Open-label extension of TOUCHSTONE study of ozanimod showed continued symptom improvement through week 44 of the extension

Safety and tolerability were consistent with previous studies of ozanimod

VIENNA--(BUSINESS WIRE)-- Celgene International Sàrl, a wholly owned subsidiary of Celgene Corporation (NASDAQ:CELG), today announced that data from the open-label extension of the TOUCHSTONE phase 2 clinical trial of ozanimod in patients with moderate to severe ulcerative colitis are to be presented at the United European Gastroenterology Week (UEGW) in Vienna, Austria and at the American College of Gastroenterology (ACG) Annual Scientific Meeting in Las Vegas. Ozanimod is an investigational selective S1P 1 and 5 receptor modulator.

“Since ulcerative colitis is a chronic condition, patients are looking for treatments that can help them over the long term,” said Dr. William Sandborn, M.D., Professor of Medicine and Chief, Division of Gastroenterology and Director, University of California San Diego Inflammatory Bowel Disease Center. “These encouraging findings suggest that continued treatment with ozanimod shows evidence of durable efficacy with an acceptable safety profile.”

TOUCHSTONE evaluated the efficacy and safety of 0.5 mg and 1 mg doses of ozanimod compared with placebo after eight weeks of treatment (induction phase) in 197 patients with moderate to severe active ulcerative colitis. Patients who achieved a clinical response at week 8 continued with their original treatment through week 32 in a maintenance phase. The primary endpoint was the proportion of patients in remission at week 8. Secondary endpoints were: the proportion of patients achieving a clinical response, the proportion of patients with mucosal improvement and the change from baseline in Mayo score. Previously reported results showed TOUCHSTONE met its primary endpoint and secondary endpoints with statistical significance for patients on the 1 mg dose of ozanimod versus placebo.

TOUCHSTONE participants in all three treatment arms entered the open-label extension if they did not respond to treatment after the induction phase, relapsed during the maintenance phase or completed the maintenance phase (170 of the 197 patients). The objective of the open-label extension phase is to evaluate the long-term efficacy and safety of daily ozanimod 1 mg.

During the extension period, treatment with ozanimod 1 mg resulted in a decrease in mean partial Mayo Score (pMS) in all treatment arms. For patients who had been treated with ozanimod 0.5 mg during the double-blind portion of the study and were switched to ozanimod 1 mg for the extension phase of the study, mean pMS score decreased from 4.5 at entry into the extension period to 1.7 at week 44. For patients who had been initially treated with ozanimod 1 mg and stayed on ozanimod 1 mg for the extension phase of the study, mean pMS score decreased from 3.3 at entry into the extension period to 1.9 at week 44. For patients who had been initially treated with placebo and were switched to ozanimod 1 mg for the extension phase of the study, mean pMS score decreased from 4.6 at entry into the extension period to 1.7 at week 44.

Treatment with ozanimod 1 mg in the extension phase also showed a decrease in the proportion of patients with rectal bleeding and moderate or severe diarrhea.

During the safety follow-up in the extension phase, which ranged from 44 weeks to over two years, the most common adverse events (> 2.0 percent) noted in the extension period were ulcerative colitis flare (5.9 percent), upper respiratory tract infection (4.1 percent), anemia (3.5 percent), nasopharyngitis (3.5 percent), transaminase elevation (3.5 percent), back pain (2.9 percent), arthralgia (2.4 percent) and headache (2.4 percent). No notable cardiac, ophthalmologic or infectious TEAEs were observed.

Serious adverse events occurred in 16 of 170 patients (9.4 percent). Serious AEs occurring in two or more patients were anemia (1.2 percent) and ulcerative colitis flare (2.4 percent).

Alanine aminotransferase and aspartate aminotransferase elevations more than three times the upper limit of normal
occurred in 4 of 170 patients (2.4 percent); all elevations were asymptomatic, less than five times the upper limit of normal, transient and resolving during ongoing treatment.

"Findings from this extension study at week 44 showed improvements in efficacy measures for patients who took ozanimod throughout both the blinded study and the extension," said Scott Smith, President, Celgene Inflammation & Immunology. "We recognize the strong need for innovative treatments that help patients with inflammatory bowel disease achieve durable results. We are committed to advancing additional transformational oral treatment options for these patients."

About the Trial

TOUCHSTONE is a phase 2, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of ozanimod (also known as RPC1063) with placebo in patients with moderate to severe active ulcerative colitis. A total of 197 patients were randomized and treated once daily with 1 mg ozanimod (n=67), 0.5 mg ozanimod (n=65) or placebo (n=65) for 8 weeks (the induction phase). The primary endpoint was the proportion of patients in remission (Mayo score ≤2, no subscore > 1) at week 8. Secondary endpoints were the proportion of patients achieving clinical response (reduction in Mayo score of ≥3 and ≥30 percent with a decrease in the rectal bleeding score of ≥1 or a rectal bleeding score ≤1), proportion of patients with mucosal improvement (endoscopy score ≤1) and the change in Mayo score. Safety assessments included ECG, Holter monitoring, pulmonary function testing, optical coherence tomography and adverse events.

For the maintenance phase, patients who achieved a clinical response at week 8 continued with their original treatment through week 32. In the open-label extension phase, all patients (n=170) were treated with ozanimod 1 mg. The week 44 visit was completed by 131 patients.

About Ozanimod

Ozanimod is a novel, oral, selective sphingosine 1-phosphate 1 and 5 receptor modulator in development for immune-inflammatory indications including inflammatory bowel disease and relapsing multiple sclerosis. Treatment with S1P receptor modulators is believed to work by interfering with S1P signaling and preventing a certain subtype (ccr7+) of lymphocytes (a type of white blood cell) from exiting the lymph nodes and contributing to tissue inflammation.

Ozanimod is an investigational compound that is not approved for any use in any country.

About Ulcerative Colitis

Ulcerative colitis is a chronic, relapsing condition triggered by an abnormal, prolonged immune response that creates long-lasting inflammation and ulcers (sores) in the mucosa (lining) of the large intestine (colon). Symptoms usually develop over time, rather than suddenly. The disease can be debilitating and can sometimes lead to life-threatening complications. Ulcerative colitis is the most common form of inflammatory bowel disease worldwide. About one in every 198 people in Europe, and one in every 402 people in North America, have ulcerative colitis. In 2004, 2.1 million prescriptions were written to treat ulcerative colitis, and 716,000 ambulatory care visits were related to the disease. In 2010, there were 107,000 hospitalizations due to ulcerative colitis.

About Celgene

Celgene International Sàrl, located in Boudry, Switzerland, is a wholly-owned subsidiary and international headquarters of Celgene Corporation. Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global pharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans,” “will,” “outlook” and similar expressions. Forward-looking statements are based on management’s current plans, estimates, assumptions and projections, and speak only as of the date they are made. Celgene undertakes no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond Celgene’s control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in Celgene’s Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission.
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