Two New Analyses - Quality of Life and Medication Adherence, Offer Physicians Insights Into Helping Ulcerative Colitis Patients Achieve Optimal Treatment Success

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Separate Sets of Research Show Treatment Improved Quality of Life in as Early as Three Weeks; Patient Adherence to Medication is Multifactorial

Results from analyses looking at factors contributing to successful treatment of ulcerative colitis (UC), were presented at Digestive Disease Week (DDW) this week. Both of these studies were funded by Procter & Gamble (P&G) Pharmaceuticals, Inc. Findings from one study offer new information on improvement of quality of life for UC patients treated with Asacol(R) (mesalamine), which is from a class of agents known as 5-ASAs. A separate study looked to pinpoint factors that contributed to non-adherence to medication in patients treated with agents from the 5-ASA class.

"Everyday, UC patients fight to stay on top of their disease. They want to be able to function as close to normal for them as possible. These results should help emphasize to physicians how effective treatment can improve quality of life," said Michel Farhat, PhD, GI Professional & Scientific Relations, P&G Pharmaceuticals. "Additionally, there may not be just one reason why patients have trouble adhering to their medication, and physicians and patients need to examine all potential factors before choosing a treatment."

Asacol Improved Quality of Life in UC Patients in as Early as Three Weeks

The abstract, "Delayed-release mesalamine significantly improved quality of life (QoL) in Patients with Mildly and Moderately Active Ulcerative Colitis (UC)," evaluated QoL in 687 patients with mildly or moderately active UC in patients treated for six weeks with delayed-release mesalamine Asacol 2.4g (marketed 400mg tablet) daily or 4.8g daily ( investigational 800mg mesalamine tablet). Data from two multicenter, randomized, double-blind, active-controlled trials were combined and analyzed, and found that patients achieved overall improvement in QoL in as early as three weeks from the start of treatment.

Building on this finding, patients who achieved overall clinical improvement at six weeks (the primary endpoint of the study) experienced a significantly greater mean QoL increase compared to patients with no clinical improvement. The primary endpoint, overall clinical improvement, was defined as improvement from baseline at week 6 in Physician Global Assessment score accompanied by an improvement in at least one other clinical parameter (rectal bleeding, stool frequency, patient functional assessment, or sigmoidoscopy) and no worsening in any of the remaining clinical features.

"The ultimate goals of UC therapy are to treat active disease and prevent relapse, in order to improve patients' quality of life," said lead author E. Jan Irvine, M.D., Head, Division of Gastroenterology, St. Michael's Hospital, Toronto, Ontario and Professor of Medicine at the University of Toronto. "These data show that Asacol did, in fact, improve quality of life in mildly and moderately active UC patients, as early as three weeks after starting therapy."

Patient Compliance to 5-ASA Therapy is Multifactorial

The study, "Predictors of 5-ASA Prescription Persistence in Patients with Ulcerative Colitis," sought to identify factors for 5-ASA therapy non-adherence in patients with UC. Of the more than 3,000 UC patients with 5-ASA prescriptions in the database, 1,530 did not refill their prescription at three months. The study identified that the most significant factors in predicting patient non-adherence at three months were gender (men were less compliant than women), psychiatric history (patients with documented psychiatric illness were less compliant) and co-pay (higher co-payments deterred patients from refilling their prescriptions).

"This study not only reaffirms previous research showing that adherence to medication is a critical issue in the treatment of UC, but also demonstrates that the factors involved in patient compliance are multifactorial," said study lead author Sunanda Kane, M.D., Associate Professor of Medicine, Section of Gastroenterology and Nutrition at the University of Chicago. "This information, adds to the pool of knowledge physicians have surrounding UC treatment to help them better understand and treat their patients."
The retrospective cohort study used records of health service utilization from the Thomson Medstat MarketScan Research database. Treatment initiation was defined as 5-ASA use from October 2002 - September 2004 with no 5-ASA use in the prior six months. 5-ASA prescription refill activity was captured at three months. Parameters of interest at index date and 12 months prior were compared between patients who refilled their prescriptions at three months, and those who did not.

In addition to its well-known consumer brands, P&G develops and markets a gastrointestinal platform that extends across pharmaceutical and over-the-counter brands. One of these brands is Asacol Delayed-Release Tablets, available by prescription only, which is indicated for ulcerative colitis (UC), a form of inflammatory bowel disease (IBD).(1) Additional information about Asacol can be found by visiting www.Asacol.com.

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. Serious adverse events may occur with Asacol. Please visit http://www.pgpharma.com/pi/US-Asacol.pdf for full prescribing information.

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(R), Asacol(R), Enablex(R), Prilosec OTC(R), Metamucil(R), Fibersure(R), Align(R), Pepto-Bismol(R), Vicks(R), ThermaCare(R), PUR(R), Crest(R) and Oral-B(R). The P&G community consists of over 135,000 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.

About Digestive Disease Week (DDW)

Digestive Disease Week (DDW)(R) 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 (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 19-24, 2007 in Washington, DC. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology.


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