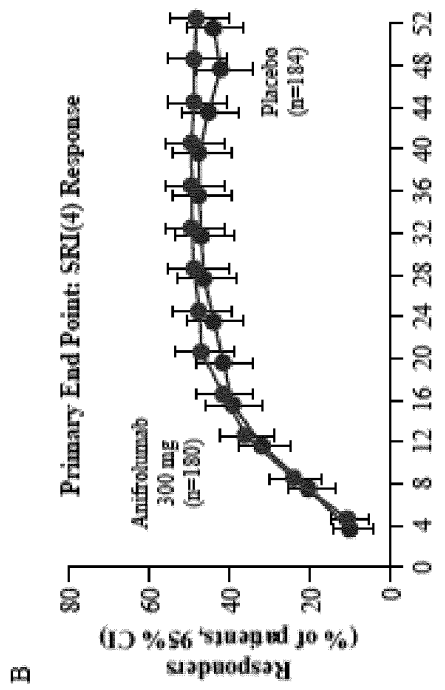

B
Analysis With Amended Rules for Restricted Medications
Primary End Point: SRI(4) Response
Responders (% of patients, 95% CI)
Study week
Antifolumab 300 mg (n=180)
Placebo (n=184)
0
20
40
60
80
0
4
8
12
16
20
24
28
32
36
40
44
48
52

FIG. 1B

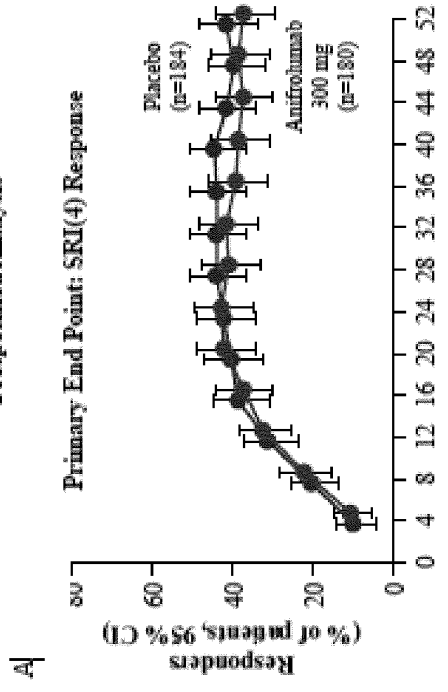

A
Prespecified Analysis
Primary End Point: SRI(4) Response
Responders (% of patients, 95% CI)
Study week
Placebo (n=184)
Antifolumab 300 mg (n=180)
0
20
40
60
80
0
4
8
12
16
20
24
28
32
36
40
44
48
52

FIG. 1A

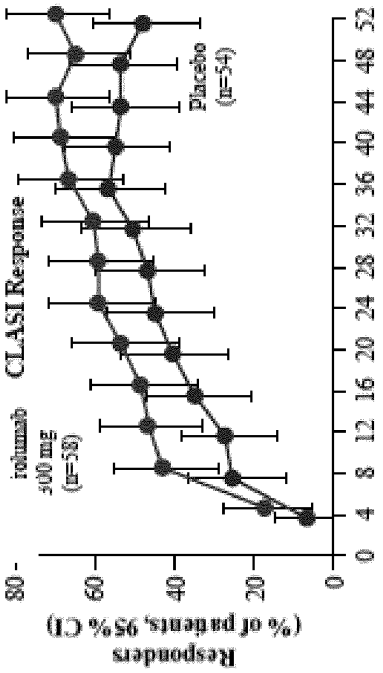

Responders
(% of patients, 95% CI)
80
60
40
20
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Study week
CLASI Response
Ani
300 mg
(n=58)
Placebo
(n=54)

FIG. 1C

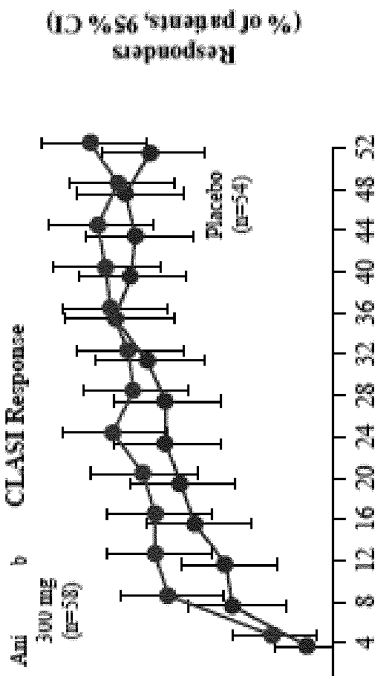

Responders
(% of patients, 95% CI)
80
60
40
20
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Study week
CLASI Response
ixekizumab
300 mg
(n=58)
Placebo
(n=54)

FIG. 1D

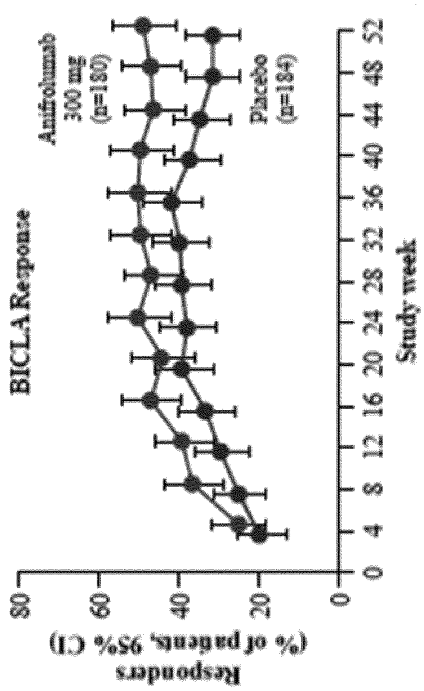

BICLA Response
Anifrolumab
300 mg
(n=180)
Placebo
(n=184)
Responders
(% of patients, 95% CI)
Study week
0
20
40
60
80
0
4
8
12
16
20
24
28
32
36
40
44
48
52

FIG. 1F

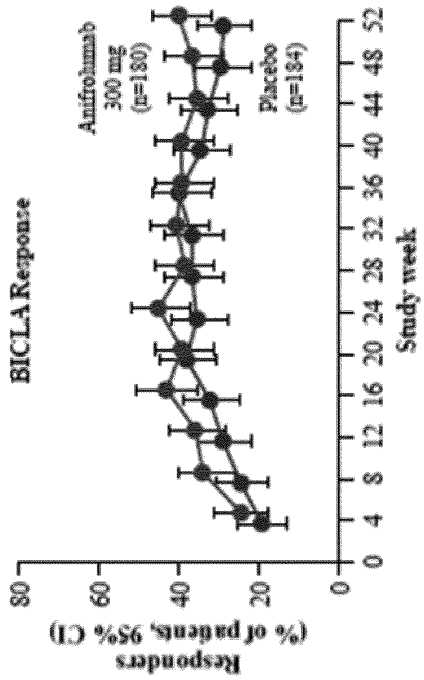

BICLA Response
Anifrolumab
300 mg
(n=180)
Placebo
(n=184)
Responders
(% of patients, 95% CI)
Study week
0
20
40
60
80
0
4
8
12
16
20
24
28
32
36
40
44
48
52

FIG. 1E

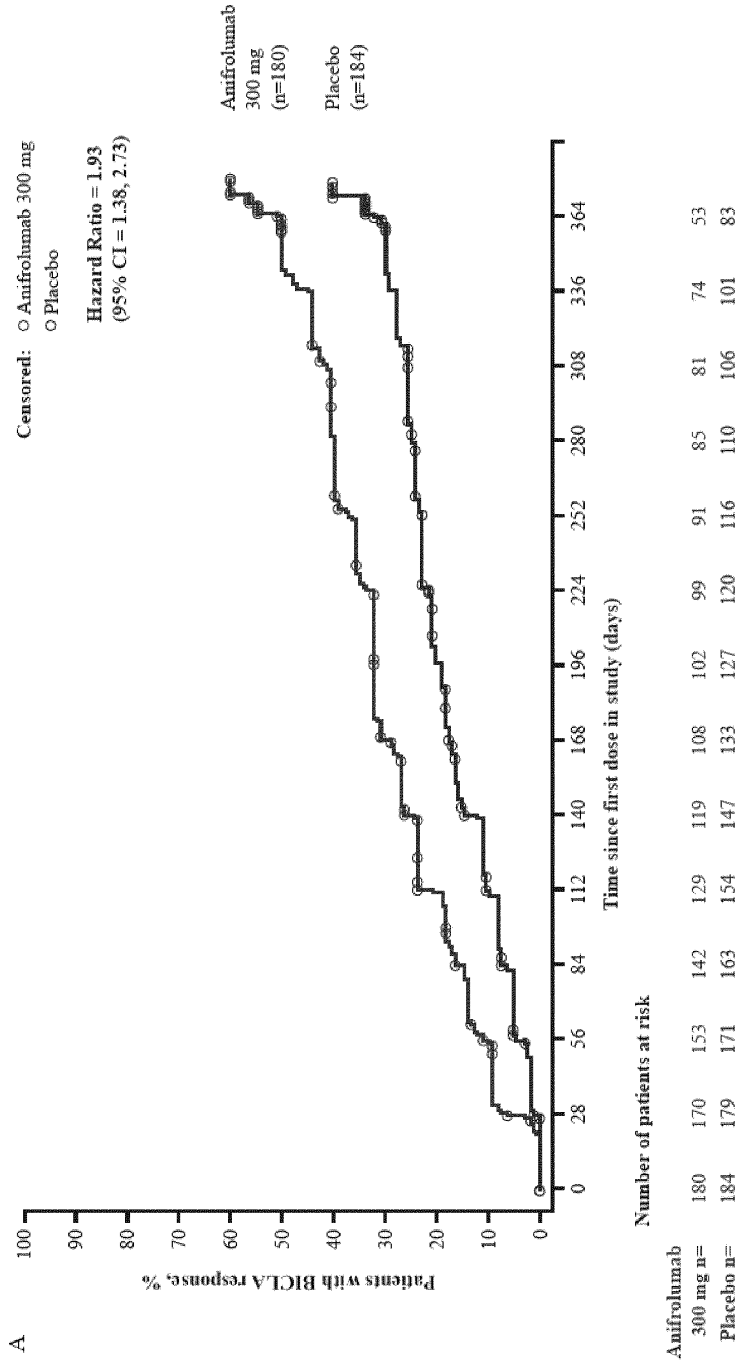

A
Patients with BICLA response, %
100
90
80
70
60
50
40
30
20
10
0
Censored: ○ Anifrolumab 300 mg
○ Placebo
Hazard Ratio = 1.93
(95% CI = 1.38, 2.73)
Anifrolumab 300 mg (n=180)
Placebo (n=184)
Time since first dose in study (days)
Number of patients at risk
Anifrolumab 300 mg n= 180 170 153 142 129 119 108 102 99 91 85 81 74 53
Placebo n= 184 179 171 163 154 147 133 127 120 116 110 106 101 83
0 28 56 84 112 140 168 196 224 252 280 308 336 364

FIG. 2A

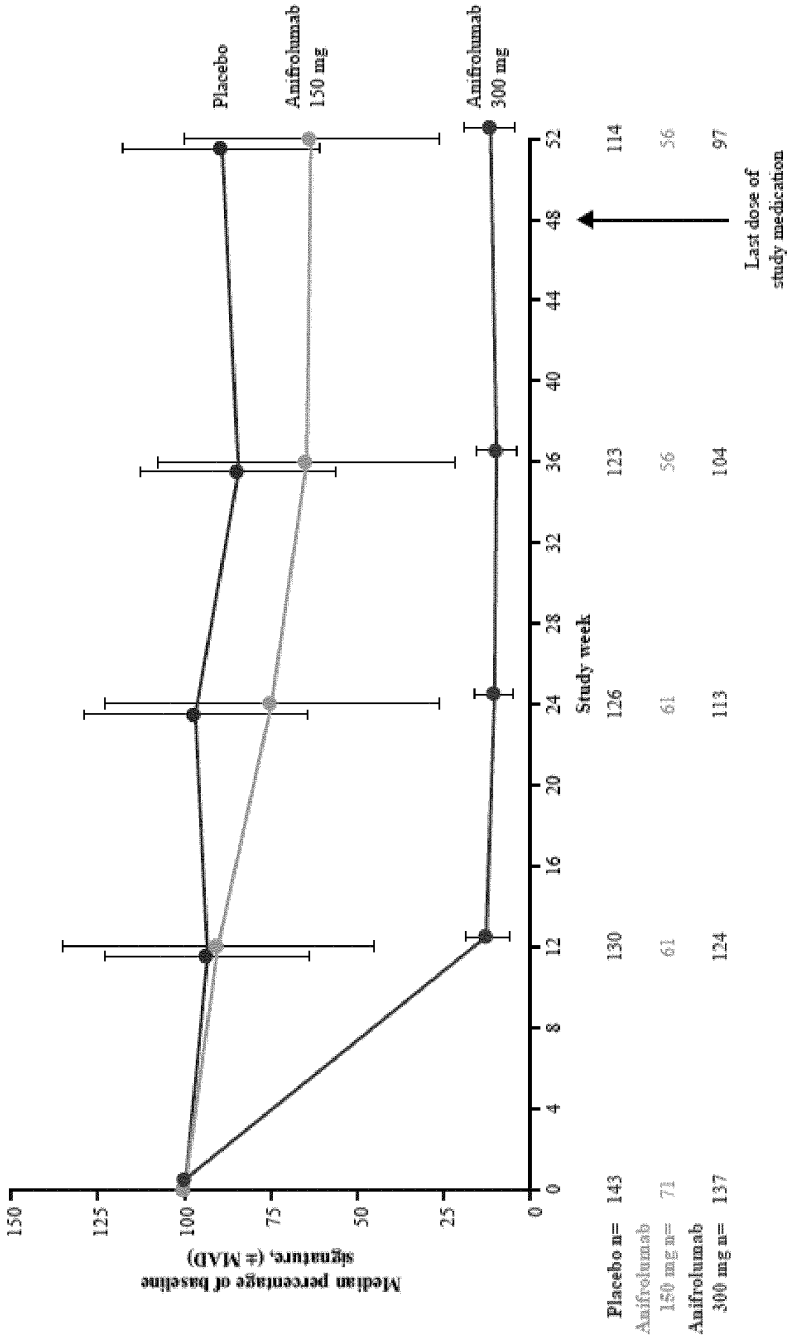

Placebo
Anifrolumab 150 mg
Anifrolumab 300 mg
Median percentage of baseline signature, (± MAD)
150
125
100
75
50
25
0
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Study week
Last dose of study medication
Placebo n= 143 130 123 114
Anifrolumab 150 mg n= 71 61 56 56
Anifrolumab 300 mg n= 137 124 104 97

FIG. 2B

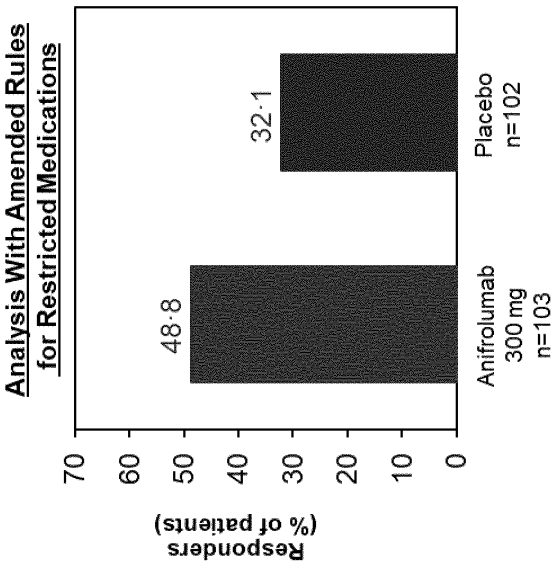

Analysis With Amended Rules for Restricted Medications
Responders (% of patients)
0
10
20
30
40
50
60
70
48·8
32·1
Anifrolumab 300 mg n=103
Placebo n=102

FIG. 3B

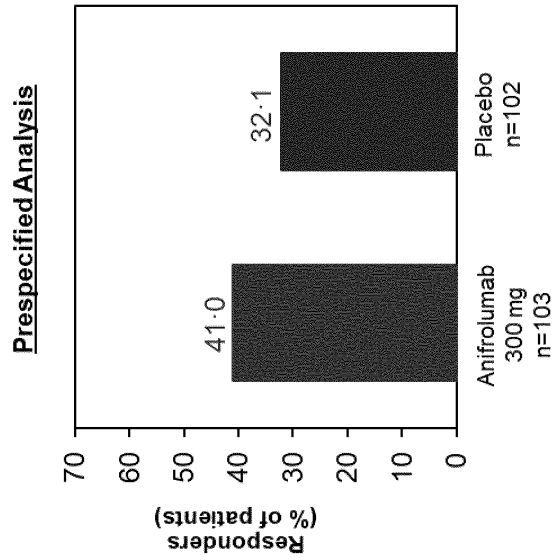

Prespecified Analysis
Responders (% of patients)
0
10
20
30
40
50
60
70
41·0
32·1
Anifrolumab 300 mg n=103
Placebo n=102

FIG. 3A

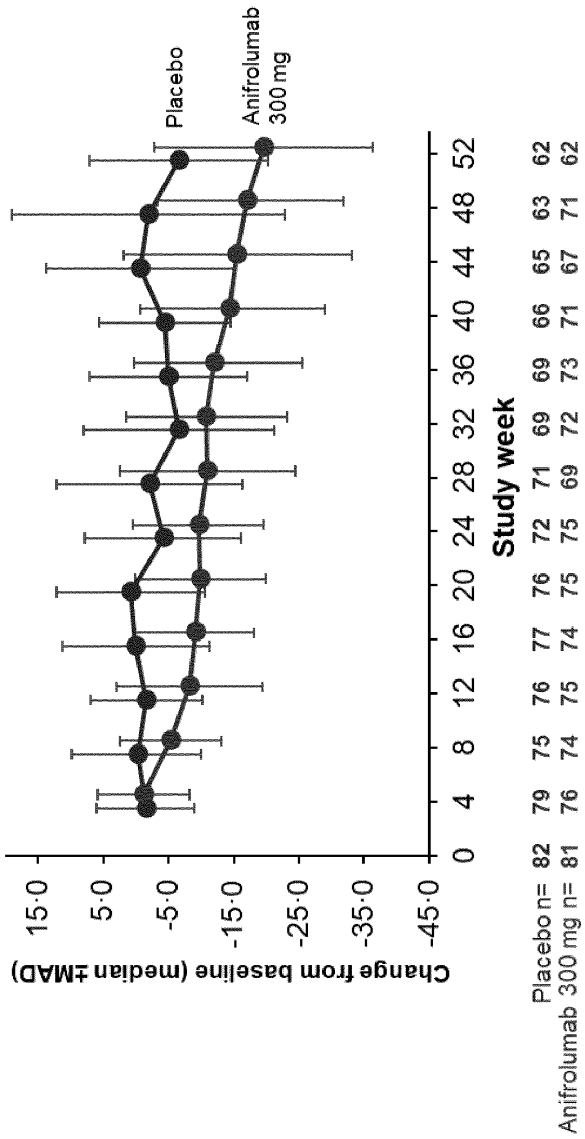

Placebo
Anifrolumab 300 mg
Change from baseline (median ±MAD)
15·0
5·0
-5·0
-15·0
-25·0
-35·0
-45·0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Study week
Placebo n= 82 79 75 76 77 76 72 71 69 72 73 71 67 71 62
Anifrolumab 300 mg n= 81 76 74 75 74 75 75 69 72 73 71 67 71 62

FIG. 4A

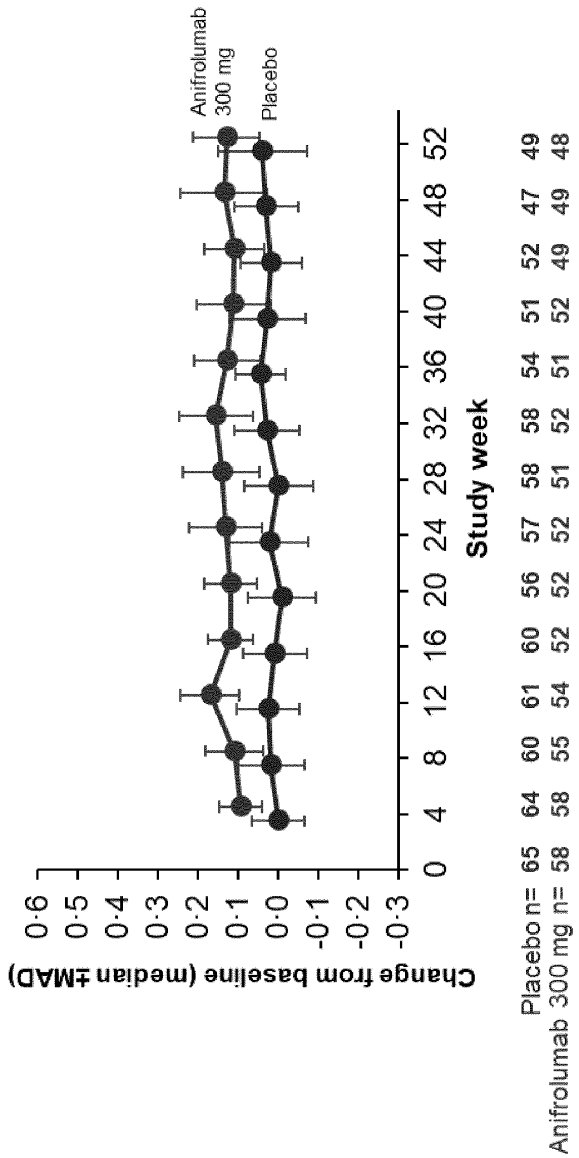

Anifrolumab 300 mg
Placebo
Change from baseline (median ±MAD)
0·6
0·5
0·4
0·3
0·2
0·1
0·0
-0·1
-0·2
-0·3
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Study week
Placebo n= 65 64 60 61 60 56 57 58 58 54 51 52 47 49
Anifrolumab 300 mg n= 58 58 55 54 52 52 52 51 52 51 52 49 49 48

FIG. 4B

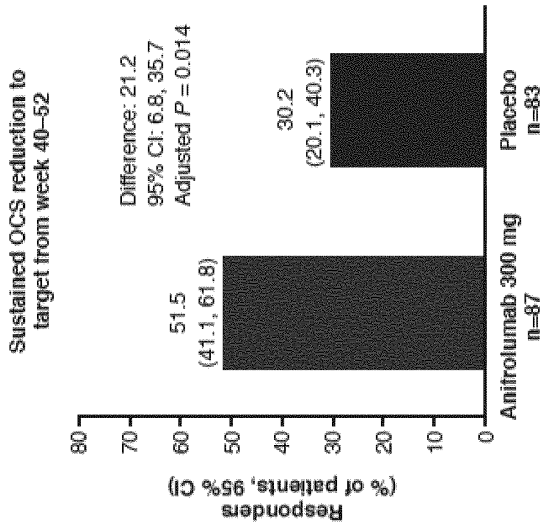

Sustained OCS reduction to target from week 40–52
Difference: 21.2
95% CI: 6.8, 35.7
Adjusted P = 0.014
51.5
(41.1, 61.8)
30.2
(20.1, 40.3)
Responders
(% of patients, 95% CI)
0
10
20
30
40
50
60
70
80
Anifrolumab 300 mg
n=87
Placebo
n=83

FIG. 5B

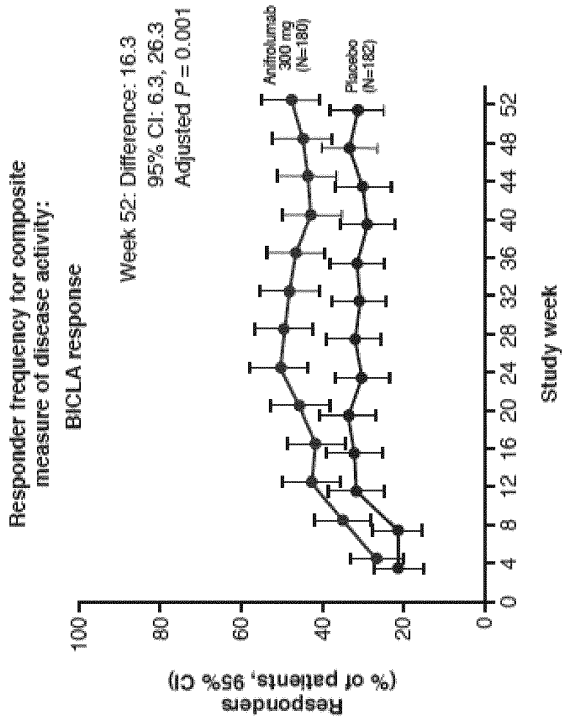

Responder frequency for composite measure of disease activity:
BICLA response
Week 52: Difference: 16.3
95% CI: 6.3, 26.3
Adjusted P = 0.001
Anifrolumab 300 mg (N=180)
Placebo (N=182)
Responders
(% of patients, 95% CI)
0
20
40
60
80
100
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Study week

FIG. 5A

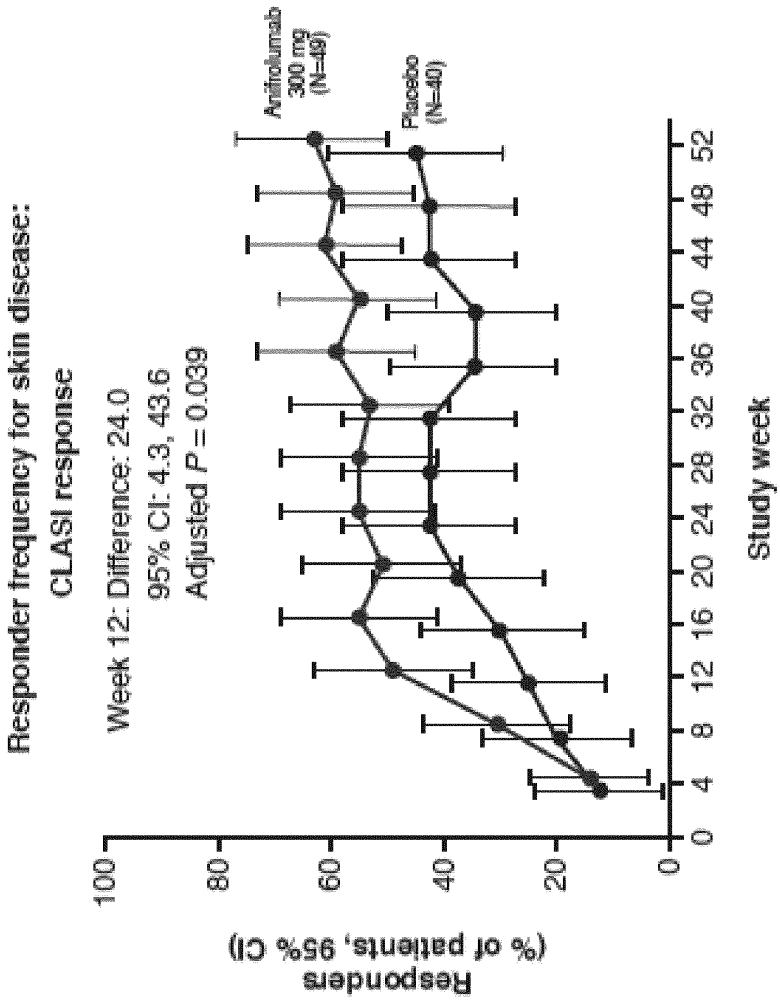

Responder frequency for skin disease:
CLASI response
Week 12: Difference: 24.0
95% CI: 4.3, 43.6
Adjusted P = 0.039
Anifrolumab 300 mg (N=49)
Placebo (N=40)
Responders (% of patients, 95% CI)
Study week
0
20
40
60
80
100
0
4
8
12
16
20
24
28
32
36
40
44
48
52

FIG. 5C

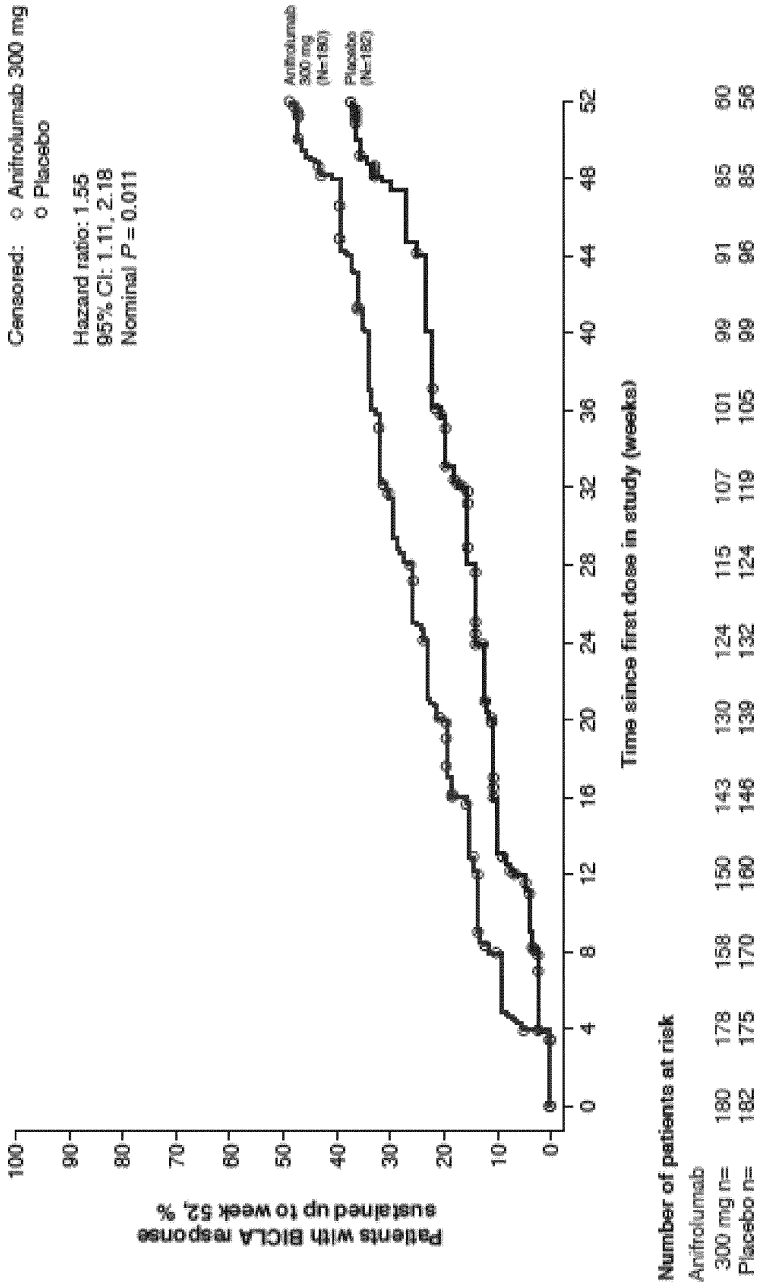

Censored: ○ Anifrolumab 300 mg
○ Placebo
Hazard ratio: 1.55
95% CI: 1.11, 2.18
Nominal P = 0.011
Anifrolumab 300 mg (N=180)
Placebo (N=182)
Patients with BICLA response sustained up to week 52, %
Time since first dose in study (weeks)
Number of patients at risk
Anifrolumab
300 mg n= 180 178 158 150 143 130 124 115 107 101 99 91 85 60
Placebo n= 182 175 170 160 148 139 132 124 119 105 99 96 85 56

FIG. 6A

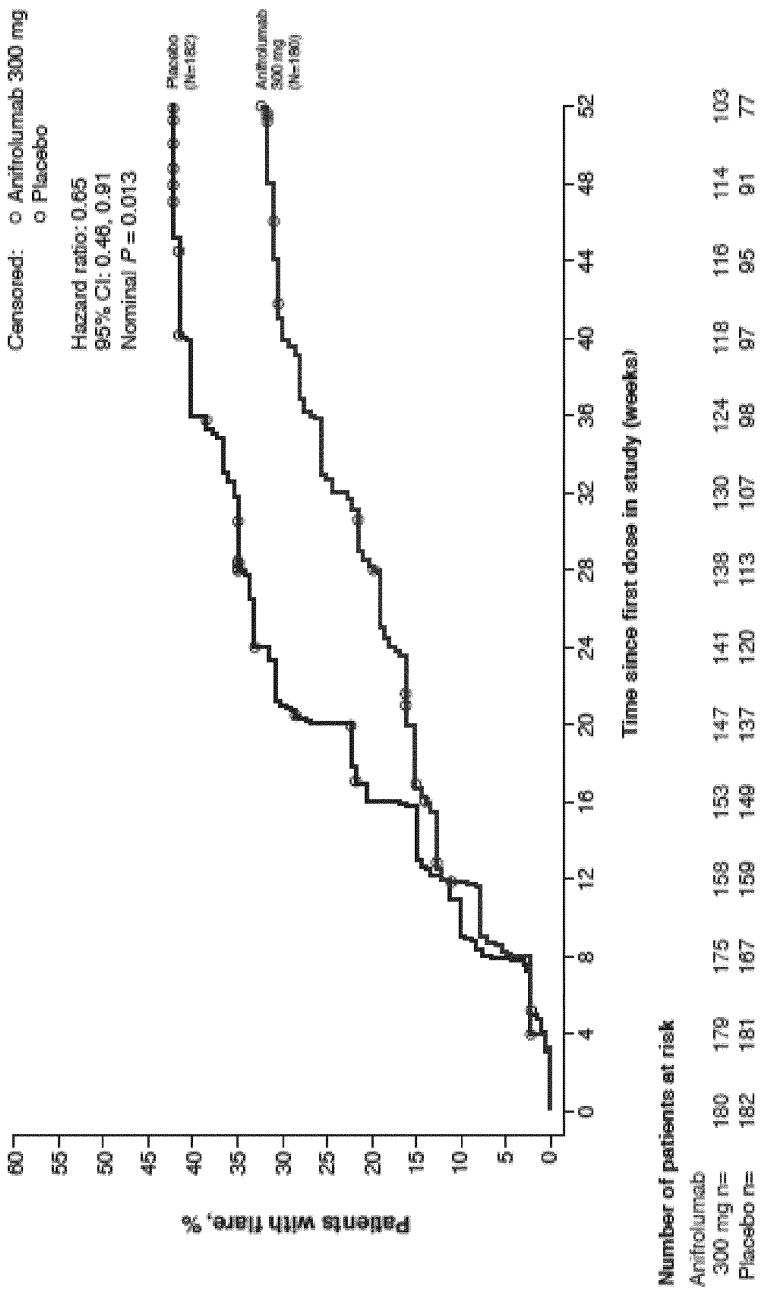

Censored: o Anifrolumab 300 mg
o Placebo
Hazard ratio: 0.65
95% CI: 0.46, 0.91
Nominal P = 0.013
Placebo (N=182)
Anifrolumab 300 mg (N=180)
Patients with flare, %
Time since first dose in study (weeks)
Number of patients at risk
Anifrolumab
300 mg n= 180 179 175 158 153 147 141 138 130 124 118 116 114 103
Placebo n= 182 181 167 159 149 137 120 113 107 98 97 95 91 77

FIG. 6B

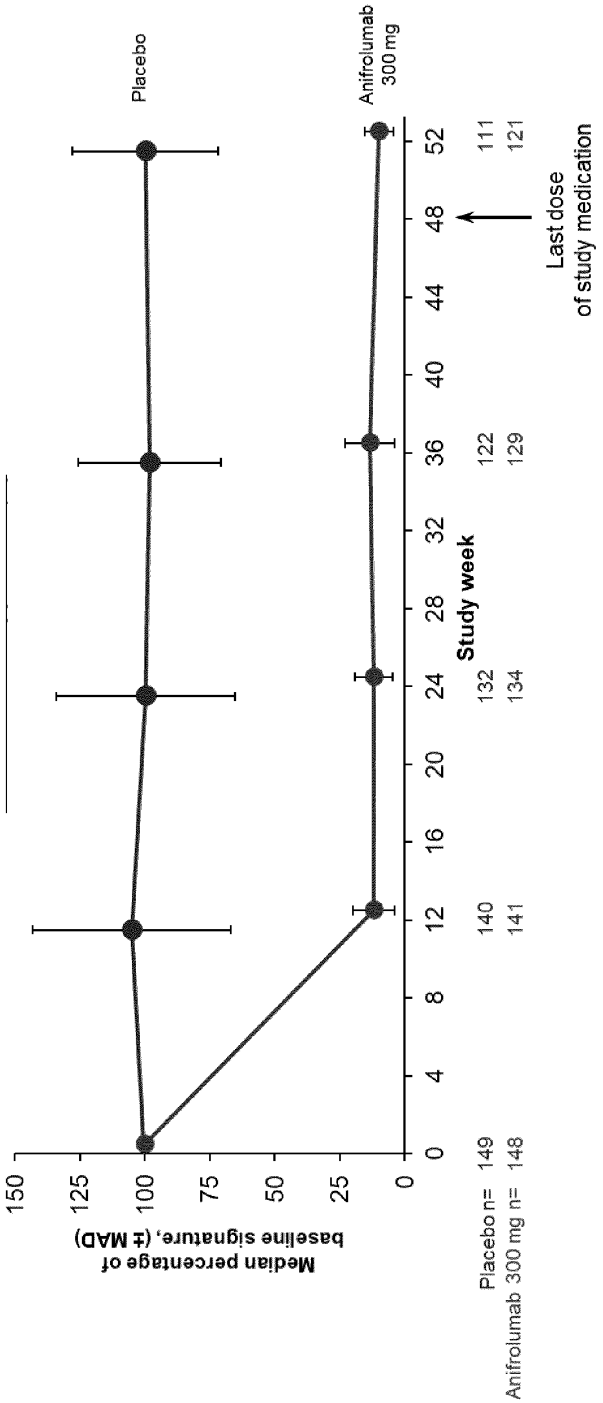

Placebo
Anifrolumab 300 mg
Median percentage of baseline signature, (± MAD)
150
125
100
75
50
25
0
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Study week
Last dose of study medication
Placebo n= 149 140 132 122 111
Anifrolumab 300 mg n= 148 141 134 129 121

FIG. 7A

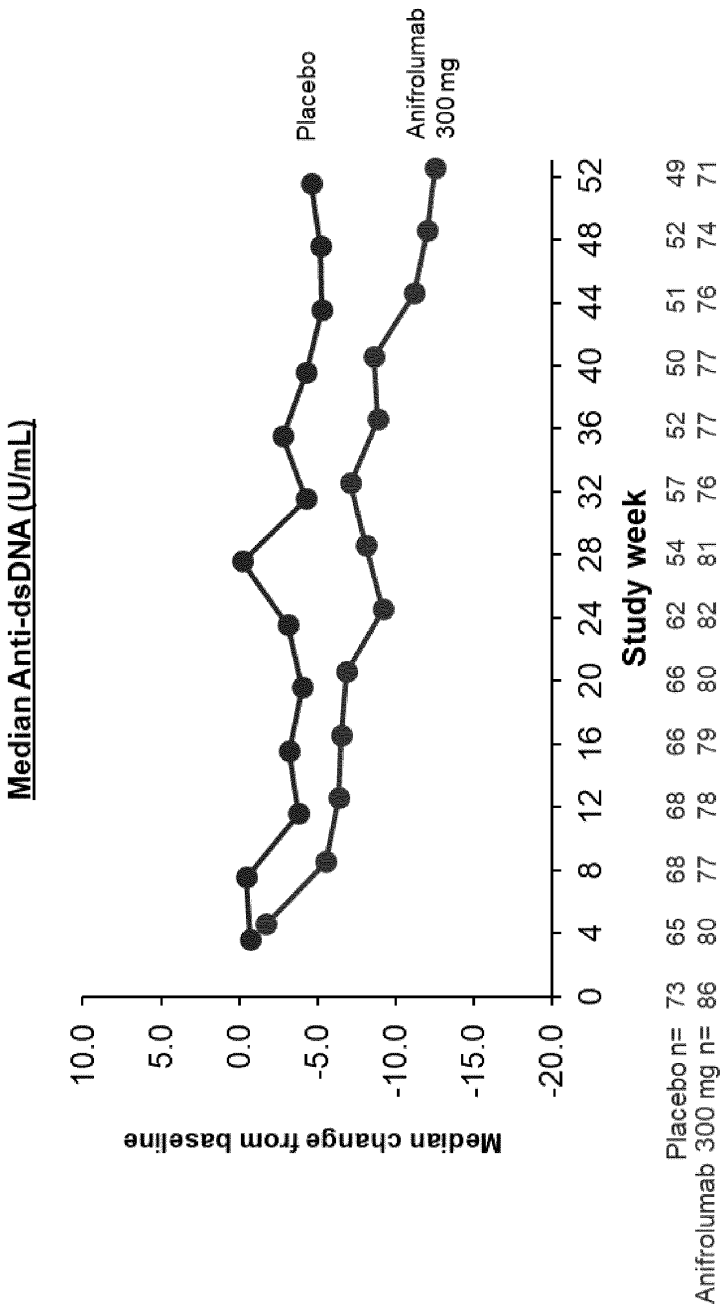

Median Anti-dsDNA (U/mL)
Placebo
Anifrolumab 300 mg
Median change from baseline
10.0
5.0
0.0
-5.0
-10.0
-15.0
-20.0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Study week
Placebo n= 73 65 68 68 66 66 62 54 57 52 50 51 52 49
Anifrolumab 300 mg n= 86 80 77 78 79 80 82 81 76 77 77 76 74 71

FIG. 7B

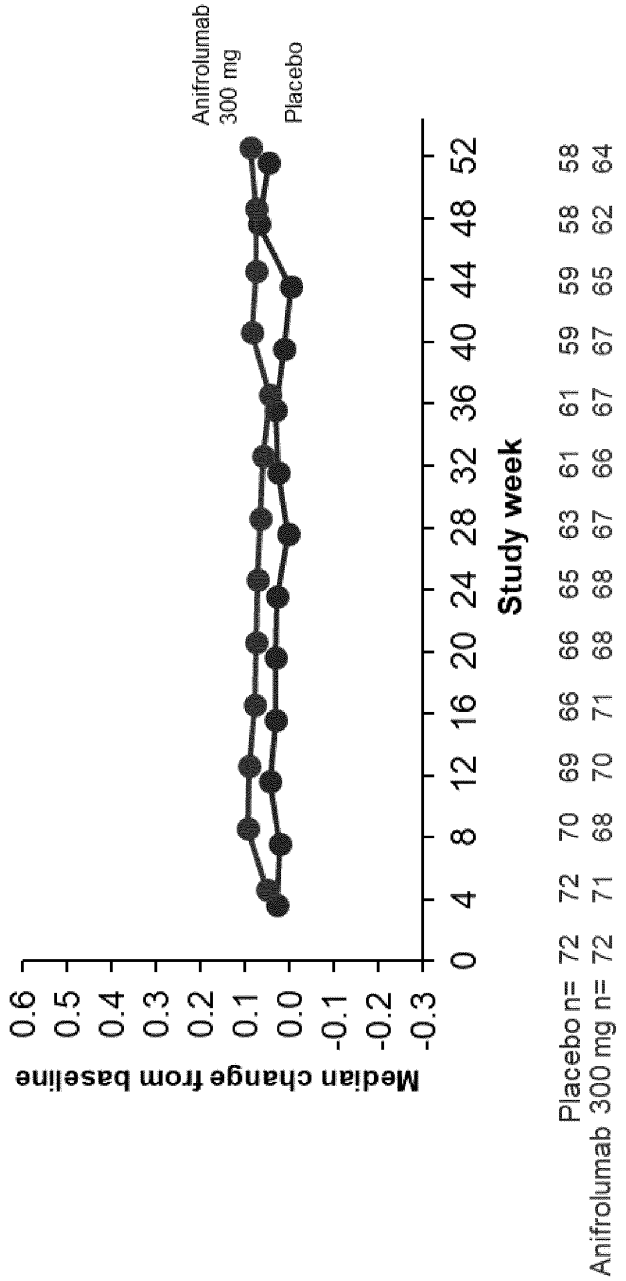

Median C3 (g/L)
Anifrolumab 300 mg
Placebo
Median change from baseline
0.6
0.5
0.4
0.3
0.2
0.1
0.0
-0.1
-0.2
-0.3
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Study week
Placebo n= 72 72 70 69 66 66 65 63 61 61 59 59 58 58
Anifrolumab 300 mg n= 72 71 68 70 71 68 68 67 66 67 67 65 62 64

FIG. 7C

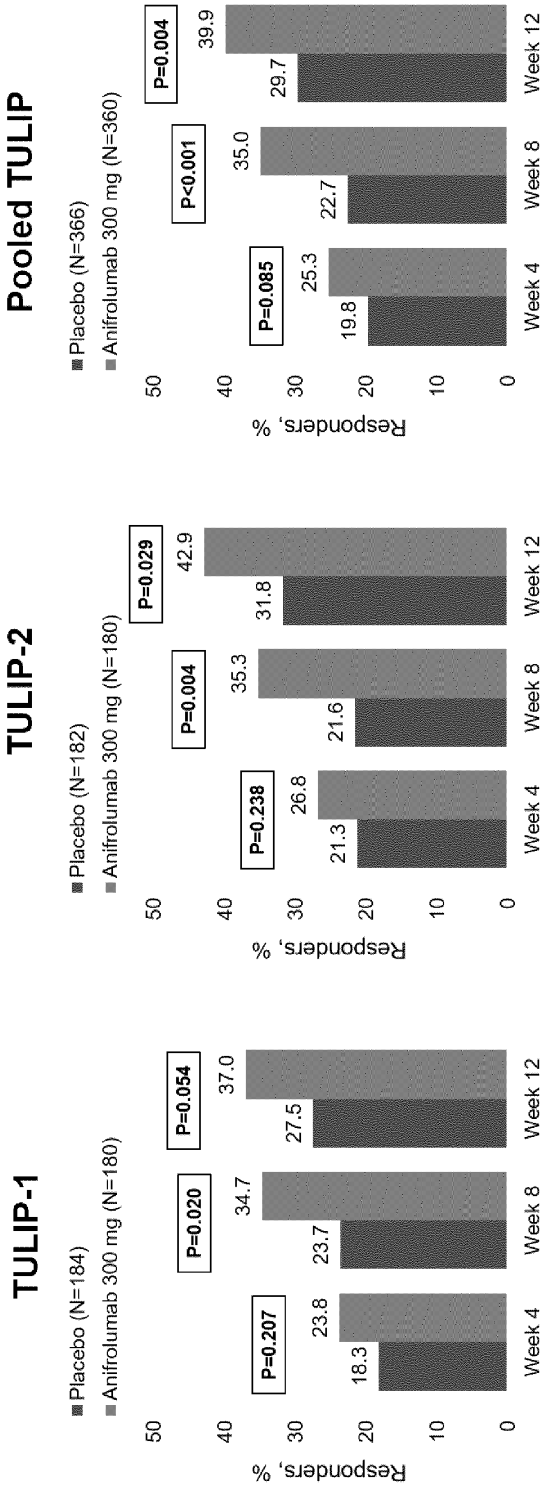


FIG. 8A

FIG. 8B

FIG. 8C

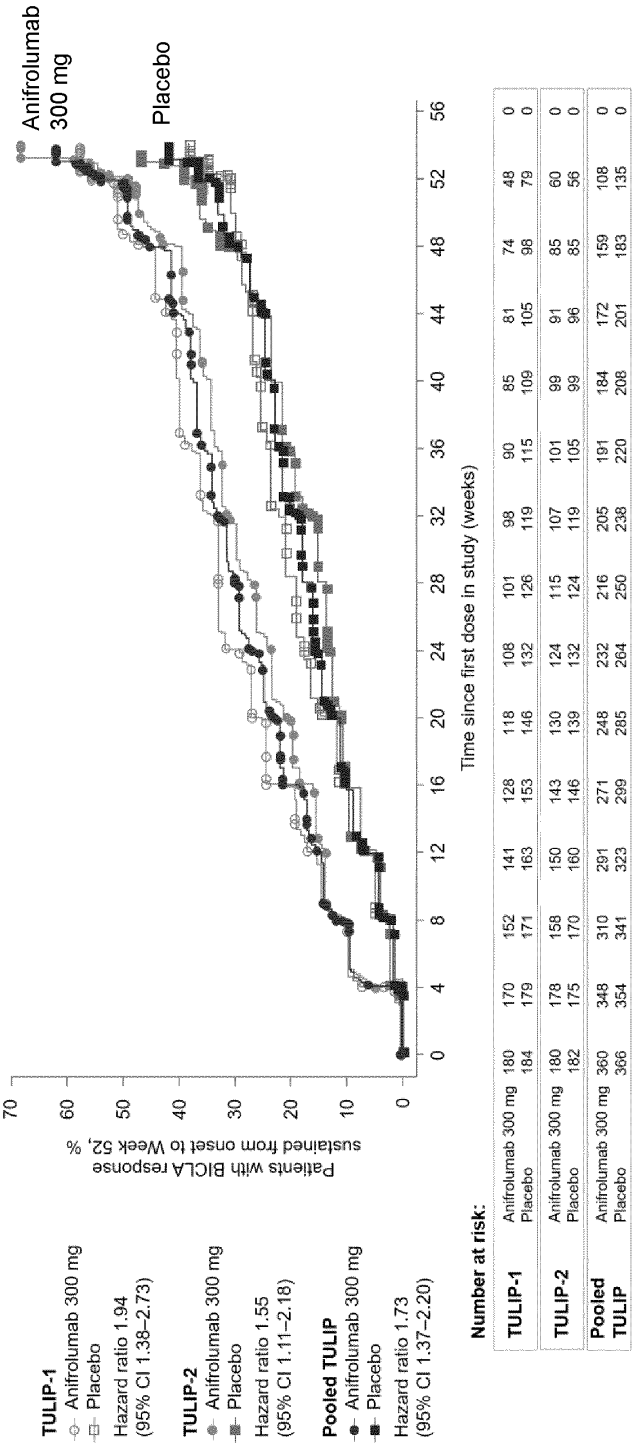

Anifrolumab 300 mg
Placebo
TULIP-1
Anifrolumab 300 mg
Placebo
Hazard ratio 1.94
(95% CI 1.38–2.73)
TULIP-2
Anifrolumab 300 mg
Placebo
Hazard ratio 1.55
(95% CI 1.11–2.18)
Pooled TULIP
Anifrolumab 300 mg
Placebo
Hazard ratio 1.73
(95% CI 1.37–2.20)
Patients with BICLA response sustained from onset to Week 52, %
70
60
50
40
30
20
10
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52 56
Time since first dose in study (weeks)
Number at risk:
TULIP-1 Anifrolumab 300 mg 180 170 152 141 128 118 108 101 98 90 85 81 74 48 0
Placebo 184 179 171 163 153 146 132 126 119 115 109 105 98 79 0
TULIP-2 Anifrolumab 300 mg 180 178 158 150 143 130 124 115 107 101 99 91 85 60 0
Placebo 182 175 170 160 146 139 132 124 119 105 99 96 85 56 0
Pooled TULIP Anifrolumab 300 mg 360 348 310 291 271 248 232 216 205 191 184 172 159 108 0
Placebo 366 354 341 323 299 285 264 250 238 220 208 201 183 135 0

FIG. 9

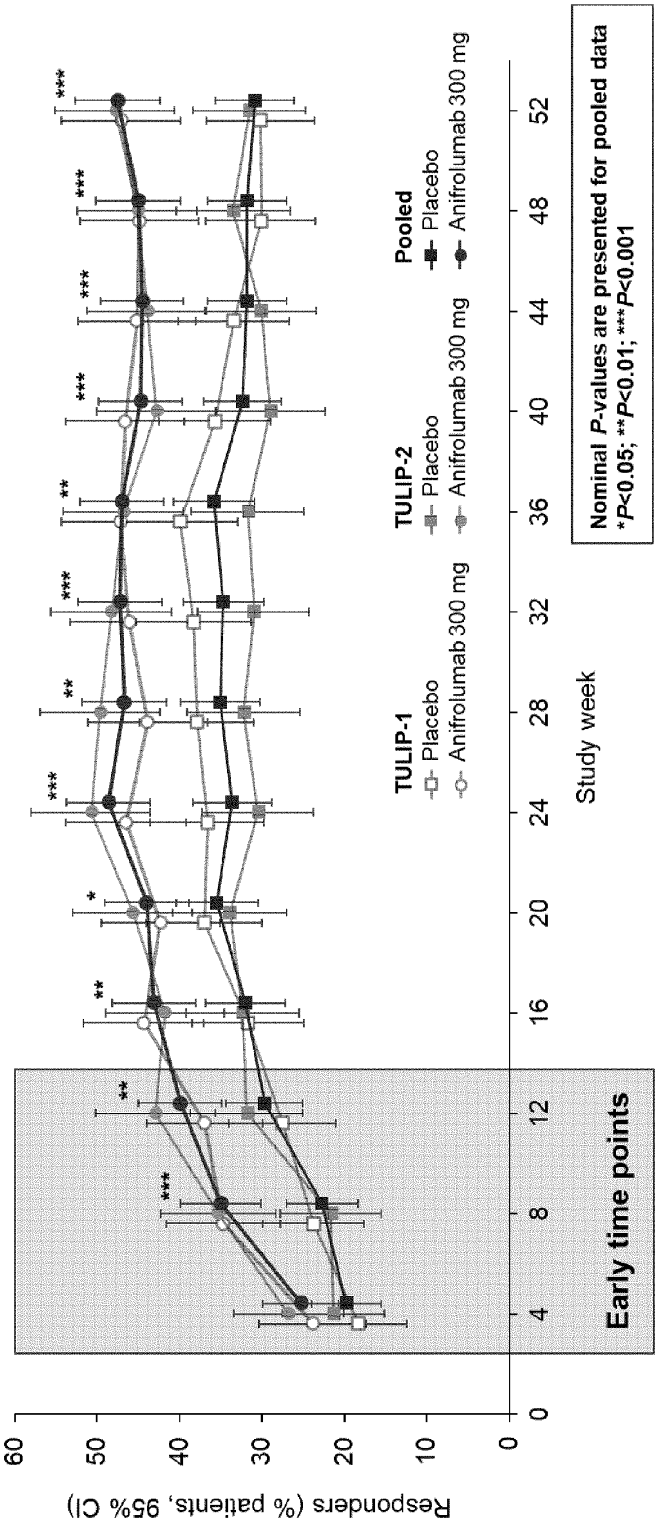

Responders (% patients, 95% CI)
0
10
20
30
40
50
60
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Study week
Early time points
TULIP-1
Placebo
Anifrolumab 300 mg
TULIP-2
Placebo
Anifrolumab 300 mg
Pooled
Placebo
Anifrolumab 300 mg
Nominal P-values are presented for pooled data
*P<0.05; **P<0.01; ***P<0.001

FIG. 10

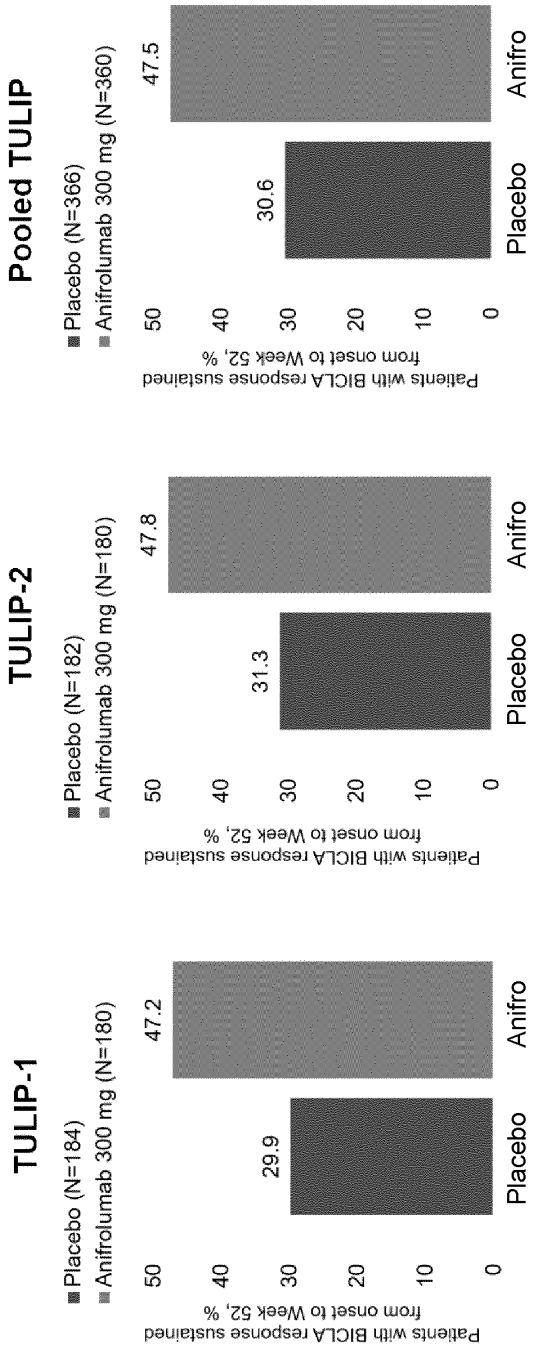


FIG. 11A

FIG. 11B

FIG. 11C

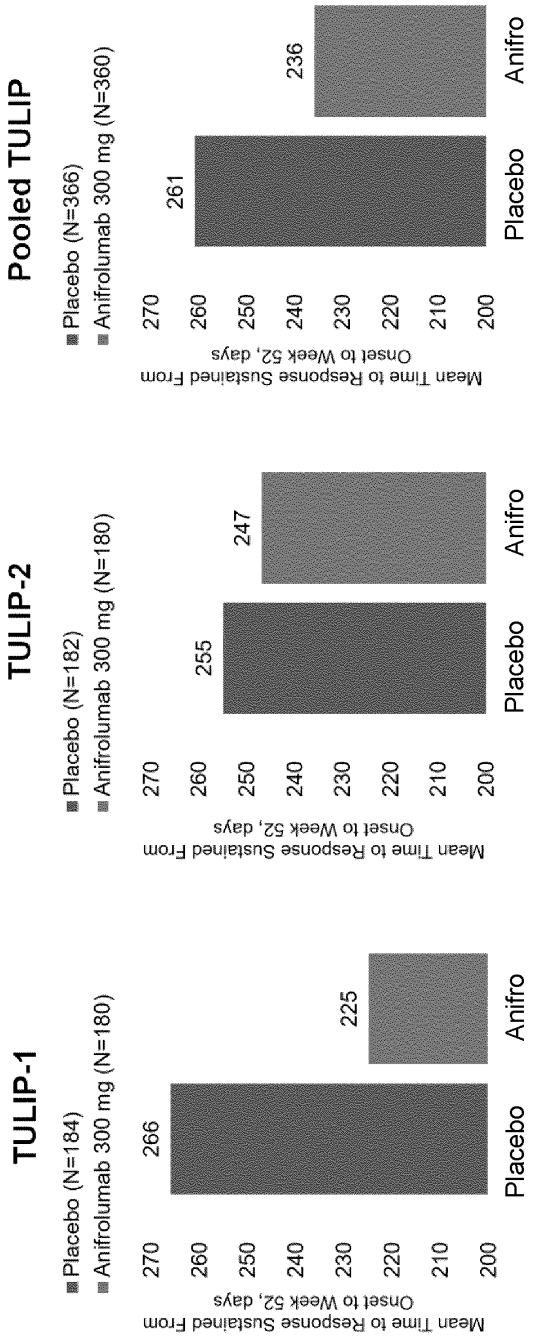


FIG. 12A

FIG. 12B

FIG. 12C

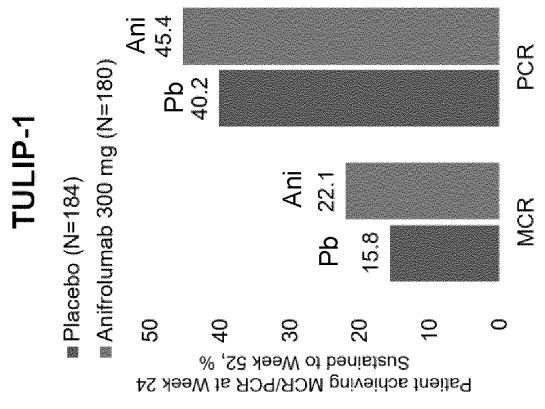


FIG. 13A

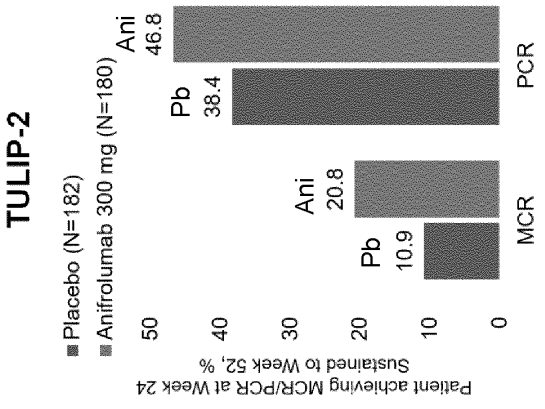


FIG. 13B

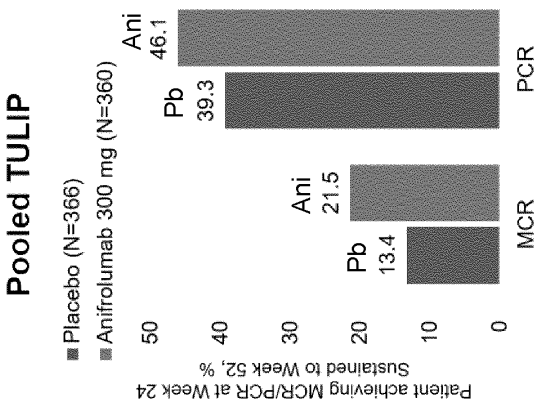


FIG. 13C

FIG. 14

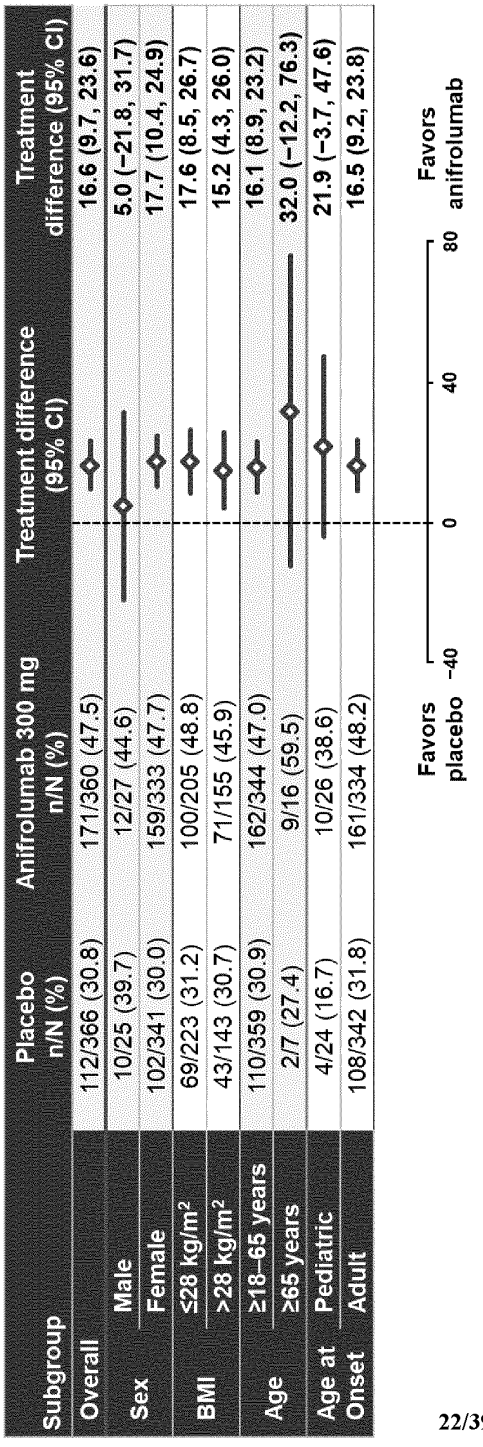

Subgroup
Placebo n/N (%)
Anifrolumab 300 mg n/N (%)
Treatment difference (95% CI)
Treatment difference (95% CI)
Overall
112/366 (30.8)
171/360 (47.5)
16.6 (9.7, 23.6)
Sex
Male
10/25 (39.7)
12/27 (44.6)
5.0 (−21.8, 31.7)
Female
102/341 (30.0)
159/333 (47.7)
17.7 (10.4, 24.9)
BMI
≤28 kg/m2
69/223 (31.2)
100/205 (48.8)
17.6 (8.5, 26.7)
>28 kg/m2
43/143 (30.7)
71/155 (45.9)
15.2 (4.3, 26.0)
Age
≥18–65 years
110/359 (30.9)
162/344 (47.0)
16.1 (8.9, 23.2)
≥65 years
2/7 (27.4)
9/16 (59.5)
32.0 (−12.2, 76.3)
Age at Onset
Pediatric
4/24 (16.7)
10/26 (38.6)
21.9 (−3.7, 47.6)
Adult
108/342 (31.8)
161/334 (48.2)
16.5 (9.2, 23.8)
Pooled TULIP
−40
0
40
80
Favors placebo
Favors anifrolumab

FIG. 15

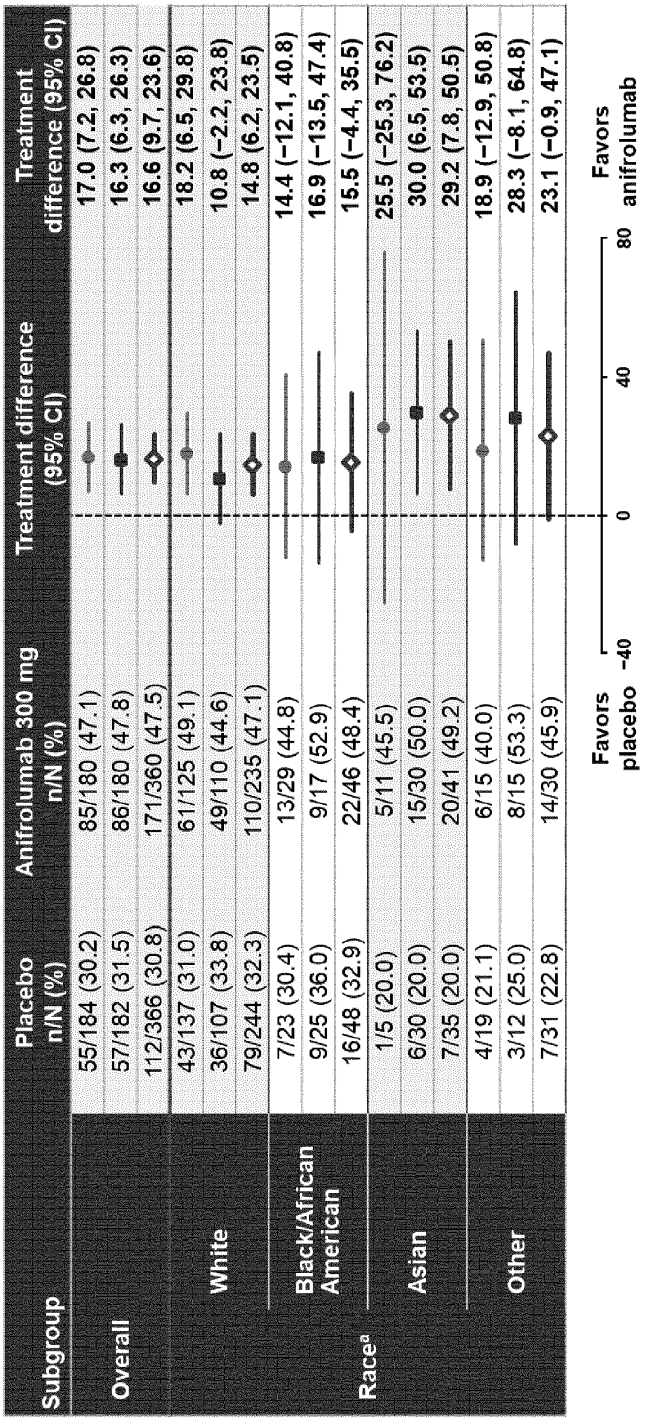

Subgroup
Placebo n/N (%)
Anifrolumab 300 mg n/N (%)
Treatment difference (95% CI)
Treatment difference (95% CI)
TULIP-1
TULIP-2
Pooled TULIP
Overall
55/184 (30.2)
85/180 (47.1)
17.0 (7.2, 26.8)
57/182 (31.5)
86/180 (47.8)
16.3 (6.3, 26.3)
112/366 (30.8)
171/360 (47.5)
16.6 (9.7, 23.6)
Race[a]
White
43/137 (31.0)
61/125 (49.1)
18.2 (6.5, 29.8)
36/107 (33.8)
49/110 (44.6)
10.8 (−2.2, 23.8)
79/244 (32.3)
110/235 (47.1)
14.8 (6.2, 23.5)
Black/African American
7/23 (30.4)
13/29 (44.8)
14.4 (−12.1, 40.8)
9/25 (36.0)
9/17 (52.9)
16.9 (−13.5, 47.4)
16/48 (32.9)
22/46 (48.4)
15.5 (−4.4, 35.5)
Asian
1/5 (20.0)
5/11 (45.5)
25.5 (−25.3, 76.2)
6/30 (20.0)
15/30 (50.0)
30.0 (6.5, 53.5)
7/35 (20.0)
20/41 (49.2)
29.2 (7.8, 50.5)
Other
4/19 (21.1)
6/15 (40.0)
18.9 (−12.9, 50.8)
3/12 (25.0)
8/15 (53.3)
28.3 (−8.1, 64.8)
7/31 (22.8)
14/30 (45.9)
23.1 (−0.9, 47.1)
−40
0
40
80
Favors placebo
Favors anifrolumab

FIG. 16

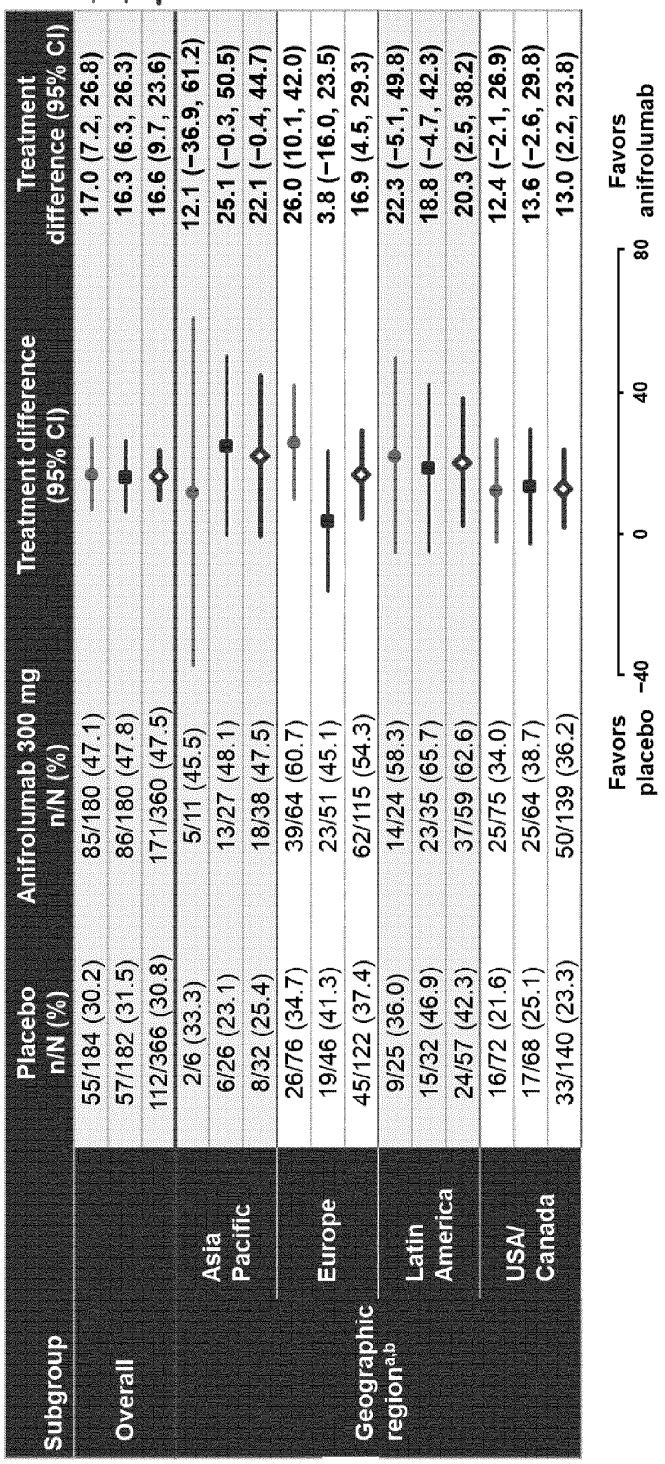

Subgroup
Placebo n/N (%)
Anifrolumab 300 mg n/N (%)
Treatment difference (95% CI)
Treatment difference (95% CI)
Overall
55/184 (30.2)
85/180 (47.1)
17.0 (7.2, 26.8)
57/182 (31.5)
86/180 (47.8)
16.3 (6.3, 26.3)
112/366 (30.8)
171/360 (47.5)
16.6 (9.7, 23.6)
Geographic region[a,b]
Asia Pacific
2/6 (33.3)
5/11 (45.5)
12.1 (−36.9, 61.2)
6/26 (23.1)
13/27 (48.1)
25.1 (−0.3, 50.5)
8/32 (25.4)
18/38 (47.5)
22.1 (−0.4, 44.7)
Europe
26/76 (34.7)
39/64 (60.7)
26.0 (10.1, 42.0)
19/46 (41.3)
23/51 (45.1)
3.8 (−16.0, 23.5)
45/122 (37.4)
62/115 (54.3)
16.9 (4.5, 29.3)
Latin America
9/25 (36.0)
14/24 (58.3)
22.3 (−5.1, 49.8)
15/32 (46.9)
23/35 (65.7)
18.8 (−4.7, 42.3)
24/57 (42.3)
37/59 (62.6)
20.3 (2.5, 38.2)
USA/ Canada
16/72 (21.6)
25/75 (34.0)
12.4 (−2.1, 26.9)
17/68 (25.1)
25/64 (38.7)
13.6 (−2.6, 29.8)
33/140 (23.3)
50/139 (36.2)
13.0 (2.2, 23.8)
TULIP-1
TULIP-2
Pooled TULIP
Favors placebo
−40
0
40
80
Favors anifrolumab

FIG. 17

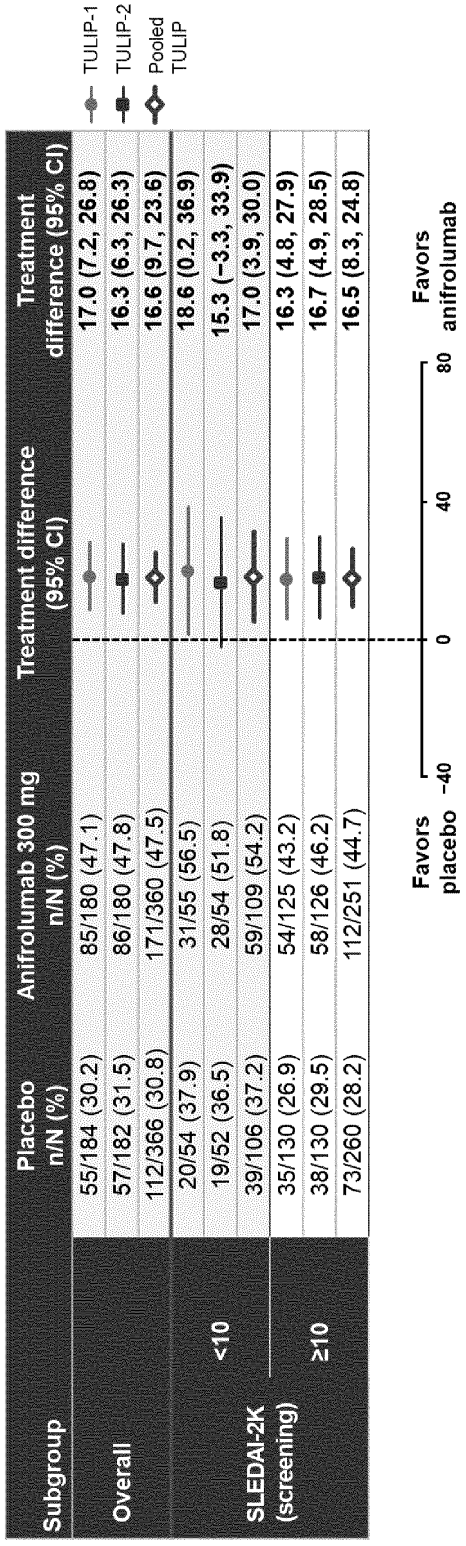

Subgroup
Placebo n/N (%)
Anifrolumab 300 mg n/N (%)
Treatment difference (95% CI)
Treatment difference (95% CI)
Overall
55/184 (30.2)
85/180 (47.1)
17.0 (7.2, 26.8)
57/182 (31.5)
86/180 (47.8)
16.3 (6.3, 26.3)
112/366 (30.8)
171/360 (47.5)
16.6 (9.7, 23.6)
SLEDAI-2K (screening)
<10
20/54 (37.9)
31/55 (56.5)
18.6 (0.2, 36.9)
19/52 (36.5)
28/54 (51.8)
15.3 (−3.3, 33.9)
39/106 (37.2)
59/109 (54.2)
17.0 (3.9, 30.0)
≥10
35/130 (26.9)
54/125 (43.2)
16.3 (4.8, 27.9)
38/130 (29.5)
58/126 (46.2)
16.7 (4.9, 28.5)
73/260 (28.2)
112/251 (44.7)
16.5 (8.3, 24.8)
TULIP-1
TULIP-2
Pooled TULIP
−40
0
40
80
Favors placebo
Favors anifrolumab

FIG. 18

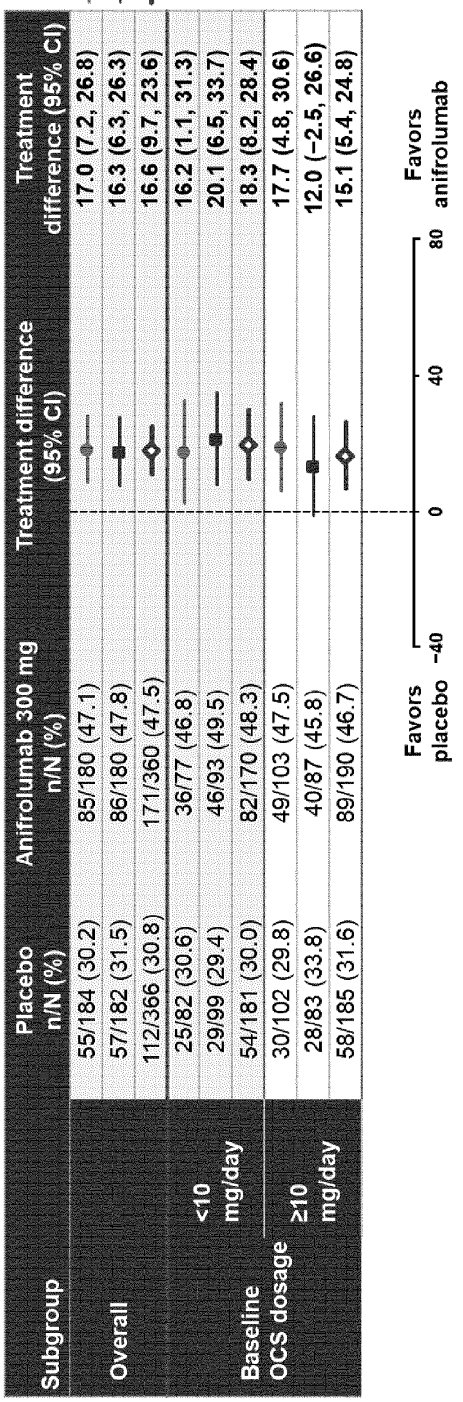

Subgroup
Placebo n/N (%)
Anifrolumab 300 mg n/N (%)
Treatment difference (95% CI)
Treatment difference (95% CI)
Overall
55/184 (30.2)
85/180 (47.1)
17.0 (7.2, 26.8)
57/182 (31.5)
86/180 (47.8)
16.3 (6.3, 26.3)
112/366 (30.8)
171/360 (47.5)
16.6 (9.7, 23.6)
Baseline OCS dosage
<10 mg/day
25/82 (30.6)
36/77 (46.8)
16.2 (1.1, 31.3)
29/99 (29.4)
46/93 (49.5)
20.1 (6.5, 33.7)
54/181 (30.0)
82/170 (48.3)
18.3 (8.2, 28.4)
≥10 mg/day
30/102 (29.8)
49/103 (47.5)
17.7 (4.8, 30.6)
28/83 (33.8)
40/87 (45.8)
12.0 (−2.5, 26.6)
58/185 (31.6)
89/190 (46.7)
15.1 (5.4, 24.8)
−40
0
40
80
Favors placebo
Favors anifrolumab
TULIP-1
TULIP-2
Pooled TULIP

FIG. 19

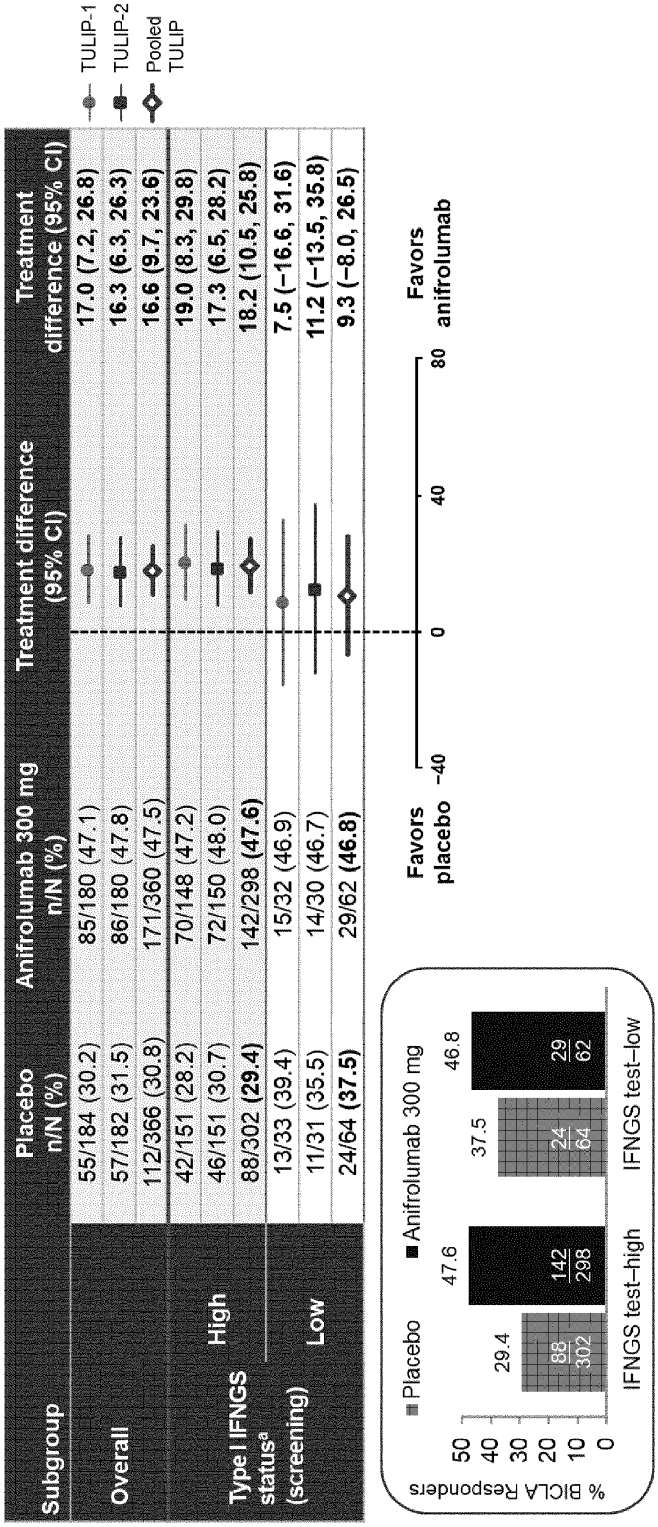

Subgroup
Placebo n/N (%)
Anifrolumab 300 mg n/N (%)
Treatment difference (95% CI)
Treatment difference (95% CI)
Overall
55/184 (30.2)
85/180 (47.1)
17.0 (7.2, 26.8)
57/182 (31.5)
86/180 (47.8)
16.3 (6.3, 26.3)
112/366 (30.8)
171/360 (47.5)
16.6 (9.7, 23.6)
Type I IFNGS status[a] (screening)
High
42/151 (28.2)
70/148 (47.2)
19.0 (8.3, 29.8)
46/151 (30.7)
72/150 (48.0)
17.3 (6.5, 28.2)
88/302 (29.4)
142/298 (47.6)
18.2 (10.5, 25.8)
Low
13/33 (39.4)
15/32 (46.9)
7.5 (−16.6, 31.6)
11/31 (35.5)
14/30 (46.7)
11.2 (−13.5, 35.8)
24/64 (37.5)
29/62 (46.8)
9.3 (−8.0, 26.5)
TULIP-1
TULIP-2
Pooled TULIP
−40
0
40
80
Favors placebo
Favors anifrolumab
Placebo
Anifrolumab 300 mg
% BICLA Responders
50
40
30
20
10
0
29.4
47.6
37.5
46.8
88
302
142
298
24
64
29
62
IFNGS test–high
IFNGS test–low

FIG. 20

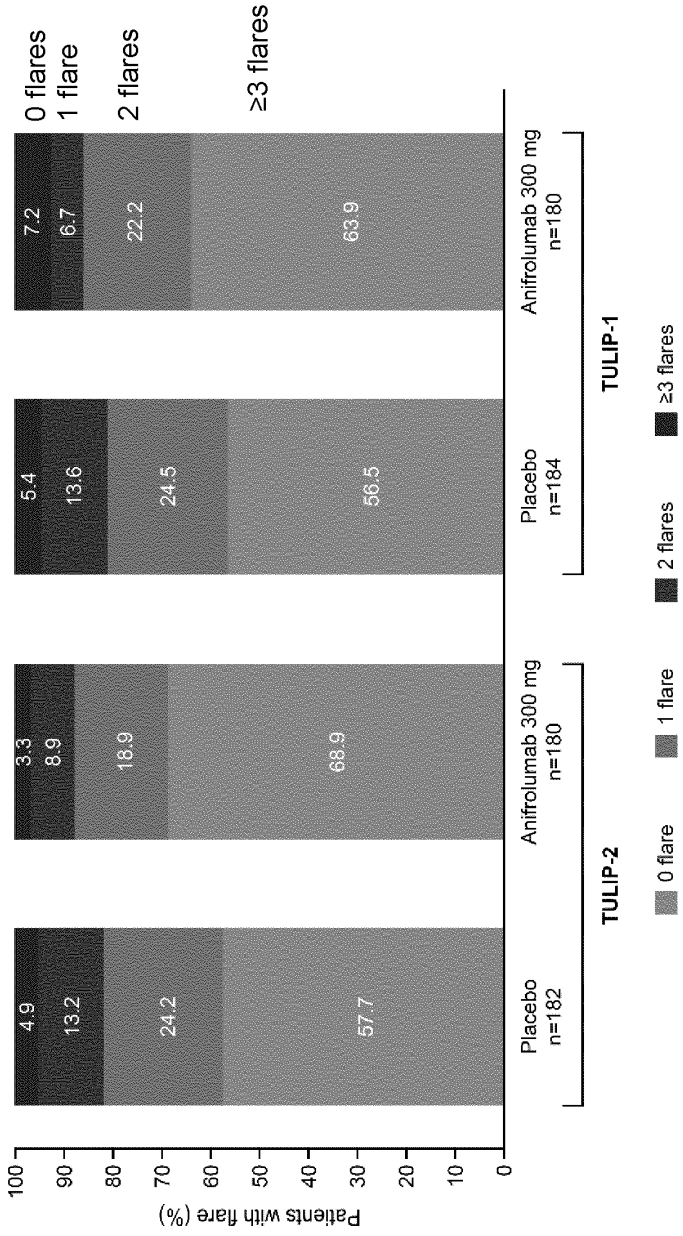

0 flares
1 flare
2 flares
≥3 flares
Patients with flare (%)
100
90
80
70
60
50
40
30
20
10
0
4.9
13.2
24.2
57.7
3.3
8.9
18.9
68.9
5.4
13.6
24.5
56.5
7.2
6.7
22.2
63.9
Placebo n=182
Anifrolumab 300 mg n=180
Placebo n=184
Anifrolumab 300 mg n=180
TULIP-2
TULIP-1
0 flare
1 flare
2 flares
≥3 flares

FIG. 21

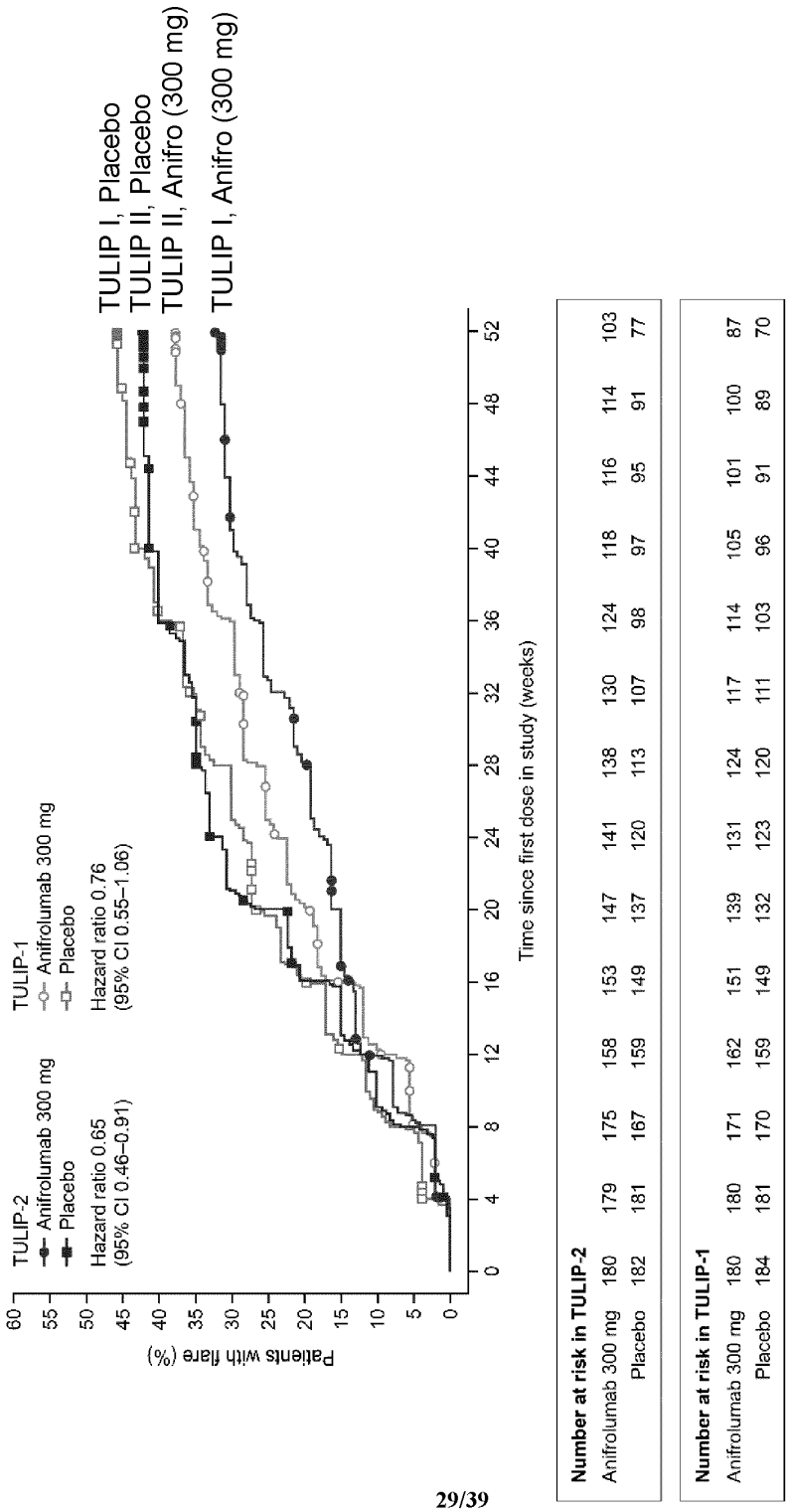

TULIP-2
Anifrolumab 300 mg
Placebo
Hazard ratio 0.65
(95% CI 0.46–0.91)
TULIP-1
Anifrolumab 300 mg
Placebo
Hazard ratio 0.76
(95% CI 0.55–1.06)
TULIP I, Placebo
TULIP II, Placebo
TULIP II, Anifro (300 mg)
TULIP I, Anifro (300 mg)
Patients with flare (%)
Time since first dose in study (weeks)
Number at risk in TULIP-2
Anifrolumab 300 mg 180 179 175 158 153 147 141 138 130 124 118 116 114 103
Placebo 182 181 167 159 149 137 120 113 107 98 97 95 91 77
Number at risk in TULIP-1
Anifrolumab 300 mg 180 180 171 162 151 139 131 124 117 114 105 101 100 87
Placebo 184 181 170 159 149 132 123 120 111 103 96 91 89 70

FIG. 22

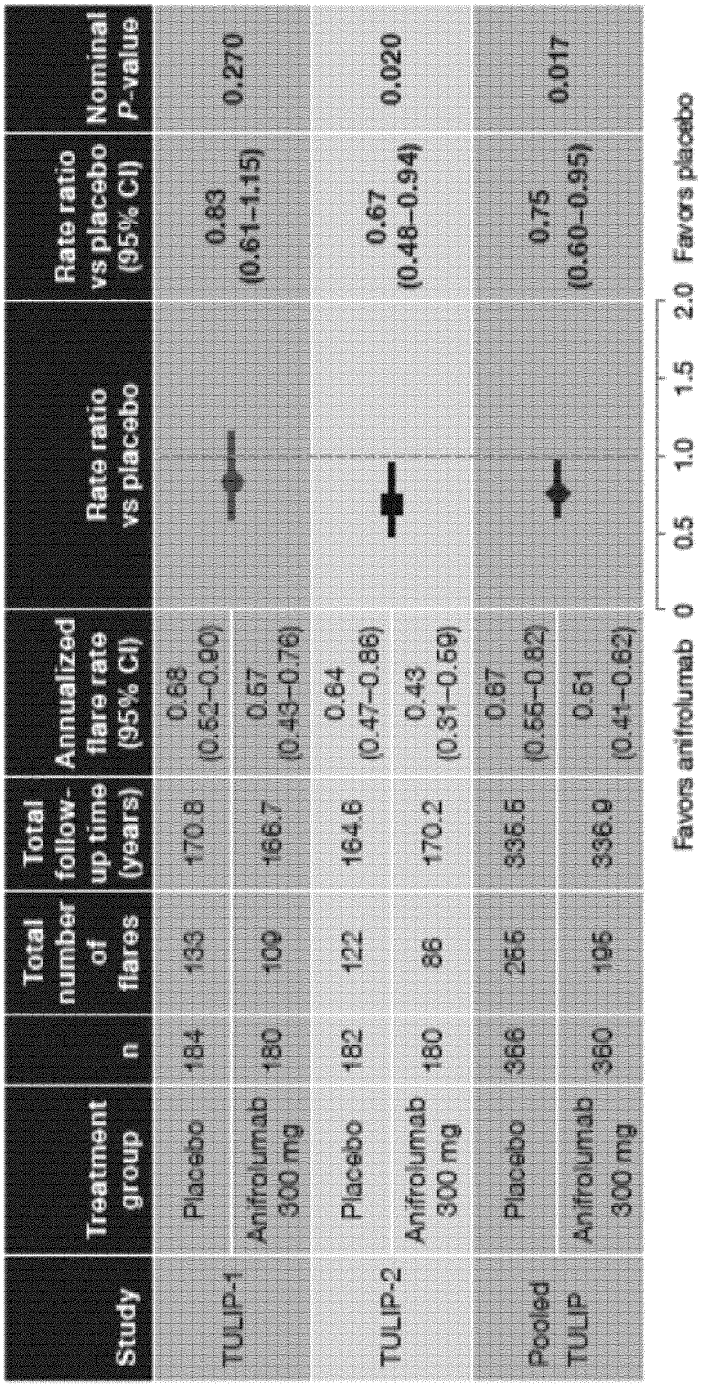

Study
Treatment group
n
Total number of flares
Total follow-up time (years)
Annualized flare rate (95% CI)
Rate ratio vs placebo
Rate ratio vs placebo (95% CI)
Nominal P-value
TULIP-1
Placebo 184 133 170.8 0.68 (0.52–0.90)
Anifrolumab 300 mg 180 109 166.7 0.67 (0.43–0.76)
0.83 (0.61–1.15) 0.270
TULIP-2
Placebo 182 122 164.6 0.64 (0.47–0.86)
Anifrolumab 300 mg 180 86 170.2 0.43 (0.31–0.59)
0.67 (0.48–0.94) 0.020
Pooled TULIP
Placebo 366 255 335.5 0.87 (0.55–0.82)
Anifrolumab 300 mg 360 195 336.9 0.61 (0.41–0.82)
0.75 (0.60–0.95) 0.017
0 0.5 1.0 1.5 2.0
Favors anifrolumab
Favors placebo

FIG. 23

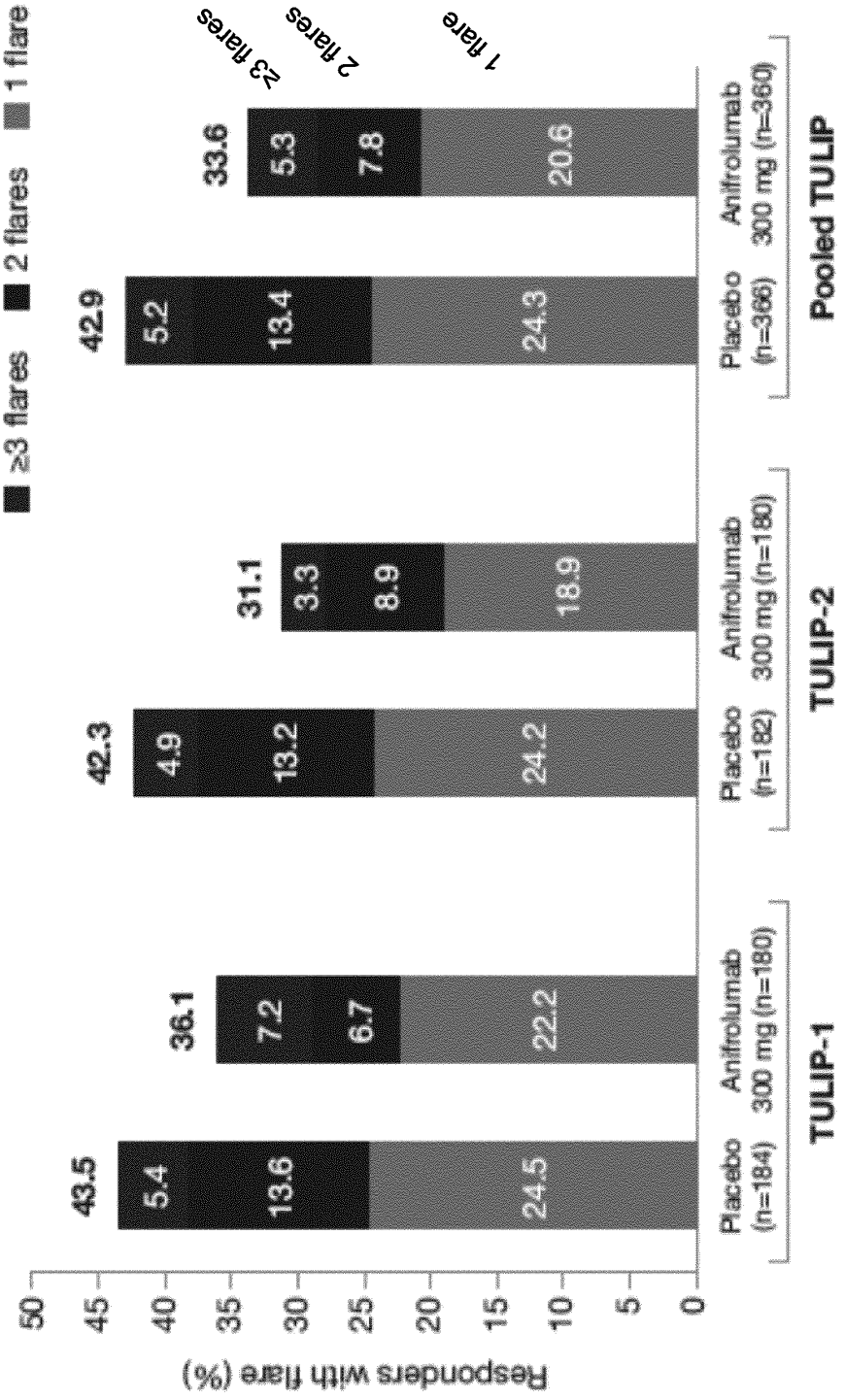

≥3 flares
2 flares
1 flare
≥3 flares
2 flares
1 flare
Responders with flare (%)
0
5
10
15
20
25
30
35
40
45
50
43.5
5.4
13.6
24.5
36.1
7.2
6.7
22.2
42.3
4.9
13.2
24.2
31.1
3.3
8.9
18.9
42.9
5.2
13.4
24.3
33.6
5.3
7.8
20.6
Placebo (n=184)
Anifrolumab 300 mg (n=180)
Placebo (n=182)
Anifrolumab 300 mg (n=180)
Placebo (n=366)
Anifrolumab 300 mg (n=360)
TULIP-1
TULIP-2
Pooled TULIP

FIG. 24

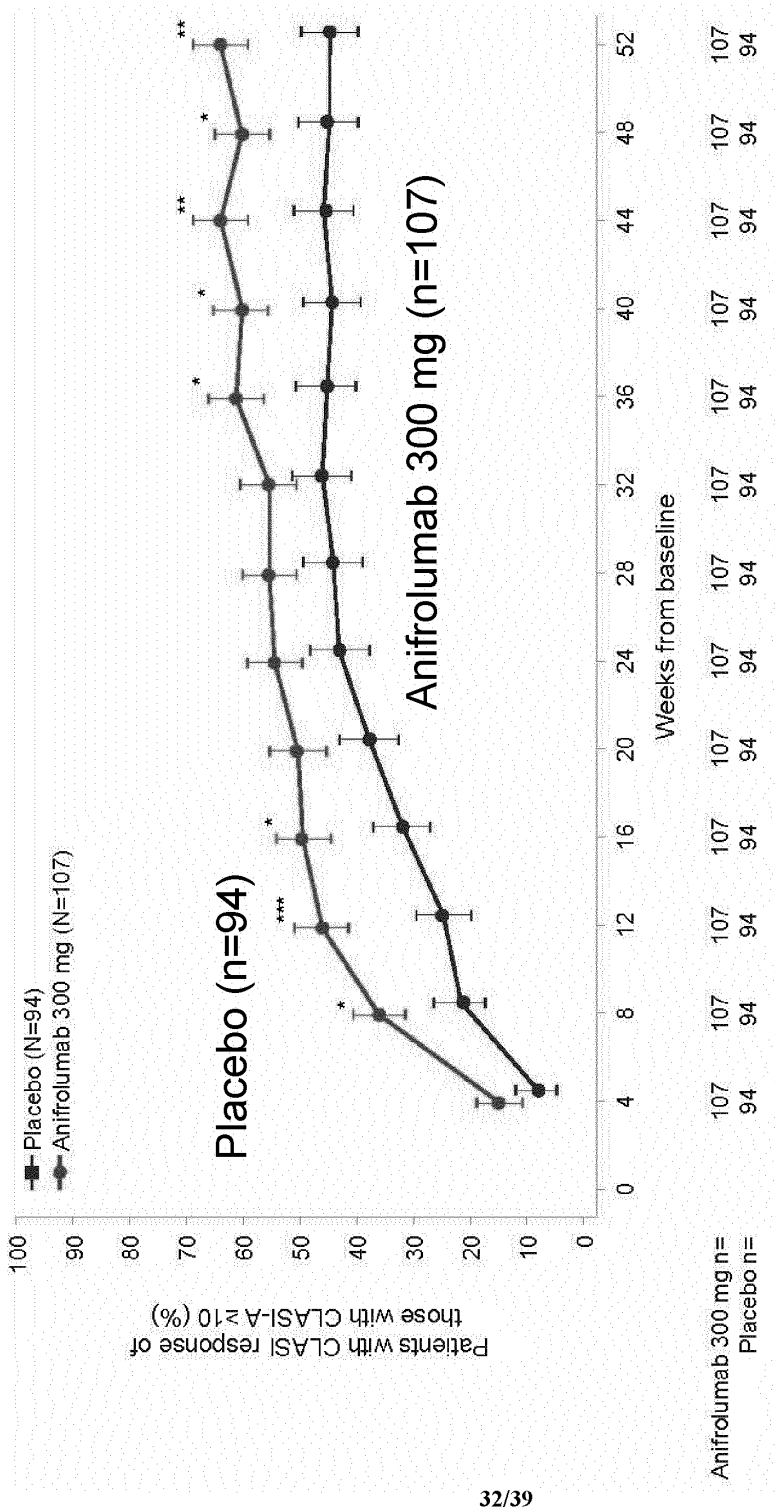

Placebo (N=94)
Anifrolumab 300 mg (N=107)
Placebo (n=94)
Anifrolumab 300 mg (n=107)
Patients with CLASI response of those with CLASI-A ≥10 (%)
Weeks from baseline
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Anifrolumab 300 mg n= 107 107 107 107 107 107 107 107 107 107 107 107 107
Placebo n= 94 94 94 94 94 94 94 94 94 94 94 94 94

FIG. 25

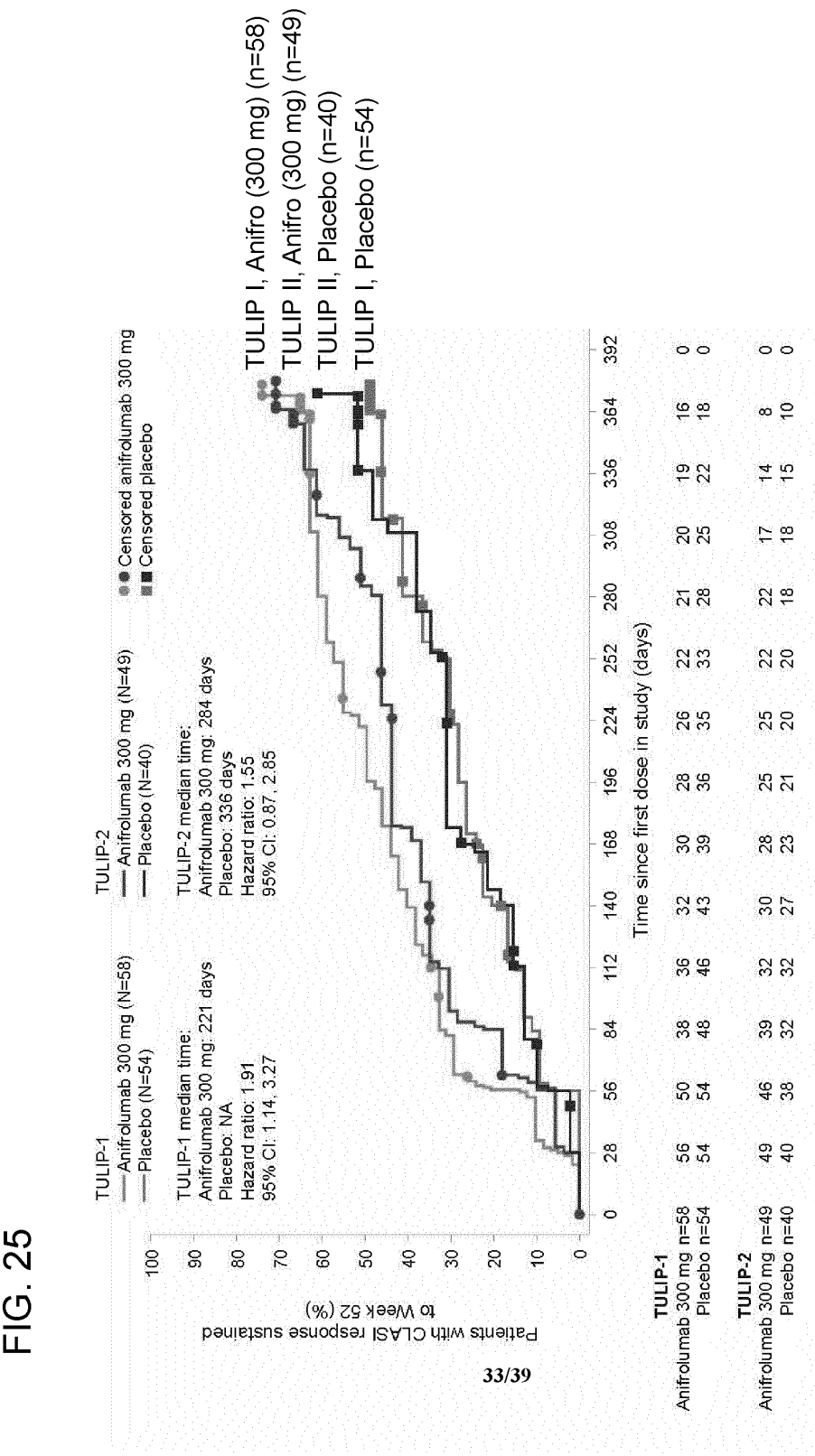
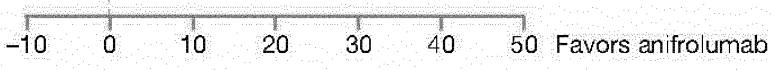

TULIP-1
Anifrolumab 300 mg (N=58)
Placebo (N=54)
TULIP-2
Anifrolumab 300 mg (N=49)
Placebo (N=40)
Censored anifrolumab 300 mg
Censored placebo
TULIP-1 median time:
Anifrolumab 300 mg: 221 days
Placebo: NA
Hazard ratio: 1.91
95% CI: 1.14, 3.27
TULIP-2 median time:
Anifrolumab 300 mg: 284 days
Placebo: 336 days
Hazard ratio: 1.55
95% CI: 0.87, 2.85
TULIP I, Anifro (300 mg) (n=58)
TULIP II, Anifro (300 mg) (n=49)
TULIP II, Placebo (n=40)
TULIP I, Placebo (n=54)
Patients with CLASI response sustained to Week 52 (%)
100
90
80
70
60
50
40
30
20
10
0
0 28 56 84 112 140 168 196 224 252 280 308 336 364 392
Time since first dose in study (days)
TULIP-1
Anifrolumab 300 mg n=58 56 50 38 36 32 30 28 26 22 21 20 19 16 0
Placebo n=54 54 54 48 46 43 39 36 35 33 28 25 22 18 0
TULIP-2
Anifrolumab 300 mg n=49 49 46 39 32 30 28 25 25 22 22 17 14 8 0
Placebo n=40 40 38 32 32 27 23 21 20 20 18 18 15 10 0

FIG. 26

		Placebo n/N (%)	Anifrolumab 300 mg n/N (%)	Treatment difference (95% CI)	Treatment difference (95% CI)	Nominal *P*-value
CLASI-A >0 at baseline						
≥50% reduction	TULIP-1	54/178 (30.7)	74/174 (42.5)		11.8 (1.8, 21.7)	0.020
	TULIP-2	54/170 (31.7)	78/174 (45.0)		13.3 (3.1, 23.5)	0.010
≥75% reduction	TULIP-1	22/178 (12.5)	39/174 (22.3)		9.8 (1.5, 18.1)	0.020
	TULIP-2	31/170 (18.6)	43/174 (24.8)		6.3 (–2.7, 15.3)	0.170
CLASI-A ≥10 at baseline						
≥50% reduction	TULIP-1	14/54 (24.9)	25/58 (43.6)		18.7 (1.4, 36.0)	0.034
	TULIP-2	10/40 (25.0)	24/49 (49.0)		24.0 (4.3, 43.6)	0.017
≥75% reduction	TULIP-1	3/54 (5.1)	13/58 (22.5)		17.4 (3.1, 31.8)	0.017
	TULIP-2	4/40 (10.0)	9/49 (18.4)		8.4 (–7.2, 23.9)	0.292



CLASI, Cutaneous Lupus Erythematosus Disease Area and Severity Index; CLASI-A, CLASI activity score.

Baseline is defined as the last measurement before randomization and investigational product dose administration on Day 1.
The difference in estimates and associated 95% CIs are calculated using a stratified Cochran–Mantel–Haenszel approach.
The nominal *P*-values presented are based on this Cochran–Mantel–Haenszel model.

FIG. 27

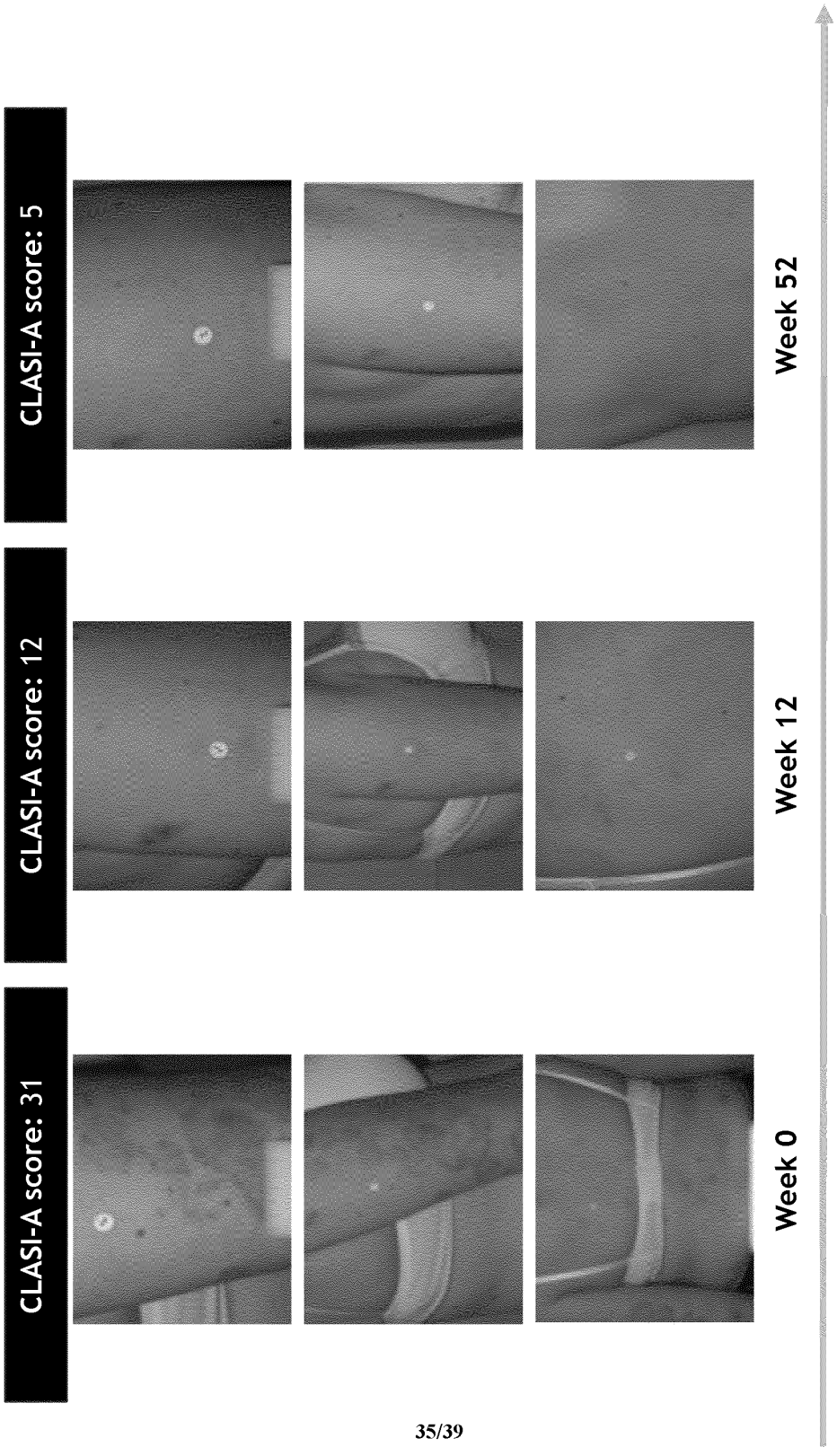

CLASI-A score: 31
CLASI-A score: 12
CLASI-A score: 5
Week 0
Week 12
Week 52

FIG. 28

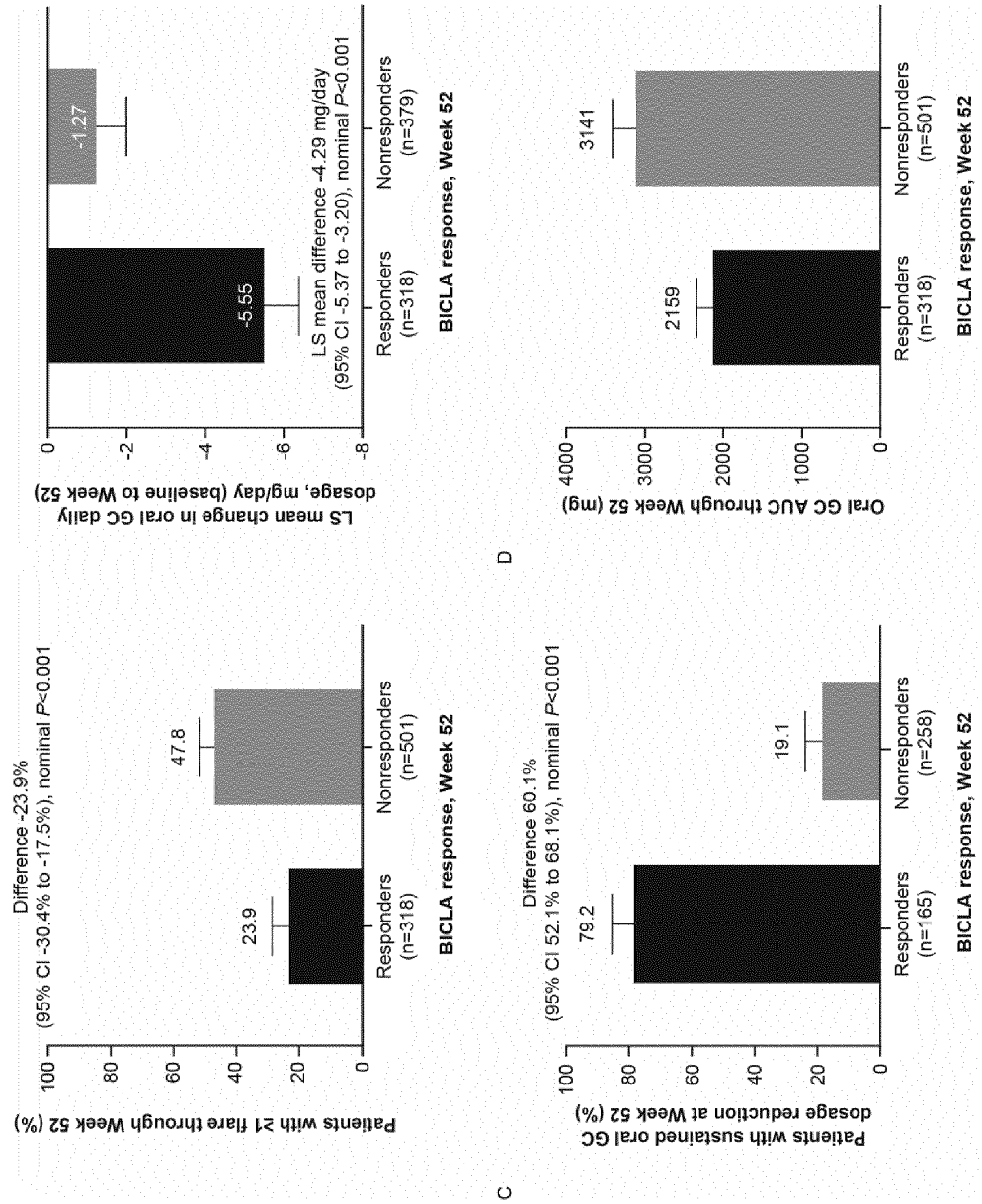
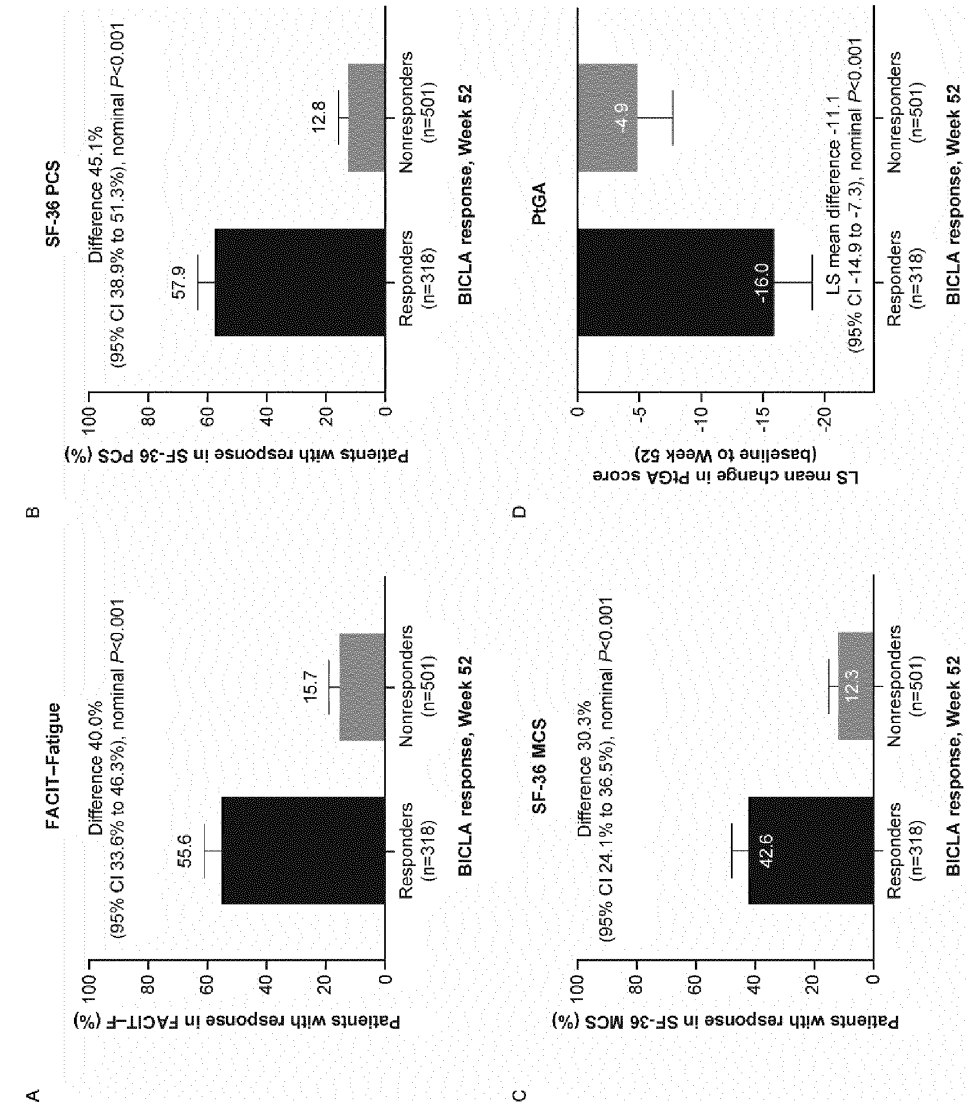

A
Patients with ≥1 flare through Week 52 (%)
100
80
60
40
20
0
Difference -23.9%
(95% CI -30.4% to -17.5%), nominal P<0.001
23.9
47.8
Responders (n=318)
Nonresponders (n=501)
BICLA response, Week 52
B
LS mean change in oral GC daily dosage, mg/day (baseline to Week 52)
0
-2
-4
-6
-8
-5.55
-1.27
LS mean difference -4.29 mg/day
(95% CI -5.37 to -3.20), nominal P<0.001
Responders (n=318)
Nonresponders (n=379)
BICLA response, Week 52
C
Patients with sustained oral GC dosage reduction at Week 52 (%)
100
80
60
40
20
0
Difference 60.1%
(95% CI 52.1% to 68.1%), nominal P<0.001
79.2
19.1
Responders (n=165)
Nonresponders (n=258)
BICLA response, Week 52
D
Oral GC AUC through Week 52 (mg)
4000
3000
2000
1000
0
2159
3141
Responders (n=318)
Nonresponders (n=501)
BICLA response, Week 52

FIG. 29


A
FACIT–Fatigue
Difference 40.0%
(95% CI 33.6% to 46.3%), nominal P<0.001
55.6
15.7
Patients with response in FACIT–F (%)
Responders (n=318)
Nonresponders (n=501)
BICLA response, Week 52
B
SF-36 PCS
Difference 45.1%
(95% CI 38.9% to 51.3%), nominal P<0.001
57.9
12.8
Patients with response in SF-36 PCS (%)
Responders (n=318)
Nonresponders (n=501)
BICLA response, Week 52
C
SF-36 MCS
Difference 30.3%
(95% CI 24.1% to 36.5%), nominal P<0.001
42.6
12.3
Patients with response in SF-36 MCS (%)
Responders (n=318)
Nonresponders (n=501)
BICLA response, Week 52
D
PtGA
-16.0
-4.9
LS mean change in PtGA score (baseline to Week 52)
LS mean difference -11.1
(95% CI -14.9 to -7.3), nominal P<0.001
Responders (n=318)
Nonresponders (n=501)
BICLA response, Week 52

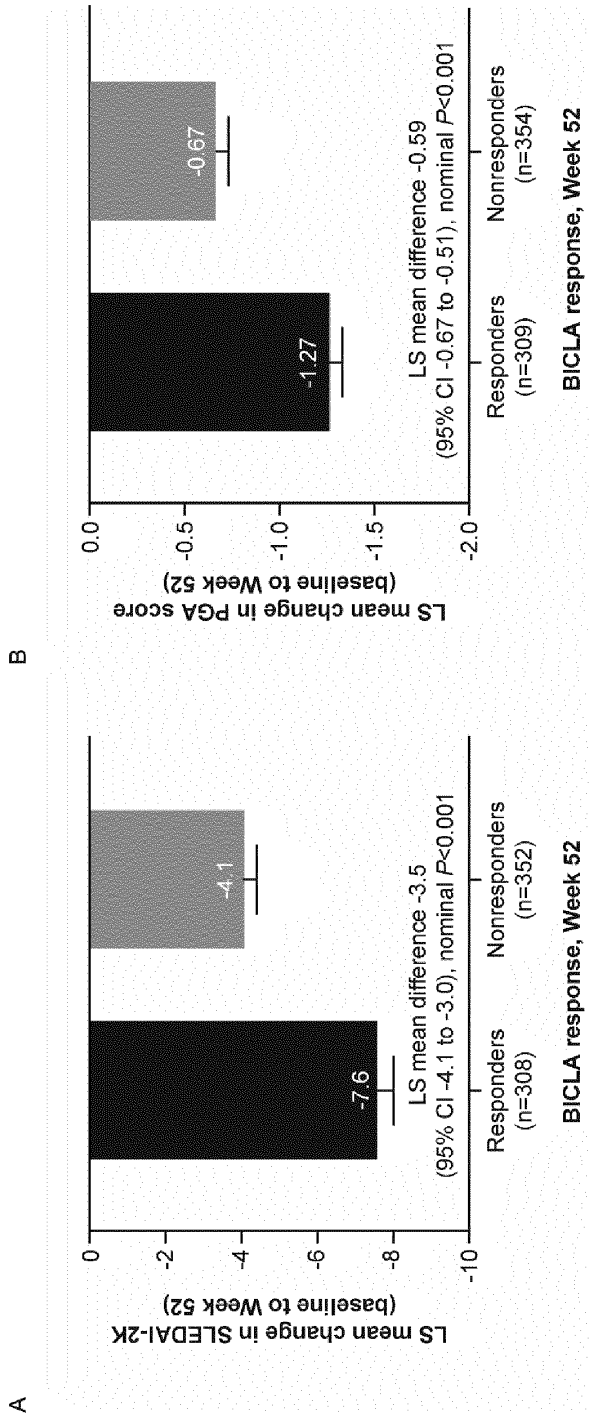
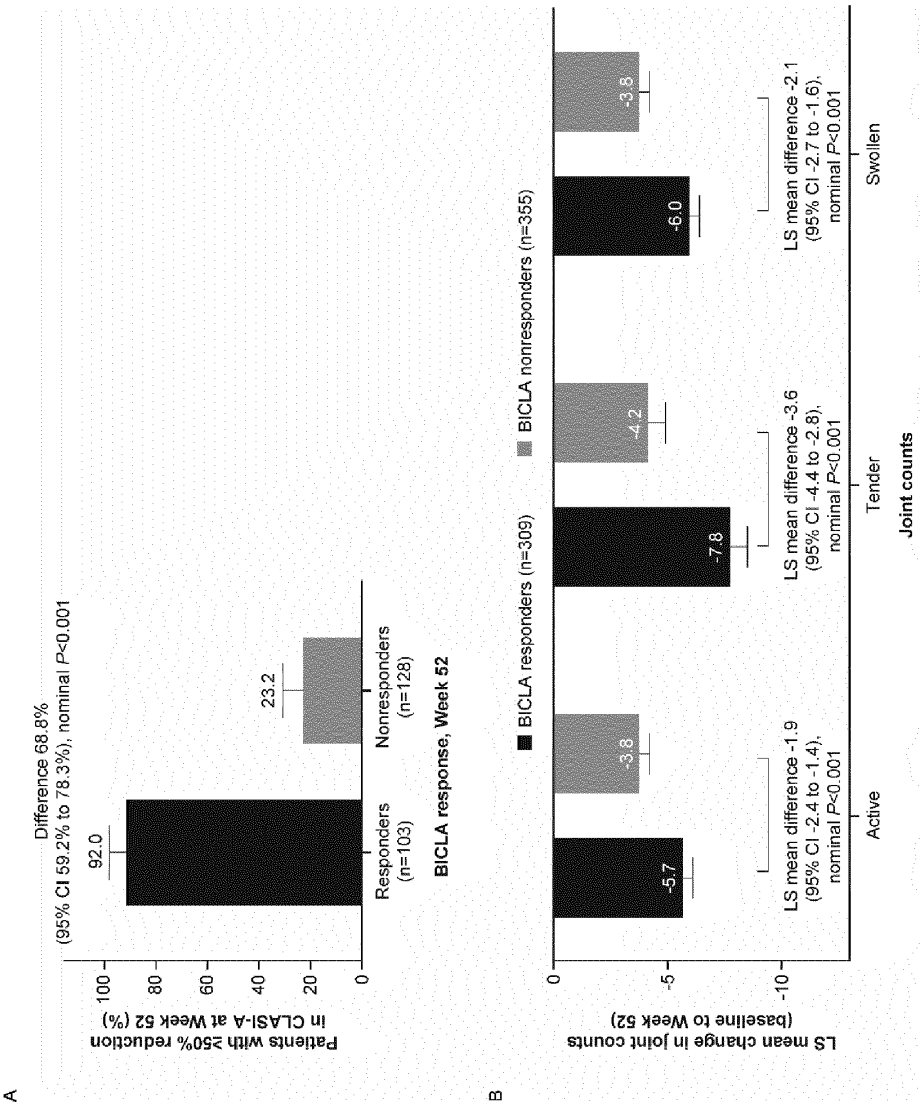

A
LS mean change in SLEDAI-2K (baseline to Week 52)
0
-2
-4
-6
-8
-10
-7.6
-4.1
LS mean difference -3.5
(95% CI -4.1 to -3.0), nominal P<0.001
Responders (n=308)
Nonresponders (n=352)
BICLA response, Week 52
B
LS mean change in PGA score (baseline to Week 52)
0.0
-0.5
-1.0
-1.5
-2.0
-1.27
-0.67
LS mean difference -0.59
(95% CI -0.67 to -0.51), nominal P<0.001
Responders (n=309)
Nonresponders (n=354)
BICLA response, Week 52

FIG. 31


A
Patients with ≥50% reduction in CLASI-A at Week 52 (%)
100
80
60
40
20
0
92.0
23.2
Difference 68.8%
(95% CI 59.2% to 78.3%), nominal P<0.001
Responders (n=103)
Nonresponders (n=128)
BICLA response, Week 52
B
LS mean change in joint counts (baseline to Week 52)
0
-5
-10
BICLA responders (n=309)
BICLA nonresponders (n=355)
-5.7
-3.8
-7.8
-4.2
-6.0
-3.8
LS mean difference -1.9 (95% CI -2.4 to -1.4), nominal P<0.001
LS mean difference -3.6 (95% CI -4.4 to -2.8), nominal P<0.001
LS mean difference -2.1 (95% CI -2.7 to -1.6), nominal P<0.001
Active
Tender
Swollen
Joint counts