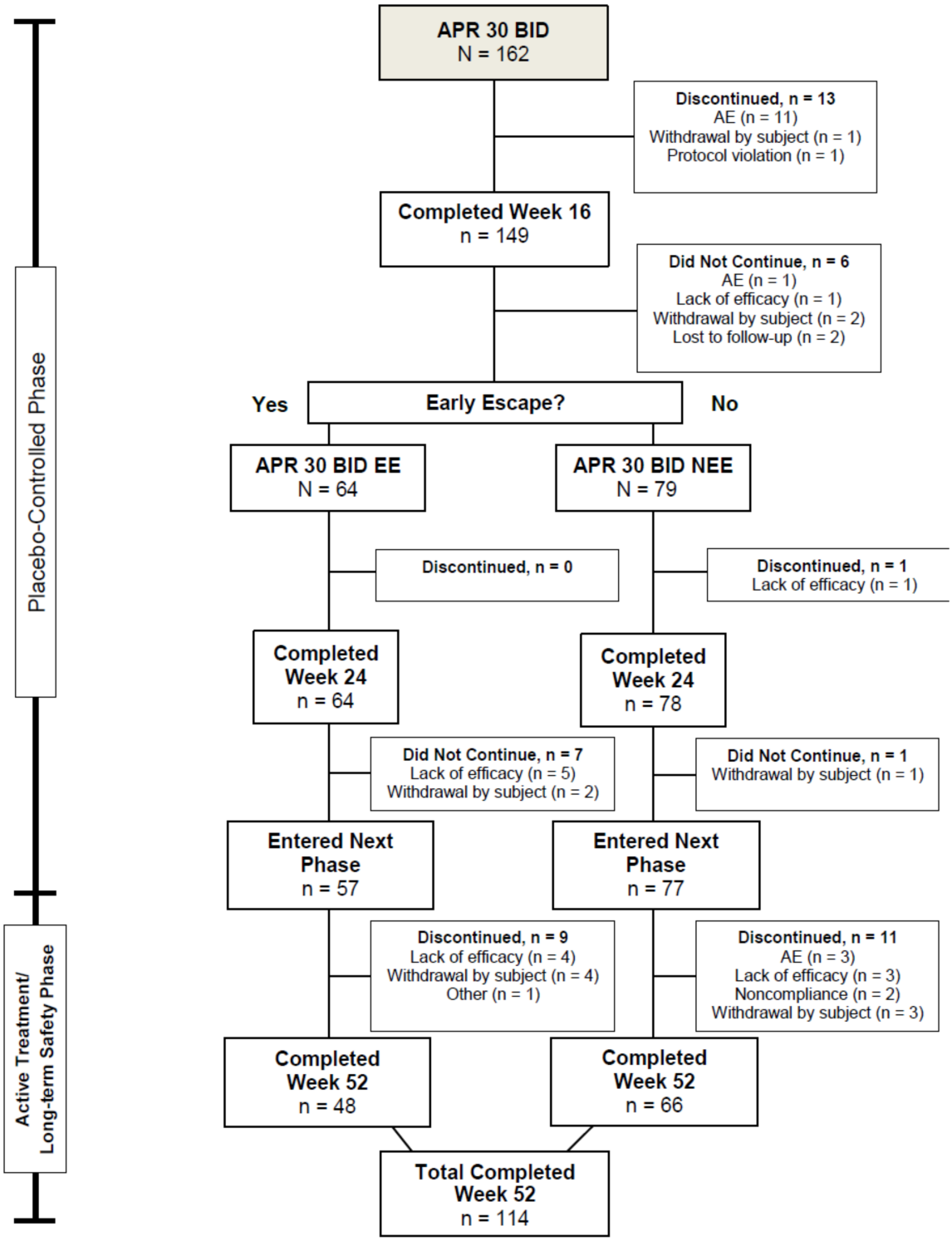
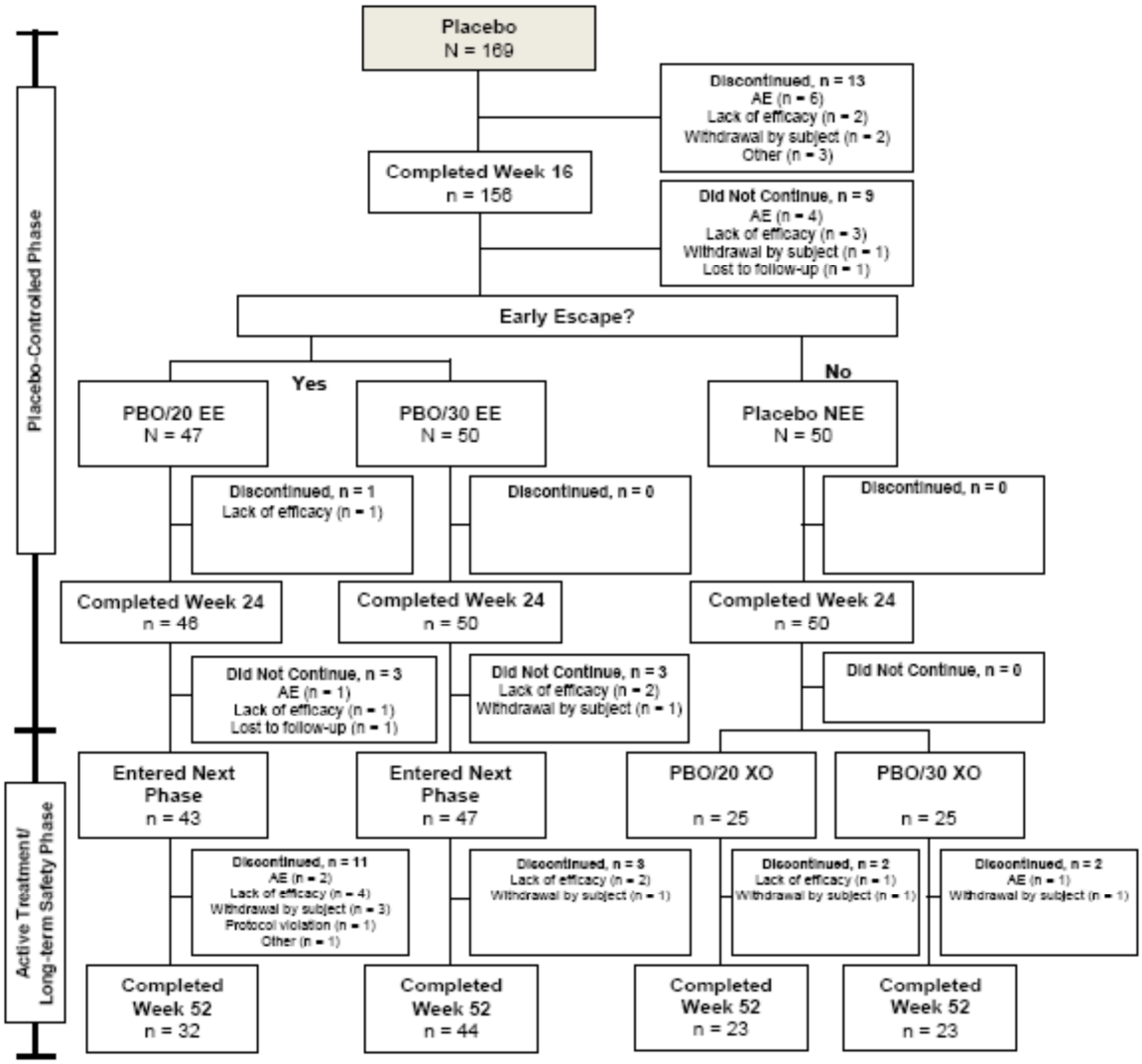
Figure 9: Disposition of Subjects Initially Randomized to APR 30 BID (Weeks 0-52) (Study PSA-003)



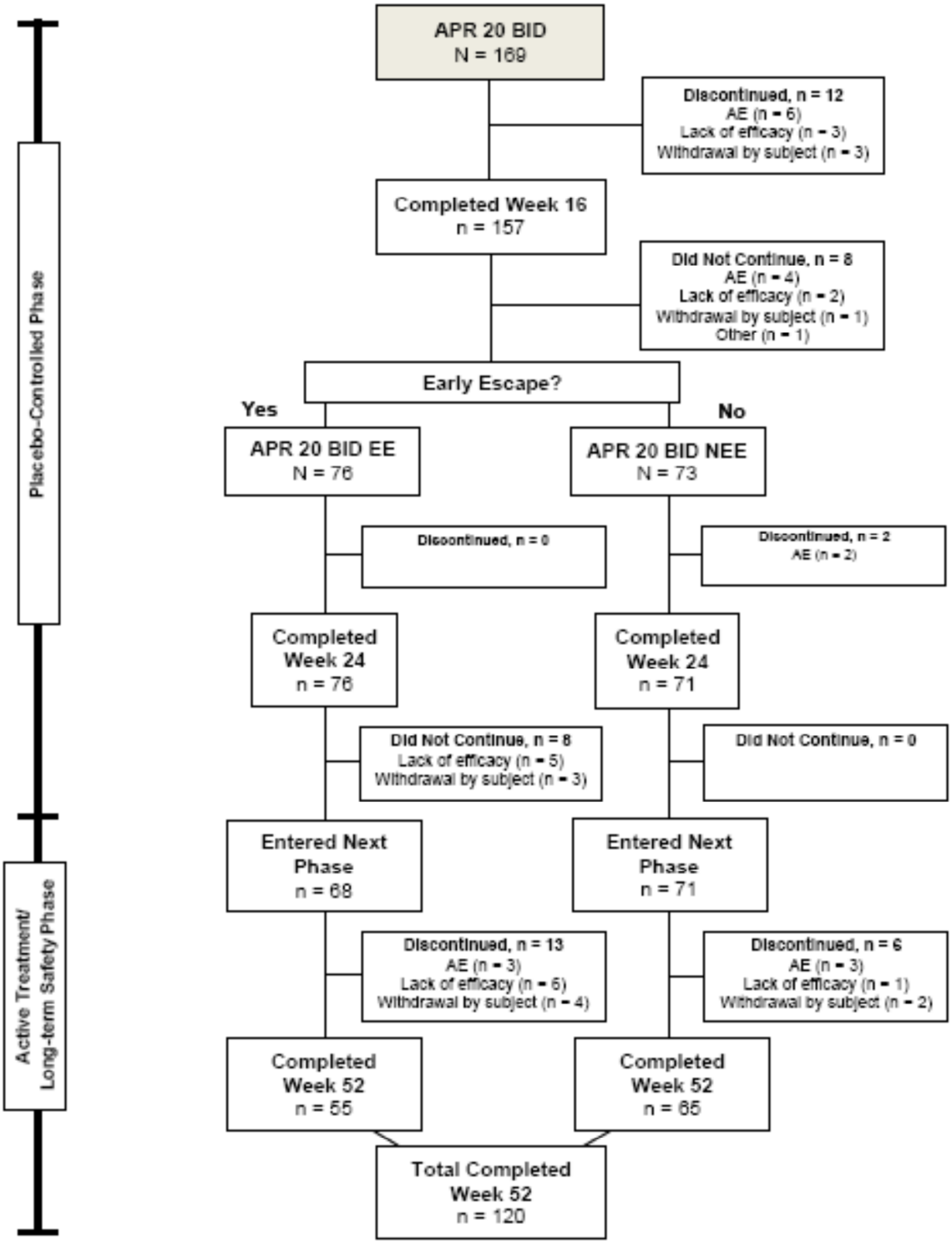
AE = adverse event; APR = apremilast; BID = twice daily; EE = early escape; NEE = no early escape.
Source: PSA-003 治験総括報告書 Table 14.1.2.1, Table 14.1.2.2, Table 14.1.2.3, Table 14.1.2.4, Table 14.1.15.2.2.

Figure 10:Disposition of Subjects Randomized to Placebo (Weeks 0-52) (Study PSA-004)



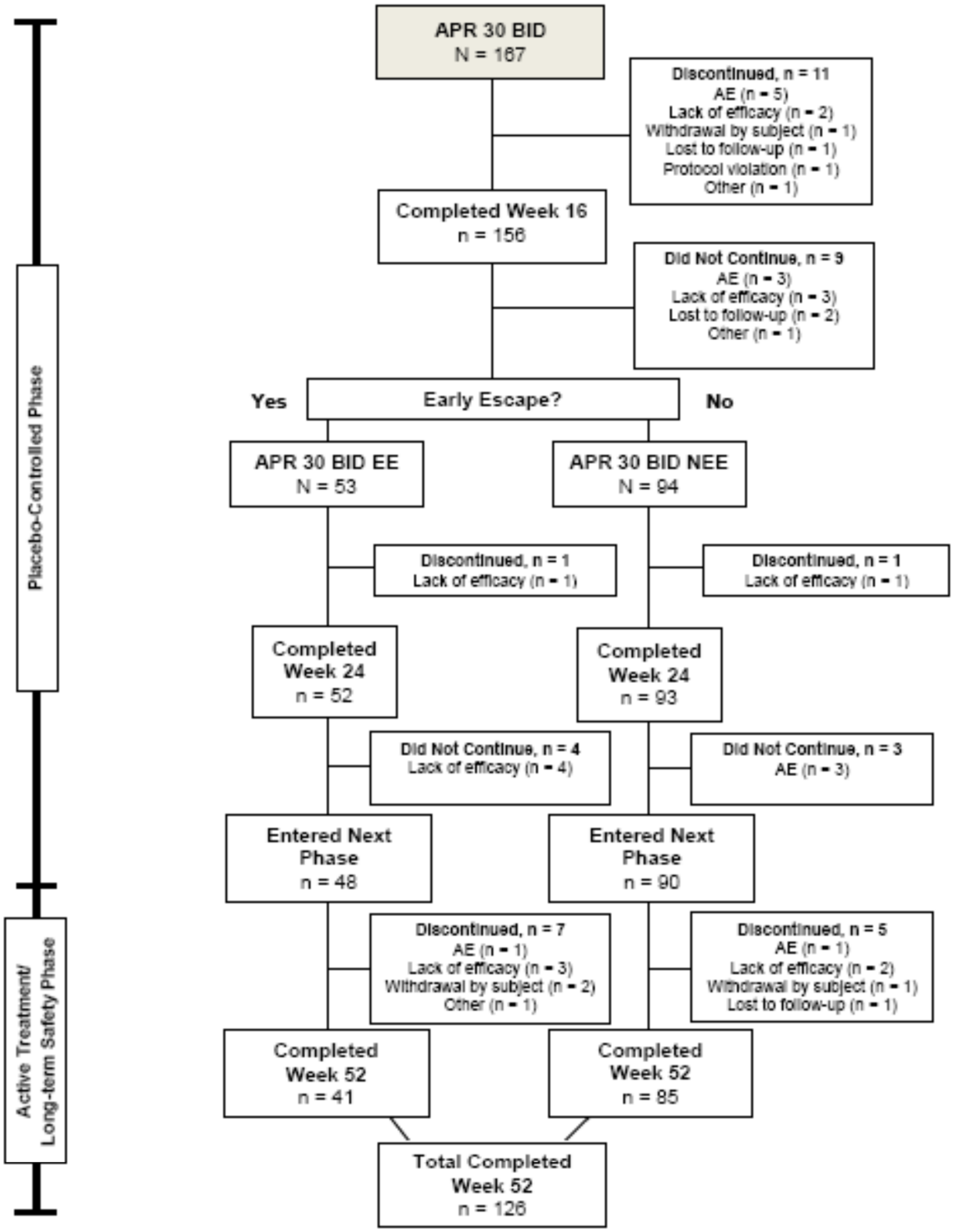
AE = adverse event; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); NEE = no early escape; PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).
Source: PSA-004 治験総括報告書 Table 14.1.2.1, Table 14.1.2.2, Table 14.1.2.3, Table 14.1.2.4, Table 14.1.15.2.1.

Figure 11:Disposition of Subjects Initially Randomized to APR 20 BID (Weeks 0-52) (Study PSA-004)



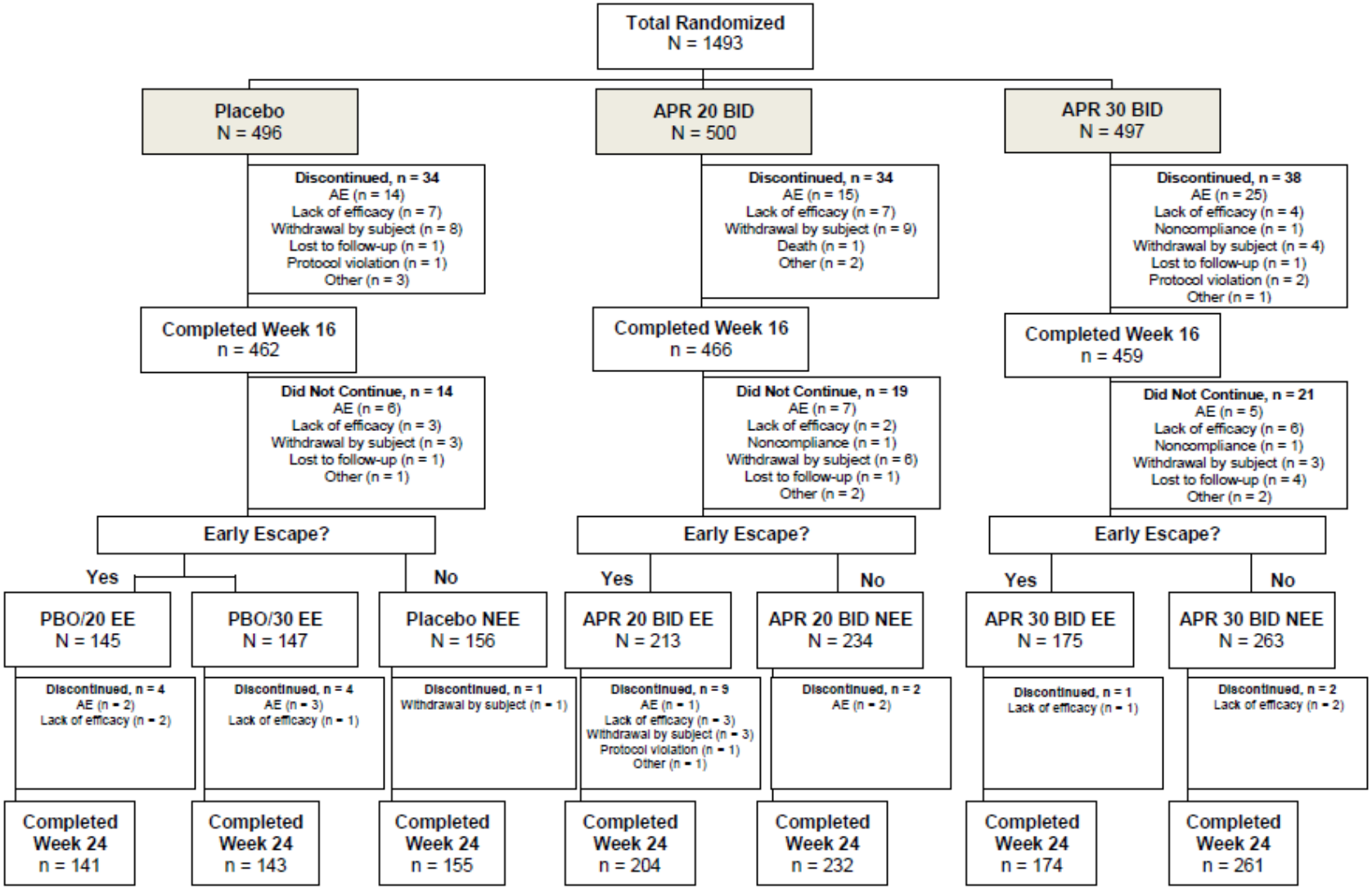
AE = adverse event; APR = apremilast; BID = twice daily; EE = early escape; NEE = no early escape.
Source: PSA-004 治験総括報告書 Table 14.1.2.1, Table 14.1.2.2, Table 14.1.2.3, Table 14.1.2.4, Table 14.1.15.2.2.

Figure 12:Disposition of Subjects Initially Randomized to APR 30 BID (Weeks 0-52) (Study PSA-004)



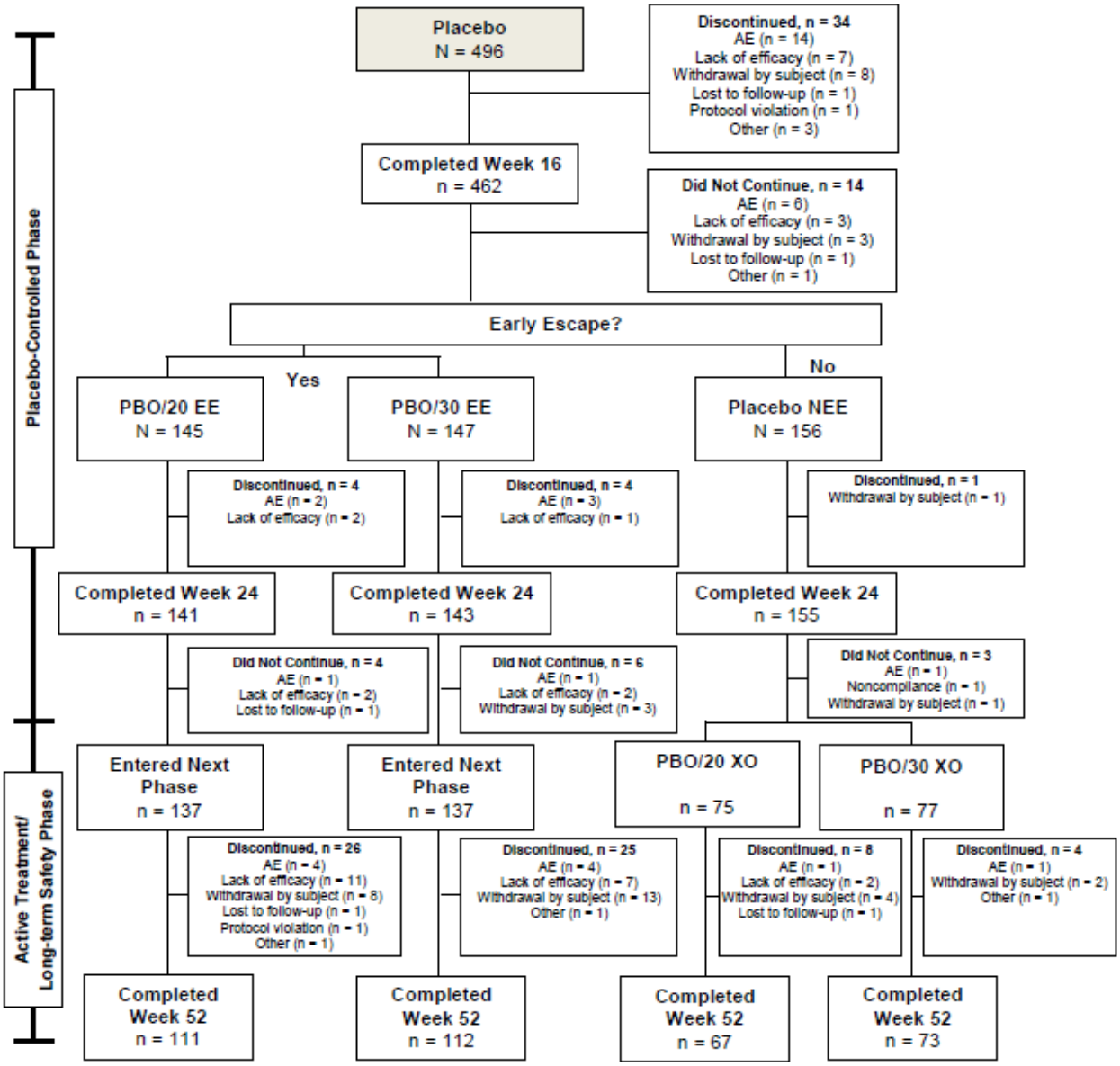
AE = adverse event; APR = apremilast; BID = twice daily; EE = early escape; NEE = no early escape.
Source: PSA-004 治験総括報告書 Table 14.1.2.1, Table 14.1.2.2, Table 14.1.2.3, Table 14.1.2.4, Table 14.1.15.2.2.

Figure 13: Disposition of Subjects During the Placebo-Controlled Phase (Weeks 0-24) (Pooled Analysis; FAS)



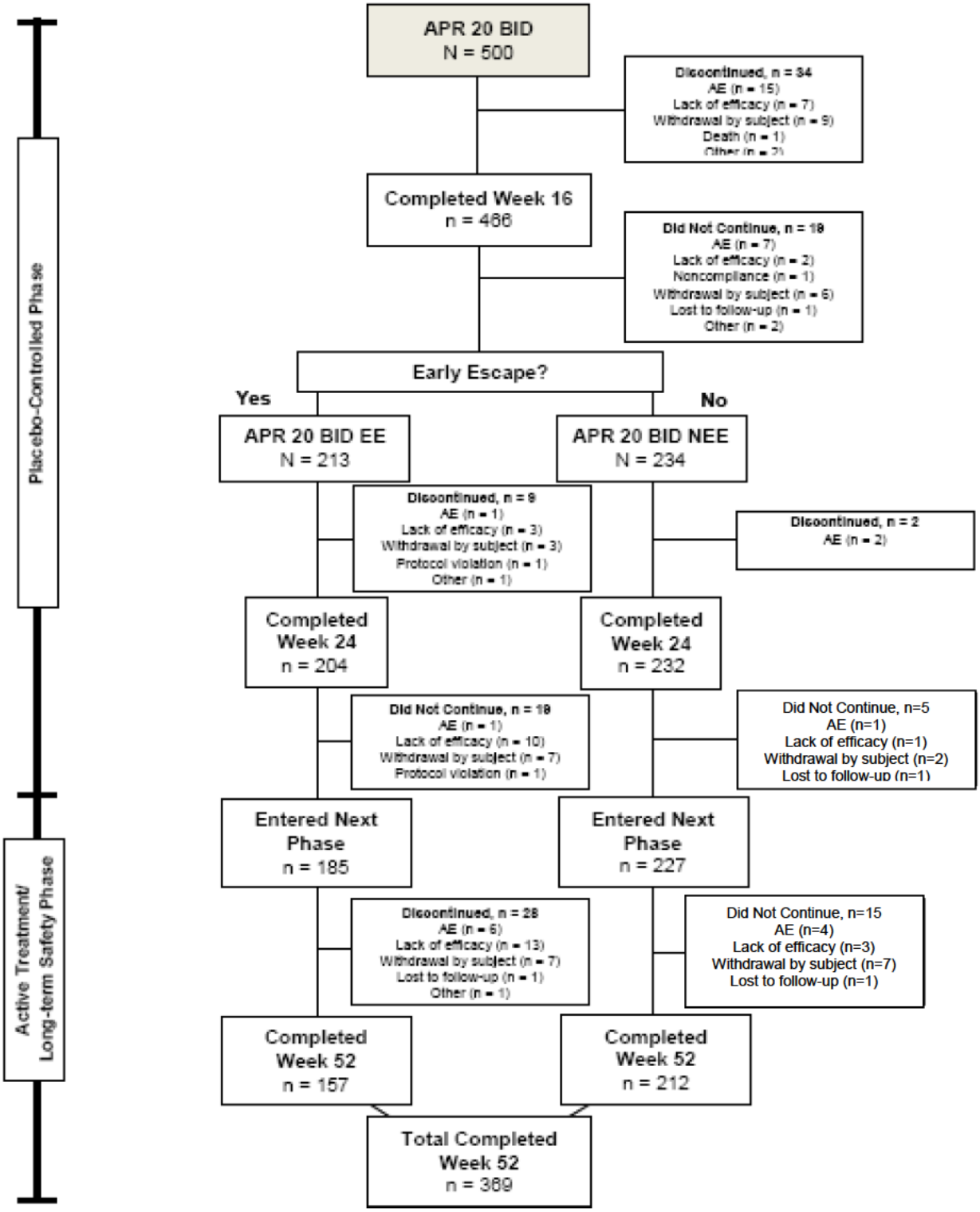
AE = adverse event; APR = apremilast; BID = twice daily; EE = early escape; FAS = full analysis set; NEE = non-early escape; PBO = placebo.
Four subjects were randomized in error in Study PSA-003, but did not receive study drug, and are therefore not included in the FAS.
Source: 5.3.5.3.2 項 有効性併合解析（PsA）Table 1.2.1.1, Table 1.2.1.3, Table 1.2.2.

Figure 14:Disposition of Subjects Randomized to Placebo (Weeks 0-52) (Pooled Analysis)



AE = adverse event; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); NEE = no early escape; PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).
Source: 5.3.5.3.2 項 有効性併合解析（PsA）Table 1.2.1.1, Table 1.2.1.3, Table 1.2.2, Table 1.3.2.1.

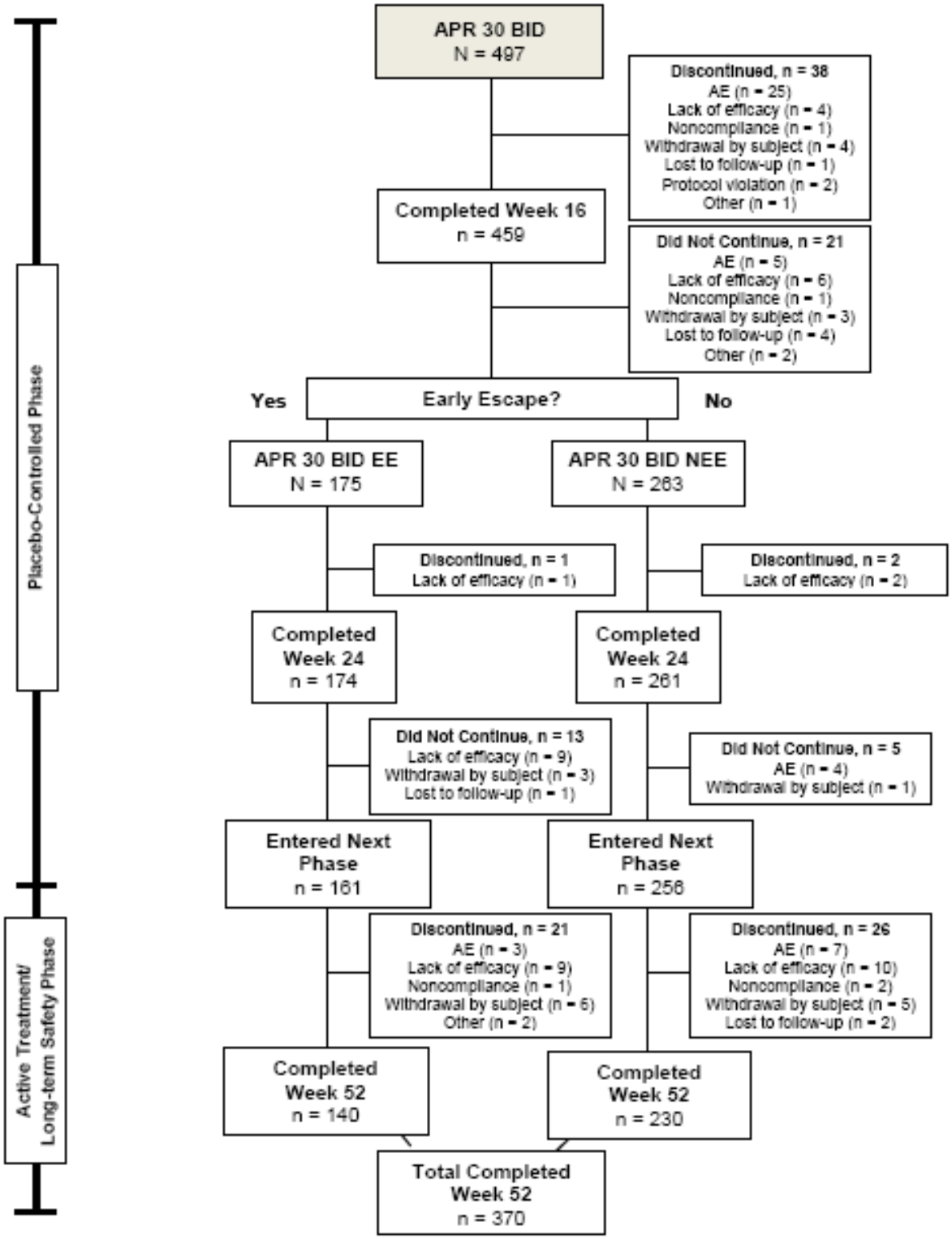
Figure 15:Disposition of Subjects Initially Randomized to APR 20 BID (Weeks 0-52) (Pooled Analysis)



AE = adverse event; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); NEE = no early escape; PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).

Source: 5.3.5.3.2 項 有効性併合解析（PsA） Table 1.2.1.1, Table 1.2.1.3, Table 1.2.2, Table 1.3.2.1, Table 1.3.2.2, Table 1.3.3.

Figure 16:Disposition of Subjects Initially Randomized to APR 30 BID (Weeks 0-52) (Pooled Analysis)



AE = adverse event; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); NEE = no early escape; PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).

Source: 5.3.5.3.2 項 有効性併合解析（PsA） Table 1.2.1.1, Table 1.2.1.3, Table 1.2.2, Table 1.3.2.1, Table 1.3.2.2, Table 1.3.3.

6.2. 人口統計学的特性

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Age (years)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Mean ± SD	51.1 ± 12.13	48.7 ± 10.99	51.4 ± 11.72	50.4 ± 11.66
Median (min – max)	53.0 (19 – 83)	50.0 (20 – 72)	53.0 (21 – 77)	51.0 (19 – 83)
PSA-003	N = 159	N = 163	N = 162	N = 484
Mean ± SD	51.2 ± 10.97	50.9 ± 11.82	50.5 ± 11.20	50.9 ± 11.32
Median (min – max)	51.0 (19 – 80)	52.0 (22 – 77)	51.5 (24 – 77)	52.0 (19 – 80)
PSA-004	N = 169	N = 169	N = 167	N = 505
Mean ± SD	49.5 ± 11.64	49.6 ± 12.10	49.9 ± 11.38	49.7 ± 11.69
Median (min – max)	50.0 (18 – 77)	51.0 (20 – 77)	50.0 (20 - 76)	50.0 (18 – 77)
Age Group, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
< 65 years	149 (88.7)	157 (93.5)	146 (86.9)	452 (89.7)
18 to < 40 years	30 (17.9)	34 (20.2)	30 (17.9)	94 (18.7)
40 to < 65 years	119 (70.8)	123 (73.2)	116 (69.0)	358 (71.0)
≥ 65 years	19 (11.3)	11 (6.5)	22 (13.1)	52 (10.3)
65 to < 75 years	14 (8.3)	11 (6.5)	20 (11.9)	45 (8.9)
75 to < 85 years	5 (3.0)	0	2 (1.2)	7 (1.4)
≥ 85 years	0	0	0	0

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Age Group, n (%) (continued)				
PSA-003	N = 159	N = 163	N = 162	N = 484
< 65 years	143 (89.9)	149 (91.4)	144 (88.9)	436 (90.1)
18 to < 40 years	22 (13.8)	30 (18.4)	30 (18.5)	82 (16.9)
40 to < 65 years	121 (76.1)	119 (73.0)	114 (70.4)	354 (73.1)
≥ 65 years	16 (10.1)	14 (8.6)	18 (11.1)	48 (9.9)
65 to < 75 years	13 (8.2)	12 (7.4)	17 (10.5)	42 (8.7)
75 to < 85 years	3 (1.9)	2 (1.2)	1 (0.6)	6 (1.2)
≥ 85 years	0	0	0	0
PSA-004	N = 169	N = 169	N = 167	N = 505
< 65 years	155 (91.7)	152 (89.9)	152 (91.0)	459 (90.9)
18 to < 40 years	36 (21.3)	35 (20.7)	30 (18.0)	101 (20.0)
40 to < 65 years	119 (70.4)	117 (69.2)	122 (73.1)	358 (70.9)
≥ 65 years	14 (8.3)	17 (10.1)	15 (9.0)	46 (9.1)
65 to < 75 years	11 (6.5)	15 (8.9)	14 (8.4)	40 (7.9)
75 to < 85 years	3 (1.8)	2 (1.2)	1 (0.6)	6 (1.2)
≥ 85 years	0	0	0	0

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Sex, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Male	88 (52.4)	85 (50.6)	76 (45.2)	249 (49.4)
Female	80 (47.6)	83 (49.4)	92 (54.8)	255 (50.6)
PSA-003	N = 159	N = 163	N = 162	N = 484
Male	74 (46.5)	68 (41.7)	67 (41.4)	209 (43.2)
Female	85 (53.5)	95 (58.3)	95 (58.6)	275 (56.8)
PSA-004	N = 169	N = 169	N = 167	N = 505
Male	78 (46.2)	79 (46.7)	79 (47.3)	236 (46.7)
Female	91 (53.8)	90 (53.3)	88 (52.7)	269 (53.3)
Race, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
White	153 (91.1)	150 (89.3)	152 (90.5)	455 (90.3)
Asian	8 (4.8)	8 (4.8)	8 (4.8)	24 (4.8)
Black	0	2 (1.2)	0	2 (0.4)
Native Hawaiian/Pacific Islander	1 (0.6)	1 (0.6)	1 (0.6)	3 (0.6)
American Indian/Alaska Native	1 (0.6)	2 (1.2)	0	3 (0.6)
Other	5 (3.0)	5 (3.0)	7 (4.2)	17 (3.4)

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Race, n (%) (continued)				
PSA-003	N = 159	N = 163	N = 162	N = 484
White	152 (95.6)	151 (92.6)	157 (96.9)	460 (95.0)
Asian	3 (1.9)	9 (5.5)	1 (0.6)	13 (2.7)
Black	2 (1.3)	1 (0.6)	1 (0.6)	4 (0.8)
Other	1 (0.6)	2 (1.2)	3 (1.9)	6 (1.2)
Missing	1 (0.6)	0	0	1 (0.2)
PSA-004	N = 169	N = 169	N = 167	N = 505
White	158 (93.5)	161 (95.3)	163 (97.6)	482 (95.4)
Black	2 (1.2)	0	0	2 (0.4)
Asian	7 (4.1)	6 (3.6)	2 (1.2)	15 (3.0)
Native Hawaiian/Pacific Islanders	1 (0.6)	0	0	1 (0.2)
American Indian/Alaska Native	0	0	0	0
Other	1 (0.6)	2 (1.2)	2 (1.2)	5 (1.0)

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Geographic Region, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
North America	81 (48.2)	73 (43.5)	69 (41.1)	223 (44.2)
Europe	39 (23.2)	41 (24.4)	42 (25.0)	122 (24.2)
Rest of world[a]	48 (28.6)	54 (32.1)	57 (33.9)	159 (31.5)
PSA-003	N = 159	N = 163	N = 162	N = 484
North America	35 (22.0)	38 (23.3)	43 (26.5)	116 (24.0)
Europe	106 (66.7)	103 (63.2)	101 (62.3)	310 (64.0)
Rest of world[a]	18 (11.3)	22 (13.5)	18 (11.1)	58 (12.0)
PSA-004	N = 169	N = 169	N = 167	N = 505
North America	48 (28.4)	58 (34.3)	58 (34.7)	164 (32.5)
Europe	75 (44.4)	79 (46.7)	78 (46.7)	232 (45.9)
Rest of world[a]	46 (27.2)	32 (18.9)	31 (18.6)	109 (21.6)

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Weight (kg)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Mean ± SD	89.84 ± 22.366	88.81 ± 21.110	87.07 ± 19.587	88.57 ± 21.041
Median (min – max)	85.45 (43.5 – 173.0)	85.50 (45.9 – 172.0)	86.60 (48.1 – 152.1)	85.50 (43.5 – 173.0)
PSA-003	N = 159	N = 163	N = 162	N = 484
Mean ± SD	84.88 ± 20.341	82.73 ± 21.922	82.70 ± 18.908	83.43 ± 20.411
Median (min – max)	84.00 (46.8 – 152.3)	80.00 (45.0 – 180.6)	80.50 (48.0 – 145.0)	82.00 (45.0 – 180.6)
PSA-004	N = 169	N = 169	N = 167	N = 505
Mean ± SD	84.45 ± 20.040	86.39 ± 20.137	83.72 ± 20.146	84.86 ± 20.099
Median (min – max)	80.60 (48.6 – 141.0)	85.00 (47.5 – 163.0)	82.40 (45.0 – 180.2)	82.60 (45.0 – 180.2)

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Body mass index (BMI), kg/m^2				
PSA-002	N = 168	N = 168	N = 168	N = 504
Mean ± SD	31.07 ± 6.580	30.90 ± 7.305	30.61 ± 5.936	30.86 ± 6.620
Median (min – max)	30.75 (17.0 – 52.5)	29.05 (18.4 – 62.9)	29.75 (19.4 – 52.0)	29.75 (17.0 – 62.9)
PSA-003	N = 159	N = 163	N = 162	N = 484
Mean ± SD	29.51 ± 6.471	29.29 ± 6.617	29.18 ± 6.176	29.32 ± 6.412
Median (min – max)	29.10 (17.6 – 50.8)	28.65 (18.0 – 53.9)	28.25 (17.6 – 52.1)	28.70 (17.6 – 53.9)
PSA-004	N = 169	N = 169	N = 167	N = 505
Mean ± SD	29.50 ± 6.433	30.09 ± 6.250	29.20 ± 6.352	29.60 ± 6.343
Median (min – max)	28.20 (19.0 – 56.2)	29.40 (17.2 – 50.6)	28.70 (16.6 – 49.7)	28.70 (16.6 – 56.2)
BMI category, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
< 25 kg/m^2	30 (17.9)	27 (16.1)	28 (16.7)	85 (16.9)
25 to < 30 kg/m^2	47 (28.0)	67 (39.9)	57 (33.9)	171 (33.9)
30 to < 35 kg/m^2	49 (29.2)	35 (20.8)	41 (24.4)	125 (24.8)
35 to < 40 kg/m^2	24 (14.3)	21 (12.5)	32 (19.0)	77 (15.3)
≥ 40 kg/m^2	18 (10.7)	18 (10.7)	10 (6.0)	46 (9.1)

Table 3: Demographic Characteristics in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Demographic Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
BMI category, n (%) (continued)				
PSA-003	N = 159	N = 163	N = 162	N = 484
< 25 kg/m^2	41 (25.8)	46 (28.2)	45 (27.8)	132 (27.3)
25 to < 30 kg/m^2	45 (28.3)	54 (33.1)	55 (34.0)	154 (31.8)
30 to < 35 kg/m^2	43 (27.0)	35 (21.5)	36 (22.2)	114 (23.6)
35 to < 40 kg/m^2	20 (12.6)	15 (9.2)	17 (10.5)	52 (10.7)
≥ 40 kg/m^2	10 (6.3)	12 (7.4)	9 (5.6)	31 (6.4)
Missing	0	1 (0.6)	0	1 (0.2)
PSA-004	N = 169	N = 169	N = 167	N = 505
< 25 kg/m^2	41 (24.3)	38 (22.5)	43 (25.7)	122 (24.2)
25 to < 30 kg/m^2	60 (35.5)	53 (31.4)	58 (34.7)	171 (33.9)
30 to < 35 kg/m^2	33 (19.5)	43 (25.4)	36 (21.6)	112 (22.2)
35 to < 40 kg/m^2	22 (13.0)	27 (16.0)	20 (12.0)	69 (13.7)
≥ 40 kg/m^2	12 (7.1)	8 (4.7)	10 (6.0)	30 (5.9)
Missing	1 (0.6)	0 (0.0)	0 (0.0)	1 (0.2)

APR = apremilast; BID = twice daily; FAS = full analysis set; Min – max = minimum to maximum; Pac. = Pacific; SD = standard deviation

[a] Rest of world countries included Australia, New Zealand, Republic of Korea, Russian Federation, South Africa, and Taiwan, province of China. A summary of subjects by country can be found in Table 14.1.3 of PSA-002 CSR, PSA-003 CSR, and PSA-004 CSR.

Source: PSA-002 治験総括報告書 Table 10, PSA-003 治験総括報告書 Table 10, PSA-004 治験総括報告書 Table 10, Table 14.1.5.1.

6.3. ベースラインの病歴

Table 4: Baseline Disease History in Studies PSA-002, PSA-003, and PSA-004 (FAS)

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Duration of PsA (years since diagnosis)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Mean ± SD	7.31 ± 7.118	7.18 ± 6.842	8.09 ± 8.092	7.53 ± 7.366
Median (min – max)	5.20 (0.5 – 38.6)	4.55 (0.5 – 33.2)	4.75 (0.5 – 40.7)	5.05 (0.5 – 40.7)
PSA-003	N = 159	N = 163	N = 162	N = 484
Mean ± SD	7.76 ± 8.254	7.83 ± 8.621	6.82 ± 7.592	7.47 ± 8.163
Median (min – max)	5.80 (0.1 – 54.4)	4.30 (0.5 – 39.8)	3.60 (0.5 – 43.4)	4.75 (0.1 – 54.4)
PSA-004	N = 169	N = 169	N = 167	N = 505
Mean ± SD	6.78 ± 6.463	7.74 ± 7.690	7.48 ± 7.646	7.33 ± 7.284
Median (min – max)	4.80 (0.5 – 28.5)	5.20 (0.2 – 41.3)	5.3 (0.4 – 57.3)	5.10 (0.2 – 57.3)
PsA type, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Symmetric polyarthritis	104 (61.9)	106 (63.1)	110 (65.5)	320 (63.5)
Asymmetrical oligoarthritis	45 (26.8)	41 (24.4)	45 (26.8)	131 (26.0)
Predominant DIP involvement	14 (8.3)	14 (8.3)	11 (6.5)	39 (7.7)
Arthritis mutilans	2 (1.2)	4 (2.4)	1 (0.6)	7 (1.4)
Predominant spondylitis	3 (1.8)	3 (1.8)	1 (0.6)	7 (1.4)

Table 4: Baseline Disease History in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
PsA type, n (%) (continued)				
PSA-003	N = 159	N = 163	N = 162	N = 484
Symmetric polyarthritis	101 (63.5)	109 (66.9)	101 (62.3)	311 (64.3)
Asymmetrical oligoarthritis	49 (30.8)	43 (26.4)	42 (25.9)	134 (27.7)
Predominant DIP involvement	4 (2.5)	7 (4.3)	7 (4.3)	18 (3.7)
Arthritis mutilans	3 (1.9)	2 (1.2)	7 (4.3)	12 (2.5)
Predominant spondylitis	1 (0.6)	2 (1.2)	5 (3.1)	8 (1.7)
Missing	1 (0.6)	0	0	1 (0.2)
PSA-004	N = 169	N = 169	N = 167	N = 505
Symmetric polyarthritis	93 (55.0)	104 (61.5)	98 (58.7)	295 (58.4)
Asymmetrical oligoarthritis	44 (26.0)	43 (25.4)	49 (29.3)	136 (26.9)
Predominant DIP involvement	16 (9.5)	10 (5.9)	10 (6.0)	36 (7.1)
Predominant spondylitis	3 (1.8)	8 (4.7)	6 (3.6)	17 (3.4)
Arthritis mutilans	13 (7.7)	4 (2.4)	4 (2.4)	21 (4.2)
History of Psoriasis (diagnosis)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Yes	168 (100.0)	167 (99.4)	166 (98.8)	501 (99.4)
No	0	1 (0.6)	2 (1.2)	3 (0.6)
PSA-003	N = 159	N = 163	N = 162	N = 484
Yes	157 (98.7)	163 (100.0)	159 (98.1)	479 (99.0)
No	1 (0.6)	0	1 (0.6)	2 (0.4)
Missing	1 (0.6)	0	2 (1.2)	3 (0.6)

Table 4: Baseline Disease History in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
History of Psoriasis (diagnosis) (continued)				
PSA-004	N = 169	N = 169	N = 167	N = 505
Yes	169 (100.0)	169 (100.0)	167 (100.0)	505 (100.0)
No	0	0	0	0
Duration of psoriasis (years since diagnosis)				
PSA-002	n = 168	n = 167	n = 166	n = 501
Mean ± SD	15.73 ± 13.013	15.52 ± 11.948	16.50 ± 12.33	15.91 ± 12.423
Median (min – max)	11.10 (0.2 – 57.6)	12.60 (0.6 – 50.8)	14.85 (0.0 – 54.7)	13.10 (0.0 – 57.6)
PSA-003	n = 157	n = 163	n = 159	n = 479
Mean ± SD	17.84 ± 13.938	17.85 ± 14.072	18.66 ± 14.468	18.12 ± 14.137
Median (min – max)	14.20 (0.0 – 62.0)	13.90 (0.4 – 56.7)	13.90 (0.5 – 58.4)	13.90 (0.0 – 62.0)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	17.79 ± 13.270	18.26 ± 14.358	17.08 ± 12.136	17.71 ± 13.272
Median (min – max)	15.30 (0.5 – 58.6)	15.40 (0.2 – 64.8)	14.80 (0.0 – 57.3)	15.30 (0 – 64.8)
Psoriasis history[a], n (%)				
PSA-002	n = 168	n = 168	n = 168	n = 504
Guttate, pustular, or erythrodermic psoriasis	0	3 (1.8)	3 (1.8)	6 (1.2)
Palmoplantar psoriasis	27 (16.1)	26 (15.5)	18 (10.7)	71 (14.1)
Plaque-type psoriasis	123 (73.2)	127 (75.6)	134 (79.8)	384 (76.2)
Nail psoriasis	116 (69.0)	114 (67.9)	114 (67.9)	344 (68.3)
Scalp psoriasis	126 (75.0)	129 (76.8)	133 (79.2)	388 (77.0)

Table 4: Baseline Disease History in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Psoriasis history[a], n (%) (continued)				
PSA-003	n = 159	n = 163	n = 162	n = 484
Guttate, pustular, or erythrodermic psoriasis	3 (1.9)	2 (1.2)	4 (2.5)	9 (1.9)
Palmoplantar psoriasis	19 (11.9)	17 (10.4)	16 (9.9)	52 (10.7)
Plaque-type psoriasis	114 (71.7)	111 (68.1)	106 (65.4)	331 (68.4)
Nail psoriasis	101 (63.5)	93 (57.1)	113 (69.8)	307 (63.4)
Scalp psoriasis	120 (75.5)	128 (78.5)	119 (73.5)	367 (75.8)
PSA-004	n = 169	n = 169	n = 167	n = 505
Guttate, pustular, or erythrodermic psoriasis	4 (2.4)	2 (1.2)	3 (1.8)	9 (1.8)
Palmoplantar psoriasis	19 (11.2)	21 (12.4)	13 (7.8)	53 (10.5)
Plaque-type psoriasis	138 (81.7)	136 (80.5)	145 (86.8)	419 (83.0)
Nail psoriasis	111 (65.7)	116 (68.6)	121 (72.5)	348 (68.9)
Scalp psoriasis	138 (81.7)	142 (84.0)	135 (80.8)	415 (82.2)

Table 4: Baseline Disease History in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Psoriasis BSA involvement, %				
PSA-002	n = 125	n = 125	n = 122	n = 372
Mean ± SD	7.74 ± 15.982	6.97 ± 13.177	7.88 ± 14.641	7.53 ± 14.611
Median (min – max)	2.00 (0.0 – 90.0)	2.00 (0.0 – 70.0)	2.00 (0.0 – 95.0)	2.00 (0.0 – 95.0)
PSA-003	n = 149	n = 153	n = 148	n = 450
Mean ± SD	7.24 ± 14.629	6.58 ± 12.011	6.97 ± 14.380	6.93 ± 13.680
Median (min – max)	2.00 (0.0 – 85.0)	2.00 (0.0 – 90.0)	2.00 (0.0 – 85.0)	2.00 (0.0 – 90.0)
PSA-004	n = 157	n = 156	n = 152	n = 465
Mean ± SD	8.28 ± 15.905	6.96 ± 10.632	7.11 ± 11.034	7.46 ± 12.759
Median (min – max)	3.00 (0.1 – 90.0)	3.00 (0.1 – 60.0)	3.00 (0.0 – 60.0)	3.00 (0.0 – 90.0)
Extent of psoriasis[b], n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
< 3% BSA involvement	100 (59.5)	91 (54.2)	86 (51.2)	277 (55.0)
≥ 3% BSA involvement	68 (40.5)	77 (45.8)	82 (48.8)	227 (45.0)
PSA-003	N = 159	N = 163	N = 162	N = 484
< 3% BSA involvement	85 (53.5)	83 (50.9)	85 (52.5)	253 (52.3)
≥ 3% BSA involvement	74 (46.5)	80 (49.1)	77 (47.5)	231 (47.7)
PSA-004	N = 169	N = 169	N = 167	N = 505
< 3% BSA involvement	80 (47.3)	78 (46.2)	77 (46.1)	235 (46.5)
≥ 3% BSA involvement	89 (52.7)	91 (53.8)	90 (53.9)	270 (53.5)

Table 4: Baseline Disease History in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Baseline PASI score				
PSA-002	n = 65	n = 76	n = 82	n= 223
Mean ± SD	9.08 ± 9.513	7.39 ± 8.727	9.17 ± 9.741	8.54 ± 9.334
Median (min – max)	5.50 (0.5 – 49.8)	4.55 (0.1 – 43.6)	5.80 (0.8 – 54.6)	5.30 (0.1 – 54.6)
PSA-003	n = 72	n = 80	n = 72	n = 224
Mean ± SD	8.59 ± 9.957	7.36 ± 6.517	7.75 ± 7.283	7.88 ± 7.985
Median (min – max)	5.40 (0.0 – 68.4)	5.20 (0.6 – 36.8)	5.15 (0.3 – 30.3)	5.20 (0.0 – 68.4)
PSA-004	n = 86	n = 87	n = 89	n = 262
Mean ± SD	7.64 ± 7.157	7.57 ± 5.173	7.86 ± 6.337	7.69 ± 6.249
Median (min – max)	5.10 (0.4 – 35.0)	5.70 (0.5 – 23.4)	5.80 (0.3 – 25.8)	5.50 (0.3 – 35.0)

APR = apremilast; BID = twice daily; BSA = body surface area; DIP = distal interphalangeal joint; FAS = full analysis set;
min – max = minimum to maximum; PASI = Psoriasis Area and Severity Index; PsA = psoriatic arthritis; SD = standard deviation

[a] Primary terms captured in the case report form.

[b] Extent of psoriasis as recorded on the case report form.

Source: PSA-002 治験総括報告書 Table 11, PSA-003 治験総括報告書 Table 11, PSA-004 治験総括報告書 Table 11, Table 14.1.6.1.

6.4. ベースラインの疾患活動性

Table 5: Baseline Disease Activity per the ACR Core Set Measures in Studies PSA-002, PSA-003, and PSA-004 (FAS)

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Tender joint count				
PSA-002	n = 168	n = 168	n = 168	n = 504
Mean ± SD	23.3 ± 15.21	22.2 ± 15.90	23.1 ± 14.45	22.9 ± 15.17
Median (min – max)	20.0 (3 – 78)	17.0 (3 – 70)	20.0 (3 – 78)	19.0 (3 – 78)
PSA-003	n = 159	n = 163	n = 162	n = 484
Mean ± SD	18.0 ± 13.52	20.3 ± 16.58	21.8 ± 16.82	20.0 ± 15.77
Median (min – max)	13.0 (3 – 66)	15.0 (3 – 78)	16.0 (3 – 78)	15.0 (3 – 78)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	18.3 ± 14.94	20.8 ± 16.78	20.9 ± 14.37	20.0 ± 15.42
Median (min – max)	13.0 (3 - 78)	15.0 (3 - 78)	18.0 (3 - 76)	15.0 (3 - 78)
Swollen joint count				
PSA-002	n = 168	n = 168	n = 168	n = 504
Mean ± SD	12.8 ± 8.84	12.5 ± 9.47	12.8 ± 7.78	12.7 ± 8.71
Median (min – max)	10.0 (3 – 56)	9.0 (3 – 58)	12.0 (3 – 47)	10.5 (3 – 58)
PSA-003	n = 159	n = 163	n = 162	n = 484
Mean ± SD	9.2 ± 6.56	10.4 ± 7.84	10.3 ± 8.10	10.0 ± 7.54
Median (min – max)	7.0 (3 – 41)	8.0 (3 – 56)	8.0 (3 – 55)	8.0 (3 – 56)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	11.1 ± 7.90	11.4 ± 9.07	11.6 ± 8.68	11.4 ± 8.55
Median (min – max)	8.0 (3 - 48)	8.0 (3 - 52)	9.0 (3 - 47)	9.0 (3 - 52)

Table 5: Baseline Disease Activity per the ACR Core Set Measures in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Subject assessment of pain (VAS) (mm)				
PSA-002	n = 167	n = 167	n = 168	n = 502
Mean ± SD	61.2 ± 20.19	54.9 ± 22.90	57.9 ± 20.24	58.0 ± 21.26
Median (min – max)	64.0 (5 – 99)	58.0 (0 – 99)	59.0 (3 – 100)	60.0 (0 – 100)
PSA-003	n = 158	n = 163	n = 160	n = 481
Mean ± SD	55.7 ± 19.73	57.3 ± 20.87	56.5 ± 20.64	56.5 ± 20.39
Median (min – max)	56.0 (13 – 100)	61.0 (4 – 99)	60.0 (0 – 98)	58.0 (0 – 100)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	55.5 ± 20.81	55.0 ± 21.26	56.8 ± 23.15	55.8 ± 21.73
Median (min – max)	57.0 (7 – 99)	57.0 (3 – 99)	60.0 (1 – 99)	58.0 (1 – 99)
Patient's (subject's) global assessment of disease activity (PGA) (mm)				
PSA-002	n = 167	n = 167	n = 168	n = 502
Mean ± SD	58.8 ± 22.32	55.3 ± 23.71	55.9 ± 21.49	56.7 ± 22.53
Median (min – max)	62.0 (6 – 100)	58.0 (1 – 100)	57.0 (1 – 98)	58.0 (1 – 100)
PSA-003	n = 157	n = 162	n = 159	n = 478
Mean ± SD	55.0 ± 20.04	57.3 ± 19.55	56.4 ± 21.36	56.3 ± 20.31
Median (min – max)	55.0 (3 – 99)	58.5 (6 – 100)	57.0 (1 – 98)	57.0 (1 – 100)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	56.1 ± 20.99	54.3 ± 20.90	56.5 ± 24.15	55.6 ± 22.03
Median (min – max)	56.0 (3 - 99)	55.0 (5 - 99)	60.0 (0 – 100)	58.0 (0 - 100)

Table 5: Baseline Disease Activity per the ACR Core Set Measures in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Evaluator's (physician's) global assessment of disease activity (EGA) (mm)				
PSA-002	n = 162	n = 166	n = 166	n = 494
Mean ± SD	55.2 ± 20.29	54.1 ± 21.77	55.7 ± 19.16	55.0 ± 20.41
Median (min – max)	57.0 (6 – 95)	57.0 (0 – 97)	57.0 (10 – 96)	57.0 (0 – 97)
PSA-003	n = 155	n = 160	n = 154	n = 469
Mean ± SD	54.5 ± 17.62	53.8 ± 17.69	56.2 ± 19.74	54.8 ± 18.35
Median (min – max)	54.0 (14 – 92)	54.0 (7 – 93)	54.5 (15 – 97)	54.0 (7 – 97)
PSA-004	n = 163	n = 162	n = 162	n = 487
Mean ± SD	52.8 ± 18.82	55.2 ± 18.82	56.1 ± 18.15	54.7 ± 18.61
Median (min – max)	51.0 (11 – 100)	56.5 (3 – 98)	58.0 (19 – 95)	55.0 (3 – 100)
HAQ-DI score				
PSA-002	n = 167	n = 167	n = 168	n = 502
Mean ± SD	1.210 ± 0.6034	1.156 ± 0.6425	1.249 ± 0.6092	1.205 ± 0.6185
Median (min – max)	1.250 (0.00 – 2.75)	1.125 (0.00 – 2.88)	1.250 (0.00 – 2.75)	1.250 (0.00 – 2.88)
PSA-003	n = 159	n = 163	n = 160	n = 482
Mean ± SD	1.164 ± 0.6005	1.133 ± 0.6161	1.220 ± 0.6248	1.172 ± 0.6137
Median (min – max)	1.250 (0.00 – 2.50)	1.125 (0.00 – 2.63)	1.250 (0.00 – 2.75)	1.250 (0.00 – 2.75)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	1.169 ± 0.6270	1.118 ± 0.6452	1.184 ± 0.6728	1.157 ± 0.6478
Median (min – max)	1.250 (0.00 – 2.63)	1.125 (0.00 – 2.63)	1.125 (0.00 – 2.88)	1.125 (0.00 – 2.88)

Table 5: Baseline Disease Activity per the ACR Core Set Measures in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
CRP (mg/dL)[a]				
PSA-002	n = 168	n = 168	n = 168	n = 504
Mean ± SD	1.066 ± 1.4356	0.904 ± 1.4085	0.844 ± 1.0236	0.938 ± 1.3037
Median (min – max)	0.494 (0.02 – 8.08)	0.453 (0.02 – 13.73)	0.491 (0.02 – 7.91)	0.479 (0.02 – 13.73)
PSA-003	n = 159	n = 163	n = 162	n = 484
Mean ± SD	1.027 ± 1.5265	1.084 ± 2.2009	0.882 ± 1.1110	0.998 ± 1.6750
Median (min – max)	0.545 (0.02 – 11.49)	0.416 (0.03 – 23.99)	0.412 (0.02 – 6.57)	0.457 (0.02 – 23.99)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	0.996 ±1.3500	0.967 ± 1.5064	1.148 ± 1.8767	1.037 ±1.5907
Median (min – max)	0.433 (0.02 – 7.05)	0.406 (0.02 – 8.72)	0.422 (0.02 – 13.22)	0.422 (0.02 – 13.22)

ACR = American College of Rheumatology; APR = apremilast; BID = twice daily ; CRP = C-reactive protein; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; min – max = minimum to maximum; SD = standard deviation; VAS = visual analog scale.

[a] Normal range for CRP was < 0.5 mg/dL.

Source: PSA-002 治験総括報告書 Table 12, PSA-003 治験総括報告書 Table 12, PSA-004 治験総括報告書 Table 12.

Table 6: Baseline Disease Activity - Measures Other Than ACR Core Set in Studies PSA-002, PSA-003, and PSA-004 (FAS)

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
SF-36v2 Physical Functioning domain score				
PSA-002	n = 166	n = 167	n = 168	n = 501
Mean ± SD	33.84 ± 10.607	35.13 ± 10.726	33.02 ± 10.248	33.99 ± 10.543
Median (min – max)	33.90 (14.9 – 57.0)	36.00 (14.9 – 54.9)	31.80 (14.9 – 54.9)	33.90 (14.9 – 57.0)
PSA-003	n = 159	n = 163	n = 160	n = 482
Mean ± SD	34.45 ± 9.898	34.54 ± 10.425	33.67 ± 10.599	34.22 ± 10.299
Median (min – max)	33.90 (14.9 – 57.0)	33.90 (14.9 – 57.0)	32.85 (14.9 – 57.0)	33.90 (14.9 – 57.0)
PSA-004	n = 168	n = 168	n = 167	n = 503
Mean ± SD	34.29 ± 10.916	34.88 ± 10.540	34.17 ± 10.495	34.45 ± 10.636
Median (min – max)	33.90 (14.9 – 57.0)	36.00 (14.9 – 57.0)	33.90 (14.9 – 54.9)	33.90 (14.9 – 57.0)
MASES[a]				
PSA-002	n = 98	n = 103	n = 114	-
Mean ± SD	5.4 ± 3.49	5.0 ± 3.31	4.4 ± 3.07	-
Median (min – max)	4.5 (1 – 13)	4.0 (1 – 13)	4.0 (1 – 13)	-
PSA-003	n = 104	n = 107	n = 101	-
Mean ± SD	4.7 ± 3.12	4.5 ± 3.36	4.5 ± 3.23	-
Median (min – max)	4.0 (1 – 12)	4.0 (1 – 13)	4.0 (1 – 13)	-
PSA-004	n = 109	n = 97	n = 112	-
Mean ± SD	4.4 ± 3.37	4.3 ± 3.14	4.5 ± 3.28	-
Median (min – max)	3.0 (1 – 13)	3.0 (1 – 13)	4.0 (1 – 13)	-

Table 6: Baseline Disease Activity - Measures Other Than ACR Core Set in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Dactylitis severity score[b]				
PSA-002	n = 68	n = 59	n = 68	-
Mean ± SD	3.3 ± 3.25	4.1 ± 4.18	2.9 ± 2.36	-
Median (min – max)	2.0 (1 – 17)	3.0 (1 – 20)	2.0 (1 – 11)	-
PSA-003	n = 66	n = 77	n = 73	-
Mean ± SD	2.6 ± 2.31	2.7 ± 2.38	2.6 ± 1.99	-
Median (min – max)	2.0 (1 – 12)	2.0 (1 – 13)	2.0 (1 – 8)	-
PSA-004	n = 71	n = 71	n = 80	-
Mean ± SD	3.8 ± 3.96	3.7 ± 3.60	4.2 ± 4.47	-
Median (min – max)	2.0 (1 – 20)	2.0 (1 – 20)	3.0 (1 – 19)	-
CDAI				
PSA-002	n = 162	n = 166	n = 166	n = 494
Mean ± SD	29.68 ± 12.038	28.44 ± 13.103	29.43 ± 11.496	29.18 ± 12.219
Median (min – max)	29.55 (5.8 – 68.9)	25.80 (2.5 – 66.2)	30.15 (6.1 – 65.0)	28.80 (2.5 – 68.9)
PSA-003	n = 153	n = 160	n = 153	n = 466
Mean ± SD	25.20 ± 11.296	25.78 ± 11.048	27.10 ± 12.314	26.02 ± 11.560
Median (min – max)	23.30 (5.5 – 62.9)	24.00 (6.3 – 59.3)	24.50 (6.3 – 71.5)	23.65 (5.5 – 71.5)
PSA-004	n = 163	n = 162	n = 162	n = 487
Mean ± SD	24.74 ± 11.549	25.91 ± 11.728	26.15 ± 10.475	25.60 ± 11.259
Median (min – max)	22.30 (2.9 – 67.7)	23.60 (3.8 – 63.7)	24.80 (8.5 – 61.6)	23.60 (2.9 – 67.7)

Table 6: Baseline Disease Activity - Measures Other Than ACR Core Set in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
DAS28(CRP)				
PSA-002	n = 167	n = 167	n = 168	n = 502
Mean ± SD	4.92 ± 0.998	4.76 ± 1.087	4.87 ± 0.996	4.85 ± 1.028
Median (min – max)	4.91 (1.6 – 7.7)	4.79 (1.2 – 7.4)	5.02 (2.3 – 7.1)	4.90 (1.2 – 7.7)
PSA-003	n = 157	n = 162	n = 159	n = 478
Mean ± SD	4.51 ± 1.083	4.60 ± 1.049	4.68 ± 1.028	4.60 ± 1.053
Median (min – max)	4.38 (1.8 – 7.6)	4.56 (2.0 – 7.4)	4.67 (2.5 – 7.4)	4.53 (1.8 – 7.6)
PSA-004	n = 169	n = 169	n = 167	n = 505
Mean ± SD	4.52 ±1.056	4.57 ± 1.090	4.64 ± 0.981	4.57 ± 1.043
Median (min – max)	4.51 (1.5 – 6.9)	4.51 (1.8 – 7.5)	4.57 (2.0 – 7.0)	4.53 (1.5 – 7.5)
FACIT-Fatigue				
PSA-002	n = 166	n = 167	n = 167	n = 500
Mean ± SD	29.32 ± 11.236	31.90 ± 11.801	30.01 ± 10.467	30.41 ± 11.212
Median (min – max)	29.50 (3.0 – 51.0)	34.00 (1.0 – 52.0)	29.00 (7.0 – 52.0)	31.00 (1.0 – 52.0)
PSA-003	n = 158	n = 162	n = 160	n = 480
Mean ± SD	30.32 ± 10.162	30.48 ± 10.036	29.90 ± 11.109	30.23 ± 10.427
Median (min – max)	31.00 (1.0 – 50.0)	30.00 (4.0 – 50.0)	30.50 (2.0 – 52.0)	31.00 (1.0 – 52.0)
PSA-004	n = 166	n = 168	n = 167	n = 501
Mean ± SD	28.91 ± 11.095	30.15 ±10.773	28.29 ±11.695	29.12 ± 11.198
Median (min – max)	29.00 (4.0 – 50.0)	30.00 (5.0 – 50.0)	28.00 (1.0 – 51.0)	30.00 (1.0 – 51.0)

Table 6: Baseline Disease Activity - Measures Other Than ACR Core Set in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Disease Characteristic Study	Placebo	APR 20 BID	APR 30 BID	Total
Rheumatoid factor, n (%)				
PSA-002				
Normal	154 (91.7)	156 (92.9)	157 (93.5)	467 (92.7)
High	14 (8.3)	12 (7.1)	10 (6.0)	36 (7.1)
Missing	0	0	1 (0.6)	1 (0.2)
PSA-003				
Normal	140 (88.1)	149 (91.4)	154 (95.1)	443 (91.5)
High	19 (11.9)	12 (7.4)	8 (4.9)	39 (8.1)
Missing	0	2 (1.2)	0	2 (0.4)
PSA-004				
Normal	163 (96.4)	154 (91.1)	153 (91.6)	470 (93.1)
High	6 (3.6)	15 (8.9)	14 (8.4)	35 (6.9)

ACR = American College of Rheumatology; APR = apremilast; BID = twice daily; CDAI = Clinical Disease Activity Index; DAS28(CRP) = 28-joint Disease Activity Score; FACIT-Fatigue = Functional Assessment of Chronic Illness Therapy – Fatigue subscale; FAS = full analysis set; min – max = minimum to maximum; SF-36v2 = 36-item Short Form Health Survey, version 2.

[a] MASES scores reported for subjects with pre-existing enthesopathy (MASES > 0) at Baseline.

[b] Dactylitis severity scores reported for subjects with pre-existing dactylitis (dactylitis severity score > 0)at Baseline.

Source: PSA-002 治験総括報告書 Table 13, PSA-003 治験総括報告書 Table 13, PSA-004 治験総括報告書 Table 13.

6.5. 乾癬性関節炎に関連する前治療及び併用療法

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior DMARD use (small molecule or biologic), n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Yes	161 (95.8)	166 (98.8)	165 (98.2)	492 (97.6)
No[a]	7 (4.2)	2 (1.2)	3 (1.8)	12 (2.4)
Number of prior DMARDs used				
1	85 (50.6)	81 (48.2)	86 (51.2)	252 (50.0)
2	41 (24.4)	54 (32.1)	50 (29.8)	145 (28.8)
3	22 (13.1)	23 (13.7)	18 (10.7)	63 (12.5)
> 3	13 (7.7)	8 (4.8)	11 (6.5)	32 (6.3)
Specific DMARDs used				
Methotrexate	140 (83.3)	141 (83.9)	140 (83.3)	421 (83.5)
Sulfasalazine	43 (25.6)	51 (30.4)	43 (25.6)	137 (27.2)
Leflunomide	22 (13.1)	23 (13.7)	26 (15.5)	71 (14.1)
Other[b]	57 (33.9)	52 (31.0)	59 (35.1)	168 (33.3)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
PSA-002 (continued)	**N = 168**	**N = 168**	**N = 168**	**N = 504**
Reason for discontinuing prior small-molecule DMARD(s)				
Never responded – treatment failure	23 (13.7)	29 (17.3)	24 (14.3)	76 (15.1)
Lost response – treatment failure	26 (15.5)	16 (9.5)	24 (14.3)	66 (13.1)
Partial response – residual disease	4 (2.4)	12 (7.1)	9 (5.4)	25 (5.0)
Lost insurance	3 (1.8)	1 (0.6)	1 (0.6)	5 (1.0)
Adverse event(s)/Tolerability	35 (20.8)	33 (19.6)	32 (19.0)	100 (19.8)
Clinical trial ended	0	0	0	0
Other	8 (4.8)	9 (5.4)	10 (6.0)	27 (5.4)
Reason for discontinuing prior biologic DMARD(s)				
Never responded – treatment failure	2 (1.2)	5 (3.0)	3 (1.8)	10 (2.0)
Lost response – treatment failure	9 (5.4)	7 (4.2)	9 (5.4)	25 (5.0)
Partial response – residual disease	8 (4.8)	2 (1.2)	2 (1.2)	12 (2.4)
Lost insurance	13 (7.7)	8 (4.8)	10 (6.0)	31 (6.2)
Adverse event(s)/Tolerability	6 (3.6)	11 (6.5)	10 (6.0)	27 (5.4)
Clinical trial ended	8 (4.8)	13 (7.7)	10 (6.0)	31 (6.2)
Other	11 (6.5)	4 (2.4)	5 (3.0)	20 (4.0)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior DMARD use (small molecule or biologic), n (%) (continued)				
PSA-003	N = 159	N = 163	N = 162	N = 484
Yes	158 (99.4)	163 (100)	157 (96.9)	478 (98.8)
No[a]	1 (0.6)	0	5 (3.1)	6 (1.2)
Number of prior DMARDs used				
1	78 (49.1)	75 (46.0)	75 (46.3)	228 (47.1)
2	53 (33.3)	51 (31.3)	52 (32.1)	156 (32.2)
3	19 (11.9)	24 (14.7)	22 (13.6)	65 (13.4)
> 3	8 (5.0)	13 (8.0)	8 (4.9)	29 (6.0)
Specific DMARDs used				
Methotrexate	138 (86.8)	141 (86.5)	137 (84.6)	416 (86.0)
Sulfasalazine	62 (39.0)	62 (38.0)	47 (29.0)	171 (35.3)
Leflunomide	33 (20.8)	32 (19.6)	34 (21.0)	99 (20.5)
Other[b]	31 (19.5)	44 (27.0)	47 (29.0)	122 (25.2)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
PSA-003 (continued)	**N = 159**	**N = 163**	**N = 162**	**N = 484**
Reason for discontinuing prior small-molecule DMARD(s)				
Never responded – treatment failure	15 (9.4)	10 (6.1)	15 (9.3)	40 (8.3)
Lost response – treatment failure	21 (13.2)	22 (13.5)	22 (13.6)	64 (13.4)
Partial response – residual disease	11 (6.9)	10 (6.1)	10 (6.2)	31 (6.4)
Lost insurance	1 (0.6)	0	1 (0.6)	2 (0.4)
Adverse event(s)/Tolerability	46 (28.9)	48 (29.4)	42 (25.9)	136 (28.1)
Clinical trial ended	0	0	0	0
Other	8 (5.0)	20 (12.3)	16 (9.9)	44 (9.1)
Reason for discontinuing prior biologic DMARD(s)				
Never responded – treatment failure	2 (1.3)	4 (2.5)	2 (1.2)	8 (1.7)
Lost response – treatment failure	4 (2.5)	5 (3.1)	5 (3.1)	14 (2.9)
Partial response – residual disease	2 (1.3)	2 (1.2)	1 (0.6)	5 (1.0)
Lost insurance	3 (1.9)	6 (3.7)	3 (1.9)	12 (2.5)
Adverse event(s)/Tolerability	6 (3.8)	8 (4.9)	8 (4.9)	22 (4.5)
Clinical trial ended	5 (3.1)	6 (3.7)	1 (0.6)	12 (2.5)
Other	5 (3.1)	7 (4.3)	7 (4.3)	19 (3.9)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior DMARD use (small molecule or biologic), n (%) (continued)				
PSA-004 (continued)	N = 169	N = 169	N = 167	N = 505
Yes	169 (100)	168 (99.4)	167 (100)	504 (99.8)
No[a]	0	1 (0.6)	0	1 (0.2)
Number of prior DMARDs used				
1	88 (52.1)	83 (49.1)	83 (49.7)	254 (50.3)
2	39 (23.1)	58 (34.3)	59 (35.3)	156 (30.9)
3	30 (17.8)	17 (10.1)	16 (9.6)	63 (12.5)
> 3	12 (7.1)	10 (5.9)	9 (5.4)	31 (6.1)
Specific DMARDs used				
Methotrexate	151 (89.3)	139 (82.2)	142 (85.0)	432 (85.5)
Sulfasalazine	39 (23.1)	30 (17.8)	46 (27.5)	115 (22.8)
Leflunomide	20 (11.8)	27 (16.0)	20 (12.0)	67 (13.3)
Other[b]	62 (36.7)	68 (40.2)	56 (33.5)	186 (36.8)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
PSA-004	**N = 169**	**N = 169**	**N = 167**	**N = 505**
Reason for discontinuing prior small-molecule DMARD(s)				
Never responded – treatment failure	24 (14.2)	17 (10.1)	18 (10.8)	59 (11.7)
Lost response – treatment failure	17 (10.1)	24 (14.2)	22 (13.2)	63 (12.5)
Partial response – residual disease	16 (9.5)	14 (8.3)	10 (6.0)	40 (7.9)
Lost insurance	3 (1.8)	1 (0.6)	1 (0.6)	5 (1.0)
Adverse event(s)/Tolerability	40 (23.7)	36 (21.3)	46 (27.5)	122 (24.2)
Clinical trial ended	1 (0.6)	1 (0.6)	1 (0.6)	3 (0.6)
Other	5 (3.0)	8 (4.7)	6 (3.6)	19 (3.8)
Reason for discontinuing prior biologic DMARD(s)				
Never responded – treatment failure	5 (3.0)	3 (1.8)	2 (1.2)	10 (2.0)
Lost response – treatment failure	5 (3.0)	7 (4.1)	7 (4.2)	19 (3.8)
Partial response – residual disease	3 (1.8)	9 (5.3)	6 (3.6)	18 (3.6)
Lost insurance	8 (4.7)	8 (4.7)	11 (6.6)	27 (5.3)
Adverse event(s)/Tolerability	13 (7.7)	11 (6.5)	10 (6.0)	34 (6.7)
Clinical trial ended	18 (10.7)	17 (10.1)	12 (7.2)	47 (9.3)
Other	9 (5.3)	7 (4.1)	5 (3.0)	21 (4.2)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior small-molecule DMARD use only				
PSA-002	N = 168	N = 168	N = 168	N = 504
Yes	120 (71.4)	129 (76.8)	124 (73.8)	373 (74.0)
Number of prior small-molecule DMARDs used				
1	81 (48.2)	77 (45.8)	83 (49.4)	241 (47.8)
2	29 (17.3)	38 (22.6)	31 (18.5)	98 (19.4)
3	8 (4.8)	12 (7.1)	7 (4.2)	27 (5.4)
> 3	2 (1.2)	2 (1.2)	3 (1.8)	7 (1.4)
PSA-003	N = 159	N = 163	N = 162	N = 484
Yes	135 (84.9)	135 (82.8)	134 (82.7)	404 (83.5)
Number of prior small-molecule DMARDs used				
1	77 (48.4)	74 (45.4)	73 (45.1)	224 (46.3)
2	44 (27.7)	42 (25.8)	43 (26.5)	129 (26.7)
3	14 (8.8)	15 (9.2)	17 (10.5)	46 (9.5)
> 3	0	4 (2.5)	1 (0.6)	5 (1.0)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior small-molecule DMARD use only (continued)				
PSA-004	N = 169	N = 169	N = 167	N = 505
Yes	121 (71.6)	118 (69.8)	124 (74.3)	363 (71.9)
Number of prior small-molecule DMARDs used				
1	84 (49.7)	76 (45.0)	79 (47.3)	239 (47.3)
2	25 (14.8)	38 (22.5)	37 (22.2)	100 (19.8)
3	12 (7.1)	2 (1.2)	7 (4.2)	21 (4.2)
> 3	0	2 (1.2)	1 (0.6)	3 (0.6)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior biologic DMARD use, n (%)				
PSA-002	N = 168	N = 168	N = 168	N = 504
Yes	41 (24.4)	37 (22.0)	41 (24.4)	119 (23.6)
No	127 (75.6)	131 (78.0)	127 (75.6)	385 (76.4)
Number of prior biologic DMARDs used				
1	26 (15.5)	24 (14.3)	31 (18.5)	81 (16.1)
2	10 (6.0)	8 (4.8)	9 (5.4)	27 (5.4)
≥ 3	5 (3.0)	5 (3.0)	1 (0.6)	11 (2.2)
Type of biologic DMARD used				
TNF blocker	39 (23.2)	33 (19.6)	37 (22.0)	109 (21.6)
1	27 (16.1)	22 (13.1)	30 (17.9)	79 (15.7)
2	9 (5.4)	10 (6.0)	7 (4.2)	26 (5.2)
≥ 3	3 (1.8)	1 (0.6)	0	4 (0.8)
Non-TNF blocker[c]	9 (5.4)	9 (5.4)	8 (4.8)	26 (5.2)
1	8 (4.8)	7 (4.2)	8 (4.8)	23 (4.6)
2	1 (0.6)	2 (1.2)	0	3 (0.6)
≥ 3	0	0	0	0
Prior biologic DMARD failure				
Yes	19 (11.3)	14 (8.3)	14 (8.3)	47 (9.3)
No	22 (13.1)	23 (13.7)	27 (16.1)	72 (14.3)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior biologic DMARD use, n (%) (continued)				
PSA-003	N = 159	N = 163	N = 162	N = 484
Yes	23 (14.5)	28 (17.2)	23 (14.2)	74 (15.3)
No	136 (85.5)	135 (82.8)	139 (85.8)	410 (84.7)
Number of prior biologic DMARDs used				
1	13 (8.2)	15 (9.2)	13 (8.0)	41 (8.5)
2	8 (5.0)	9 (5.5)	5 (3.1)	22 (4.5)
≥ 3	2 (1.3)	4 (2.5)	5 (3.1)	11 (2.3)
Type of biologic DMARD used				
TNF blocker	20 (12.6)	27 (16.6)	22 (13.6)	69 (14.3)
1	11 (6.9)	16 (9.8)	15 (9.3)	42 (8.7)
2	8 (5.0)	10 (6.1)	5 (3.1)	23 (4.8)
≥ 3	1 (0.6)	1 (0.6)	2 (1.2)	4 (0.8)
Non-TNF blocker[c]	4 (2.5)	6 (3.7)	7 (4.3)	17 (3.5)
1	2 (1.3)	5 (3.1)	6 (3.7)	13 (2.7)
2	2 (1.3)	1 (0.6)	1 (0.6)	4 (0.8)
≥ 3	0	0	0	0
Prior biologic DMARD failure				
Yes	8 (5.0)	10 (6.1)	7 (4.3)	25 (5.2)
No	15 (9.4)	18 (11.0)	16 (9.9)	49 (10.1)

Table 7: Prior Use of PsA-Related Therapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

PsA-related Therapy	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Prior biologic DMARD use, n (%) (continued)				
PSA-004	N = 169	N = 169	N = 167	N = 505
Yes	48 (28.4)	50 (29.6)	43 (25.7)	141 (27.9)
No	121 (71.6)	119 (70.4)	124 (74.3)	364 (72.1)
Number of prior biologic DMARDs used				
1	29 (17.2)	35 (20.7)	32 (19.2)	96 (19.0)
2	16 (9.5)	11 (6.5)	7 (4.2)	34 (6.7)
≥ 3	3 (1.8)	4 (2.4)	4 (2.4)	11 (2.2)
Type of biologic DMARD used				
TNF blocker	45 (26.6)	48 (28.4)	39 (23.4)	132 (26.1)
1	32 (18.9)	39 (23.1)	29 (17.4)	100 (19.8)
2	11 (6.5)	7 (4.1)	8 (4.8)	26 (5.1)
≥ 3	2 (1.2)	2 (1.2)	2 (1.2)	6 (1.2)
Non-TNF blocker[c]	8 (4.7)	11 (6.5)	7 (4.2)	26 (5.1)
1	6 (3.6)	11 (6.5)	7 (4.2)	24 (4.8)
2	2 (1.2)	0	0	2 (0.4)
≥ 3	0	0	0	0
Prior biologic DMARD failure				
Yes	12 (7.1)	18 (10.7)	14 (8.4)	44 (8.7)
No	36 (21.3)	32 (18.9)	29 (17.4)	97 (19.2)

APR = apremilast; BID = twice daily; DMARD = disease-modifying antirheumatic drug; FAS = full analysis set; PsA = psoriatic arthritis; TNF = tumor necrosis factor

[a] These are patients who deviated from the protocol as a priori treatment was required.

[b] Other DMARDs included abatacept, acitretin, adalimumab, alefacept, anakinra, auranofin, azathioprine, bucillamine, briakinumab, certolizumab pegol, chloroquine/hydroxychloroquine, ciclosporin, efalizumab, etanercept, gold, golimumab, infliximab, mesalazine, mycophenolate mofetil, sodium aurothiomalate, tocanol, ustekinumab, and other monoclonal antibodies and investigational products.

[c] Non-TNF blocker biologic DMARDs included abatacept, alefacept, anakinra, briakinumab, efalizumab, ustekinumab, other monoclonal antibodies, and other investigational products.

Source: PSA-002 治験総括報告書 Table 14, Table 14.1.7, PSA-003 治験総括報告書 Table 14, Table 14.1.7, PSA-004 治験総括報告書 Table 14, Table 14.1.7.

Table 8: Baseline (Concomitant) Use of PsA-RelatedTherapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)

Study PsA-Related Therapy Used	Number (%) of Subjects			
	Placebo	**APR 20 BID**	**APR 30 BID**	**Total**
PSA-002	**N = 168**	**N = 168**	**N = 168**	**N = 504**
Baseline DMARD use, n (%)[b]	110 (65.5)	111 (66.1)	106 (63.1)	327 (64.9)
1 DMARD	100 (59.5)	99 (58.9)	94 (56.0)	293 (58.1)
2 DMARDs	10 (6.0)	10 (6.0)	12 (7.1)	32 (6.3)
3 DMARDs	0	2 (1.2)	0	2 (0.4)
> 3 DMARDs	0	0	0	0
Methotrexate	90 (53.6)	95 (56.5)	88 (52.4)	273 (54.2)
Leflunomide	11 (6.5)	10 (6.0)	9 (5.4)	30 (6.0)
Sulfasalazine	18 (10.7)	16 (9.5)	20 (11.9)	54 (10.7)
Other[a]	1 (0.6)	4 (2.4)	1 (0.6)	6 (1.2)
Oral corticosteroids, n (%)	12 (7.1)	25 (14.9)	16 (9.5)	53 (10.5)
With concomitant DMARD	12 (7.1)	20 (11.9)	12 (7.1)	44 (8.7)
Without concomitant DMARD	0	5 (3.0)	4 (2.4)	9 (1.8)
NSAIDs, n (%)	118 (70.2)	123 (73.2)	120 (71.4)	361 (71.6)
Narcotics/analgesics, n (%)	27 (16.1)	32 (19.0)	25 (14.9)	84 (16.7)

Table 8: Baseline (Concomitant) Use of PsA-RelatedTherapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Study PsA-Related Therapy Used	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
PSA-003	**N = 159**	**N = 163**	**N = 162**	**N = 484**
Baseline DMARD use, n (%)[b]	113 (71.1)	114 (69.9)	113 (69.8)	340 (70.2)
1 DMARD	97 (61.0)	99 (60.7)	99 (61.1)	295 (61.0)
2 DMARDs	16 (10.1)	14 (8.6)	14 (8.6)	44 (9.1)
3 DMARDs	0	1 (0.6)	0	1 (0.2)
> 3 DMARDs	0	0	0	0
Methotrexate	94 (59.1)	94 (57.7)	91 (56.2)	279 (57.6)
Leflunomide	17 (10.7)	17 (10.4)	21 (13.0)	55 (11.4)
Sulfasalazine	17 (10.7)	18 (11.0)	12 (7.4)	47 (9.7)
Other[a]	1 (0.6)	1 (0.6)	3 (1.9)	5 (1.0)
Oral corticosteroids, n (%)	20 (12.6)	36 (22.1)	25 (15.4)	81 (16.7)
With concomitant DMARD	15 (9.4)	31 (19.0)	21 (13.0)	67 (13.8)
Without concomitant DMARD	5 (3.1)	5 (3.1)	4 (2.5)	14 (2.9)
NSAIDs, n (%)	108 (67.9)	115 (70.6)	114 (70.4)	337 (69.6)
Narcotics/analgesics, n (%)	22 (13.8)	22 (13.5)	22 (13.6)	66 (13.6)

Table 8: Baseline (Concomitant) Use of PsA-RelatedTherapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Study PsA-Related Therapy Used	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
PSA-004	**N=169**	**N=169**	**N=167**	**N=505**
Baseline DMARD use, n (%)[b]	101 (59.8)	104 (61.5)	101 (60.5)	306 (60.6)
1 DMARD	96 (56.8)	97 (57.4)	97 (58.1)	290 (57.4)
2 DMARDs	5 (3.0)	7 (4.1)	4 (2.4)	16 (3.2)
3 DMARDs	0	0	0	0
> 3 DMARDs	0	0	0	0
Methotrexate	91 (53.8)	88 (52.1)	83 (49.7)	262 (51.9)
Leflunomide	5 (3.0)	12 (7.1)	8 (4.8)	25 (5.0)
Sulfasalazine	10 (5.9)	10 (5.9)	14 (8.4)	34 (6.7)
Other[a]	0	1 (1.6)	0	1 (0.2)
Oral corticosteroids, n (%)	16 (9.5)	34 (20.1)	23 (13.8)	73 (14.5)
With concomitant DMARD	14 (8.3)	25 (14.8)	15 (9.0)	54 (10.7)
Without concomitant DMARD	2 (1.2)	9 (5.3)	8 (4.8)	19 (3.8)
NSAIDs, n (%)	115 (68.0)	121 (71.6)	121 (72.5)	357 (70.7)
Narcotics/analgesics, n (%)	18 (10.7)	20 (11.8)	24 (14.4)	62 (12.3)

Table 8: Baseline (Concomitant) Use of PsA-RelatedTherapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Study PsA-Related Therapy Used	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Baseline MTX dose, mg/week				
PSA-002	n = 90	n = 95	n = 88	n = 273
Mean ± SD	16.97 ± 5.132	16.21 ± 5.194	16.73 ± 5.379	16.63 ± 5.225
Median (min – max)	15.00 (7.5 – 25.0)	15.00 (7.5 – 30.0)	16.25 (5.0 – 25.0)	15.00 (5.0 – 30.0)
PSA-003	n = 94	n = 94	n = 91	n = 279
Mean ± SD	14.63 ± 4.945	15.45 ± 4.549	14.58 ± 4.653	14.89 ± 4.720
Median (min – max)	15.00 (5.0 – 25.0)	15.00 (7.5 – 25.0)	16.25 (5.0 – 25.0)	15.00 (5.0 – 25.0)
PSA-004	n = 91	n = 88	n = 83	n = 262
Mean ± SD	14.73 ± 5.458	15.00 ± 4.580	14.52 ± 5.007	14.75 ± 5.018
Median (min – max)	15.00 (2.5 – 25.0)	15.00 (5.0 – 25.0)	15.00 (5.0- 25.0)	15.00 (2.5 – 25.0)
Baseline SSZ dose, g/day				
PSA-002	n = 18	n =16	n =20	n =54
Mean ± SD	2.39 ± 0.850	2.16 ± 0.769	2.25 ± 1.032	2.27 ± 0.889
Median (min – max)	2.00 (1.0 – 4.0)	2.00 (1.0 – 4.0)	2.00 (1.0 – 4.5)	2.00 (1.0 – 4.5)
PSA-003	n =17	n =18	n =12	n =47
Mean ± SD	1.65 ± 0.523	1.89 ± 0.502	1.92 ± 0.669	1.81 ± 0.557
Median (min – max)	2.00 (0.5 – 2.0)	2.00 (0.5 – 3.0)	2.00 (1.0 – 3.0)	2.00 (0.5 – 3.0)

Table 8: Baseline (Concomitant) Use of PsA-RelatedTherapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Study PsA-Related Therapy Used	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Baseline SSZ dose, mg/week (continued)				
PSA-004	n =10	n =10	n =14	n =34
Mean ± SD	1.80 ± 0.422	1.50 ± 0.471	1.75 ± 0.510	1.69 ± 0.477
Median (min – max)	2.00 (1.0 – 2.0)	1.50 (1.0 – 2.0)	2.00 (0.5 – 2.0)	2.00 (0.5 – 2.0)
Baseline LEF dose, mg/day				
PSA-002	n = 11	n = 10	n = 9	n = 30
Mean ± SD	16.36 ± 5.045	17.50 ± 5.401	17.78 ± 4.410	17.17 ± 4.857
Median (min – max)	20.00 (10.0 – 20.0)	20.00 (5.0 – 20.0)	20.00 (10.0 – 20.0)	20.00 (5.0 – 20.0)
PSA-003	n = 17	n = 17	n = 21	n= 55
Mean ± SD	18.24 ± 3.930	18.24 ± 3.930	17.76 ± 4.227	18.05 ± 3.978
Median (min – max)	20.00 (10.0 – 20.0)	20.00 (10.0 – 20.0)	20.00 (8.6 – 20.0)	20.00 (8.6 – 20.0)
PSA-004	n = 5	n = 12	n = 8	n = 25
Mean ± SD	18.00 ± 4.472	19.17 ± 2.887	20.00 ± 0.000	19.20 ± 2.769
Median (min – max)	20.00 (10.0 – 20.0)	20.00 (10.0 – 20.0)	20.00 (20.0 – 20.0)	20.00 (10.0 – 20.0)

Table 8: Baseline (Concomitant) Use of PsA-RelatedTherapies in Studies PSA-002, PSA-003, and PSA-004 (FAS)（つづき）

Study PsA-Related Therapy Used	Number (%) of Subjects			
	Placebo	APR 20 BID	APR 30 BID	Total
Baseline oral prednisone dose, mg/day[c]				
PSA-002	n = 12	n = 25	n = 16	n = 53
Mean ± SD	6.04 ± 2.491	6.09 ± 2.894	6.06 ± 2.175	6.07 ± 2.558
Median (min – max)	5.00 (2.5 – 10.0)	5.00 (0.7 – 10.0)	5.00 (3.0 – 10.0)	5.00 (0.7 – 10.0)
PSA-003	n = 20	n = 36	n = 25	n = 81
Mean ± SD	6.69 ± 3.042	6.28 ± 2.419	6.00 ± 2.394	6.29 ± 2.558
Median (min – max)	5.00 (1.3 – 10.0)	5.00 (2.5 – 10.0)	5.00 (2.5 – 10.0)	5.00 (1.3 – 10.0)
PSA-004	n = 16	n = 34	n = 23	n = 73
Mean ± SD	6.41 ± 2.410	6.58 ± 2.449	6.51 ± 2.732	6.52 ± 2.499
Median (min – max)	5.00 (2.5 – 10.0)	5.00 (1.3 – 10.0)	5.00 (1.0 – 10.0)	5.00 (1.0 – 10.0)

APR = apremilast; DMARD = disease-modifying antirheumatic drug; LEF = leflunomide; min – max = minimum to maximum; MTX = methotrexate; NSAID = nonsteroidal anti-inflammatory drug; SD = standard deviation; SSZ = sulfasalazine.

[a] Other DMARDs in Study PSA-002 included azathioprine, etanercept, hydroxychloroquine, and mesalazine. Other DMARDs in Study PSA-003 included chloroquine sulfate, hydroxychloroquine, tocanol, and ustekinumab. Other DMARDs in Study PSA-004 included azathioprine, etanercept, hydroxychloroquine, and mesalazine. Etanercept and ustekinumab are prior medications captured as baseline medications because the dates of last dose were incomplete and are therefore imputed as being used at baseline.

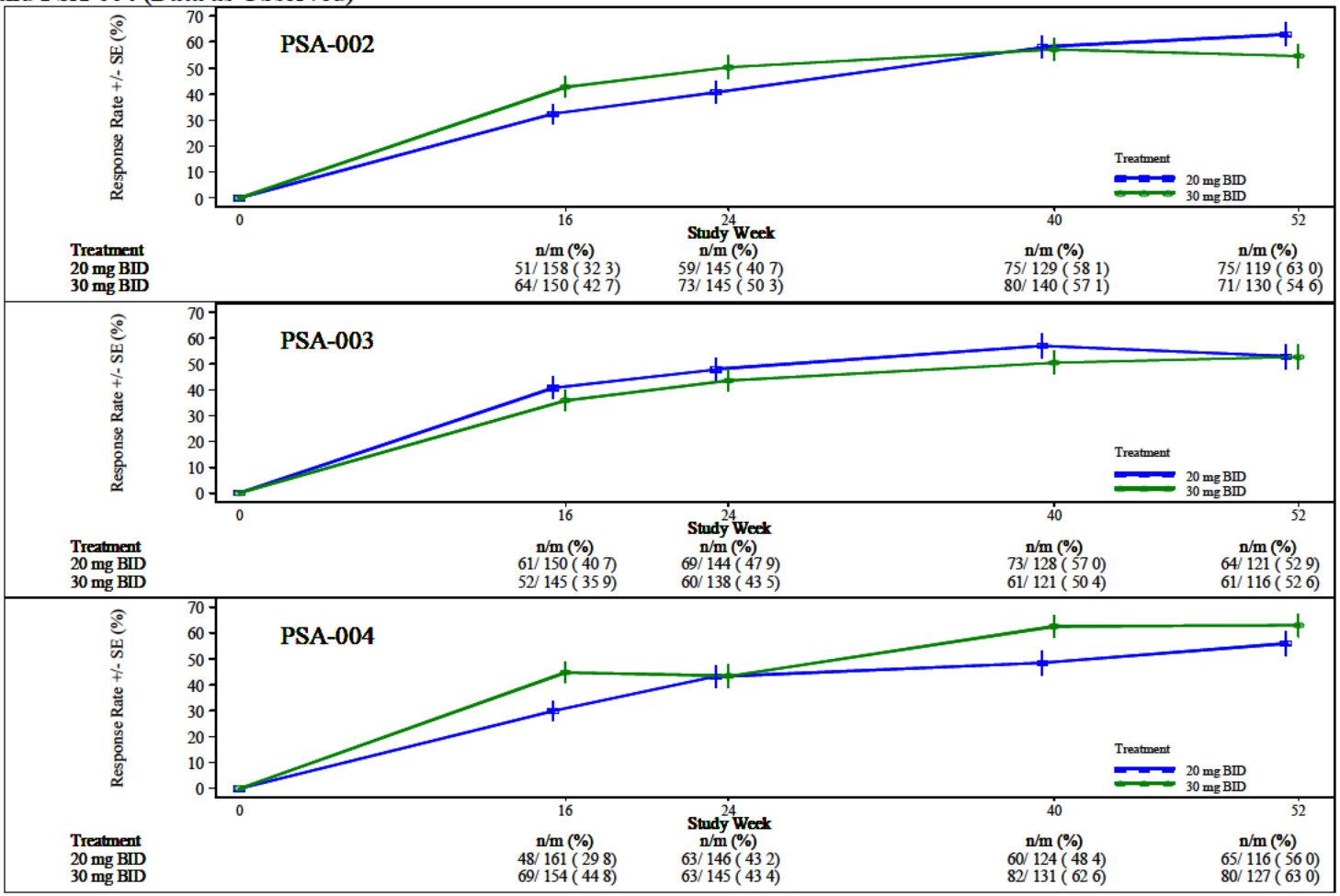
[b] Baseline DMARD use as recorded on case report form.

[c] Prednisone or equivalent.

Source: PSA-002 治験総括報告書 Table 15, PSA-003 治験総括報告書 Table 15, PSA-004 治験総括報告書 Table 15.

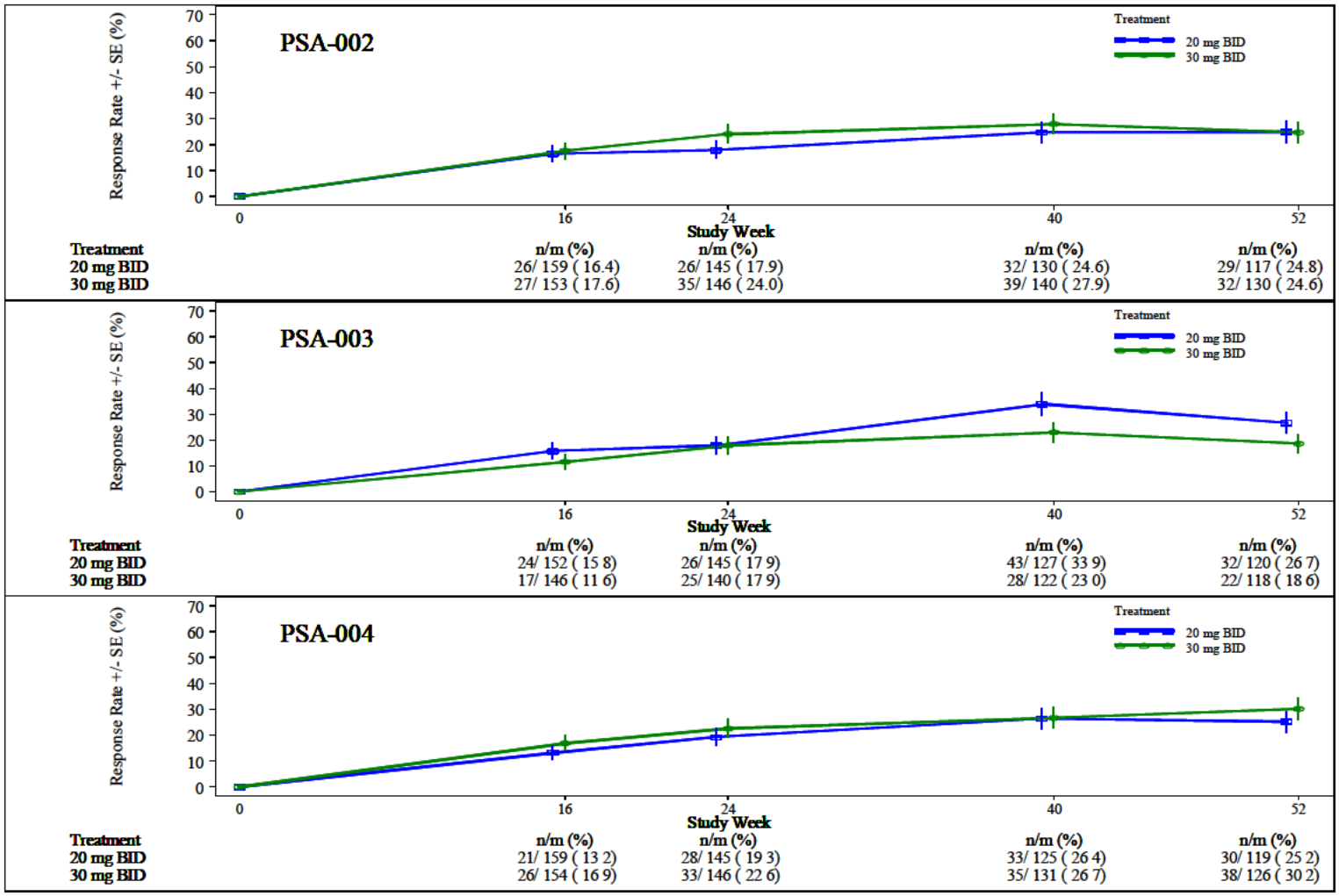
6.6. Modified ACR 20/50/70 を達成した被験者の割合

Figure 17: Modified ACR 20 Responses During Weeks 0-52 Among Subjects Initially Randomized to Apremilast in Studies PSA-002, PSA-003, and PSA-004 (Data as Observed)



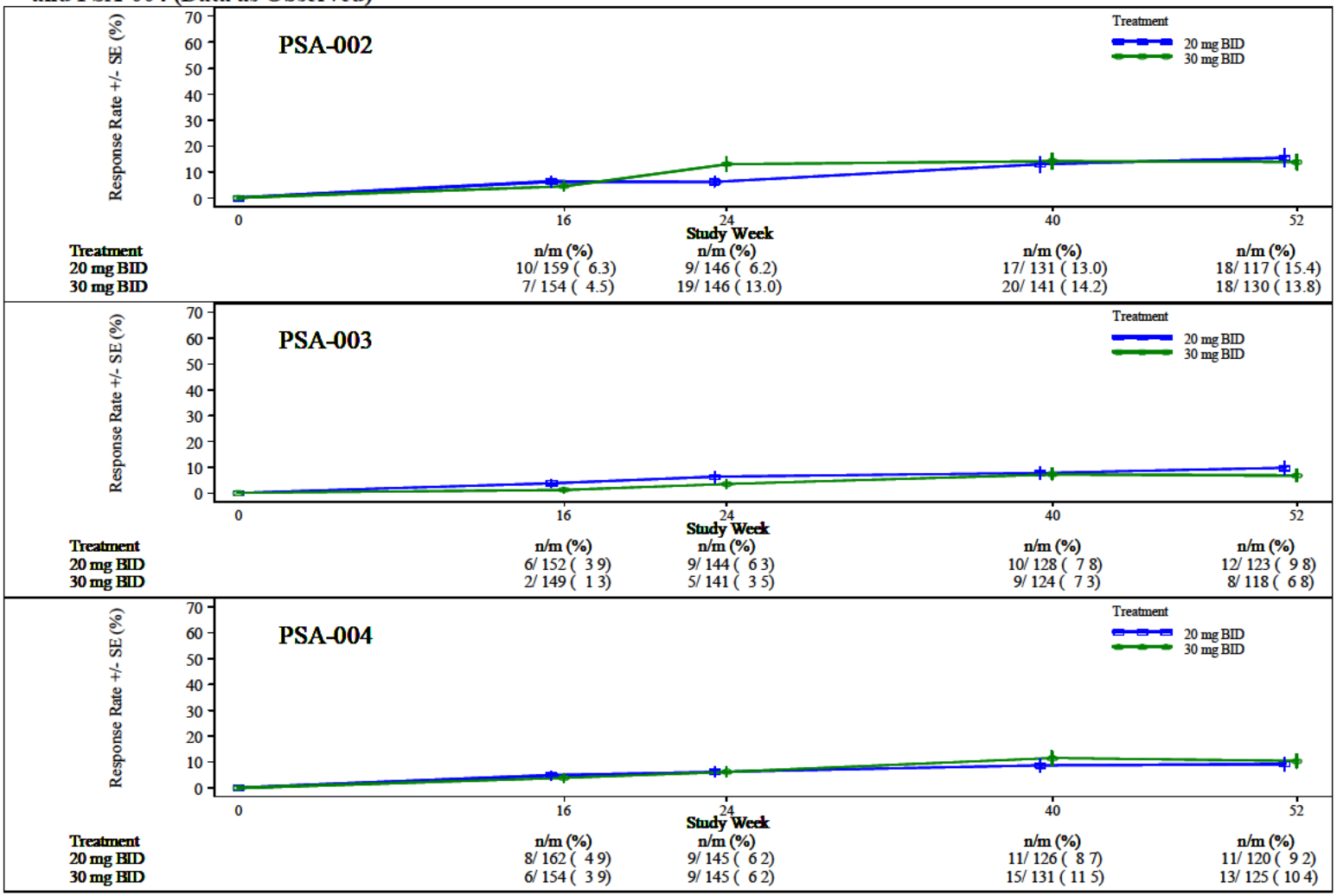
ACR 20 = American College of Rheumatology 20% response criteria; BID = twice daily; n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); SE = standard error.
Note: This analysis includes only subjects who were randomized to apremilast at baseline; therefore, study visits correspond also to exposure to apremilast.
Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.
Source: PSA-002 治験総括報告書 Table 14.2.41.1, PSA-003 治験総括報告書 Table 14.2.41.1, PSA-004 治験総括報告書 Table 14.2.41.1.

Figure 18:Modified ACR 50 Responses During Weeks 0-52 Among Subjects Initially Randomized to Apremilast in Studies PSA-002, PSA-003, and PSA-004 (Data as Observed)



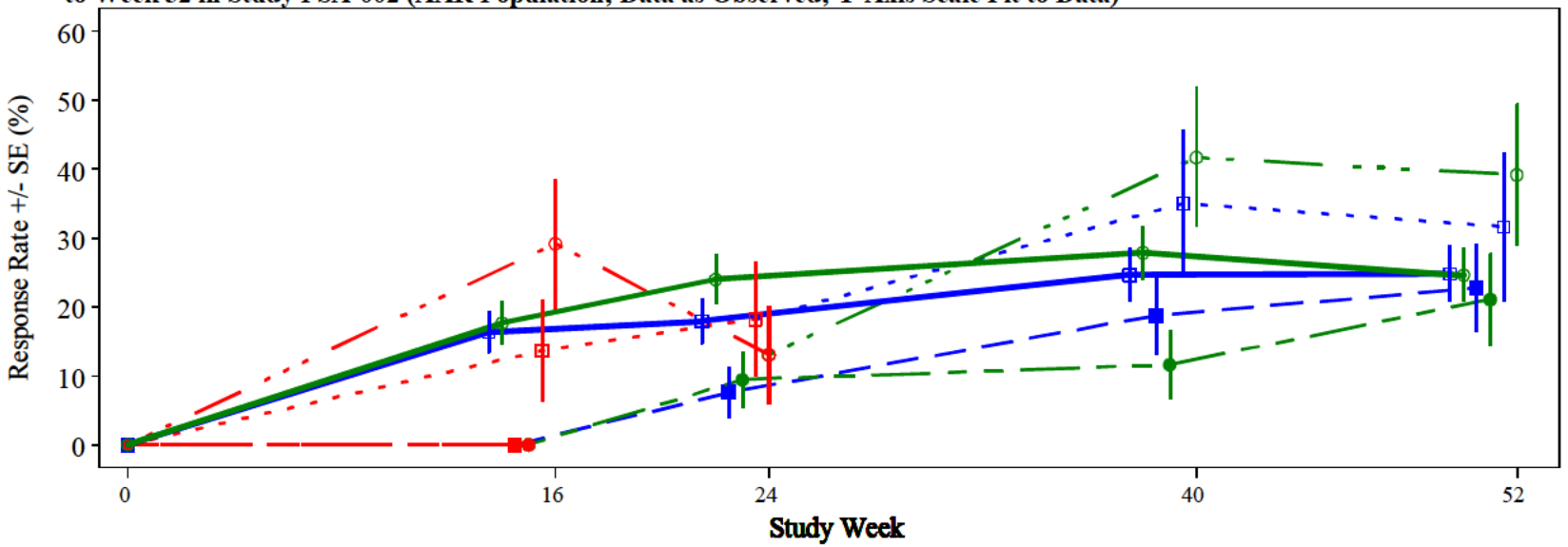
ACR 50 = American College of Rheumatology 50% response criteria; BID = twice daily; n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); SE = standard error.
Note: This analysis includes only subjects who were randomized to apremilast at baseline; therefore, study visits correspond also to exposure to apremilast.
Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.
Source: PSA-002 治験総括報告書 Table 14.2.43.1, PSA-003 治験総括報告書 Table 14.2.43.1, PSA-004 治験総括報告書 Table 14.2.43.1.

Figure 19:Modified ACR 70 Responses During Weeks 0-52 Among Subjects Initially Randomized to Apremilast in Studies PSA-002, PSA-003, and PSA-004 (Data as Observed)



ACR 70 = American College of Rheumatology 70% response criteria; BID = twice daily; n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); SE = standard error.
Note: This analysis includes only subjects who were randomized to apremilast at baseline; therefore, study visits correspond also to exposure to apremilast.
Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.
Source: PSA-002 治験総括報告書 Table 14.2.44.1, PSA-003 治験総括報告書 Table 14.2.44.1, PSA-004 治験総括報告書 Table 14.2.44.1.

Figure 20:Proportion of All Subjects Exposed to Apremilast Achieving Modified ACR 50 Responses During the Apremilast-exposure Period up to Week 52 in Study PSA-002 (AAR Population; Data as Observed; Y-Axis Scale Fit to Data)



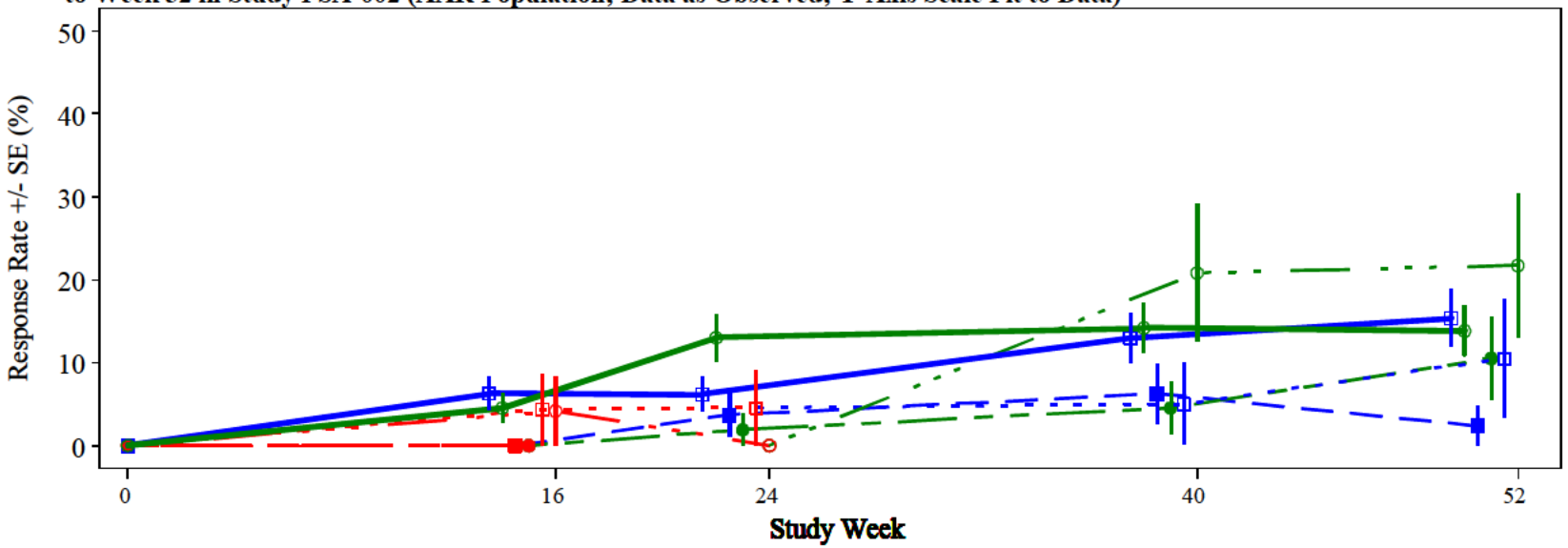
Treatment	n/m (%)	n/m (%)	n/m (%)	n/m (%)
20 mg BID	26/159 (16.4)	26/145 (17.9)	32/130 (24.6)	29/117 (24.8)
30 mg BID	27/153 (17.6)	35/146 (24.0)	39/140 (27.9)	32/130 (24.6)
PBO/20 EE	0/ 54 (0.0)	4/ 53 (7.5)	9/ 48 (18.8)	10/ 44 (22.7)
PBO/20 XO	3/ 22 (13.6)	4/ 22 (18.2)	7/ 20 (35.0)	6/ 19 (31.6)
PBO/30 EE	0/ 53 (0.0)	5/ 53 (9.4)	5/ 43 (11.6)	8/ 38 (21.1)
PBO/30 XO	7/ 24 (29.2)	3/ 23 (13.0)	10/ 24 (41.7)	9/ 23 (39.1)

AAR = apremilast subjects as initially randomized/re-randomized; ACR 50 = American College of Rheumatology 50% response criteria; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).

Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.

Source: PSA-002 治験総括報告書 Table 14.2.43.1.

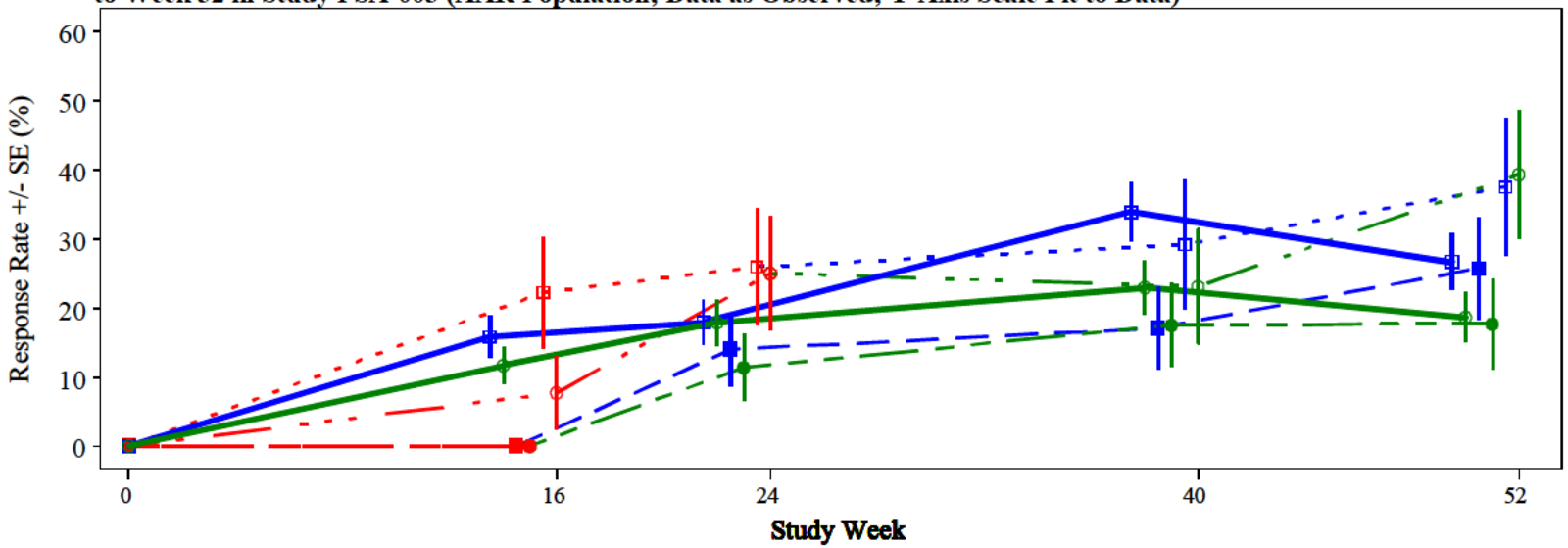
Figure 21:Proportion of All Subjects Exposed to Apremilast Achieving Modified ACR 70 Responses During the Apremilast-exposure Period up to Week 52 in Study PSA-002 (AAR Population; Data as Observed; Y-Axis Scale Fit to Data)



Treatment	n/m (%)	n/m (%)	n/m (%)	n/m (%)
20 mg BID	10/159 (6.3)	9/146 (6.2)	17/131 (13.0)	18/117 (15.4)
30 mg BID	7/154 (4.5)	19/146 (13.0)	20/141 (14.2)	18/130 (13.8)
PBO/20 EE	0/ 54 (0.0)	2/ 54 (3.7)	3/ 48 (6.3)	1/ 43 (2.3)
PBO/20 XO	1/ 23 (4.3)	1/ 22 (4.5)	1/ 20 (5.0)	2/ 19 (10.5)
PBO/30 EE	0/ 53 (0.0)	1/ 53 (1.9)	2/ 44 (4.5)	4/ 38 (10.5)
PBO/30 XO	1/ 24 (4.2)	0/ 24 (0.0)	5/ 24 (20.8)	5/ 23 (21.7)

AAR = apremilast subjects as initially randomized/re-randomized; ACR 70 = American College of Rheumatology 70% response criteria; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).
Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.
Source: PSA-002 治験総括報告書 Table 14.2.44.1.

Figure 22:Proportion of All Subjects Exposed to Apremilast Achieving Modified ACR 50 Responses During the Apremilast-exposure Period up to Week 52 in Study PSA-003 (AAR Population; Data as Observed; Y-Axis Scale Fit to Data)



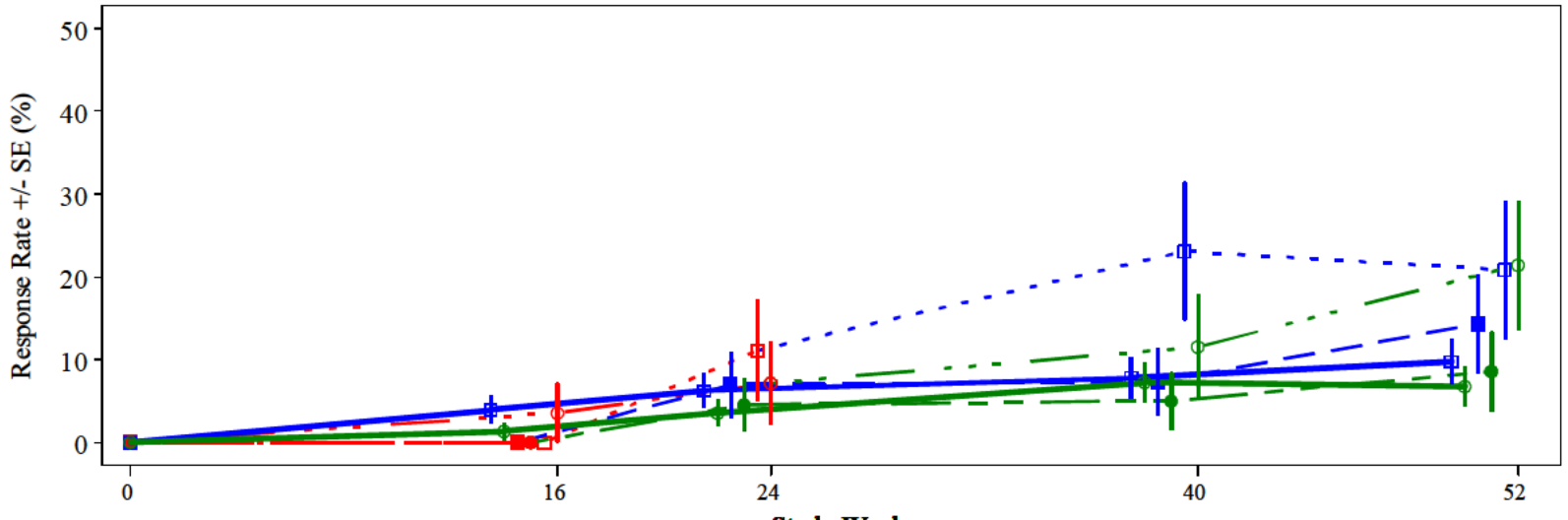
Treatment	n/m (%)	n/m (%)	n/m (%)	n/m (%)
20 mg BID	24/152 (15.8)	26/145 (17.9)	43/127 (33.9)	32/120 (26.7)
30 mg BID	17/146 (11.6)	25/140 (17.9)	28/122 (23.0)	22/118 (18.6)
PBO/20 EE	0/ 44 (0.0)	6/ 43 (14.0)	7/ 41 (17.1)	9/ 35 (25.7)
PBO/20 XO	6/ 27 (22.2)	7/ 27 (25.9)	7/ 24 (29.2)	9/ 24 (37.5)
PBO/30 EE	0/ 44 (0.0)	5/ 44 (11.4)	7/ 40 (17.5)	6/ 34 (17.6)
PBO/30 XO	2/ 26 (7.7)	7/ 28 (25.0)	6/ 26 (23.1)	11/ 28 (39.3)

AAR = apremilast subjects as initially randomized/re-randomized; ACR 50 = American College of Rheumatology 50% response criteria; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).

Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.

Source: PSA-003 治験総括報告書 Table 14.2.43.1.

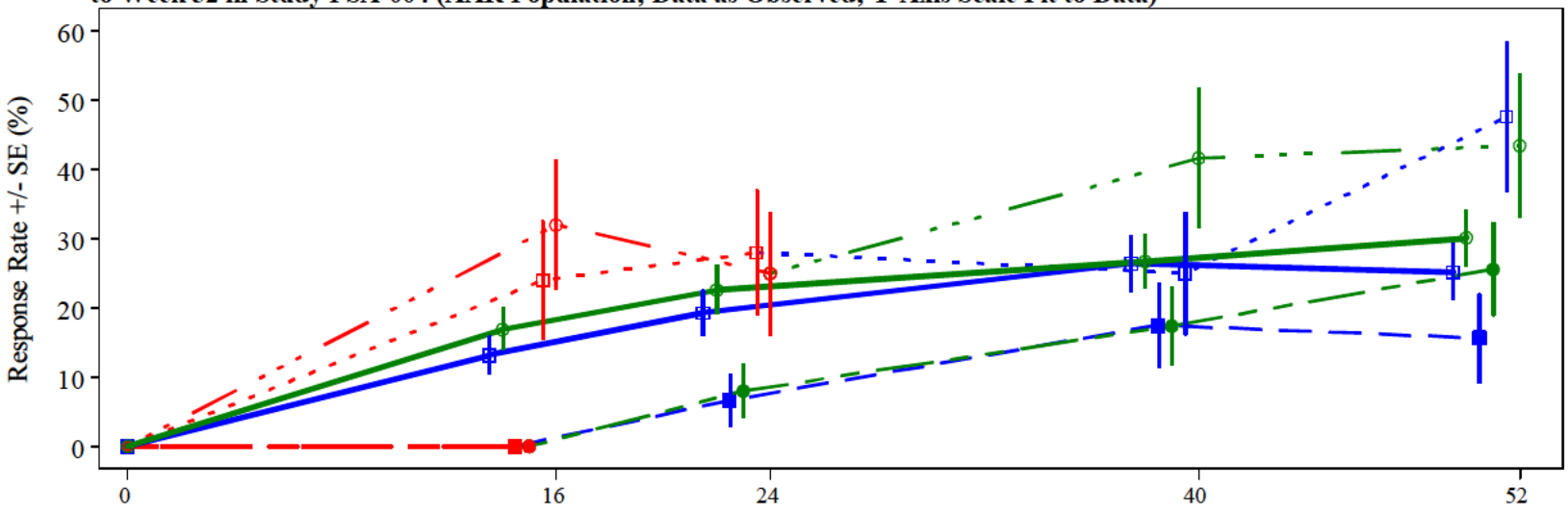
Figure 23:Proportion of All Subjects Exposed to Apremilast Achieving Modified ACR 70 Responses During the Apremilast-exposure Period up to Week 52 in Study PSA-003 (AAR Population; Data as Observed; Y-Axis Scale Fit to Data)



Treatment	n/m (%)	n/m (%)	n/m (%)	n/m (%)
20 mg BID	6/152 (3.9)	9/144 (6.3)	10/128 (7.8)	12/123 (9.8)
30 mg BID	2/149 (1.3)	5/141 (3.5)	9/124 (7.3)	8/118 (6.8)
PBO/20 EE	0/ 44 (0.0)	3/ 43 (7.0)	3/ 41 (7.3)	5/ 35 (14.3)
PBO/20 XO	0/ 27 (0.0)	3/ 27 (11.1)	6/ 26 (23.1)	5/ 24 (20.8)
PBO/30 EE	0/ 44 (0.0)	2/ 44 (4.5)	2/ 40 (5.0)	3/ 35 (8.6)
PBO/30 XO	1/ 28 (3.6)	2/ 28 (7.1)	3/ 26 (11.5)	6/ 28 (21.4)

AAR = apremilast subjects as initially randomized/re-randomized; ACR 70 = American College of Rheumatology 70% response criteria; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).
Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.
Source: PSA-003 治験総括報告書 Table 14.2.44.1.

Figure 24:Proportion of All Subjects Exposed to Apremilast Achieving Modified ACR 50 Responses During the Apremilast-exposure Period up to Week 52 in Study PSA-004 (AAR Population; Data as Observed; Y-Axis Scale Fit to Data)



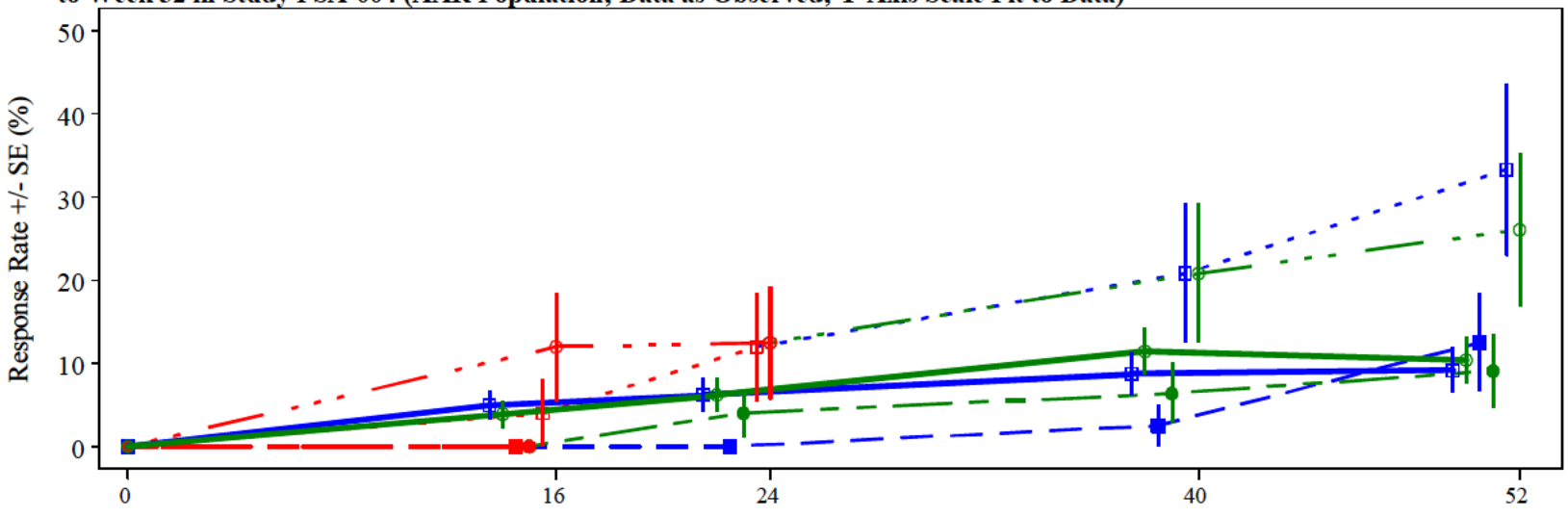
Treatment	n/m (%)	n/m (%)	n/m (%)	n/m (%)
20 mg BID	21/159 (13.2)	28/145 (19.3)	33/125 (26.4)	30/119 (25.2)
30 mg BID	26/154 (16.9)	33/146 (22.6)	35/131 (26.7)	38/126 (30.2)
PBO/20 EE	0/ 47 (0.0)	3/ 45 (6.7)	7/ 40 (17.5)	5/ 32 (15.6)
PBO/20 XO	6/ 25 (24.0)	7/ 25 (28.0)	6/ 24 (25.0)	10/ 21 (47.6)
PBO/30 EE	0/ 50 (0.0)	4/ 50 (8.0)	8/ 46 (17.4)	11/ 43 (25.6)
PBO/30 XO	8/ 25 (32.0)	6/ 24 (25.0)	10/ 24 (41.7)	10/ 23 (43.5)

AAR = apremilast subjects as initially randomized/re-randomized; ACR 50 = American College of Rheumatology 50% response criteria; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).

Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.

Source: PSA-004 治験総括報告書 Table 14.2.43.1.

Figure 25:Proportion of All Subjects Exposed to Apremilast Achieving Modified ACR 70 Responses During the Apremilast-exposure Period up to Week 52 in Study PSA-004 (AAR Population; Data as Observed; Y-Axis Scale Fit to Data)



Treatment	n/m (%)	n/m (%)	n/m (%)	n/m (%)
20 mg BID	8/162 (4.9)	9/145 (6.2)	11/126 (8.7)	11/120 (9.2)
30 mg BID	6/154 (3.9)	9/145 (6.2)	15/131 (11.5)	13/125 (10.4)
PBO/20 EE	0/ 47 (0.0)	0/ 46 (0.0)	1/ 40 (2.5)	4/ 32 (12.5)
PBO/20 XO	1/ 25 (4.0)	3/ 25 (12.0)	5/ 24 (20.8)	7/ 21 (33.3)
PBO/30 EE	0/ 50 (0.0)	2/ 50 (4.0)	3/ 47 (6.4)	4/ 44 (9.1)
PBO/30 XO	3/ 25 (12.0)	3/ 24 (12.5)	5/ 24 (20.8)	6/ 23 (26.1)

AAR = apremilast subjects as initially randomized/re-randomized; ACR 70 = American College of Rheumatology 70% response criteria; APR = apremilast; BID = twice daily; EE = early escape (re-randomized to apremilast at Week 16); n/m = number of responders/number of subjects with sufficient data for definitive determination of response status at each time point (including subjects who discontinued early between the preceding visit and the visit in question); PBO = placebo; XO = cross-over (re-randomized to apremilast at Week 24).

Note: To enhance visual clarity, the data points collected at Weeks 16, 24, 40, and 52 are displayed in a staggered fashion above the hash mark for the corresponding time point.

Source: PSA-004 治験総括報告書 Table 14.2.44.1.