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Celgene Announces Positive Results from RADIANCE, the Second Pivotal Phase III Trial of Oral Ozanimod in Patients with Relapsing Multiple Sclerosis

Study met the primary endpoint of annualized relapse rate (ARR) and key secondary MRI endpoints of T2 and GdE lesions, compared to interferon (IFN) β-1a (Avonex®); a very low rate of disability progression observed across the three treatment groups in the pooled analysis; disability endpoint not met

Safety and tolerability consistent with prior phase II and III studies

New Drug Application submission to the U.S. Food and Drug Administration planned by end of 2017

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that its phase III RADIANCE trial, evaluating the efficacy and safety of ozanimod, an investigational oral, selective S1P 1 and 5 receptor modulator, in patients with relapsing multiple sclerosis (RMS), met the primary endpoint in reducing annualized relapse rate (ARR), compared to weekly interferon (IFN) β-1a (Avonex®).

RADIANCE evaluated two doses (0.5 mg and 1 mg) of oral ozanimod, with patients treated for two years. The trial enrolled 1,313 RMS patients in 21 countries. Both ozanimod 0.5 mg and 1 mg doses demonstrated statistically significant and clinically meaningful reductions in the primary endpoint of ARR and the key secondary endpoints of the number of new or enlarging T2 MRI lesions over 24 months of treatment compared to Avonex and the number of gadolinium-enhancing MRI lesions at 24 months of treatment compared to Avonex®.

In a pre-specified pooled analysis of the time to confirmed disability progression in both the RADIANCE and SUNBEAM phase III trials, a very low rate of disability progression was observed across the three treatment groups, and ozanimod did not reach statistical significance compared to Avonex®. Additionally, both doses of ozanimod demonstrated statistically significant reductions in brain atrophy compared to Avonex® in each phase III trial.

The overall safety and tolerability profile was consistent with results from the recently completed phase III SUNBEAM RMS trial and previously reported phase II trials.

"The results of the phase III RADIANCE trial confirm the data observed in SUNBEAM and are consistent with the long-term phase II RADIANCE trial," said Bruce Cree, MD, Ph.D., Associate Professor of Neurology, Multiple Sclerosis Center, University of California, San Francisco. "The significant effects seen with ozanimod on relapse and MRI outcomes, including brain volume loss, coupled with the safety and tolerability profile observed in the two phase III trials, represent an exciting advancement for a disease which needs additional oral therapies with favorable benefit-risk profiles."

"We are excited by the results seen to-date across both pivotal trials, which further validated ozanimod's promising benefit-risk profile relative to current therapies," said Terrie Curran, President of Celgene Inflammation and Immunology. "We plan to begin submitting global registration dossiers by the end of the year to bring this oral therapy to patients with relapsing multiple sclerosis."

Further analyses of the RADIANCE trial are ongoing. In February 2017, Celgene announced positive top-line results from the second active comparator phase III, SUNBEAM, in RMS. Detailed results from the RADIANCE and SUNBEAM trials will be presented at an upcoming medical congress. A New Drug Application submission to the U.S. Food and Drug Administration, based on the combined SUNBEAM and RADIANCE trials for RMS, is expected by the end of 2017.

About RADIANCE

RADIANCE 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 (0.5 mg and 1 mg) against weekly intramuscular interferon beta-1a (Avonex®) over a 24 month treatment period. The study included 1,313 RMS patients across 147 sites in 21 countries.

The primary endpoint of the trial is ARR over 24 months. The key secondary endpoints are: the number of new or enlarging hyperintense T2-weighted brain MRI lesions over 24 months and the number of GdE brain MRI lesions 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 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 (0.5 mg and 1 mg) against weekly intramuscular interferon beta-1a (Avonex®) over a 24 month treatment period. The study included 1,346 RMS patients across 152 sites in 20 countries.

The primary endpoint of the trial was ARR during the treatment period. The key secondary endpoints were: the number of new or enlarging hyperintense T2-weighted brain MRI lesions over 12 months and the number of GdE brain MRI lesions at month 12.

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 receptors 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 receptors is believed 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 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 with severe multiple sclerosis 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.

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, and there is no apparent progression of disease. RMS is the most common disease course at the time of diagnosis. Approximately 85 percent of people are initially diagnosed with relapsing multiple sclerosis, compared with 10-15 percent with progressive forms of the disease.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical 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. 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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