October 19, 2017

Phase III Efficacy and Safety Data for Oral Ozanimod in Relapsing Multiple Sclerosis to Be Presented at MSParis2017 - 7th Joint ECTRIMS - ACTRIMS Meeting

Ozanimod highlighted in two oral presentations detailing results from phase III SUNBEAM™ and RADIANCE™ trials in RMS

Additional clinical and non-clinical poster presentations will further characterize the profile of ozanimod

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that new data on the efficacy and safety of ozanimod, a novel, oral, selective, sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator, in relapsing multiple sclerosis (RMS) were accepted for the MSParis2017 - 7th Joint ECTRIMS - ACTRIMS Meeting, which is being held in Paris, October 25-28, 2017.

"Our strong presence at this year's meeting and the breadth of data being presented on ozanimod highlight our commitment to bringing forth ozanimod as a potential novel, oral therapeutic option for people with multiple sclerosis," said Terrie Curran, President, Celgene Inflammation and Immunology.

Full results from the phase III SUNBEAM™ and RADIANCE™ Part B studies evaluating two doses of oral ozanimod compared with Avonex® (interferon beta-1a) (IFN) in people with RMS will be presented as an oral and a late-breaking oral presentation, respectively.

Abstracts at a Glance

Oral Presentations:

Abstract #A-858-0029-00786; Friday, October 27, 2017, 2:52 p.m. - 3:04 p.m. CET / 8:52 a.m. - 9:04 a.m. EDT
Ozanimod demonstrates efficacy and safety in a phase 3 trial of relapsing multiple sclerosis (SUNBEAM); G. Comi
Location: Parallel Session 13: Update on relapsing-remitting MS management, Hall A

Abstract #A-858-0000-02736; Saturday, October 28, 2017, 9:42 a.m. - 9:54 a.m. CET / 3:42 a.m. - 3:54 a.m. EDT
Ozanimod vs interferon β-1a: clinical and MRI results of RADIANCE part B - a 2-year phase 3 trial in relapsing multiple sclerosis; J.A. Cohen
Location: Parallel Session 16: Late Breaking News, Hall A

Poster Presentations:

Abstract #A-858-0032-00784; Thursday, October 26, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Cardiac safety of ozanimod in a QT/QTc trial and a phase 2 trial in RMS; G. Comi
Location: Poster Session 1, Poster Exhibition

Abstract #A-858-0015-00126; Thursday, October 26, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Effect of ozanimod (RPC1063) on action potential parameters in adult human Purkinje fibres; N. Abi-Gerges
Location: Poster Session 1, Poster Exhibition

Abstract #A-858-0027-00623; Thursday, October 26, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Lower baseline levels of vitamin D are associated with a higher risk of new lesion development in patients with relapsing multiple sclerosis; G.J. Opiteck
Location: Poster Session 1, Poster Exhibition

Abstract #A-858-0029-00488; Thursday, October 26, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Ozanimod does not impact cytotoxic T lymphocyte function in vitro demonstrating differentiation from fingolimod's activity on SET-PP2A; D. Guimond
Location: Poster Session 1, Poster Exhibition

Abstract #A-858-0032-00482; Thursday, October 26, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Ozanimod has an improved nonclinical safety profile relative to fingolimod; S. Meier-Davis
Location: Poster Session 1, Poster Exhibition

Abstract #A-858-0032-00480; Friday, October 27, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Comparison of reproductive and juvenile nonclinical findings between ozanimod and fingolimod; S. Meier-Davis
Location: Poster Session 2, Poster Exhibition

Abstract #A-858-0015-00626; Friday, October 27, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Fingolimod activates the 5-HT1A receptor in S1P3R/5-HT1A heterooligomer complexes in vivo; K. Dines
Location: Poster Session 2, Poster Exhibition

Abstract #A-858-0000-02744; Friday, October 27, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Ozanimod demonstrates preservation of brain volume at 1 and 2 years in two phase 3 trials of relapsing multiple sclerosis (SUNBEAM and RADIANCE); D.L. Arnold
Location: Poster Session 2, Poster Exhibition

Abstract #A-858-0030-00783; Friday, October 27, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Ozanimod (RPC1063) is potentially neuroprotective through direct activity on Th1 and Th17 T cell expansion and migration, monocyte migration and microglia expansion; D. Guimond
Location: Poster Session 2, Poster Exhibition

Abstract #A-858-0030-00485; Friday, October 27, 2017, 3:30 p.m. - 5:00 p.m. CET / 9:30 a.m. - 11:00 a.m. EDT
Ozanimod (RPC1063) is potentially neuroprotective through direct CNS effects; K.R. Taylor Meadows
Location: Poster Session 2, Poster Exhibition

E-posters

Abstract #A-858-0032-00490
Lack of clinically meaningful changes in cardiac effects from co-administration of ozanimod and a beta-blocker or a calcium channel blocker; J.Q. Tran

Abstract #A-858-0027-00781
Ozanimod (RPC1063) reduces the plasma biomarker neurofilament light chain in preclinical rodent models of multiple sclerosis; K.R. Taylor Meadows

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 (1.0 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 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 (1.0 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 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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