PWE-032

52-WEEK CLINICAL EFFICACY WITH ADALIMUMAB IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS WHO FAILED CORTICOSTEROIDS AND/OR IMMUNOSUPPRESSANTS

doi:10.1136/gut.2011.239301.295

W Reinisch,[1,*] W J Sandborn,[2] A Kumar,[3] P F Pollack,[3] A Lazar,[4] R B Thakkar[3] *[1]Medical University Vienna, Vienna, Austria; [2]Mayo Clinic, Rochester, Minnesota, USA; [3]Abbott, Abbott Park, Illinois, USA; [4]Abbott GmbH & Co. KG, Ludwigshafen, Germany*

Introduction We report week-52 results from an open-label extension that assessed the efficacy and safety of adalimumab (ADA) in anti-TNF–naïve patients with moderately to severely active ulcerative colitis (UC).

Methods Patients were adults with UC (Mayo scores ≥6 points and endoscopic subscores ≥2 points) despite treatment with corticosteroids and/or immunosuppressants. After an 8-week, randomised, placebo-controlled period, patients could enter an open-label extension to receive ADA 40 mg every other week (eow) as maintenance therapy through week 52. Data were analyzed with non-responder imputation (NRI); missing scores and values after adjustment to weekly dosing (for flares/non-response) were imputed as treatment failures. Modified NRI (mNRI) analyses (post-hoc), which did not count patients who dose escalated as failures, and as-observed analyses were also performed.

Results Of 390 patients in the primary analysis population, 360 received open-label ADA eow and 117 had their dosages increased to weekly ADA. Mean/median changes in Mayo (0–12) and partial Mayo (0–9) scores from baseline to week 52 (observed values, N=274) were –5.0/–5.0 and –3.7/–4.0, respectively (all p<0.001). The table 1 summarises rates of clinical remission and other secondary end points at week 52. Remission rates at week 52 were 25.6% (NRI) and 29.5% (mNRI). No deaths or cases of tuberculosis were reported.

Conclusion Treatment with open-label ADA 40-mg eow/weekly generally maintained clinical remission and other efficacy end points in patients with moderately to severely active UC. The safety profile in UC was consistent with the known safety profile of ADA.

Competing interests W. Reinisch Speaker bureau with: Ferring, Conflict with: Abbott, Centocor, UCB, W. Sandborn Grant/Research Support from: Abbott, CentocorOrthoBiotech, UCB, Consultant for: Abbott, CentocorOrthoBiotech, UCB, A. Kumar Conflict with: Abbott, P. Pollack Shareholder with: Abbott, Employee of: Abbott, A. Lazar Shareholder with:

Table 1 PWE-032 Clinical remission and major secondary end points at week 52: all ADA[a]

	NRI (N=390)	mNRI (N=390)	As observed (N=274)
Clinical remission[b], n (%)	**100 (25.6)**	**115 (29.5)**	**115 (42.0)**
Clinical response[c], n (%)	166 (42.6)	209 (53.6)	209 (76.3)
Endoscopy subscore ≤1, n (%)	148 (37.9)	182 (46.7)	182 (66.4)
Rectal bleeding score ≤1, n (%)	185 (47.4)	246 (63.1)	246 (89.1)[d]
Stool frequency score ≤1, n (%)	145 (37.2)	175 (44.9)	175 (63.4)[d]

[a]Pools all randomised groups.
[b]Mayo score ≤2 with no individual subscore >1.
[c]Decrease from baseline in Mayo score ≥3 points and ≥30%, and rectal bleeding subscore 0 or 1 or decrease from baseline ≥1 point.
[d]N=276.

Abbott, Employee of: Abbott, R. Thakkar Shareholder with: Abbott, Employee of: Abbott.

Keywords adalimumab, clinical trial, ulcerative colitis.