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55 - EFFECT OF USTEKINUMAB MAINTENANCE THERAPY ON STOOL FREQUENCY AND RECTAL BLEEDING THROUGH 2 YEARS IN THE UNIFI PHASE 3 STUDY IN ULCERATIVE COLITIS

L. Peyrin-Biroulet¹, M.T. Abreu², S. Danese³, C. Marano, Y. Zhou⁴, H. Zhang⁴, R.W.L. Leong⁵, D. Rowbotham⁶, R. Panaccione⁷ and W.J. Sandborn⁸

¹Nancy University Hospital, Université de Lorraine, Nancy (France). ²University of Miami Miller School of Medicine, Miami, FL (USA). ³Humanitas Research Hospital, Milan (Italy). ⁴Janssen Research & Development, LLC, Spring House, PA (USA). ⁵The University of New South Wales and Macquarie University (Australia). ⁶Auckland City Hospital, University of Auckland (New Zealand). ⁷University of Calgary, Calgary, AB (Canada). ⁸University of California San Diego, La Jolla, CA (USA).

Resumen

Introduction: The UNIFI randomized-withdrawal maintenance study evaluated subcutaneous (SC) ustekinumab (UST) in patients (pts) with moderately to severely active ulcerative colitis (UC). Pts who completed the maintenance study (WK44) could enter a long-term extension (LTE) through 220 weeks (wks). We evaluated the effect of UST maintenance therapy on stool frequency & rectal bleeding through 92wks.

Methods: Pts were eligible to dose adjust (PBO to q8w; q12w to q8w; q8w to q8w [sham dose adjustment]) starting at Wk56 and the recorded number of stools and rectal bleeding symptoms for 7 days before each visit. Proportions of pts with Mayo stool frequency subscores of 0 (normal number of stools) or 1 (1-2 stools more than normal) or rectal bleeding subscores of 0 (no blood seen) were evaluated. Absolute stool number was summarized.

Results: Pts in LTE included UST 90 mg q12w: n = 141 and UST 90 mg q8w: n = 143. Absolute stool number in UST q12w and q8w groups were 6.6 & 6.5 stools/day, respectively, at induction baseline and decreased to 2.8 and 2.7, respectively, by maintenance baseline. Reductions achieved at maintenance baseline were maintained at Wk92 (2.7 & 2.2, respectively). At induction baseline, only 12.8% & 18.2% of pts, respectively, had Mayo stool frequency subscores of 0 or 1. By maintenance baseline, 80.9% & 80.4%, respectively, had Mayo stool frequency subscores of 0 or 1, and these were maintained through Wk92 (79.4% & 86.7% at Wk92, respectively). At induction baseline, 9.2% & 7.0%, respectively, had no blood seen in the stool (Mayo rectal bleeding subscore of 0). By maintenance baseline, 87.2% & 84.6%, respectively, had no blood seen in the stool & these were maintained through Wk92 (86.5% & 88.8%) (table).

Table: Stool frequency and rectal bleeding symptoms through Wk92 in randomized pts who entered the LTE

	UST 90 mg q12w (N=141)	UST 90 mg q8w (N=143)
Absolute Stool Numbers, mean (SD)^a		
Induction Wk 0	6.6 (3.22)	6.5 (3.16)
Maintenance Wk 0	2.8 (1.62)	2.7 (1.53)
Maintenance Wk 44 ^{b,c}	2.4 (1.49)	2.3 (1.34)
Wk 92 of LTE ^{b,c}	2.7 (2.48)	2.2 (1.60)
Absolute Stool Number =3, % (n)^a		
Induction Wk 0	6.4 (9)	13.3 (19)
Maintenance Wk 0	68.8 (97)	63.6 (91)
Maintenance Wk 44 ^{b,c}	78.0 (110)	80.4 (115)
Wk 92 of LTE ^{b,c}	72.3 (102)	75.5 (108)
Stool Frequency Subscores of 0 or 1, % (n)^a		
Induction Wk 0	12.8 (18)	18.2 (26)
Maintenance Wk 0	80.9 (114)	80.4 (115)
Maintenance Wk 44 ^{b,c}	83.7 (118)	90.2 (129)
Wk 92 of LTE ^{b,c}	79.4 (112)	86.7 (124)
Rectal Bleeding Subscores of 0, % (n)^a		
Induction Wk 0	9.2 (13)	7.0 (10)
Maintenance Wk 0	87.2 (123)	84.6 (121)
Maintenance Wk 44 ^{b,c}	97.2 (137)	90.2 (129)
Wk 92 of LTE ^{b,c}	86.5 (122)	88.8 (127)

a: Pts who underwent dose adjustment were not considered treatment failures.

b: Pts who had an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening UC prior to wk92 visit were considered not to have a Mayo subscore indicating inactive or mild disease from the time of event onward.

c: Pts who had a missing Mayo subscore at a timepoint were considered not to have a subscore indicating inactive or mild disease for that Mayo subscore.

Conclusions: Among pts in the LTE, reductions in stool frequency and rectal bleeding achieved after IV UST induction were maintained through 2 years of UST SC maintenance. These data support the durability of response to UST in UC.