Phase 2 Maintenance Data from Oral Ozanimod TOUCHSTONE Study in Ulcerative Colitis Presented at UEG Week

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BOUDRY, Switzerland--(BUSINESS WIRE)--Celgene International Sàrl, a wholly owned subsidiary of Celgene Corporation (NASDAQ: CELG), today presented results from the maintenance phase of the TOUCHSTONE phase 2 clinical trial of Ozanimod, an investigational compound, in patients with moderate to severe ulcerative colitis at the United European Gastroenterology (UEG) Week in Barcelona, Spain. This abstract was awarded a UEG Week Top Abstract Prize, which is given to the top five abstracts submitted to UEG Week.

The TOUCHSTONE trial 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 ulcerative colitis. 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 in the 8-week induction phase.

The abstract, titled A RANDOMIZED, DOUBLE-BLEND, PLACEBO-CONTROLLED TRIAL OF OZANIMOD, AN ORAL S1P RECEPTOR MODULATOR, IN MODERATE TO SEVERE ULCERATIVE COLITIS: RESULTS OF THE MAINTENANCE PERIOD OF THE TOUCHSTONE STUDY, can be viewed [here](#). The week 32 results from TOUCHSTONE were previously presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting in Honolulu, October 16-21.

"Data from the maintenance phase, together with those from the induction phase of the TOUCHSTONE trial of Ozanimod are promising and warrant further investigation in patients with ulcerative colitis," 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.

"Patients with ulcerative colitis currently need new therapies," said Scott Smith, President, Celgene Inflammation & Immunology. "Based on these results, and as part of our commitment to bringing innovative medicines to this patient community, we look forward to continued study of this novel therapeutic approach for ulcerative colitis in phase 3 trials."

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% 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 AEs.

For the maintenance phase, patients who achieved a clinical response at week 8 continued with their original treatment through week 32.

About Ozanimod

Ozanimod is a small molecule sphingosine 1-phosphate 1 and 5 receptor modulator in development for immune-inflammatory indications including relapsing multiple sclerosis and inflammatory bowel disease. Treatment with S1P receptor modulators is believed to work by interfering with S1P signaling and blocks the response of lymphocytes (a type of white blood cell) to exit signals from the lymph nodes, sequestering them within the nodes. The result is thought to be a downward modulation of circulating lymphocytes and anti-inflammatory activity by inhibiting cell migration to sites of 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](http://www.celgene.com). Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn and YouTube.

**About Receptos**

Receptos Inc., located in San Diego, CA, is a wholly-owned subsidiary and research division of Celgene Corporation.

**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 Corporation 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 other reports filed with the U.S. Securities and Exchange Commission.

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