Treatment of Ulcerative Colitis With Asacol Improved Patient Quality of Life in as Early as Three Weeks, According to New Data Analysis

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Patients with ulcerative colitis (UC) treated with Asacol(R) (mesalamine) delayed-release tablets demonstrated a statistically significant improvement in overall quality of life in as early as three weeks according to a new data analysis by Procter & Gamble Pharmaceuticals, Inc., which provides quantified evidence to support a long-held assumption.

"The goals of UC therapy are to treat active disease and prevent relapse in order to improve quality of life, and now the data tell us that Asacol does, in fact, improve quality of life for patients, as quickly as three weeks from the start of therapy," said lead author E. Jan Irvine, MD, Head, Division of Gastroenterology, St. Michael's Hospital, Toronto, Ontario. The data were presented at the Crohn's and Colitis Foundation's national research and clinical conference, "Advances in the Inflammatory Bowel Diseases."

UC is a form of inflammatory bowel disease (IBD). Asacol is indicated for the treatment of mildly to moderately active UC and for the maintenance of remission of UC. Improved quality of life with Asacol had not previously been evaluated.

This data analysis was based on results from the ASCEND I and II studies -- sponsored by Procter & Gamble Pharmaceuticals. The ASCEND studies were two Phase III, multi-center, double-blind, randomized, active-control, 6-week studies of patients with active UC. Patients received oral Asacol 2.4 g/day, the indicated dose for treatment, in the active control arm. Quality of life was assessed using the Inflammatory Bowel Disease Questionnaire (IBDQ) at baseline, three weeks and six weeks.

The IBDQ is a reliable tool for measuring health-related quality of life in patients with UC. The 32-item questionnaire examines four aspects of patients' lives: bowel symptoms, systemic symptoms, emotional function, and social function. The change in IBDQ score from baseline in each group was assessed. Total IBDQ scores range from 32-224 with a higher score indicating a better quality of life.

The studies included a randomized total of 687 patients, of whom, 349 received Asacol 2.4 g/day and were included in the quality of life analysis. The mean age was 43.1 years; 53.3 percent of patients were female; and mean baseline IBDQ score was 143. Treatment with Asacol provided a significant improvement in the overall IBDQ scores at both three weeks and six weeks (28.3 and 38.1 point improvement respectively, p<0.0001 versus baseline). Additionally, all IBDQ subscores (bowel symptoms, systemic symptoms, emotional health, and social function) were significantly improved at both three weeks and six weeks, p<0.0001 versus baseline.

About Ulcerative Colitis
UC involves inflammation of the lining of the colon and rectum. It varies in clinical severity with patients having mild, moderate or severe disease. Treatment depends on the extent and severity of disease.

UC causes flares followed by periods of remission. During a flare, in which the rectum or colon become inflamed, people experience symptoms such as diarrhea, rectal bleeding, abdominal cramping and an urgent need to go to the bathroom. Flares can vary in duration and intensity. While UC is a lifelong condition, medication may help control flares.

UC affects people of all ages, but is often diagnosed during early adulthood. The causes of this condition are unknown, but may involve heredity, infection or the immune system.

About Asacol(R) (mesalamine) Delayed-Release Tablets 400 mg
Asacol is indicated for the treatment of mildly to moderately active UC (the indicated dosage is two 400 mg tablets tid for 6 weeks) and for the maintenance of remission of UC (the indicated dosage is 1.6 g/day in divided doses).

Asacol was well-tolerated in clinical studies. Overall, the incidence of adverse events with Asacol was comparable to placebo.

In pivotal clinical studies of mildly to moderately active UC, the most frequent adverse events reported for Asacol and placebo, respectively, were headache (35% vs. 36%), abdominal pain (18% vs. 14%), eructation (16% vs. 15%), pain (14% vs. 8%) and nausea (13% vs. 15%); for the maintenance of remission of UC, the most frequent adverse events were headache (50% vs. 50%), rhinitis (42% vs. 36%), diarrhea (35% vs. 50%), abdominal pain (32% vs. 44%) and flatulence (24% vs. 30%).

Asacol is contraindicated in patients with hypersensitivity to salicylates. Caution should be exercised when using Asacol in patients with known renal dysfunction or history of renal disease. It is recommended that all patients have an evaluation of
renal function prior to initiation of Asacol tablets and periodically while on Asacol therapy. As with other mesalamine-containing products, serious adverse events may occur with Asacol. Please visit http://www.pgpharma.com/pi/US-Asacol.pdf for full prescribing information.

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