



April 24, 2018

New Analyses from Pivotal Phase III Trials of Oral Ozanimod in Relapsing Multiple Sclerosis To Be Presented at the 2018 American Academy of Neurology Annual Meeting

Reductions in annualized relapse rates shown in pivotal trials with ozanimod were consistent in subgroups including baseline disability, gadolinium-enhanced lesion status and prior exposure to disease-modifying therapies versus interferon beta-1a (Avonex®)

Ozanimod showed effects on cortical grey matter volume and thalamic volume

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced additional phase III data analyses evaluating the efficacy and safety of ozanimod, a novel, oral, selective sphingosine 1-phosphate 1 (S1P₁) and 5 (S1P₅) receptor modulator, versus interferon beta-1a (IFN β-1a) (Avonex®) in patients with relapsing multiple sclerosis (RMS). These additional data analyses from the SUNBEAM™ and RADIANCE™ Part B trials are being presented at the 2018 American Academy of Neurology (AAN) Annual Meeting in Los Angeles, April 21-27, 2018.

"These new analyses of the pivotal SUNBEAM and RADIANCE Part B trials provide robust evidence that supports ozanimod as a potential new therapeutic option in a broad spectrum of patients with relapsing multiple sclerosis," said Ludwig Kappos, M.D., Chair of the Department of Neurology at the University of Basel and a presenter of one of the abstracts. "The reduction in annualized relapse rates with ozanimod in these trials was consistent across a range of pre-specified subgroups versus interferon beta-1a."

The phase III SUNBEAM and RADIANCE Part B studies evaluated two doses of oral ozanimod (1 mg and 0.5 mg ozanimod HCl) compared with IFN β-1a in patients with RMS. In the new analyses, several pre-specified subgroups, including disability severity at baseline (EDSS ≤3.5 vs. EDSS > 3.5), presence of gadolinium-enhanced lesions at baseline and prior treatment with disease-modifying therapies, were assessed. Data from these analyses, to be presented in an oral session on April 25, show dose-dependent effects of ozanimod on annualized relapse rates (ARR) versus IFN β-1a across these subgroups that were consistent with the primary endpoint of both SUNBEAM and RADIANCE Part B.

A pair of poster presentations on April 24 examined reductions in brain volume loss, a measure associated with multiple sclerosis (MS) disease progression, for ozanimod compared with IFN β-1a. As previously reported for SUNBEAM at one year and for RADIANCE Part B at two years, whole brain volume loss was reduced relative to IFN β-1a for both the 1 mg dose of ozanimod and the 0.5 mg dose. For both doses, all comparisons were nominally significant.

Additional data in the presentations from exploratory endpoints examined volume loss of specific segments of the brain. Increasing evidence suggests that disease-related damage to grey matter is of major importance in MS. The data analyses to be presented show reductions in cortical grey matter loss and thalamic volume loss are consistent with the reductions in whole brain volume loss seen in SUNBEAM at one year for ozanimod compared with IFN β-1a. Likewise, reductions in cortical grey matter loss and thalamic volume loss are consistent with the reductions in whole brain volume loss seen in RADIANCE Part B at two years.

In the clinical trials, adverse reactions that occurred in at least 5 percent of patients in either ozanimod treatment group, with at least a 1 percent difference greater than the IFN β-1a group, were nasopharyngitis, headache, increased alanine aminotransferase, upper respiratory tract infection, hypertension, increased gamma-glutamyltransferase, pharyngitis and urinary tract infections.

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

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 (0.92 mg and 0.46 mg, equivalent to 1 mg and 0.5 mg

ozanimod HCl, respectively) 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 included the 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 (0.92 mg and 0.46 mg, equivalent to 1 mg and 0.5 mg ozanimod HCl, respectively) 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 included the 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 (S1P₁) and 5 (S1P₅) receptor modulator in development for immune-inflammatory indications including relapsing multiple sclerosis, ulcerative colitis and Crohn's disease.

Selective binding with S1P₁ is believed to inhibit a specific subset 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 S1P₅ is thought to activate specific cells within the central nervous system (CNS). This has the potential to enhance remyelination (when the body is able to repair damaged myelin after inflammation is reduced) and prevent synaptic defects. Ultimately, neurological damage may be prevented.

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. Approximately 85 percent of patients with MS have the relapsing form of the disease, 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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