Celgene Corporation (NASDAQ:CELG) today announced that the Company has submitted a New Drug Application to the U.S. Food and Drug Administration (FDA) for ozanimod for the treatment of adults with relapsing forms of multiple sclerosis (RMS). Ozanimod is an oral, sphingosine 1-phosphate (S1P) receptor modulator, which binds with high affinity selectively to S1P subtypes 1 (S1P₁) and 5 (S1P₅).

The pivotal efficacy and safety data provided in the application result from the SUNBEAM™ and RADIANCE™ Part B phase 3, multicenter, randomized, double-blind, double-dummy, active-controlled trials.

“New oral treatment options with differentiated profiles like ozanimod are needed to help address an unmet need for people with relapsing forms of MS,” said Jay Backstrom, M.D., Chief Medical Officer for Celgene. “With concurrent applications in the U.S. and EU, we look forward to advancing this promising medicine through the regulatory review process to provide a new option for the treatment of RMS in 2020.”

Earlier this month, the Company also submitted a Marketing Authorization Application to the European Medicines Agency for adults with relapsing-remitting multiple sclerosis.

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

About SUNBEAM™
SUNBEAM is a pivotal, phase 3, 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®) for at least 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 annualized relapse rates (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 whole brain volume at month 12. Cortical grey and thalamic volume changes were also prospectively assessed versus active comparator.

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 3 trials.
About RADIANCE™
RADIANCE Part B is a pivotal, phase 3, 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 150 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 whole brain volume at month 24. Cortical grey and thalamic volume changes were also prospectively assessed versus active comparator.

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 3 trials.

About Ozanimod
Ozanimod is an oral, sphingosine 1-phosphate (S1P) receptor modulator, which binds with high affinity selectively to S1P subtypes 1 (S1P₁) and 5 (S1P₅). Ozanimod causes lymphocyte retention in lymphoid tissues. The mechanism by which ozanimod exerts therapeutic effects in multiple sclerosis is unknown, but may involve the reduction of lymphocyte migration into the central nervous system.

Ozanimod is in development for immune-inflammatory indications including RMS, ulcerative colitis and Crohn's disease.

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. MS 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 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, including factors related to the proposed transaction between Bristol-Myers Squibb and Celgene, such as, but not limited to, the risks that: management’s time and attention is diverted on transaction related issues; disruption from the transaction make it more difficult to maintain business, contractual and operational relationships; pending legal proceedings or any future litigation instituted against Bristol-Myers Squibb, Celgene or the combined company could delay or prevent the proposed transaction; and Bristol-Myers Squibb, Celgene or the combined company is unable to retain key personnel.

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