



## 69 - LONG-TERM (5-YEAR) MAINTENANCE OF CLINICALLY MEANINGFUL IMPROVEMENT IN HEALTH- RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH MODERATE TO SEVERE CROHN'S DISEASE (CD) TREATED WITH USTEKINUMAB IN THE IM-UNITI LONG- TERM EXTENSION (LTE) STUDY

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### Resumen

**Introduction:** In the IM-UNITI study, subcutaneous ustekinumab (UST) was safe & efficacious for maintenance in moderately to severely active CD patients who responded to UST induction therapy. In the IM-UNITI LTE, UST maintained clinically meaningful improvement in HRQoL through Week (W) 140. We present the final HRQoL results for patients receiving UST in LTE study through 5 years (W252).

**Methods:** Patients completing the W44 IM-UNITI study safety & efficacy evaluations were eligible to continue in the LTE (UST 90 mg every 12W [Q12W] or UST 90 mg Q8W; placebo not evaluated). HRQoL was assessed using the Inflammatory Bowel Disease Questionnaire (IBDQ) & Medical Outcomes Study 36-Item Short Form (SF-36). Clinically meaningful improvement was defined as an IBDQ change  $\geq 16$  points or change in SF-36 mental component summary (MCS) or physical component summary (PCS) score  $\geq 5$  points. Data for all treated patients from randomized/nonrandomized populations were summarized through W252. For continuous endpoints, patients with treatment failure between W44-W252 had induction baseline (BL) values carried forward and patients with insufficient data had last value carried forward. Binary endpoints were analyzed using a nonresponder imputation approach.

**Results:** Mean IBDQ & SF-36 scores (tables) at maintenance BL were comparable for both UST regimens. At W252, for both UST regimens, improvements in IBDQ & SF-36 scores that were achieved by maintenance BL were maintained; further improvement was observed in IBDQ bowel & emotional symptoms scores. From BL to W252, clinically meaningful improvement in IBDQ total score was achieved (Q12W: 40.8%; Q8W: 43.2%). Clinically meaningful improvement was also observed in SF-36 PCS (Q12W: 37.5%; Q8W: 37.7%) and MCS scores (Q12W: 33.9%; Q8W: 31.0%).

**Table 1. Inflammatory Bowel Disease Questionnaire (IBDQ) scores through Week 252 in randomized and nonrandomized patients who entered the long-term extension study**

Outcome	Ustekinumab 90 mg SC Q12W (N=213)	Ustekinumab 90 mg SC Q8W (N=354)
Total score		
Maintenance BL, mean (SD)	148.0 (36.15)	151.8 (36.61) <sup>a</sup>
Change from maintenance BL to W252, mean (SD) <sup>b</sup>	16.7 (41.35)	16.0 (40.22) <sup>c</sup>
Clinically meaningful improvement from induction BL to W252, n (%) <sup>d</sup>	87 (40.8)	153 (43.2)
Bowel symptoms		
Maintenance BL, mean (SD)	47.8 (10.75)	48.2 (11.22)
Change from maintenance BL to W252, mean (SD) <sup>b</sup>	5.1 (13.62)	5.4 (12.95) <sup>a</sup>
Emotional symptoms		
Maintenance BL, mean (SD)	55.1 (15.50)	57.0 (15.00)
Change from maintenance BL to W252, mean (SD) <sup>b</sup>	6.2 (15.63)	5.4 (15.52) <sup>a</sup>
Systemic function		
Maintenance BL, mean (SD)	20.1 (6.46)	20.8 (6.37)
Change from maintenance BL to W252, mean (SD) <sup>b</sup>	2.6 (7.78)	2.7 (7.22) <sup>a</sup>
Social function		
Maintenance BL, mean (SD)	25.0 (7.60)	25.6 (7.60) <sup>a</sup>
Change from maintenance BL to W252, mean (SD) <sup>b</sup>	2.8 (8.19)	2.7 (7.78) <sup>c</sup>

BL, baseline; CD, Crohn's disease; Q8W, every 8 weeks; Q12W, every 12 weeks; SC, subcutaneous; SD, standard deviation; W, week.

<sup>a</sup>N=353

<sup>b</sup>Patients who had a treatment failure between Week 44 and Week 252 had their induction baseline value carried forward and patients who had insufficient data had their last value carried forward.

<sup>c</sup>N=352

<sup>d</sup>Defined as a change of  $\geq 16$  points; patients who had a treatment failure between Week 44 and Week 252 or who had insufficient data were considered not to have achieved clinically meaningful improvement.

**Table 2. Medical Outcomes Study 36-Item Short Form (SF-36) scores through Week 252 in patients who entered the long-term extension study**

Outcome	Ustekinumab 90 mg SC Q12W (N=192)	Ustekinumab 90 mg SC Q8W (N=332)
Physical component summary		
Maintenance BL, mean (SD)	43.65 (8.189)	43.77 (8.291)
Change from maintenance BL to W252, mean (SD) <sup>a</sup>	3.10 (8.750)	3.70 (8.725) <sup>b</sup>
Clinically meaningful improvement from induction BL to W252, n (%) <sup>c</sup>	72 (37.5)	125 (37.7)
Mental component summary		
Maintenance BL, mean (SD)	42.51 (11.466)	43.82 (11.253)
Change from maintenance BL to W252, mean (SD) <sup>a</sup>	2.86 (11.513)	1.74 (11.772) <sup>b</sup>
Clinically meaningful improvement from induction BL to W252, n (%) <sup>c</sup>	65 (33.9)	103 (31.0)

BL, baseline; CD, Crohn's disease; Q8W, every 8 weeks; Q12W, every 12 weeks; SC, subcutaneous; SD, standard deviation; W, week.

<sup>a</sup>Patients who had a treatment failure between Week 44 and Week 252 had their induction baseline value carried forward and patients who had insufficient data had their last value carried forward.

<sup>b</sup>N=331

<sup>c</sup>Defined as a change of  $\geq 5$  points; patients who had a treatment failure between Week 44 and Week 252 or who had insufficient data were considered not to have achieved clinically meaningful improvement.

**Conclusions:** Long-term (5 years) treatment with UST 90 mg (Q12W/Q8W) was effective at maintaining improvements in HRQoL that were achieved during UST induction therapy in CD patients.