Study Data Show Asacol(R) (Mesalamine) is Effective in Treating All Extents of Ulcerative Colitis Including Isolated Proctitis

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Findings reinforce the benefits of Asacol for ulcerative colitis patients

Data from two Phase III clinical trials support that Asacol, an oral, non-steroidal medication that belongs to the class of agents known as 5-aminosalicylic acids (5-ASAs), is an effective and well-tolerated treatment for patients with all extents of ulcerative colitis (UC), including isolated proctitis. The results showed that patients with isolated proctitis who took Asacol, dosed at 2.4 g/day for six weeks, experienced significant improvement as early as three weeks, and sustained improvement at six weeks, of UC symptoms. At six weeks 83 percent of patients had improvement in rectal bleeding, 75 percent had mucosal healing and 57 percent had reduced stool frequency. These data were presented today at the Crohn's & Colitis Foundation of America's (CCFA) National Research and Clinical Conference/Sixth Annual Advances in the Inflammatory Bowel Diseases (IBD) Meeting.

Treatment of UC patients is impacted by the fact that most patients would choose oral therapy over other routes of delivery, such as rectal therapy(1). However, approximately 30 percent of UC patients have isolated proctitis(2), a condition that is thought to be a challenge to treat with oral medication alone.

“A common misperception among physicians is that all oral 5-ASA studies have included proctitis patients; however, this is not the case,” says Dr. Seymour Katz, Clinical Professor of Medicine at the New York University School of Medicine. “The positive findings from these Asacol studies reassure physicians that Asacol is one treatment that has been proven effective throughout the entire colon, even the most distal portions, and should help guide physicians how to effectively treat their UC patients.”

Additional Study Details

Data from two Phase III, multi-center, randomized, double-blind, 6-week, active-controlled studies of similar design (ASCEND I&II) were combined and analyzed. The aim of this analysis was to evaluate the efficacy of oral delayed-release Asacol dosed at 2.4 g/day to treat active UC flares in patients with isolated proctitis.

This analysis included data from the Asacol 2.4 g/day active control arms of these two studies. Of the 349 patients who received Asacol 2.4 g/day, 63 had isolated proctitis, 205 had left-sided disease (proctosigmoiditis and left-sided colitis) and 81 had pancolitis. To be included in the studies, patients had to have mildly to moderately active UC and a baseline score in either or both the rectal bleeding and stool frequency clinical assessments of at least 1 (based on 4-point scale, 0-3). Patients were prohibited from taking rectal therapies and were only treated with Asacol. Clinical analyses included improvement in rectal bleeding and stool frequency defined as a decrease from baseline of at least 1 point/grade. Mucosal healing was also evaluated in patients who had a baseline endoscopy subscore of 2 or greater. Mucosal healing was defined as an endoscopy subscore of 0 or 1.

After six weeks, 76 percent of patients in both the left-sided disease and pancolitis groups experienced an improvement in rectal bleeding. Additionally, 74 percent of patients with left-sided disease experienced an improvement in stool frequency and 70 percent achieved mucosal healing. Of the patients with pancolitis, 70 percent had improvement of stool frequency and 71 percent experienced mucosal healing. Asacol 2.4 g/day was well-tolerated, with adverse events and laboratory findings consistent with those described in previous trials and the current prescribing information.

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.
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 to be taken three times a day for six 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 5-ASA therapy for UC, with more than 20 million prescriptions written since its introduction in 1992(3,4).

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 percent vs. 36 percent), abdominal pain (18 percent vs. 14 percent), eructation (16 percent vs. 15 percent), pain (14 percent vs. 8 percent) and nausea (13 percent vs. 15 percent); for the maintenance of remission of UC, the most frequent adverse events were headache (50 percent vs. 50 percent), rhinitis (42 percent vs. 36 percent), diarrhea (35 percent vs. 50 percent), abdominal pain (32 percent vs. 44 percent) and flatulence (24 percent vs. 30 percent).

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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