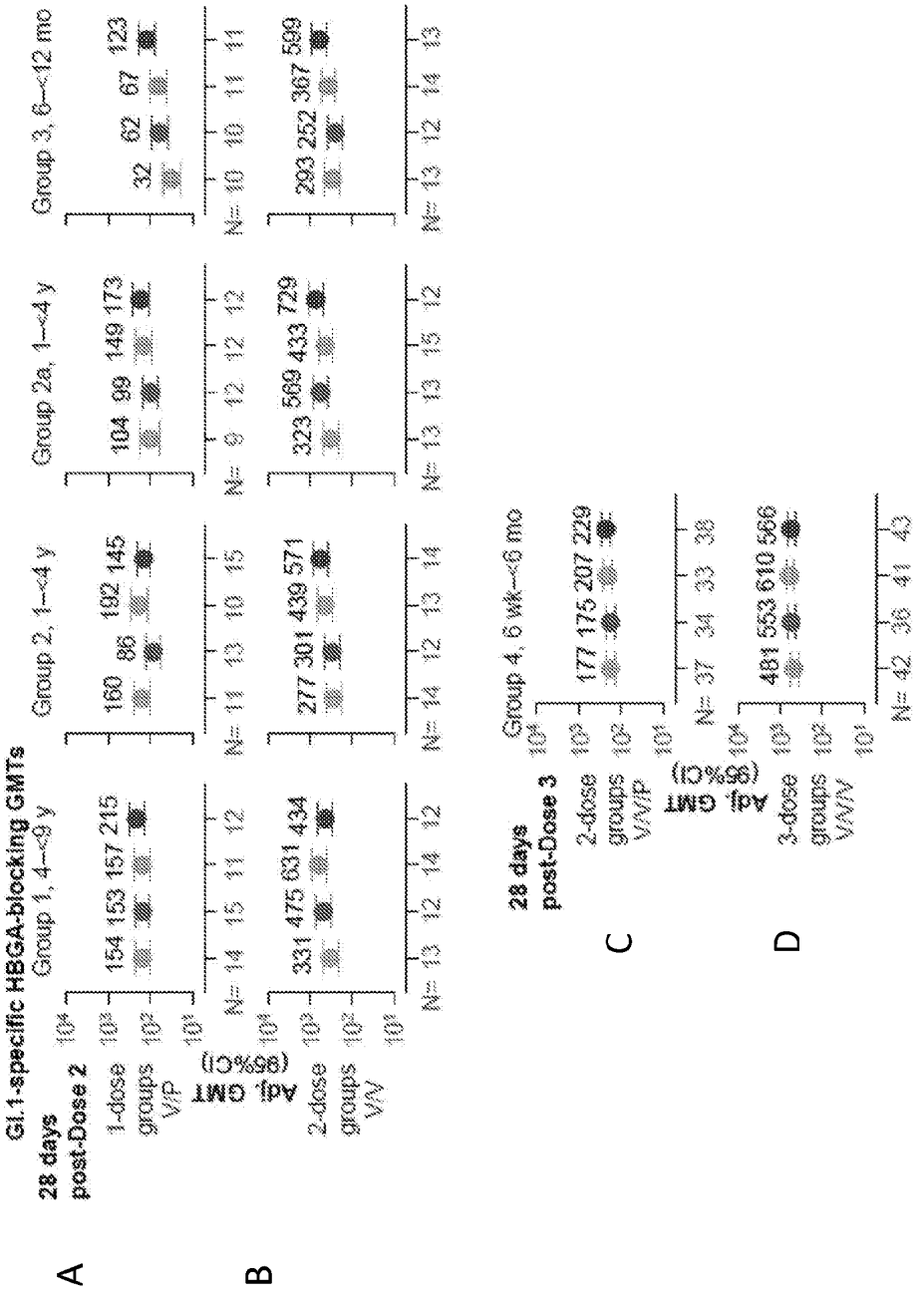

GI.1-specific HBGA-blocking GMTs
28 days post-Dose 2
Adj. GMT (95%CI)
A
B
1-dose groups V/P
2-dose groups V/V
Group 1, 4–<9 y
Group 2, 1–<4 y
Group 2a, 1–<4 y
Group 3, 6–<12 mo
154 153 157 215
331 475 631 434
160 86 192 145
277 301 439 571
104 99 149 173
323 569 433 729
32 62 67 123
293 252 367 599
N= 14 15 11 12
N= 13 12 14 12
N= 11 13 10 15
N= 14 12 13 14
N= 9 12 12 12
N= 13 13 15 12
N= 10 10 11 11
N= 13 12 14 13
28 days post-Dose 3
Adj. GMT (95%CI)
C
D
2-dose groups V/V/P
3-dose groups V/V/V
Group 4, 6 wk–<6 mo
177 175 207 229
481 553 610 566
N= 37 34 33 38
N= 42 36 41 43

FIG. 5A-D

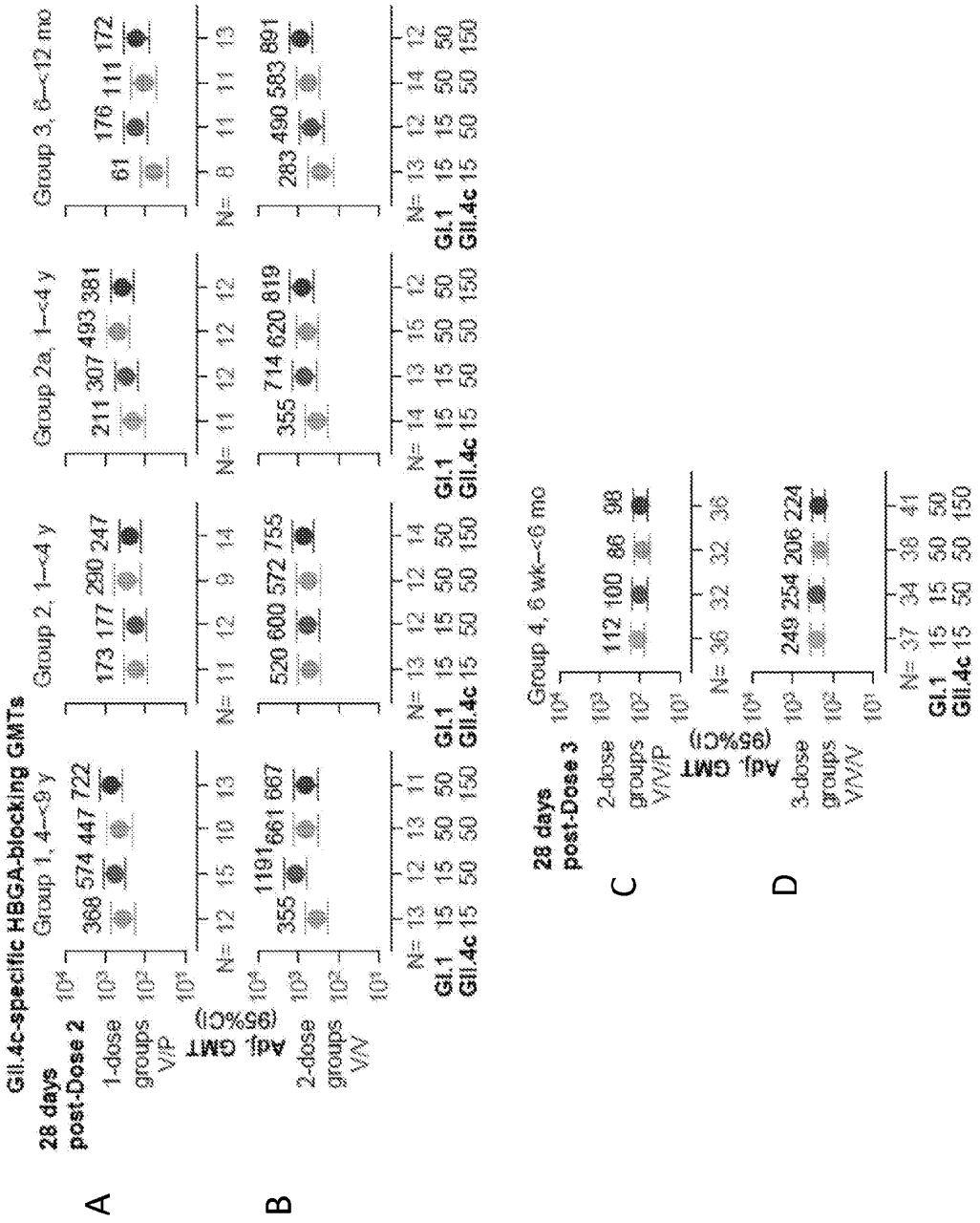

GII.4c-specific HBGA-blocking GMTs
28 days post-Dose 2
A
Group 1, 4–<9 y
Group 2, 1–<4 y
Group 2a, 1–<4 y
Group 3, 6–<12 mo
1-dose groups V/P
2-dose groups V/V
Adj. GMT (95%CI)
368 574 447 722
173 177 290 247
211 307 493 381
61 176 111 172
B
1191 661 667
355
520 600 572 755
355 714 620 819
283 490 563 891
N= 12 15 10 13
N= 11 12 9 14
N= 11 12 12 12
N= 8 11 11 13
N= 13 12 13 11
N= 13 12 12 14
N= 14 13 15 12
N= 13 12 14 12
GI.1 15 15 50 50
GII.4c 15 50 50 150
GI.1 15 15 50 50
GII.4c 15 50 50 150
GI.1 15 15 50 50
GII.4c 15 50 50 150
GI.1 15 15 50 50
GII.4c 15 50 50 150
28 days post-Dose 3
Group 4, 6 wk–<6 mo
C
2-dose groups V/V/P
112 100 86 93
N= 36 32 32 36
D
3-dose groups V/V/V
249 254 206 224
N= 37 34 38 41
GI.1 15 15 50 50
GII.4c 15 50 50 150

FIG. 6A-6B

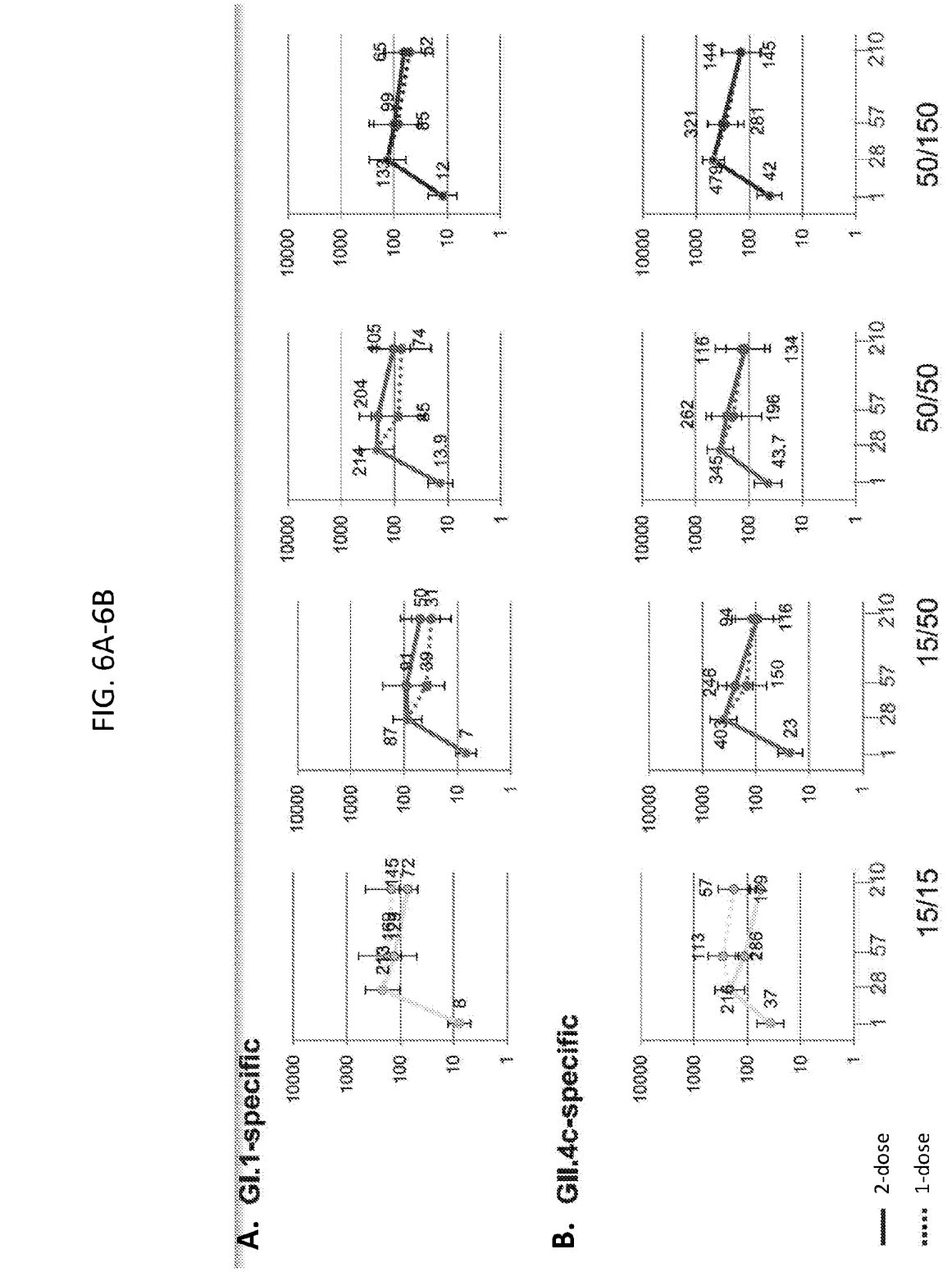

A. GI.1-specific
B. GII.4c-specific
15/15
15/50
50/50
50/150
2-dose
1-dose
10000
1000
100
10
1
1
28
57
210

FIG. 7A-7B

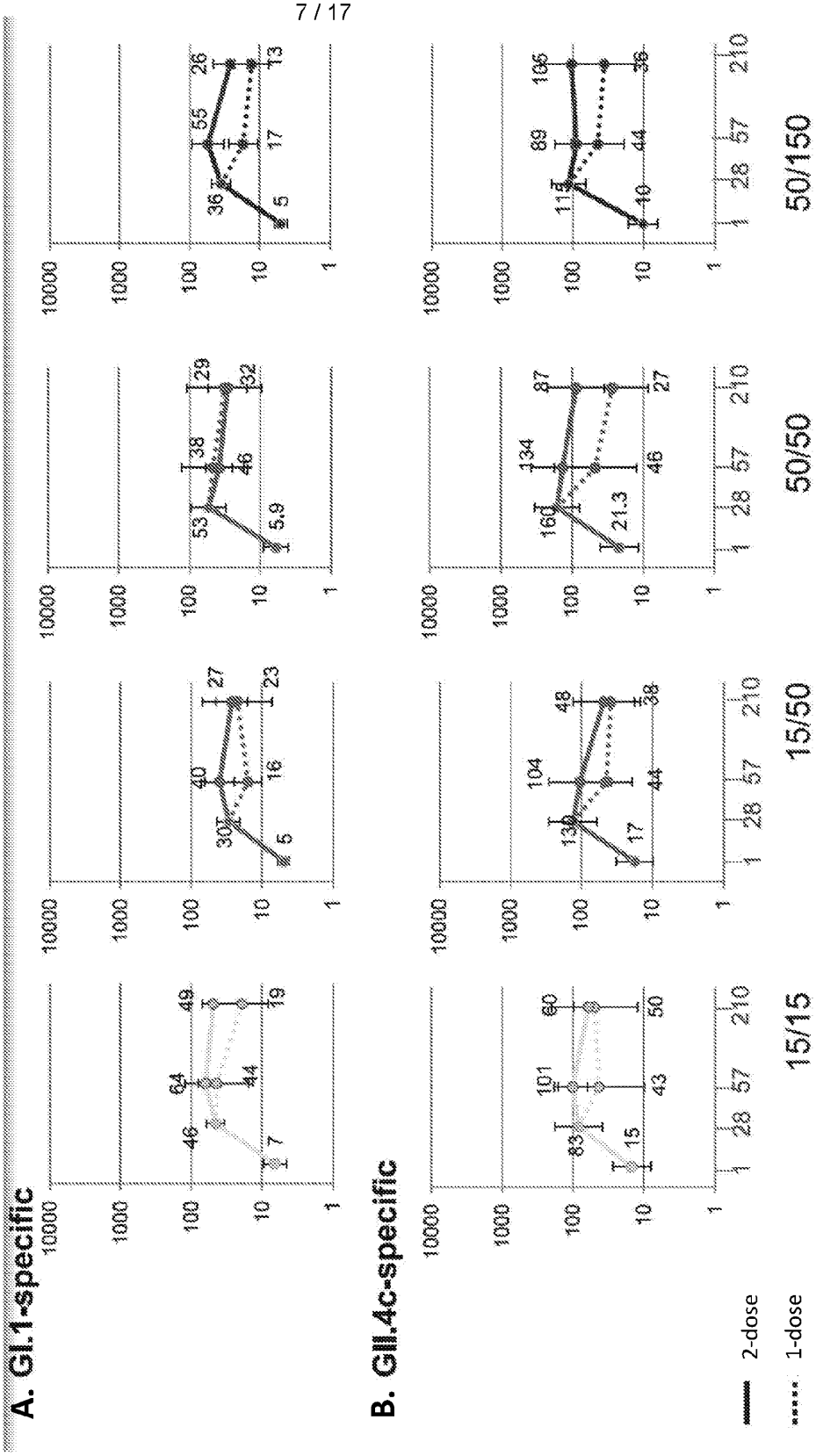

A. GI.1-specific
B. GII.4c-specific
15/15
15/50
50/50
50/150
2-dose
1-dose
10000
1000
100
10
1
1
28
57
210

FIG. 8A-8B

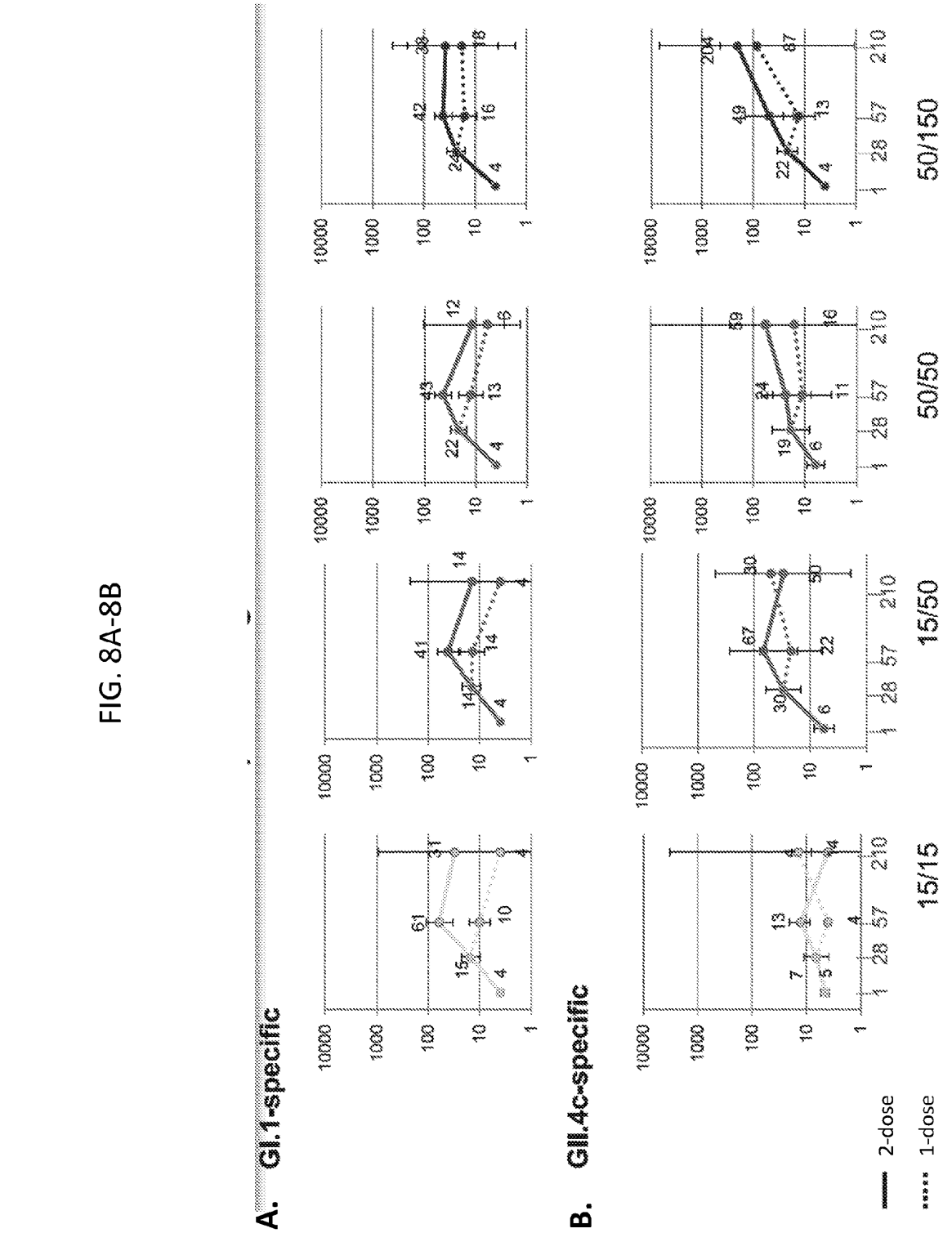

A. GI.1-specific
B. GII.4c-specific
15/15
15/50
50/50
50/150
2-dose
1-dose
10000
1000
100
10
1
1
28
57
210

FIG. 9A-9B

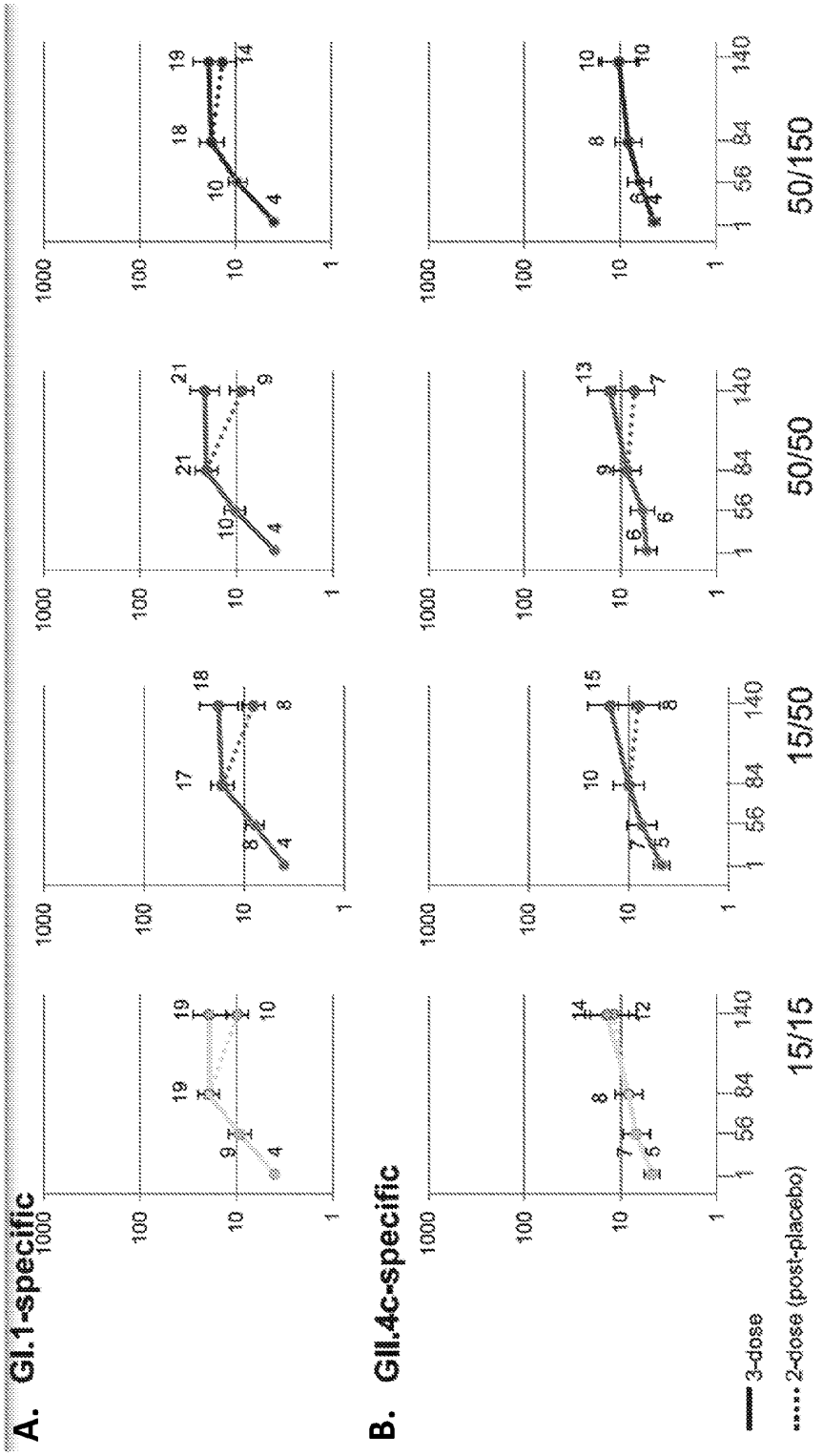

A. GI.1-specific
B. GII.4c-specific
15/15
15/50
50/50
50/150
3-dose
2-dose (post-placebo)

FIG. 10

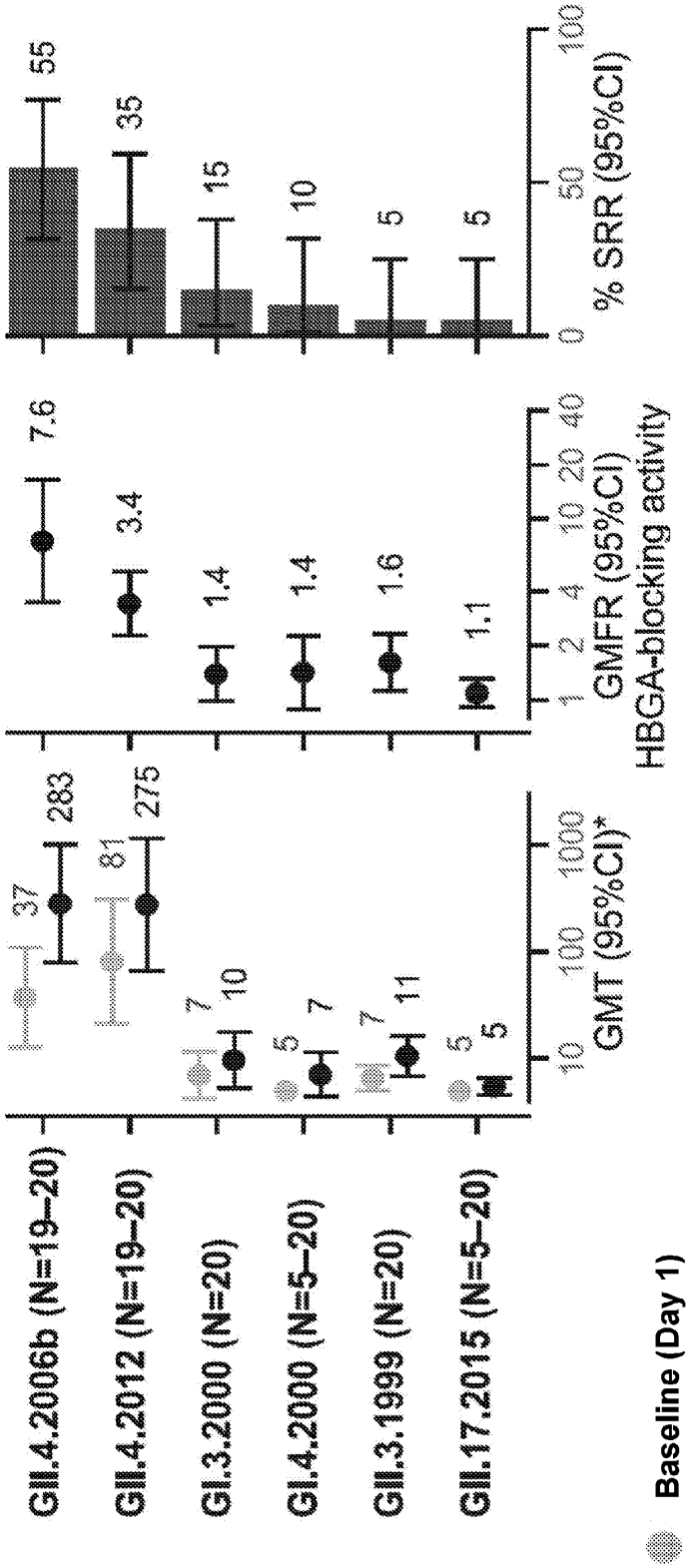

GII.4.2006b (N=19–20)
GII.4.2012 (N=19–20)
GI.3.2000 (N=20)
GI.4.2000 (N=5–20)
GII.3.1999 (N=20)
GII.17.2015 (N=5–20)
37
283
81
275
7
10
5
7
7
11
5
5
10
100
1000
GMT (95%CI)*
7.6
3.4
1.4
1.4
1.6
1.1
1
2
4
10
20
40
GMFR (95%CI)
HBGA-blocking activity
55
35
15
10
5
5
0
50
100
% SRR (95%CI)
Baseline (Day 1)
After 2nd Dose

FIG. 11A

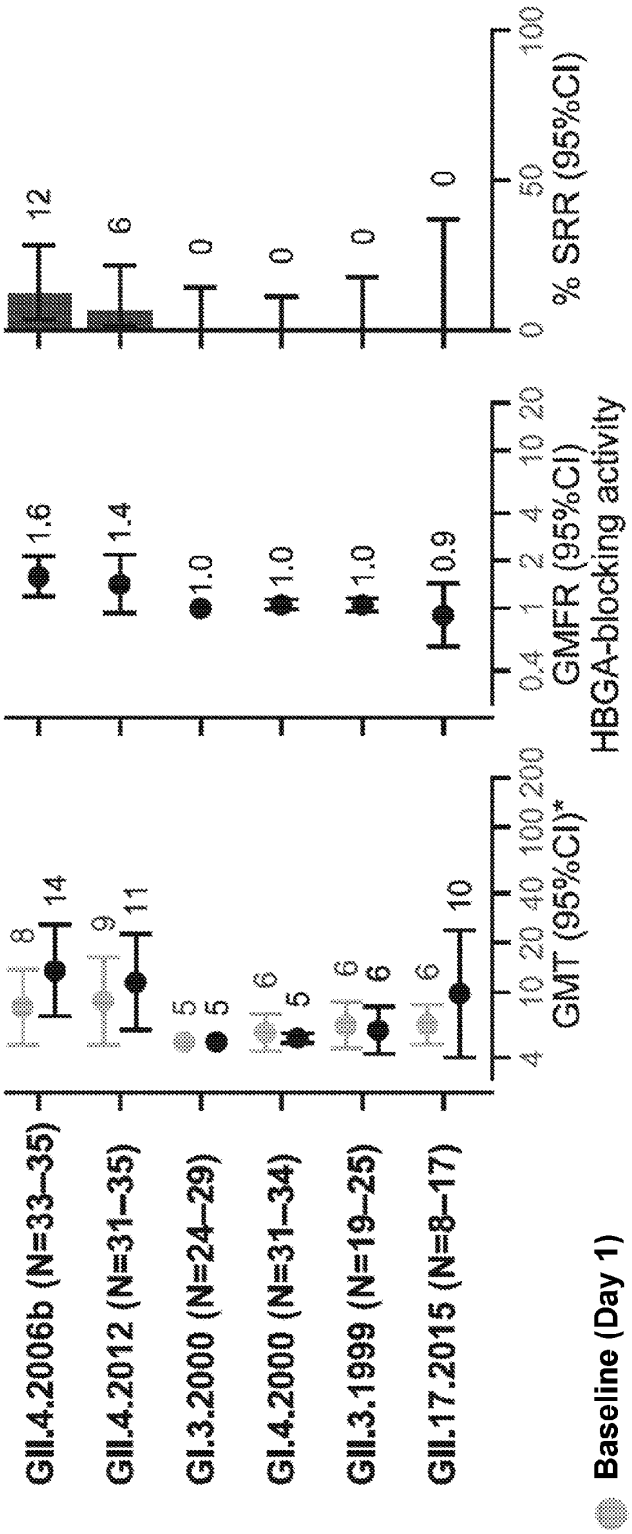

GII.4.2006b (N=33–35)
GII.4.2012 (N=31–35)
GI.3.2000 (N=24–29)
GI.4.2000 (N=31–34)
GII.3.1999 (N=19–25)
GII.17.2015 (N=8–17)
8
14
9
11
5
5
6
5
6
6
6
10
4 10 20 40 100 200
GMT (95%CI)*
1.6
1.4
1.0
1.0
1.0
0.9
0.4 1 2 4 10 20
GMFR (95%CI)
HBGA-blocking activity
12
6
0
0
0
0
0 50 100
% SRR (95%CI)
Baseline (Day 1)
After 1st Dose

FIG. 11B

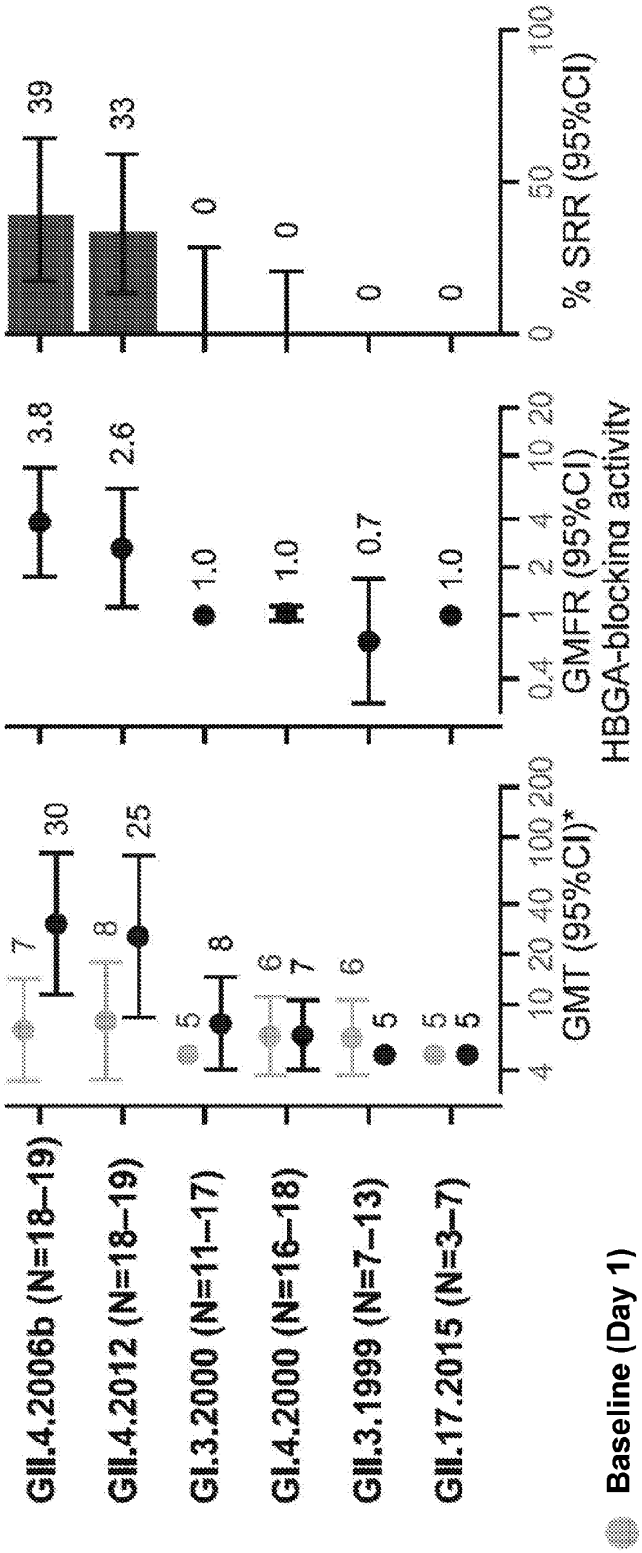

GII.4.2006b (N=18–19)
GII.4.2012 (N=18–19)
GI.3.2000 (N=11–17)
GI.4.2000 (N=16–18)
GII.3.1999 (N=7–13)
GII.17.2015 (N=3–7)
GMT (95%CI)*
4 10 20 40 100 200
GMFR (95%CI)
HBGA-blocking activity
0.4 1 2 4 10 20
% SRR (95%CI)
0 50 100
Baseline (Day 1)
After 2nd Dose

FIG. 12A

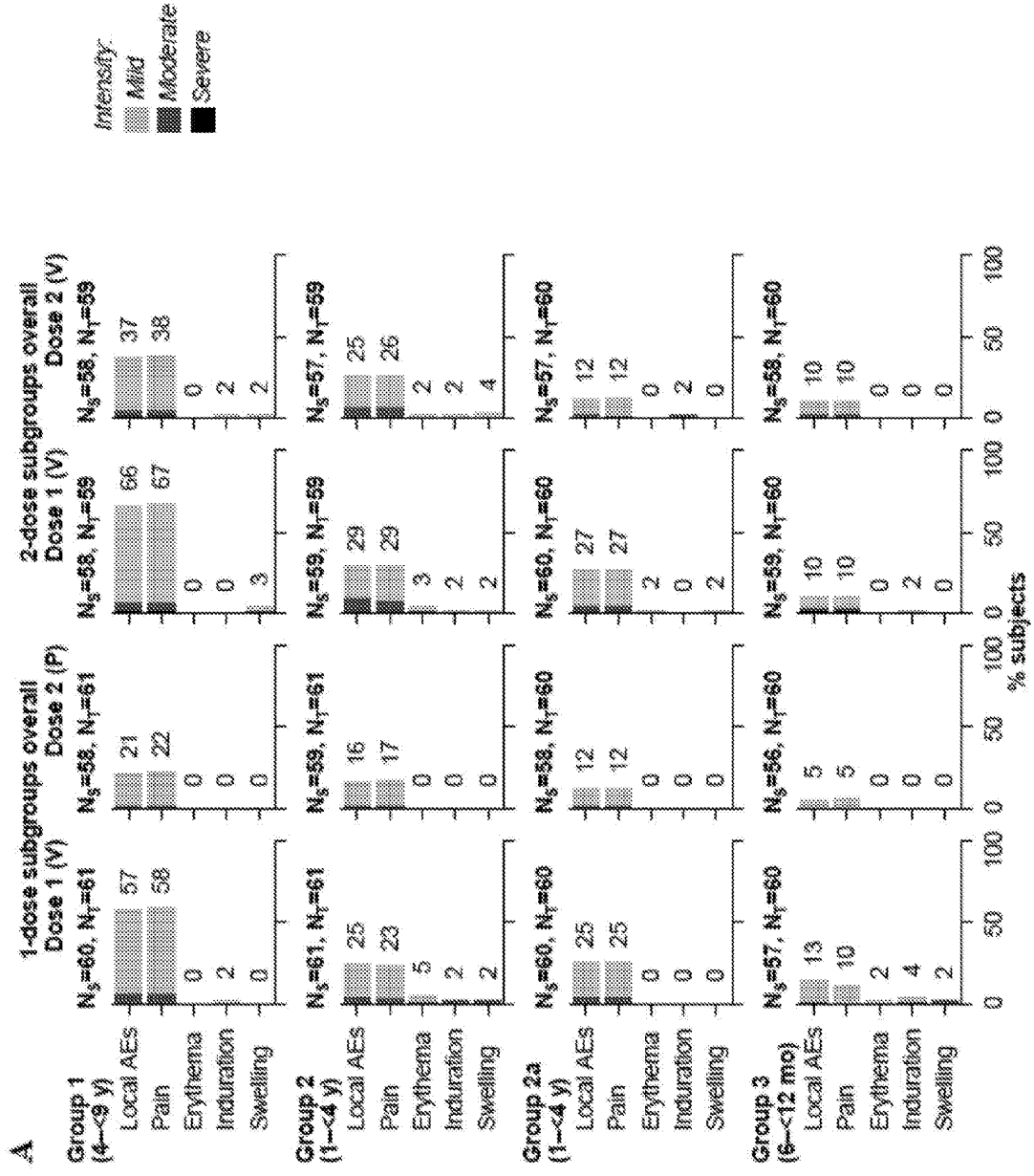

A
1-dose subgroups overall
Dose 1 (V)
Dose 2 (P)
2-dose subgroups overall
Dose 1 (V)
Dose 2 (V)
Intensity:
Mild
Moderate
Severe
Group 1 (4–<9 y)
Group 2 (1–<4 y)
Group 2a (1–<4 y)
Group 3 (6–<12 mo)
Local AEs
Pain
Erythema
Induration
Swelling
% subjects

FIG. 12B

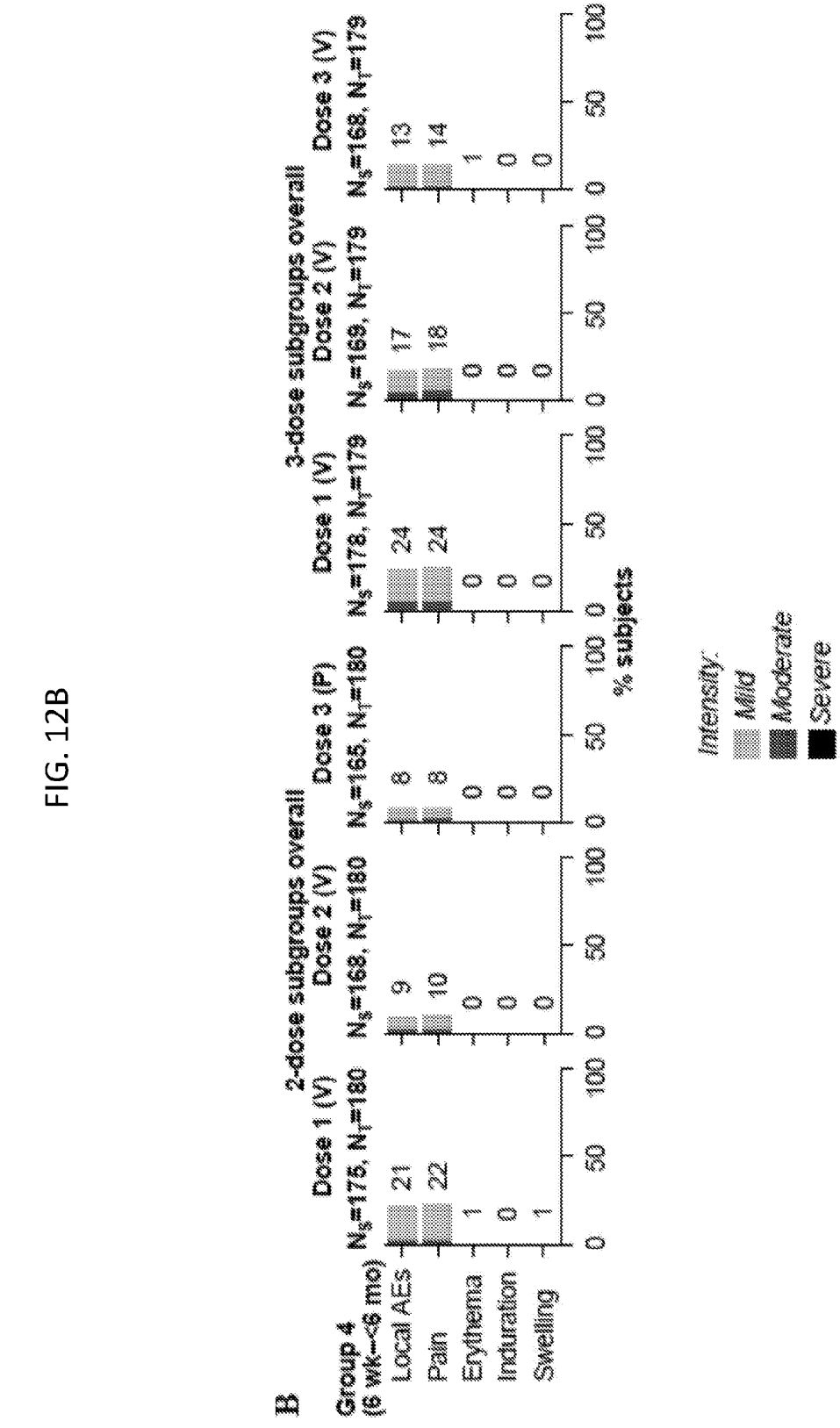

B
2-dose subgroups overall
3-dose subgroups overall
Group 4
(6 wk–<6 mo)
Dose 1 (V)
Dose 2 (V)
Dose 3 (P)
Dose 3 (V)
N_S=175, N_T=180
N_S=168, N_T=180
N_S=165, N_T=180
N_S=178, N_T=179
N_S=169, N_T=179
N_S=168, N_T=179
Local AEs
Pain
Erythema
Induration
Swelling
21
22
1
0
1
9
10
0
0
0
8
8
0
0
0
24
24
0
0
0
17
18
0
0
0
13
14
1
0
0
0
50
100
% subjects
Intensity:
Mild
Moderate
Severe

FIG. 13A

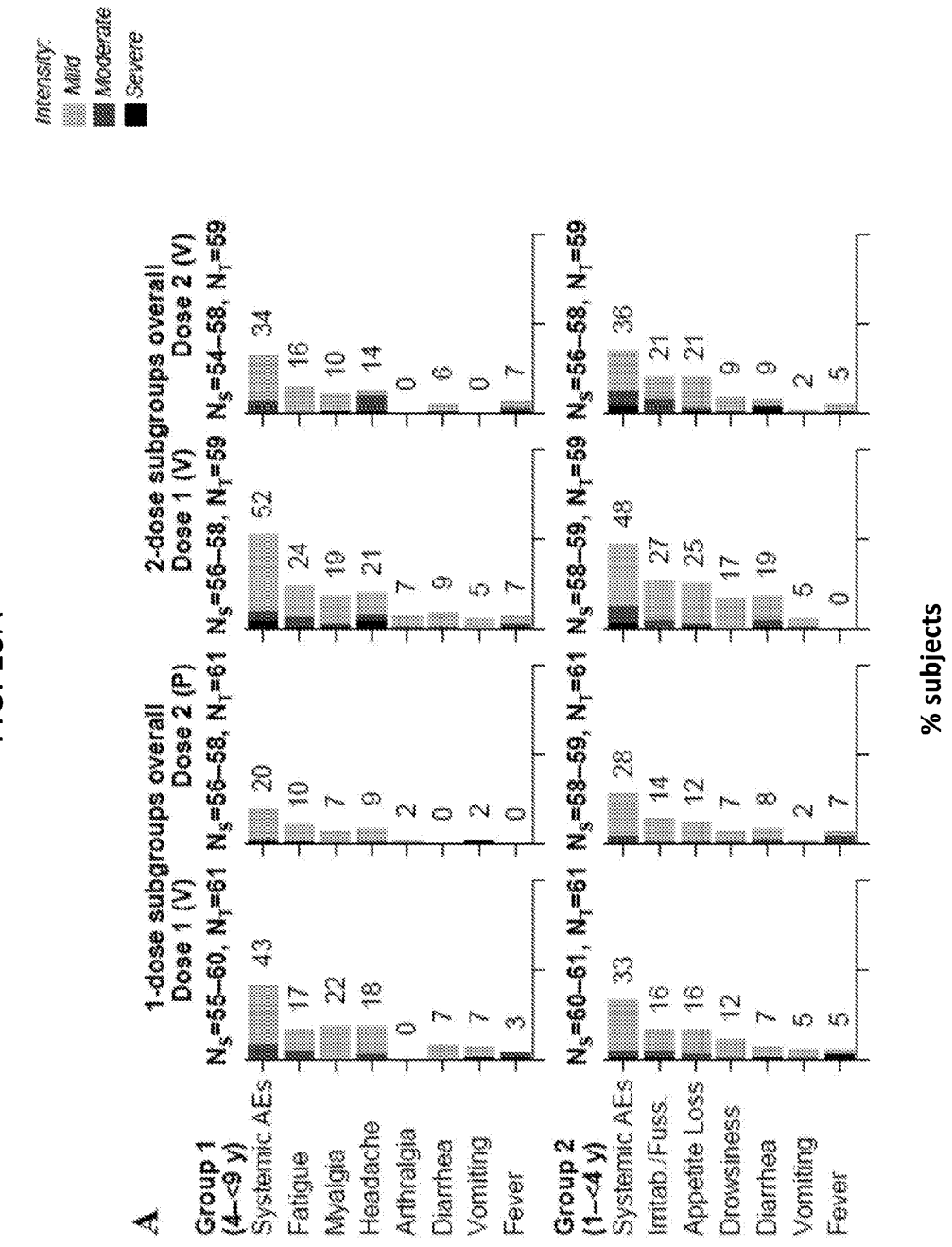

A
Intensity:
Mild
Moderate
Severe
1-dose subgroups overall
Dose 1 (V)
Dose 2 (P)
2-dose subgroups overall
Dose 1 (V)
Dose 2 (V)
Group 1 (4–<9 y)
Ns=55–60, NT=61
Ns=56–58, NT=61
Ns=56–58, NT=59
Ns=54–58, NT=59
Systemic AEs
Fatigue
Myalgia
Headache
Arthralgia
Diarrhea
Vomiting
Fever
43
17
22
18
0
7
7
3
20
10
7
9
2
0
2
0
62
24
19
21
7
9
5
7
34
16
10
14
0
6
0
7
Group 2 (1–<4 y)
Ns=60–61, NT=61
Ns=58–59, NT=61
Ns=58–59, NT=59
Ns=56–58, NT=59
Systemic AEs
Irritab./Fuss.
Appetite Loss
Drowsiness
Diarrhea
Vomiting
Fever
33
16
16
12
7
5
5
28
14
12
7
8
2
7
48
27
25
17
19
5
0
36
21
21
9
9
2
5
% subjects

FIG. 13B

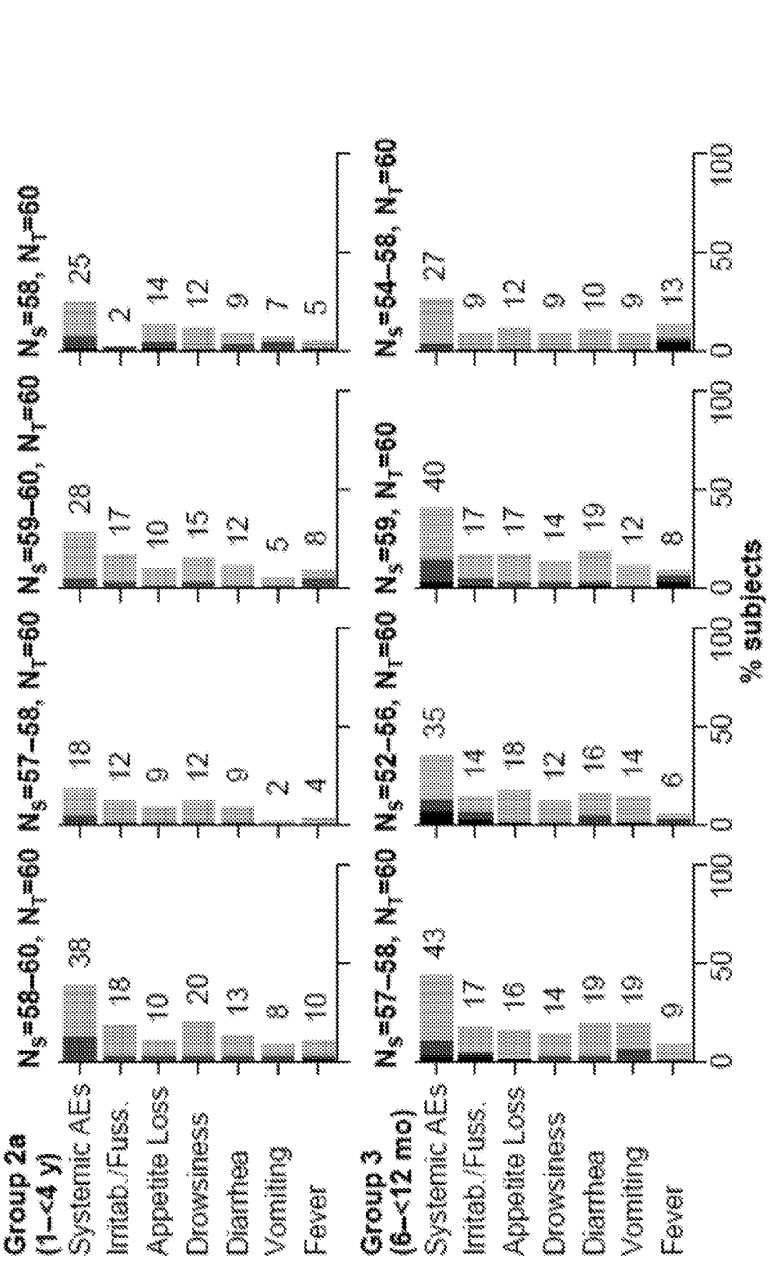
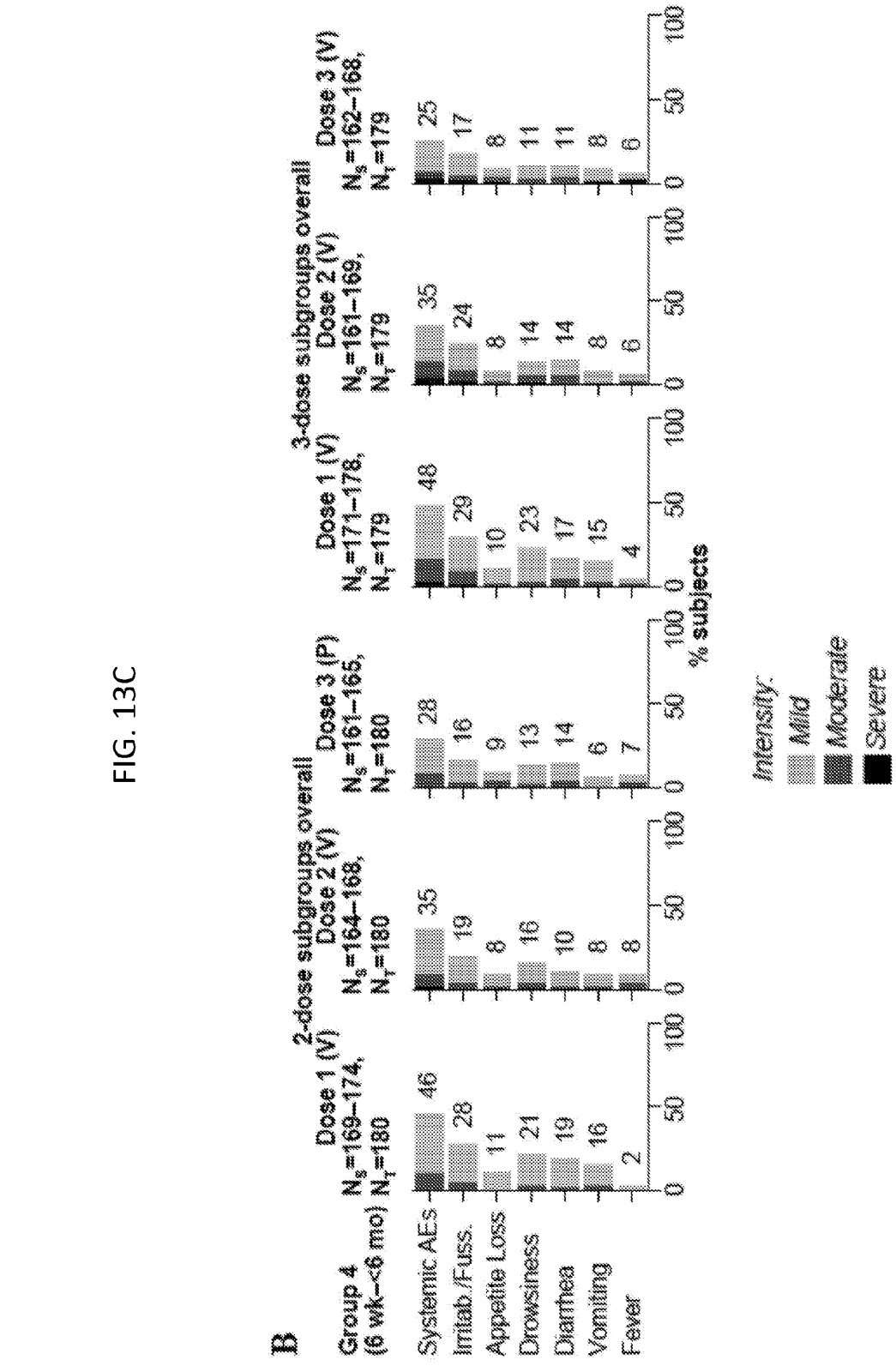

Intensity:
Mild
Moderate
Severe
Group 2a (1–<4 y)
N_S=58–60, N_T=60
N_S=57–58, N_T=60
N_S=59–60, N_T=60
N_S=58, N_T=60
Systemic AEs 38 18 28 25
Irritab./Fuss. 18 12 17 2
Appetite Loss 10 9 10 14
Drowsiness 20 12 15 12
Diarrhea 13 9 12 9
Vomiting 8 2 5 7
Fever 10 4 8 5
Group 3 (6–<12 mo)
N_S=57–58, N_T=60
N_S=52–66, N_T=60
N_S=59, N_T=60
N_S=54–58, N_T=60
Systemic AEs 43 35 40 27
Irritab./Fuss. 17 14 17 9
Appetite Loss 16 18 17 12
Drowsiness 14 12 14 9
Diarrhea 19 16 19 10
Vomiting 19 14 12 9
Fever 9 6 8 13
0 50 100
% subjects

FIG. 13C


B
2-dose subgroups overall
3-dose subgroups overall
Group 4 (6 wk–<6 mo)
Dose 1 (V) Ns=169–174, NT=180
Dose 2 (V) Ns=164–168, NT=180
Dose 3 (P) Ns=161–165, NT=180
Dose 1 (V) Ns=171–178, NT=179
Dose 2 (V) Ns=161–169, NT=179
Dose 3 (V) Ns=162–168, NT=179
Systemic AEs
Irritab./Fuss.
Appetite Loss
Drowsiness
Diarrhea
Vomiting
Fever
46 28 11 21 19 16 2
35 19 8 16 10 8 8
28 16 9 13 14 6 7
48 29 10 23 17 15 4
35 24 8 14 14 8 6
25 17 8 11 11 8 6
0 50 100
% subjects
Intensity:
Mild
Moderate
Severe