October 27, 2017

Efficacy and Safety Results from First Phase III Trial of Oral Ozanimod (SUNBEAM™) Versus an Active Comparator in Relapsing Multiple Sclerosis Presented at MSParis2017 - 7th Joint ECTRIMS - ACTRIMS Meeting

Ozanimod demonstrated superiority versus interferon beta-1a (Avonex®) in reducing annualized relapse rates and MRI brain lesions

Incidence of adverse events and serious adverse events similar to Avonex

Safety and tolerability profile consistent with prior phase II studies

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced detailed results from the phase III SUNBEAM™ trial evaluating the efficacy and safety of ozanimod, a novel, oral, selective sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator, versus a first-line treatment, Avonex® (interferon beta-1a) (IFN), in patients with relapsing multiple sclerosis (RMS). The results were presented at the MSParis2017 - 7th Joint ECTRIMS - ACTRIMS Meeting, which is being held in Paris, October 25-28, 2017.

"People living with relapsing multiple sclerosis are still in need of additional oral treatment options with favorable benefit-risk profiles," said Giancarlo Comi, M.D., Professor, Department of Neurology, Università Vita-Salute San Raffaele, Chairman, Department of Neurology and Neurorehabilitation, Scientific Institute, Milan, Italy, and an author of the abstract. "The SUNBEAM data support the potential of ozanimod as a new therapeutic option in this patient population."

The SUNBEAM study evaluated two doses (1 mg and 0.5 mg) of oral ozanimod in 1,346 patients with RMS in 20 countries treated for at least one year. A significant reduction in annualized relapse rate (ARR) was demonstrated for ozanimod 1 mg (ARR=0.18, $p < 0.0001$) and for ozanimod 0.5 mg (ARR=0.24, $p=0.0013$) compared with IFN (ARR=0.35) over an average of 13.6 months of treatment.

Ozanimod demonstrated a significant reduction in new or enlarging T2 lesions over one year for 1 mg (48 percent, $p < 0.0001$) and 0.5 mg (25 percent, $p=0.0032$) compared with IFN. A significant reduction in gadolinium-enhanced MRI lesions at 1 year was also demonstrated for ozanimod 1 mg (63 percent, $p < 0.0001$) and ozanimod 0.5 mg (34 percent, $p=0.0182$) compared with IFN.

In SUNBEAM, a reduction in brain volume loss, a measure associated with MS disease progression, was observed for the ozanimod dose groups compared with the IFN group. Whole brain volume loss was reduced by 33 percent with the 1 mg dose of ozanimod (median percent change from baseline to 1 year: -0.39, nominally significant $p < 0.0001$) and by 12 percent in the 0.5 mg group (-0.50, $p=0.06$) versus IFN (-0.57) at one year.

In a pre-specified pooled analysis of the SUNBEAM and RADIANCE™ Part B studies, ozanimod did not reach statistical significance compared with IFN in the time to 3-month confirmed disability progression. A very low rate of disability progression was observed across all treatment groups. In SUNBEAM, the number of patients with 3-month confirmed disability progression by the end of the study was 13 (2.9 percent) in the ozanimod 1 mg group and 17 (3.8 percent) in the ozanimod 0.5 mg group compared with 19 (4.2 percent) in the IFN group.

Treatment-emergent adverse events (AEs) were experienced by 59.8 percent of patients on ozanimod 1 mg, 57.2 percent on ozanimod 0.5 mg and 75.5 percent on IFN. The most common AEs in ozanimod-treated patients were nasopharyngitis, headache and upper respiratory infection. AEs of alanine aminotransferase increased were low, transient and generally resolved without study drug discontinuation. The overall incidences of serious AEs were similar across treatment arms (ozanimod 1 mg, 2.9 percent; 0.5 mg, 3.5 percent; IFN, 2.5 percent). The percentages of patients who discontinued study drug due to AEs were 2.9 percent for ozanimod 1 mg, 1.5 percent for 0.5 mg and 3.6 percent for IFN.

No second degree or higher atrioventricular blocks were reported. Infection rates were similar across treatment arms; serious infection rates were low and similar across treatment arms, with no serious opportunistic infections in ozanimod-

treated patients. The overall safety and tolerability profile was consistent with results from the previously reported phase II RADIANCE Part A study in RMS.

Detailed results from the second phase III trial of ozanimod (RADIANCE Part B) will be presented tomorrow, October 28 at 9:42 a.m. CEST in Hall A.

About SUNBEAM™

SUNBEAM is a pivotal, phase III, multicenter, randomized, double-blind, double-dummy, active-controlled trial evaluating the efficacy, safety and tolerability of two doses of oral ozanimod (1 mg and 0.5 mg) against weekly intramuscular interferon beta-1a (Avonex®) over a 12-month treatment period. The study included 1,346 people living with RMS across 152 sites in 20 countries.

The primary endpoint of the trial was ARR during the treatment period. The secondary MRI endpoints were number of new or enlarging hyperintense T2-weighted brain MRI lesions over 12 months, number of gadolinium-enhanced brain MRI lesions at month 12 and percent change from baseline in brain volume at month 12.

An analysis of the time to onset of 3-month confirmed disability progression was pre-specified using pooled data from both the SUNBEAM and RADIANCE Part B phase III trials.

About RADIANCE™

RADIANCE Part B is a pivotal, phase III, multicenter, randomized, double-blind, double-dummy, active-controlled trial evaluating the efficacy, safety and tolerability of two doses of oral ozanimod (1 mg and 0.5 mg) against weekly intramuscular interferon beta-1a (Avonex®) over a 24-month treatment period. The study included 1,320 people living with RMS across 147 sites in 21 countries.

The primary endpoint of the trial was ARR over 24 months. The secondary MRI endpoints were number of new or enlarging hyperintense T2-weighted brain MRI lesions over 24 months, number of gadolinium-enhanced brain MRI lesions at month 24 and percent change from baseline in brain volume at month 24.

An analysis of the time to onset of 3-month confirmed disability progression was pre-specified using pooled data from both the SUNBEAM and RADIANCE Part B phase III trials.

About Ozanimod

Ozanimod is a novel, oral, selective, sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator in development for immune-inflammatory indications including relapsing multiple sclerosis, ulcerative colitis and Crohn's disease. Selective binding with S1PR1 is believed to inhibit a specific sub set of activated lymphocytes from migrating to sites of inflammation. The result is a reduction of circulating T and B lymphocytes that leads to anti-inflammatory activity. Importantly, immune surveillance is maintained.

Selective binding with S1PR5 is thought to activate specific cells within the CNS. This has the potential to enhance remyelination and prevent synaptic defects. Ultimately, neurological damage may be prevented.

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

About Multiple Sclerosis

Multiple sclerosis (MS) is a disease in which the immune system attacks the protective myelin sheath that covers the nerves. The myelin damage disrupts communication between the brain and the rest of the body. Ultimately, the nerves themselves may deteriorate — a process that's currently irreversible. Signs and symptoms vary widely, depending on the amount of damage and the nerves affected. Some people living with MS may lose the ability to walk independently, while others experience long periods of remission during which they develop no new symptoms. Multiple sclerosis affects approximately 400,000 people in the U.S. and approximately 2.5 million people worldwide.

Relapsing multiple sclerosis (RMS) is characterized by clearly defined attacks of worsening neurologic function. These attacks — often called relapses, flare-ups or exacerbations — are followed by partial or complete recovery periods (remissions), during which symptoms improve partially or completely with no apparent progression of disease. RMS is the most common disease course at the time of diagnosis. Approximately 85 percent of patients are initially diagnosed with RMS, compared with 10-15 percent with progressive forms of the disease.

About Celgene

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 next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. 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. We undertake 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 our 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 our Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission.

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