Asacol Induced Rapid Mucosal Healing in Ulcerative Colitis Patients

Release Date:
Tuesday, May 23, 2006 11:00 am EDT

Terms: P&G Corporate Announcements

Dateline City: LOS ANGELES

A new data analysis shows that Asacol(R) (mesalamine) delayed-release 400 mg tablets (2.4 g/day) and investigational 800 mg mesalamine tablets (4.8 g/day) induced endoscopically measured mucosal healing in patients with moderately active ulcerative colitis (UC). These findings were presented today at the annual Digestive Disease Week meeting, taking place in the Los Angeles Convention Center.

Two treatment groups were analyzed, one given Asacol 2.4 g/day and the other given 4.8 g/day mesalamine. In as early as three weeks, 65 percent of patients taking 4.8 g/day mesalamine experienced mucosal healing. By six weeks, 80 percent of these patients experienced mucosal healing. In the lower dose group, 58 percent of patients experienced mucosal healing at three weeks and 68 percent by six weeks. According to the American College of Gastroenterology guidelines, the goals for treating active UC are to treat symptoms as well as mucosal inflammation.

"With 68 percent of the patients with moderate UC achieving mucosal healing on Asacol 2.4 g/day by six weeks, an additional benefit has been demonstrated in a product that is already proven in efficacy with an excellent safety profile," said lead author, Gary R. Lichtenstein, M.D., professor of medicine and Director of the Center for Inflammatory Bowel Diseases at the Hospital of the University of Pennsylvania in Philadelphia. "Mucosal healing has been a topic of interest in UC lately, now we have evidence that Asacol heals the mucosa" Dr. Lichtenstein said.

The findings were presented in a poster titled "Endoscopically measured mucosal healing of delayed-release oral mesalamine 4.8 g/day versus 2.4 g/day." The analysis pooled data from two Phase III, multi-center, randomized, double-blind, 6-week, controlled studies of similar design (ASCEND I and II). Mucosal healing was defined as endoscopy subscore of 0 or 1. Patients with moderately active UC (defined as a baseline Physician's Global Assessment score of 2) and baseline endoscopy subscore greater than or equal to 2 were included in this analysis. A total of 423 analyzable patients with moderate UC were randomized in the two studies, of which 391 patients met criteria for this analysis.

About Ulcerative Colitis

Ulcerative colitis involves inflammation of the lining of the colon and rectum. It varies in clinical severity with patients having mild, moderate or severe disease and in extent of the colon affected. Treatment depends on the severity of disease. It causes flares followed by periods of remission. During a flare, in which the rectum and/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 ulcerative colitis is a lifelong condition, flares can be managed with medication.

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

About Digestive Disease Week

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 20-25, 2006 at the Los Angeles Convention Center. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit http://www.ddw.org.

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%), and eructation (16% vs 15%); for the maintenance of remission of UC, the most frequent adverse events were headache (50% vs 50%), rhinitis (42% vs 36%), and diarrhea (35% vs 50%).

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.

About Procter & Gamble (NYSE: PG)

Three billion times a day, P&G brands touch the lives of people around the world. The company has one of the strongest portfolios of trusted, quality, leadership brands, including Actonel, Pampers, Tide, Ariel, Always, Whisper, Pantene, Mach3, Bounty, Dawn, Pringles, Folgers, Charmin, Downy, Lenor, Iams, Crest, Oral-B, Duracell, Olay, Head & Shoulders, Wella, Gillette, and Braun. The P&G community consists of almost 140,000 employees working in over 80 countries worldwide. Please visit http://www.pg.com for the latest news and in-depth information about P&G and its brands.

Language:
English

Contact:
Procter & Gamble
Corporate Media Center, +1-866-PROCTER (+1-866-776-2837)
or
Elaine Plummer, +1-513-622-3662

Ticker Slug:
Ticker: PG
Exchange: NYSE