

ONLINE SUPPLEMENT

Patients. Shorter durations of biological anti-tumor necrosis factor- α (TNF) treatment were acceptable in documented cases of TNF-antagonist intolerance. Biologic anti-TNF medications could have been discontinued for any reason (e.g., lack of efficacy, adverse events [AEs]).

Study design. The PSUMMIT 2 study was conducted according to the Declaration of Helsinki and International Committee on Harmonisation good clinical practices. The protocol was reviewed and approved by each site's governing institutional review board or ethics committee, reflecting national requirements for study conduct approval. All patients provided written informed consent.

Ustekinumab and placebo were supplied in a prefilled syringe as a single-use, sterile solution. Identically-appearing placebo injections were administered to maintain the study blind, including placebo injections at wk20 and wk24 in ustekinumab-treated patients.

Assessments. Fatigue during the previous week was measured using the 13-item Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) questionnaire. Each FACIT-Fatigue question is graded on a 5-point scale (0=not at all; 4=very much); accordingly, scores can range from 0 to 52 and a lower score reflects more severe fatigue. A change of 4 points is considered meaningful improvement in patients with rheumatoid arthritis.[30] The presence of antibodies to ustekinumab was determined by a validated electrochemiluminescent immunoassay (ECLIA) method using the Meso Scale Discovery (MSD[®]) platform (Gaithersburg, MD, USA).

Statistical analysis. To control for multiplicity of testing for the primary endpoint and major secondary endpoint analyses, major secondary analyses were performed sequentially and were

contingent upon the success of the primary endpoint analysis. For each endpoint, the test between the combined ustekinumab and placebo groups was performed first. If that test was significant at the 0.05-level, then the pairwise comparison between each dose group and the placebo group was performed. The test for the combined group and ≥ 1 pairwise comparison needed to be significant to proceed to the next endpoint.

The planned sample size of 300 patients (100 patients per group) was estimated to provide >99% power to detect a significant difference between the placebo and at least one ustekinumab dose group ($\alpha=0.05$) in the primary endpoint, assuming effect sizes of 20-25% and 25-30%, respectively, among patients not receiving and receiving methotrexate (MTX).

The AE data were summarized as counts and percentages by treatment group and Medical Dictionary for Regulatory Activities (Version 14.1) system-organ class and preferred term, and changes in laboratory parameters were summarized using descriptive statistics. Major cardiovascular AEs (MACE) were predefined to include cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke. Event rates adjusted for length of follow-up were determined for serious AEs, serious infections, and MACE.

Disposition and baseline characteristics. The first patient provided informed consent on February 26, 2010, and the last patient completed the wk24 and wk60 visits on March 21, 2012 and November 15, 2012, respectively. The trial was conducted at 71 sites in European (168 randomized patients) and North American (144 randomized patients) countries. Seventy-four (23.7%) patients prematurely discontinued study agent through wk60 (Figure S1).

Baseline demographic and disease characteristics were generally well balanced across the treatment groups. Overall, randomized patients demonstrated significant impairment in physical function (median Health Assessment Questionnaire Disability Index [HAQ-DI] score of 1.3) and increased inflammation (median C-reactive protein [CRP] level of 9.3 mg/L) (Table 1). Among randomized patients, 47.1-52.4% were receiving concomitant MTX at baseline and 55.2-59.6% had previously received at least one TNF-antagonist, most commonly etanercept, adalimumab, and infliximab. Baseline American College of Rheumatology (ACR) response core set parameters were generally consistent between patients who did and did not receive concomitant MTX, but indicated more active disease in anti-TNF-experienced versus anti-TNF-naïve patients (Table 1).

Immunogenicity. The incidence of anti-drug antibodies (ADA) against ustekinumab across all treatment groups through wk60 was 9.3% (26 of the 279 patients with evaluable serum samples). The incidence of ADA through wk60 was lower in patients who received concomitant MTX (6.4%) when compared with those who did not receive concomitant MTX (12.3%). Patients who were positive for ADA tended to have lower clinical efficacy when compared with patients who were negative for ADA. However, the ADA positivity did not preclude a clinical response. There was no apparent association between development of ADA and the development of injection-site reactions.

Physical function and quality of life. Improvements in HAQ-DI scores at wk24 were significantly greater among ustekinumab than placebo-treated patients ($p \leq 0.001$; Table S2). Significantly greater proportions of ustekinumab-treated patients achieved a clinically

meaningful ≥ 0.3 -unit improvement in HAQ-DI scores versus placebo ($p < 0.01$; Table S2), and improvements were generally maintained through wk52 (Table S3).

Significant improvements in quality of life were also demonstrated when assessed using SF-36 physical summary and DLQI scores through wk24 (Table S2). Improvements were maintained through wk52 (Table S3).

FACIT-Fatigue scores were significantly improved from baseline to wk24 in ustekinumab-treated patients (all median improvements=3.0) relative to placebo treatment (0.0, all $p < 0.01$). Similarly, significantly higher proportions of ustekinumab- (all 49.0%) than placebo- (25.8%; all $p < 0.001$) treated patients experienced clinically meaningful improvement (i.e., ≥ 4 points) in fatigue from baseline to wk24 (Table S2). Improvements (i.e., ≥ 4 points) in FACIT-Fatigue score were generally sustained through wk52 (Table S3).

Safety. The most common AEs through wk16 in ustekinumab-treated patients were nasopharyngitis (8.7%), headache (4.8%), and arthralgia (4.3%) (Table 4). The proportions of patients reporting AEs and the types of AEs were generally similar for patients receiving and not receiving MTX at baseline. Similar proportions of ustekinumab- and placebo-treated patients reported AEs among patients who were previously treated with at least one biologic anti-TNF agent and were not appreciably different between these anti-TNF-experienced patients and anti-TNF-naïve patients (data not shown). Nasopharyngitis (13.2%), upper respiratory tract infection (9.1%), headache (7.7%), psoriasis (5.9%), bronchitis (5.6%), and psoriatic arthropathy (5.2%) were the only AEs reported for $> 5\%$ of ustekinumab-treated patients through wk60 (Table S2).

Sixteen patients discontinued study agent due to an AE through wk24, including 5 (2.1%) ustekinumab-treated patients and 11 (10.6%) placebo-treated patients (Table 4). Excluding patients receiving only placebo before discontinuing treatment, 11 (3.8%) ustekinumab-treated patients discontinued study agent because of an AE through wk60 (Table S2).

Through wk60, two (1.1%) patients receiving ustekinumab 45 mg and four (3.2%) receiving ustekinumab 90 mg had an injection-site reaction, compared with five (1.6%) patients who received any placebo injection. All injection-site reactions were mild, and none resulted in discontinuation of study agent. Through wk60, no anaphylactic or serum sickness-like reactions associated with study agent were observed.

Table S1. Baseline patient demographics and disease characteristics among anti-TNF-experienced patients

	Placebo	UST 45 mg	UST 90 mg
ANTI-TNF-EXPERIENCED PTS, N=	62 (59.6)	60 (58.3)	58 (55.2)
Women	31 (50.0)	37 (61.7)	36 (62.1)
Age, years	48.5 (37.0, 55.0)	49.0 (39.0, 55.0)	48.0 (40.0, 56.0)
Body mass index, kg/m²	31.5 (26.8, 38.0)	30.9 (26.6, 38.9)	33.2 (26.3, 38.5)
Duration of disease, years			
Psoriatic arthritis	7.1 (4.1, 12.5)	7.3 (4.1, 13.7)	5.7 (2.5, 10.5)
Psoriasis	12.3 (8.3, 22.4)	15.5 (7.1, 24.7)	12.6 (7.3, 23.4)
Swollen joint count (0-66)	11.0 (7.0, 17.0)	14.5 (7.5, 20.5)	12.5 (7.0, 19.0)
Tender joint count (0-68)	24.0 (12.0, 31.0)	24.0 (16.5, 40.5)	25.5 (17.0, 43.0)
CRP, mg/L	8.7 (4.2, 22.3)	15.0 (4.9, 37.0)	10.9 (6.9, 26.8)
HAQ-DI score (0-3)	1.3 (0.8, 1.8)	1.4 (0.8, 2.0)	1.6 (0.9, 1.9)
Prior TNF-antagonist(s) used			
Adalimumab	37 (59.7)	31 (51.7)	33 (56.9)
Etanercept	41 (66.1)	42 (70.0)	32 (55.2)
Infliximab	29 (46.8)	37 (61.7)	30 (51.7)
Golimumab	5/62 (8.1)	7/60 (11.7)	4/58 (6.9)
Certolizumab-Pegol	2/62 (3.2)	0/60 (0.0)	1/58 (1.7)
Reason for discontinuation of anti-TNF¹			
Lack of efficacy	38 (61.3)	37 (61.7)	40 (69.0)
Intolerance	13 (21.0)	10 (16.7)	10 (17.2)
Lack of efficacy/intolerance	45 (72.6)	40 (66.7)	45 (77.6)
Other	26 (41.9)	26 (43.3)	24 (41.4)
Number of prior anti-TNF agents			
1	30 (48.4)	23 (38.3)	28 (48.3)
2	14 (22.6)	20 (33.3)	20 (34.5)
≥3	18 (29.0)	17 (28.3)	10 (17.2)
Use of prior anti-TNF ≥ 1 year			
Adalimumab	20/37 (54.1)	14/31 (45.2)	15/33 (45.5)
Etanercept	20/41 (48.8)	23/42 (54.8)	18/32 (56.3)
Infliximab	21/29 (72.4)	20/37 (54.1)	22/30 (73.3)
Golimumab	0/5 (0.0)	1/7 (14.3)	1/4 (25.0)
Certolizumab-Pegol	0/2 (0.0)	0/0 (-)	0/1 (0.0)

Data are reported as n (%) or median (interquartile range) unless noted otherwise.

¹Patients may have had ≥1 reason for discontinuation.

CRP= C-reactive protein, HAQ-DI=Health Assessment Questionnaire disability index, TNF=tumor necrosis factor α , UST=ustekinumab

Table S2. Summary of additional secondary efficacy endpoints at week 24 among randomised patients

	Placebo (N = 104)	UST 45 mg (N = 103)	UST 90 mg (N = 105)	Combined UST (N = 208)
DAS28-CRP/EULAR response¹	31 (29.8)	56 (54.4)***	56 (53.3)***	112 (53.8)***
DAS28-CRP < 2.6	4 (3.8)	11 (10.7)	16 (15.2)**	27 (13.0)*
Patients with dactylitis²	25/33 (75.8)	30/46 (65.2)	22/38 (57.9)	52/84 (61.9)
Patients with enthesitis³	60/68 (88.2)	53/70 (75.7)*	49/70 (70.0)**	102/140 (72.9)**
BASDAI response⁴				
BASDAI20	10/18 (55.6)	15/25 (60.0)	11/21 (52.4)	26/46 (56.5)
BASDAI50	1/18 (5.6)	7/25 (28.0)	8/21 (38.1)*	15/46 (32.6)**
BASDAI score < 3	1/18 (5.6)	8/25 (32.0)	6/21 (28.6)	14/46 (30.4)
PASI90 response⁵	3/80 (3.8)	24/80 (30.0)***	36/81 (44.4)***	60/161 (37.3)***
HAQ-DI score- Improvement ≥ 0.3 units	17 (16.3)	35 (34.0)**	40 (38.1)***	75 (36.1)***
Change in SF-36 summary scores, n=	97	99	97	196
Mental component	0.0 (-3.2, 4.9)	0.7 (-3.6, 7.9)	2.2 (-3.6, 10.8)	1.2 (-3.6, 9.2)
Physical component	0.0 (-0.8, 4.0)	2.7 (-0.7, 9.1)**	3.5 (-0.2, 10.1)**	3.3 (-0.7, 9.8)***
FACIT-Fatigue score				
Change from baseline	0.0 (-1.0, 4.0)	3.0 (-2.0, 12.0)**	3.0 (0.0, 9.0)**	3.0 (-1.0, 10.0)**
Patients with improvement ≥ 4	25/97 (25.8)	49/100 (49.0)***	47/96 (49.0)***	96/196 (49.0)***
DLQI score⁵				
Change from baseline	0.0 (-4.0, 2.0)	-6.0 (-12.0, -1.0)***	-6.0 (-10.0, -2.0)***	-6.0 (-12.0, -2.0)***
Score = 0/1 ⁶	8/72 (11.1)	26/73 (35.6)***	29/68 (42.6)***	55/141 (39.0)***

*, **, *** indicate p < 0.05, 0.01, 0.001, respectively, versus placebo.

Data are reported as n (%), n/N (%), or median (interquartile range).

¹A “good” or “moderate” EULAR DAS28 response.

²Among patients with dactylitis at baseline.

³Among patients with enthesitis at baseline; based on MASES ≥ 1.

⁴Among patients with spondylitis/peripheral joint involvement at baseline.

⁵Among patient with ≥ 3% BSA psoriasis involvement at baseline.

⁶Among patients with DLQI > 1 at baseline.

ACR=American College of Rheumatology, BASDAI=Bath Ankylosing Spondylitis Disease Activity Index, BSA= body surface area, CI=confidence interval, CRP= C-reactive protein, DAS28-CRP=28-joint Disease Activity Score employing CRP, DLQI=Dermatology Life Quality Index, EULAR=European League Against Rheumatism, FACIT-Fatigue=Functional Assessment of Chronic Illness Therapy-Fatigue, HAQ-DI=Health Assessment Questionnaire disability index, MASES=Maastricht Ankylosing Spondylitis Enthesitis Score, MTX=methotrexate, PASI=Psoriasis Area and Severity Index, SF-36=36-item Short-Form health survey, TNF=tumor necrosis factor α , UST=ustekinumab

Table S3. Summary of observed efficacy data at week 52 among randomized patients. Patients in the placebo group who did not crossover to ustekinumab 45 mg were excluded.

	Placebo→ UST 45 mg (N = 206)	UST 45 mg (N = 205)	UST 90 mg (N = 204)	Combined UST (N = 409)
ACR response, N=	77	94	95	189
ACR20	43 (55.8)	44 (46.8)	46 (48.4)	90 (47.6)
ACR50	22 (28.6)	26 (27.7)	25 (26.3)	51 (27.0)
ACR70	12 (15.6)	12 (12.8)	17 (17.9)	29 (15.3)
ACR response - Anti-TNF-naive patients, N =	37	40	41	81
ACR20	27 (73.0)	24 (60.0)	24 (58.5)	48 (59.3)
ACR50	15 (40.5)	16 (40.0)	14 (34.1)	30 (37.0)
ACR70	7 (18.9)	9 (22.5)	13 (31.7)	22 (27.2)
ACR response - Anti-TNF-experienced patients, N =	40	54	54	108
ACR20	16 (40.0)	20 (37.0)	22 (40.7)	42 (38.9)
ACR50	7 (17.5)	10 (18.5)	11 (20.4)	21 (19.4)
ACR70	5 (12.5)	3 (5.6)	4 (7.4)	7 (6.5)
DAS28-CRP / EULAR response¹	53 (68.8)	56 (59.6)	59 (62.1)	115 (60.8)
% change in dactylitis score², n=	24 -100.0 (-100.0, -33.3)%	44 -95.0 (-100.0, 0.0)%	38 -90.9 (-100.0, 0.0)%	82 -95.0 (-100.0, 0.0)%
% change in entheses score³, n=	53 -33.3 (-100.0, 0.0)%	66 -36.7 (-87.5, 0.0)%	71 -60.0 (-100.0, 0.0)%	137 -50.0 (-100.0, 0.0)%
PASI response⁴	57	69	73	142
PASI75	32 (56.1)	39 (56.5)	47 (64.4)	86 (60.6)
PASI90	21 (36.8)	26 (37.7)	36 (49.3)	62 (43.7)
PASI75 response¹ - Anti-TNF-naive patients	19/27 (70.4)	26/33 (78.8)	27/33 (81.8)	53/66 (80.3)
PASI75 response¹ - Anti-TNF-experienced patients	13/30 (43.3)	13/36 (36.1)	20/40 (50.0)	33/76 (43.4)
HAQ-DI score, n =	77	94	95	189
Improvement ≥ 0.3 units	29 (37.7)	33 (35.1)	42 (44.2)	75 (39.7)
Change from baseline	-0.1 (-0.5, 0.0)	-0.3 (-0.5, 0.0)	-0.3 (-0.5, 0.0)	-0.3 (-0.5, 0.0)
HAQ-DI score - Anti-TNF-naive patients, N =	37	40	41	81
Change from baseline	-0.38 (-0.63, 0.00)	-0.25 (-0.44, 0.00)	-0.36 (-0.50, 0.00)	-0.25 (-0.50, 0.00)
HAQ-DI score - Anti-TNF-experienced patients, N =	40	54	54	108
Change from baseline	0.00 (-0.13, 0.13)	-0.13 (-0.50, 0.00)	-0.13 (-0.50, 0.00)	-0.13 (-0.50, 0.00)
Change in SF-36 summary scores, n=	77	93	95	188
Mental component	0.8 (-3.3, 7.2)	0.0 (-2.8, 8.3)	1.4 (-1.3, 10.1)	0.5 (-2.2, 9.0)
Physical component	2.7 (0.0, 10.3)	3.0 (0.0, 9.3)	3.9 (0.0, 10.3)	3.4 (0.0, 10.3)

Table S3. Summary of observed efficacy data at week 52 among randomized patients. Patients in the placebo group who did not crossover to ustekinumab 45 mg were excluded.

	Placebo→ UST 45 mg (N = 206)	UST 45 mg (N = 205)	UST 90 mg (N = 204)	Combined UST (N = 409)
DLQI score⁴				
Change from baseline, n=	57	69	71	140
Score = 0/1 ^{4,5}	-5.0 (-10.0, -2.0) 21/56 (37.5)	-6.0 (-11.0, -1.0) 23/67 (34.3)	-7.0 (-13.0, -1.0) 30/65 (46.2)	-6.0 (-12.5, -1.0) 53/132 (40.2)
FACIT-Fatigue score, n=				
Change from baseline	77	94	95	189
Improvement ≥ 4	2.0 (-1.0; 9.0) 34 (44.2)	3.0 (0.0; 10.0) 45 (47.9)	3.0 (0.0; 10.0) 44 (46.3)	3.0 (0.0; 10.0) 89 (47.1)

Data are reported as n (%), n/N (%), or median (interquartile range).

¹A “good” or “moderate” DAS28-CRP response.

²Among patients with dactylitis in ≥1 digit at baseline.

³Among patients with enthesitis at baseline, i.e., PsA-modified MASES ≥1.

⁴Among patient with ≥ 3% BSA psoriasis skin involvement at baseline.

⁵ Among patients with DLQI >1 at baseline.

ACR=American College of Rheumatology, BSA=body surface area, CRP=C-reactive protein, DAS28-CRP=28-joint Disease Activity Score employing CRP, DLQI=Dermatology Life Quality Index, EULAR=European League Against Rheumatism, FACIT-Fatigue=Functional Assessment of Chronic Illness Therapy-Fatigue, HAQ-DI= Health Assessment Questionnaire disability index, MASES=Maastricht Ankylosing Spondylitis Enthesitis Score, PASI=Psoriasis Area and Severity Index, PsA=psoriatic arthritis, SF-36=36-item Short-Form health survey, TNF=tumor necrosis factor α , UST=ustekinumab

Table S4. Summary of AEs through week 24 and week 60 among treated patients.

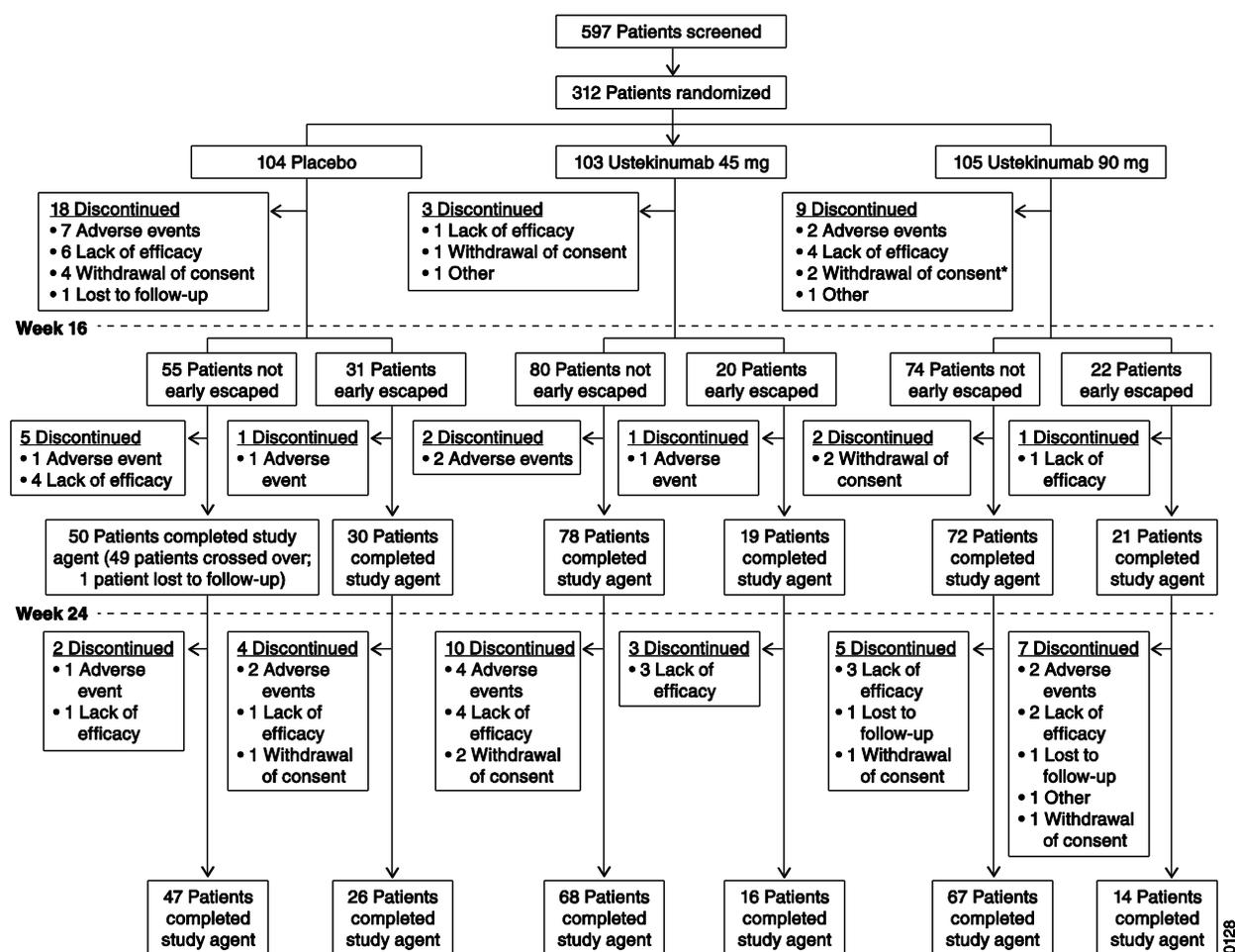
	-----Week 24 ¹ -----					-----Week 60 ¹ -----			
	Placebo (N=104)	Placebo→ UST 45 mg ¹ (N=31)	UST 45 mg (N=103)	UST 90 mg (N=104)	All UST (N=238)	Placebo→ UST 45 mg (N=80)	UST 45 mg (N=103)	UST 90 mg (N=104)	All UST (N=287)
Mean weeks of follow-up	19.4	8.2	23.8	23.3	21.6	37.3	54.1	53.1	49.0
AEs, n (%)	66 (63.5)	13 (41.9)	73 (70.9)	72 (69.2)	158 (66.4)	44 (55.0)	81 (78.6)	81 (77.9)	206 (71.8)
<u>Common (> 5%) AEs²</u>									
<i>Nasopharyngitis</i>	8 (7.7)	0 (0.0)	10 (9.7)	13 (12.5)	23 (9.7)	3 (3.8)	15 (14.6)	20 (19.2)	38 (13.2)
<i>Upper resp tract infect</i>	4 (3.8)	3 (9.7)	10 (9.7)	6 (5.8)	19 (8.0)	4 (5.0)	12 (11.7)	10 (9.6)	26 (9.1)
<i>Headache</i>	5 (4.8)	2 (6.5)	7 (6.8)	6 (5.8)	15 (6.3)	5 (6.3)	8 (7.8)	9 (8.7)	22 (7.7)
<i>Psoriasis</i>	-	-	-	-	-	3 (3.8)	9 (8.7)	5 (4.8)	17 (5.9)
<i>Bronchitis</i>	-	-	-	-	-	2 (2.5)	5 (4.9)	9 (8.7)	16 (5.6)
<i>Psoriatic arthropathy</i>	-	-	-	-	-	1 (1.3)	10 (9.7)	4 (3.8)	15 (5.2)
Discontinued study agent due to AEs, n (%)	11 (10.6)	0 (0.0)	2 (1.9)	3 (2.9)	5 (2.1)	1 (1.3%)	6 (5.8%)	4 (3.8%)	11 (3.8%)
Serious AEs, n (%)³	5 (4.8)	1 (3.2)	0 (0.0)	2 (1.9)	3 (1.3)	3 (3.8)	6 (5.8)	6 (5.8)	15 (5.2)
Investigator-reported infection	30 (29.7)	4 (12.9)	42 (40.8)	36 (34.6)	82 (34.5)	23 (28.8)	54 (52.4)	57 (54.8)	134 (46.7)

¹ At week 16, patients with <5% improvement from baseline in both tender and swollen joint counts entered blinded early escape, such that patients receiving ustekinumab 45 mg increased to 90 mg and patients receiving placebo switched to ustekinumab 45 mg; patients receiving ustekinumab 90 mg continued with their blinded dose regimen. Placebo patients who did not early escape at week 16 crossed over to ustekinumab 45 mg at week 24. AEs through week 52 are cumulative and include those reported through week 24.

² AEs > 5% of all ustekinumab patients at week 60; AEs are ordered according to decreasing frequency for the combined ustekinumab group at week 60.

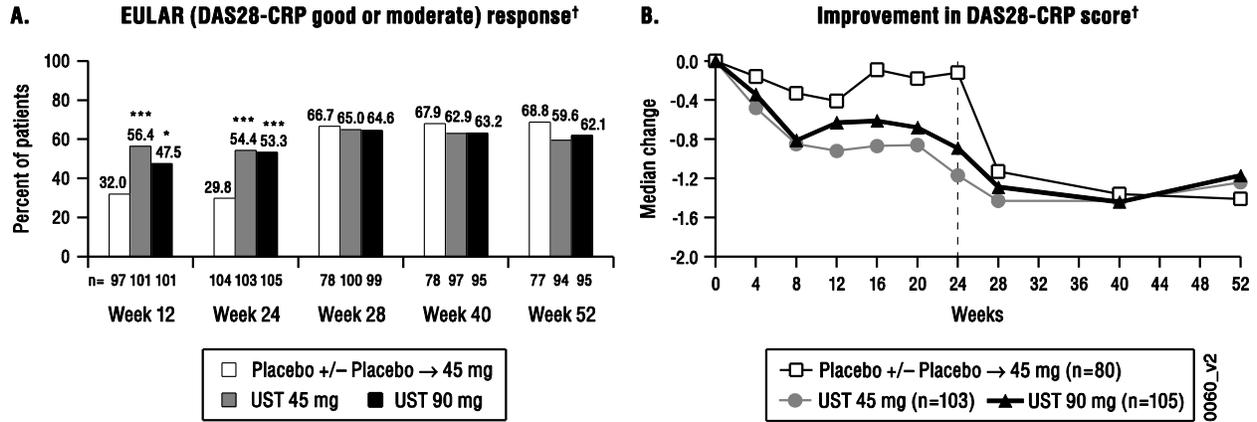
³ See Table 4 for details of serious AEs through week 16 and week 24. Between week 24 and week 60, serious AEs were reported for an additional 12 patients, including two placebo→UST 45 mg patients (umbilical hernia, breast cancer), six patients receiving UST 45 mg (myocardial infarction, unstable angina, gastrointestinal hemorrhage/thrombocytopenia, upper gastrointestinal hemorrhage/ myocardial infarction, joint effusion, intestinal hemorrhage/inguinal scar contracture), and four patients receiving UST 90 mg (renal failure/candidiasis/hypotension/myocardial infarction/septic shock/vertebral fracture/syncope, suicide attempt, gastric ulcer hemorrhage, inguinal hernia). In addition, the 90-mg patient who had serious renal injury/syncope through week 24 also had serious psoriasis and bacteremia reported through week 60, and the 90-mg patient who had serious arthritis through week 24 also had serious arthritis and arteriosclerosis reported through week 60).

Note: AEs with “-“ did not meet the criteria for “common” (see footnote 2). AEs=adverse events, UST=ustekinumab



*Includes 1 patient who was randomized, but not treated

Figure S1. Patient disposition through week 60. Note that of the 597 patients screened, 312 were randomized into the study; the majority (70%, 200/285) of screening failures did not meet the inclusion criterion requiring patients to have ≥ 5 swollen and tender joints at screening *and* baseline and a CRP concentration ≥ 3.0 mg/L at screening only. Pertaining to reasons for discontinuation of study agent, AEs related to lack of efficacy are grouped with other cases of discontinuation due to lack of efficacy. Patients who discontinued study agent included 53/180 (29.4%) anti-TNF-experienced (41.9%-placebo, 21.7%-45 mg, 24.1%-90mg) and 21/132 (15.9%) anti-TNF-naïve (12%-placebo, 14%-45 mg, 21%-90 mg). AEs=adverse events, PsA=psoriatic arthritis, PsO=psoriasis

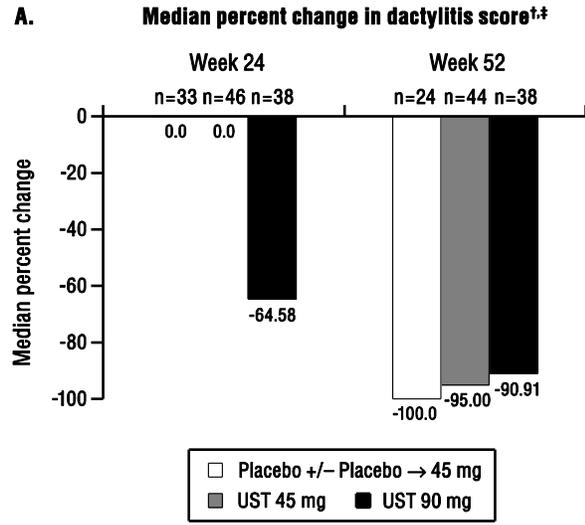


[†]For patients who qualified for early escape, data at or prior to week 16 were carried forward through week 24. After week 24, observed data were used.

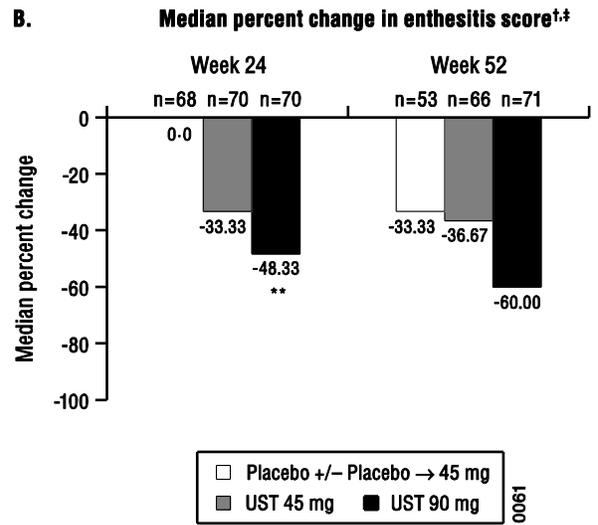
*p<0.05 vs placebo.

***p<0.001 vs placebo.

Figure S2. Proportions of patients achieving EULAR response (“good” or “moderate” DAS28-CRP response) at weeks 12, 24 and 52 (A) and **median change from baseline in DAS28-CRP score** over time through week 52 (B), with the vertical dotted line indicating the time after which data handling rules changed as noted in the figure footnote. Note that patients randomized to placebo who did not receive ustekinumab are excluded after week 24. *DAS28-CRP=28-joint count Disease Activity Score employing C-reactive protein, EULAR=European League Against Rheumatism, UST=ustekinumab*



[†] Among randomized patients with dactylitis at baseline.
[‡] For patients who qualified for early escape, data at or prior to week 16 were carried forward through week 24. After week 24, observed data were used.



[†] Among randomized patients with enthesitis at baseline.
[‡] For patients who qualified for early escape, data at or prior to week 16 were carried forward through week 24. After week 24, observed data were used.
 **p<0.01 vs placebo.

Figure S3. Additional efficacy assessments, including median percent change from baseline to weeks 24 and 52 in dactylitis (A) and PsA-modified MASES enthesitis scores (B) among patients with dactylitis and enthesitis, respectively, at baseline. MASES=Maastricht Ankylosing Spondylitis Enthesitis Score, PsA=psoriatic arthritis, UST=ustekinumab

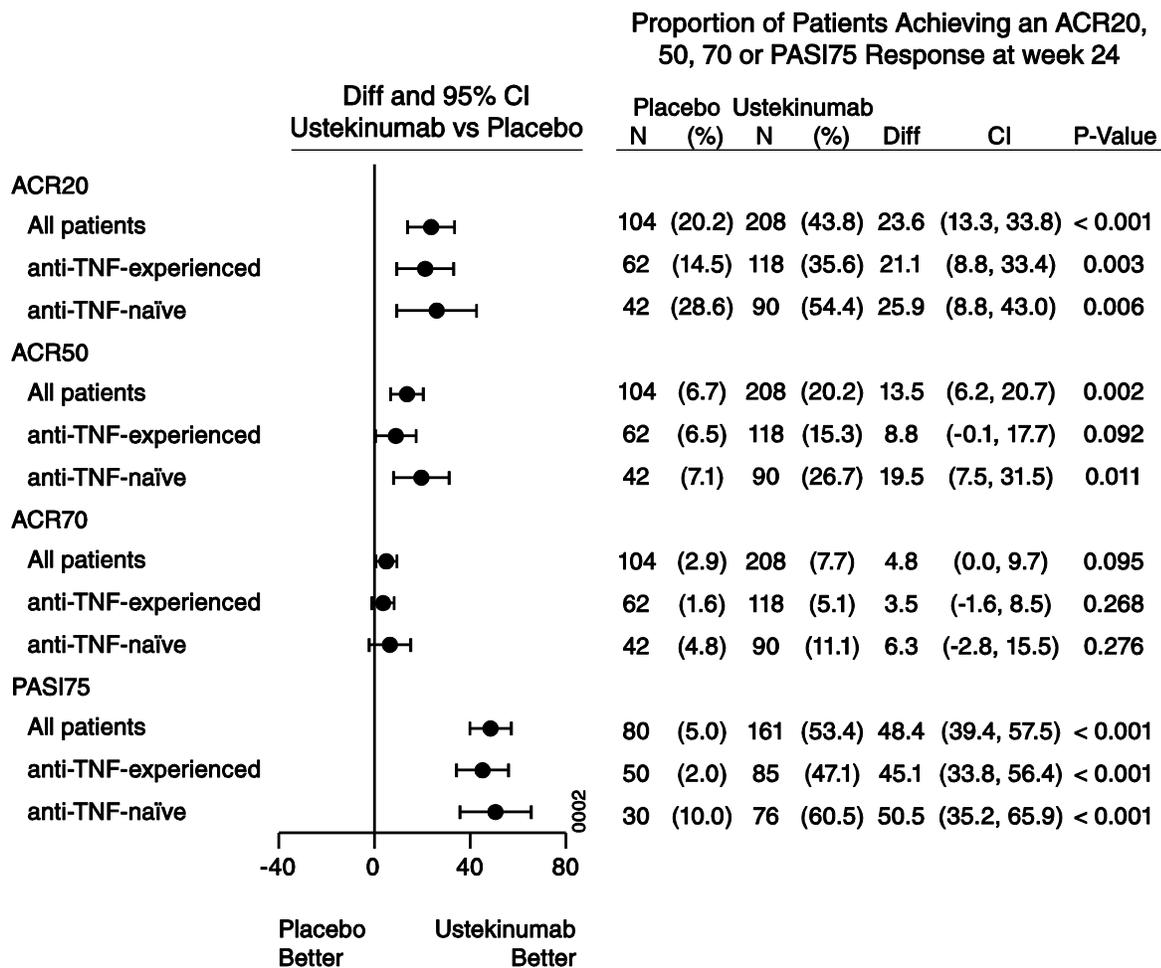


Figure S4. Difference and 95% confidence intervals (CIs) for comparing proportions of patients who achieved at least 20% (ACR20), 50% (ACR50), and/or 70% (ACR70) improvement in the American College of Rheumatology response criteria and/or at least 75% improvement in the Psoriasis Area and Severity Index (PASI75) at week 24 in the combined group versus the placebo group; randomized patients. *diff*=difference, *TNF*=anti-tumor necrosis factor α .