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Efficacy and Safety Results from Second Phase III Trial (RADIANCE™ Part B) of Oral Ozanimod 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 at two years

Incidence of adverse events and serious adverse events similar to Avonex

Safety and tolerability profile consistent with prior phase II and III studies

Global registrations on track to begin by end of 2017

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced detailed results from the phase III RADIANCE™ Part B 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 MSParis2017 - 7th Joint ECTRIMS - ACTRIMS Meeting, which was held in Paris, October 25-28, 2017.

"As physicians, we recognize the increased need for additional effective and safe therapeutic options for use earlier in the treatment of RMS," said Bruce Cree, M.D., Ph.D., M.A.S., Associate Professor of Clinical Neurology at the University of California San Francisco Weill Institute for Neurosciences and an author of the abstract. "Based on these data, ozanimod has the potential to provide RMS patients and their physicians a novel oral option for treating this debilitating illness."

The RADIANCE Part B study evaluated two doses (1 mg and 0.5 mg) of oral ozanimod compared with IFN in 1,320 patients with RMS in 21 countries treated for two years. A significant reduction in annualized relapse rate (ARR) was demonstrated for ozanimod 1 mg (ARR=0.17, $p < 0.0001$) and for ozanimod 0.5 mg (ARR=0.22, $p=0.0167$) compared with IFN (ARR=0.28) over two years of treatment.

A significant reduction in new or enlarging T2 lesions was demonstrated for ozanimod 1 mg (42 percent, $p < 0.0001$) and 0.5 mg (34 percent, $p=0.0001$) compared with IFN. A significant reduction in gadolinium-enhanced MRI lesions was also demonstrated for ozanimod 1 mg (53 percent, $p=0.0006$) and ozanimod 0.5 mg (47 percent, $p=0.0030$) compared with IFN.

In RADIANCE Part B, a reduction in brain volume loss, a measure associated with MS disease progression, was observed for both ozanimod doses compared with IFN. Whole brain volume loss was reduced by 27 percent with the 1 mg dose of ozanimod (median percent change from baseline to 2 years: -0.69, nominally significant $p < 0.0001$) and by 25 percent in the 0.5 mg group (-0.71, nominally significant $p < 0.0001$) versus IFN (-0.94) at two years.

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. Of the 2,659 patients assessed, the number of patients with 3-month confirmed disability progression by the end of the study was 67 (7.6 percent) patients in the ozanimod 1 mg group and 58 (6.5 percent) in the ozanimod 0.5 mg group compared with 69 (7.8 percent) in the IFN group. In RADIANCE Part B, the number of patients with 3-month confirmed disability progression by the end of the study was 54 (12.5 percent) in the ozanimod 1 mg group and 41 (9.3 percent) in the ozanimod 0.5 mg group compared with 50 (11.3 percent) in the IFN group.

Treatment-emergent adverse events (AEs) were experienced by 75 percent of patients on ozanimod 1 mg, 74 percent on ozanimod 0.5 mg and 83 percent on IFN. Most AEs were mild; the most common AEs across all treatment groups were nasopharyngitis, headache, alanine aminotransferase increased, influenza-like illness, hypertension, gamma-glutamyl transferase increased, pharyngitis and urinary tract infection. AEs of alanine aminotransferase increased were low, transient and generally resolved without study drug discontinuation. The overall incidences of serious AEs were low and similar across treatment arms (ozanimod 1 mg, 6.5 percent; 0.5 mg, 7.1 percent; IFN, 6.4 percent). The percentages of patients who discontinued study drug due to AEs were 3.0 percent for ozanimod 1 mg, 3.2 percent for ozanimod 0.5 mg and 4.1

percent for IFN.

No second degree or higher atrioventricular blocks were observed. Serious cardiac AEs were 0.0 percent for ozanimod 1 mg, 0.7 percent for ozanimod 0.5 mg and 0.5 percent for IFN. Infection rates were similar across treatment arms; serious infection rates were low and similar across treatment arms, with no serious opportunistic infections.

The overall safety and tolerability profile was consistent with results from the previously reported phase II RADIANCE Part A and phase III SUNBEAM studies in RMS.

"Given the totality of the data for ozanimod, we believe that the benefit-risk profile supports pursuing ozanimod as a potential new oral therapeutic option and look forward to filing regulatory submissions in the U.S. by the end of 2017 and in the EU in the first half of 2018," said Terrie Curran, President, Celgene Inflammation and Immunology.

Celgene will host a live webcast from the MSParis2017 - 7th Joint ECTRIMS - ACTRIMS Meeting today at 12 p.m. EDT (6 p.m. CEST). Members of Celgene's management team and clinical investigators will discuss the data presentations at the ECTRIMS Meeting. The webcast will be available in the Investor Relations section of the Company's website at www.celgene.com.

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 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 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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