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Celgene to Acquire Impact Biomedicines, Adding Fedratinib to Its Pipeline of Novel Therapies for Hematologic Malignancies

- *Fedratinib is a highly selective JAK2 kinase inhibitor that is being evaluated for myelofibrosis and polycythemia vera*
- *Fedratinib demonstrated clinical improvement in a phase III trial with treatment-naïve myelofibrosis patients and in a phase II trial with myelofibrosis patients resistant or intolerant to ruxolitinib*
- *A New Drug Application (NDA) submission for fedratinib in myelofibrosis is planned for mid-2018*

SUMMIT, N.J. & SAN DIEGO--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) and Impact Biomedicines today announced the signing of a definitive agreement in which Celgene will acquire Impact Biomedicines, which is developing fedratinib for myelofibrosis and polycythemia vera. Under the terms of the agreement, Celgene will pay approximately $1.1 billion upfront and up to $1.25 billion in contingent payments based on regulatory approval milestones for myelofibrosis. Additional future payments for regulatory approvals in additional indications and sales-based milestones are also possible.

Fedratinib, a highly selective JAK2 kinase inhibitor, was evaluated in 877 patients across 18 clinical trials. In a randomized, placebo-controlled, phase III pivotal trial (JAKARTA-1) for patients with treatment-naïve myelofibrosis, fedratinib demonstrated statistically significant improvements in the primary and secondary endpoints of splenic response and total symptom score, respectively. In an exploratory subgroup analysis, these improvements were observed regardless of a patient's baseline platelet count.

A multi-center, single-arm phase II trial (JAKARTA-2) evaluated fedratinib in myelofibrosis patients who were found to be resistant or intolerant to ruxolitinib (Jakafi®), a JAK1/JAK2 inhibitor. In this second-line setting, fedratinib demonstrated clinically meaningful improvements in splenic response and total symptom score.

As previously reported, JAKARTA-2 was stopped prematurely due to a clinical hold placed on the fedratinib program by the U.S. Food and Drug Administration (FDA) after potential cases of Wernicke's encephalopathy (WE) were reported in eight out of 877 patients receiving one or more doses (less than one percent of treated patients). The FDA removed the clinical hold in August 2017.

Based on the reported benefit risk profile of fedratinib from the JAKARTA-1 and JAKARTA-2 clinical trials, regulatory applications in myelofibrosis are planned beginning in the middle of 2018.

"Myelofibrosis is a disease with high unmet medical need as the number of patients who are ineligible for or become resistant to existing therapy continues to increase," said Nadim Ahmed, President, Hematology and Oncology for Celgene. "We believe fedratinib is uniquely positioned as a potential treatment for myelofibrosis and it provides strategic options for us to build leadership in this disease with luspatercept and other pipeline assets."

"We launched Impact Biomedicines and based on our thorough review of the data, fedratinib presents a compelling risk benefit profile in both treatment-naïve patients and patients who are resistant or intolerant to other JAK2 therapies," said Dr. John Hood, Chief Executive Officer of Impact. "We believe Celgene is the ideal organization to follow through on our mission of maximizing fedratinib's potential for patients with myelofibrosis."

Deal Terms

Under the terms of the agreement, Celgene will make an upfront cash payment of approximately $1.1 billion. In addition, Impact Biomedicines' shareholders are eligible to receive contingent payments based on regulatory approval and sales-based milestones. The maximum aggregate amount payable for regulatory approval milestones is $1.4 billion relating to approvals for myelofibrosis and other indications. Starting from global annual net sales of $1.0 billion, aggregate tiered sales-based milestone payments could total a maximum of $4.5 billion if global annual net sales exceed $5.0 billion.

Credit Suisse acted as financial advisor and Hogan Lovells acted as legal counsel to Celgene on the transaction. PJT Partners acted as exclusive financial advisor and Latham & Watkins acted as exclusive legal counsel to Impact Biomedicines on the transaction. The acquisition is subject to customary closing conditions and applicable waiting period under the Hart Scott Rodino Antitrust Improvements Act. The transaction is expected to close in the first quarter of 2018.

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.

About Impact Biomedicines

Impact Biomedicines is pioneering the development of life changing treatments for patients with complex cancers. The Company's pipeline is centered around fedratinib, a highly selective oral small molecule JAK2 kinase inhibitor that is being developed initially for the treatment of myelofibrosis (MF) and polycythemia vera (PV). Impact was financed by Medicxi and Oberland Capital.

Forward-Looking Statement

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 Securities and Exchange Commission.

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