CELGENE CORP /DE/

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 17, 2017

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	001-34912	22-2711928
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

86 Morris Avenue, Summit, New Jersey	07901
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (908) 673-9000

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01 OTHER EVENTS

On February 17, 2017, Celgene Corporation issued a press release announcing certain results of its phase 3 SUNBEAM trial, evaluating the efficacy and safety of ozanimod, an investigational oral, selective S1P 1 and 5 receptor modulator, in patients with relapsing multiple sclerosis. Attached hereto and incorporated herein by reference as Exhibit 99.1 is the press release announcement.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

Exhibit 99.1 – Press Release dated February 17, 2017

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELGENE CORPORATION

Date: February 17, 2017

By: /s/ Peter N. Kellogg
Peter N. Kellogg
Executive Vice President and
Chief Financial Officer
(principal financial and accounting officer)

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated February 17, 2017

EXHIBIT 99.1

CELGENE ANNOUNCES POSITIVE RESULTS FROM PHASE III SUNBEAM TRIAL OF ORAL OZANIMOD IN PATIENTS WITH RELAPSING MULTIPLE SCLEROSIS

Study met its primary endpoint in reducing annualized relapse rate (ARR) and measured secondary endpoints, compared to interferon (IFN) β-1a (Avonex ®)

Safety and tolerability consistent with phase II studies

Confirmatory phase III RADIANCE trial data expected in Q2 of 2017

SUMMIT, N.J. – (FEBRUARY 17, 2017) — Celgene Corporation (NASDAQ: CELG) today announced that its phase III SUNBEAM 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 ®).

SUNBEAM evaluated two orally administered treatment doses (0.5 mg and 1 mg) of ozanimod, with patients treated for at least one year. The randomized phase III trial enrolled 1,346 RMS patients in 20 countries.

Top-line data show that both the ozanimod 1 mg and 0.5 mg treatment arms demonstrated statistically significant and clinically meaningful improvements compared to Avonex ® for the primary endpoint of ARR and the measured secondary endpoints of the number of gadolinium-enhancing MRI lesions and the number of new or enlarging T2 MRI lesions at month 12. As agreed to in the Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration, a pre-specified analysis on the time to onset of disability progression will be conducted using pooled results from both the SUNBEAM and RADIANCE phase III trials.

The overall safety and tolerability profile was consistent with results from previously reported phase II RMS (RADIANCE) and phase II ulcerative colitis (TOUCHSTONE) trials.

“The safety and efficacy results from SUNBEAM are consistent with the long-term results from the phase II trial (RADIANCE). These data add to the growing body of evidence supporting the use of ozanimod as a disease modifying therapy for relapsing forms of multiple sclerosis,” said Bruce Cree, Associate Professor of Neurology, Multiple Sclerosis Center, Department of Neurology, University of California San Francisco. “We look forward to the continued study of ozanimod as well as presentation of the full results of the phase III trial at an upcoming international scientific meeting.”

“People living with multiple sclerosis need additional therapies and we are pleased that oral ozanimod showed meaningful improvements across primary and measured secondary endpoints in this study,” said Scott Smith, President of Celgene Inflammation and Immunology. “We look forward to data from the confirmatory phase III RADIANCE trial in the second quarter as we advance toward planned regulatory submissions by year-end.”

About SUNBEAM
SUNBEAM is a phase III multicenter, randomized, double-blind, double-dummy, active-controlled study assessing the efficacy, safety and tolerability of two orally administered doses of ozanimod (0.5 mg and 1 mg) against weekly intramuscular interferon beta-1a (Avonex ®) over a minimum of a 12-month treatment period. The study included 1,346 RMS patients across 152 sites in 20 countries.

The primary endpoint of the active comparator trial is ARR during the treatment period. The measured secondary endpoints are: 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. The time to onset of disability progression as defined by a sustained worsening in EDSS of 1.0 points or more, confirmed after 3 months and 6 months, will be analyzed as part of a pre-specified pooled analysis of SUNBEAM and RADIANCE data.

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 . 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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