Supplementary Table 2. Efficacy Endpoints in the Maintenance Study (Overall and East-Asian Population; Assessment at Week 44 Unless Otherwise Specified)

Variable	Overall population					East-Asian population				
	Randomized			Nonrandomized		Randomized			Nonrandomized	
	Placebo (n = 175)	UST 90 mg (q12w) (n = 172)	UST 90 mg (q8w) (n = 176)	Responders to placebo (n = 103)	Delayed responders (n = 157)	Placebo (n = 31)	UST 90 mg (q12w) (n = 21)	UST 90 mg (q8w) (n = 26)	Responders to placebo (n = 11)	Delayed responders (n = 22)
Clinical remission, n (%)	42 (24.0)	66 (38.4)	77 (43.8)	21 (20.4)	47 (29.9)	7 (22.6)	10 (47.6)	5 (19.2)	1 (9.1)	2 (9.1)
Clinical response through week 44, n (%)	78 (44.6)	117 (68.0)	125 (71.0)	47 (45.6)	98 (62.4)	11 (35.5)	16 (76.2)	12 (46.2)	4 (36.4)	14 (63.6)
Symptomatic remission, n (%)	79 (45.1)	107 (62.2)	119 (67.6)			13 (41.9)	15 (71.4)	13 (50.0)		
Sustained partial Mayo remission through week 44, n (%)	80 (45.7)	107 (62.2)	121 (68.8)			15 (48.4)	15 (71.4)	13 (50.0)		
Histo-endoscopic mucosal healing,[a] n (%)	41 (24.1)	66 (38.8)	79 (45.9)			7 (23.3)	10 (47.6)	8 (30.8)		
Histologic improvement,[b] n (%)	55 (32.9)	88 (54.0)	99 (59.3)			10 (33.3)	15 (75.0)	11 (44.0)		
IBDQ, change from baseline to week 44, median[c] (IQR)	−7.0 (−40.0; 8.0)	1.5 (−14.0; 16.5)	5.0 (−7.0; 20.0)			−6.0 (−31.0; 8.0)	0.0 (−11.0; 17.0)	−2.0 (−28.0; 5.0)		
Efficacy by biologic failure status										
Prior biologic failure, n	88	70	91			20	12	19		
Clinical remission, n (%)	15 (17.0)	16 (22.9)	36 (39.6)			5 (25.0)	4 (33.3)	3 (15.8)		
Clinical response through week 44, n (%)	34 (38.6)	39 (55.7)	59 (64.8)			9 (45.0)	7 (58.3)	7 (36.8)		
Biologic naïve or no biologic failure, n	87	102	85			11	9	7		
Clinical remission, n (%)	27 (31.0)	50 (49.0)	41 (48.2)			2 (18.2)	6 (66.7)	2 (28.6)		
Clinical response through week 44, n (%)	44 (50.6)	78 (76.5)	66 (77.6)			2 (18.2)	9 (100.0)	5 (71.4)		

[a]Excludes patients whose mucosal healing status cannot be determined at week 44 due to an unevaluable biopsy (i.e., a biopsy that was collected, but could not be assessed due to sample preparation or technical errors). Note that patients who had an unevaluable biopsy at week 44, but who did not achieve endoscopic healing, were considered not to have mucosal healing. Overall population: n = 170, 170 and 172 and East-Asian population: n = 30, 21 and 26 for placebo, UST 90 mg (q12w) and UST 90 mg (q8w), respectively.

[b]Excludes patients with an unevaluable biopsy (i.e., a biopsy that was collected, but could not be assessed due to sample preparation or technical errors) at week 44. Overall population: n = 167, 163 and 167 and East-Asian population: n = 30, 20 and 25 for placebo, UST 90 mg (q12w) and UST 90 mg (q8w), respectively.

[c]Patients who had a prohibited change in UC medication, an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the week +44 visit had their week 0 value of the induction study carried forward from the time of the event onward. Patients who had a missing IBDQ score at a timepoint had their last available value carried forward. Overall population: n = 173, 172 and 174 and East-Asian population: n = 31, 21 and 26 for placebo, UST 90 mg (q12w) and UST 90 mg (q8w), respectively.

UST, ustekinumab; q12w, every 12 weeks; q8w, every 8 weeks; IBDQ, Inflammatory Bowel Disease Questionnaire; IQR, interquartile range; UC, ulcerative colitis; AE, adverse event.

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