New Analysis of Study Data Shows That Asacol(R) (Mesalamine) Delivers Rapid Symptom Relief for Ulcerative Colitis Patients

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Symptom resolution results based on stringent endpoint of clinical remission is more clinically relevant, beneficial to patients

An analysis of data to be presented tomorrow at the American College of Gastroenterology (ACG) Annual Scientific Meeting found that Asacol, dosed at 2.4 g/day, provided rapid symptom relief in patients with mildly to moderately active ulcerative colitis (UC). The analysis was based on data pooled from the ASCEND I and II studies, which included 349 patients dosed at 2.4 g/day. Results indicated that the median time to clinical remission was 26 days. A subgroup of patients with mild UC saw a median time to clinical remission even faster, in 14 days. Time to clinical remission was defined as the first day of three consecutive days of resolution of both rectal bleeding and increased stool frequency.

The time to clinical remission endpoint utilized in this analysis represents a rigorous requirement. "If one only looks at the first day of symptom relief, the patient could relapse on the next day," said Dan Present, MD, co-author of the study and Clinical Professor of Medicine at the Mount Sinai Medical Center. "Sustained symptom resolution is what I want to provide my patients. Therefore, data supporting three consecutive days of complete resolution of symptoms is important to me."

A recent survey, published in Inflammatory Bowel Diseases, found that 97 percent of patients surveyed reported that a highly effective treatment is very important when choosing a treatment for UC.1) "Speed of relief is a significant component of efficacy, and is a key treatment goal in active UC," said Dr. Present. "The data demonstrating speed to clinical remission further support Asacol as a trusted UC therapy that helps patients treat UC flares by rapidly bringing their symptoms under control."

Additional Study Details

The purpose of this analysis was to evaluate time to clinical remission in patients with mildly and moderately active UC receiving 2.4 g/day of Asacol delayed-release tablets. Data from the 2.4 g/day active control arms of the ASCEND I and II studies was assessed. Clinical remission was defined as resolution (score=0) of both rectal bleeding (RB) and stool frequency (SF). Resolution of RB was defined as the absence of visible blood in stools. Resolution of SF was defined as a patients return to his/her normal number of stools per day. Patients had to have symptoms at baseline to be included in the analysis. Time to clinical remission was defined as the first day of three consecutive days of complete symptom resolution based on symptoms recorded by patients daily through an Interactive Voice Response System (IVRS).

In the two studies, 349 patients received 2.4 g/day. Based on IVRS data, the median time to clinical remission in patients with mildly and moderately active UC was 26 days (95% CI 24, 33).

About Ulcerative Colitis (UC)

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 a delayed-release oral mesalamine tablet 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 is a non-steroidal medication that belongs to the class of agents known as 5-aminosalicylic acids (5-ASAs) and is the number one most prescribed oral sulfa-free 5-ASA therapy for UC with more than 20 million prescriptions written since its introduction in 1992.2,3)
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 www.Asacol.com/pdf/us-asacol.pdf for full prescribing information. Additional information about Asacol can be found by visiting www.Asacol.com.

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(1) Loftus, EV. Inflamm Bowel Dis. 2006; 12:1107-1113.

(2) This information is an estimate derived from the use of information under license from IMS National Prescription Data for the 12-month period ending February 2007. IMS expressly reserves all rights, including rights of copying, distribution and republication.


Language:
English

Contact:
P&G Pharmaceuticals, Inc.
Barbara Miller, +1-513-622-4350
or
Manning, Selvage & Lee PR for P&G
Danielle Brown, +1-212-468-3194

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