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Celgene's announcement of the acquisition of Impact Biomedicines positions Celgene to challenge the market share of Incyte & Novartis' JAK1/2 inhibitor Jakafi (ruxolitinib), the first and only JAK inhibitor approved by the FDA for myelofibrosis, according to GlobalData , a leading data and analytics company.

On January 7th 2018, Celgene and Impact Biomedicines announced the signing of a definitive agreement in which Celgene will acquire Impact Biomedicines, which is developing its sole clinical candidate, fedratinib, a highly selective JAK2 kinase inhibitor for myelofibrosis and polycythemia vera (PV).

Volkan Gunduz, PhD, Senior Healthcare Analyst at GlobalData , comments: "With a new drug application for fedratinib expected in mid-2018 and backed by ample clinical efficacy data in first- and second-line treatment of myelofibrosis, GlobalData anticipates that the deal will quickly bring Celgene to the center stage in this treatment space."

Initially owned by Sanofi, fedratinib had an extensive clinical development program encompassing myelofibrosis, PV, essential thrombocytopenia (ET), and solid tumors. Despite the promising clinical efficacy, the occurrence of potential cases of Wernicke's encephalopathy (WE) in eight out of 877 patients receiving fedratinib, resulted in a clinical hold on the fedratinib program in 2013 and subsequent transfer of the rights of the candidate from Sanofi to Impact Biomedicines.

The FDA hold was not lifted until August 2017 and was a major setback to the clinical development of fedratinib, significantly delaying its commercialization, providing more time to Incyte and Novartis to further strengthen the position of Jakafi, which has been marketed in the US for myelofibrosis since 2011.

Dr. Gunduz continues: "Despite having fallen behind, GlobalData anticipates that fedratinib will pose a significant threat to Jakafi's market share in myelofibrosis for a number of reasons. The lack of an effective standard of care for patients who are progressing on or intolerant to Jakafi and the encouraging clinical efficacy of fedratinib in a similar patient population in the JAKARTA-2 trial indicates that fedratinib will readily be adopted in the second-line treatment of

myelofibrosis.

“The activity of fedratinib in Jakafi-resistant patients could provide a rationale for opting for a more selective JAK inhibitor in the front-line setting to provide more durable responses and long-term benefit.”

In addition, while spleen responses with fedratinib were independent of JAK2 mutational status in the JAKARTA trial, a trend for higher responses to Jakafi appeared in the COMFORT-I trial in patients with the JAK2V617 mutation versus those without the mutation ($p = 0.07$). Further validation of this observation could carve up a significant portion from the treatment-naïve patient pool for treatment with fedratinib as mutations in JAK2 occur in approximately 50% of patients in myelofibrosis.

Confirmation of nuances in clinical efficacy will help to differentiate the late comer fedratinib from the already established Jakafi in the myelofibrosis market. Unlike Impact Biomedicines, Celgene’s commercial experience and strong presence in oncology and hematology will result in the robust uptake of fedratinib in the myelofibrosis space following its prospective launch in early 2019, according to GlobalData.