

ONLINE SUPPLEMENTAL TEXT

Statistical analyses

Sensitivity analyses. The four sensitivity analyses on the major secondary endpoint, i.e., change from baseline to week (wk)24 in the total van der Heijde-Sharp (vdH-S) score modified for psoriatic arthritis (PsA) combined across both studies, that were performed to test the robustness of findings included: 1) only patients who completed study agent administration as prescribed through wk24 and had no missing data at either baseline or wk24, 2) only patients who did not meet the early escape criteria at wk16, 3) only data from original radiograph readers, and 4) only data from patients with no missing data at both baseline and wk24 (observed data analysis).

Sample size estimation. Each individual study was powered to detect significant treatment differences in reducing the signs and symptoms of PsA for the primary endpoint. Based on the initial power assumptions, the treatment effect for preventing structural damage was expected to be similar for the two studies, and based on the prespecified integrated analyses combining two studies (approximately 600 from the first study and 300 from the second study), the combined dataset provides approximately 84% power to detect a significant treatment effect for at least one ustekinumab group as compared with the placebo group.

Table S1. Baseline PsA-modified vdH-S scores; randomized patients in PSUMMIT-1 and PSUMMIT-2

	Placebo	Ustekinumab	
		45mg	90mg
Patients in PSUMMIT-1 + PSUMMIT-2, N	306	303	300
Total PsA-modified vdH-S score			
Mean \pm SD	28.0 \pm 55.8	30.4 \pm 50.7	28.0 \pm 42.1
Median (IQ range)	9.5 (3.0, 29.5)	11.5 (3.5, 33.5)	10.5 (3.5, 34.5)
-Patients in PSUMMIT-1, N	203	201	200
Total PsA-modified vdH-S score			
Mean \pm SD	29.9 \pm 59.3	30.1 \pm 51.7	28.5 \pm 42.0
Median (IQ range)	11.0 (3.0, 30.5)	11.0 (3.5, 32.5)	11.8 (3.5, 36.5)
-Patients in PSUMMIT-2, N	103	102	100
Total PsA-modified vdH-S score			
Mean \pm SD	24.3 \pm 48.0	31.1 \pm 48.9	26.9 \pm 42.6
Median (IQ range)	7.0 (2.0, 22.5)	13.0 (3.5, 34.5)	8.5 (3.3, 30.3)
-anti-TNF-naïve patients, N	42	43	45
Total PsA-modified vdH-S score			
Mean \pm SD	27.3 \pm 59.8	29.0 \pm 48.6	26.3 \pm 40.0
Median (IQ range)	11.0 (3.0, 19.5)	17.5 (2.5, 32.0)	9.5 (4.0, 28.5)
-anti-TNF-experienced patients, N	61	59	55
Total PsA-modified vdH-S score			
Mean \pm SD	22.2 \pm 38.3	32.6 \pm 49.4	27.4 \pm 44.9
Median (IQ range)	5.5 (2.0, 27.8)	11.0 (3.5, 41.0)	7.0 (3.0, 30.5)

¹ Missing x-ray data were imputed via linear extrapolation if x-ray data were available at two time points during the period from wk0-wk24 or from wk24-wk52 or, if radiographic data were insufficient for linear extrapolation, via assignment of the median of the change in the total scores based on all patients within the same MTX stratification at the missing visit.

anti-TNF – anti-tumor necrosis factor alpha, *IQ* - interquartile, *MTX* – methotrexate, *PsA* - psoriatic arthritis, *SD* – standard deviation, *vdH-S* - van der Heijde-Sharp

Table S2. Summary of change from baseline in total PsA-modified vdH-S score at week 24 by study and/or patient subgroup; randomized patients

	Placebo	Ustekinumab		
		Combined	45mg	90mg
<u>Integrated data analysis of change from baseline to week 24 in total vdH-S score in the PSUMMIT-1 and PSUMMIT-2 studies, N</u>				
	310	617	308	309
<i>MTX use reported at baseline</i>				
<u>-MTX use, N</u>				
Mean ± SD	145	307	153	154
Median (IQ range)	0.8 (1.8)	0.5 (2.3)	0.6 (2.3)	0.5 (2.2)
<u>-No MTX use, N</u>				
Mean ± SD	165	310	155	155
Median (IQ range)	1.1 (5.0)	0.3 (2.3)	0.3 (1.9)	0.3 (2.6)
<i>Body weight at baseline</i>				
<u>-Patients with weight ≤ 100 kg at baseline, N</u>				
Mean ± SD	228	454	227	227
Median (IQ range)	1.2 (4.4)	0.3 (1.9)	0.3 (2.2)	0.3 (1.6)
<u>-Patients with weight >100 kg at baseline, N</u>				
Mean (SD)	82	162	81	81
Median	0.3 (1.3)	0.7 (3.0)	0.6 (1.9)	0.8 (3.9)
	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 1.0)	0.0 (0.0, 0.5)
<u>Mean change from baseline in total vdH-S score in individual studies</u>				
<i>PSUMMIT-1, N</i>				
Mean ± SD	206	409	205	204
Median (IQ range)	1.2 ± 4.5	0.2 ± 1.7	0.3 ± 1.9	0.2 ± 1.4
p-value	0.0 (0.0, 1.5)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (-0.3, 0.5)
		<0.001	0.001	<0.001
<i>PSUMMIT-2, N</i>				
Mean ± SD	104	208	103	105
Median (IQ range)	0.5 ± 1.9	0.7 ± 3.0	0.7 ± 2.4	0.8 ± 3.6
p-value	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 1.0)	0.0 (0.0, 0.5)
		0.755	0.605	0.965
<u>- anti-TNF-naïve patients, N</u>				
Mean ± SD	42	90	43	47
Median (IQ range)	0.4 ± 1.5	0.5 ± 1.8	0.7 ± 1.6	0.4 ± 1.9
p-value	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 0.5)
		0.669	0.345	0.852
<u>- anti-TNF-experienced patients, N</u>				
Mean ± SD	62	118	60	58
Median (IQ range)	0.6 ± 2.1	0.9 ± 3.7	0.7 ± 2.8	1.1 ± 4.5
p-value	0.0 (0.0, 0.0)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)
		0.956	0.865	0.752

^a No missing data imputation rules were applied.

anti-TNF – anti-tumor necrosis factor alpha, *IQ* – interquartile, *MTX* – methotrexate, *PsA* – psoriatic arthritis, *SD* – standard deviation, *vdH-S* – van der Heijde-Sharp