CERTOLIZUMAB PEGOL IMPROVES WORK PRODUCTIVITY AND THE ABILITY TO PERFORM DAILY ACTIVITIES IN PATIENTS WITH CROHN’S DISEASE: DATA FROM PRECISE 2

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Introduction: Potential benefits on work productivity of biological therapies for Crohn’s disease (CD) have not been thoroughly assessed. Certolizumab pegol is a Fab’ fragment of a humanised anti-TNF monoclonal antibody, currently in development for the treatment of CD and other autoimmune diseases. The PRECISE 2 maintenance trial reported good efficacy and tolerability for certolizumab pegol 400mg in CD compared with placebo. This analysis investigated the effect of certolizumab pegol on work productivity and daily activity impairment in patients with CD during PRECISE 2.

Methods: Patients with active CD (CD Activity Index (CDAI) score of 220-450 points) who demonstrated a clinical response to induction therapy (subcutaneous certolizumab pegol 400mg, Weeks 0, 2 and 4) at Week 6 were subsequently randomised to receive certolizumab pegol 400mg sc or placebo every 4 weeks from Week 8 to 24. The work productivity and activity impairment (WPAI) questionnaire, a validated instrument that evaluates four dimensions of work productivity and activity impairment, was administered at Weeks 0 and 26. The mean percentage change from Weeks 0 to 26 was calculated for each dimension and compared across treatment groups using Student’s t-test.

Results: Patients receiving certolizumab pegol experienced significantly greater improvement in WPAI scores, for all four dimensions, than those receiving placebo (p<0.001). It is also notable that patients assigned to active treatment missed, on average, 9.9% less work due to CD than those who received placebo (p=0.030).

Conclusions: Certolizumab pegol therapy improved both work productivity and the ability to carry out daily activities of patients with active CD in PRECISE 2. Assuming such benefits persist, treatment with certolizumab pegol may result in an important reduction in absenteeism and improved work-place productivity.

CD-68 POSITIVE CELLS IN BUCCAL MUCOSA AS DIAGNOSTIC MARKER FOR IBD

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Introduction: It is well known that Crohn’s disease (CD) may involve any part of gastrointestinal tract, including oral cavity. The aim of this study, was to determine if there are some microbiological and/or pathohistological changes in apparently normal buccal mucosa that can be a reliable marker for differentiating patients with inflammatory bowel disease (IBD) from healthy population and CD from ulcerative colitis (UC).

Methods: The presence of microaggregates of CD-68 positive cells (immunostained macrophages) at the section from buccal mucosa was investigated (picture 1.). We involved 52 patients with previously clinical and pathohistological diagnosed IBD (30 with CD and 22 patients with UC). The control group was matched for sex and age between IBD patients who were hospitalized for trauma in maxillofacial region and needed surgical approach thru oral cavity. The microaggregates of macrophages in buccal mucosa were found in 17 patients with CD and in 4 patients with UC (p=0.0121).

Results: The microaggregates of immunostained macrophages in buccal mucosa were found in 17 patients with CD and in 4 patients with UC (p=0.0121). In controls there were 3 positive for the respective findings (p=0.0241). The counts of bacteria in saliva or in smear of oral cavity were also measured. There was neither statistic difference in Candida albicans positive between IBD patients and controls nor CD vs. UC patients.

Conclusion: The microaggregates of macrophages were detected in apparently normal buccal mucosa more frequently in patients with CD than in patients with UC and controls. The finding leads us to conclusion that CD-68 positive cells can be helpful marker that can make difference between CD and UC patients, but further studies are necessary.