10 December 2020
EMA/CHMP/636661/2020
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Inrebic

fedratinib

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Inrebic[2], intended for the treatment of primary myelofibrosis and of myelofibrosis secondary to polycythaemia vera or essential thrombocythaemia. The applicant for this medicinal product is Celgene Europe BV.

Inrebic will be available as 100-mg capsules. The active substance in Inrebic is fedratinib, a protein kinase inhibitor (ATC code: L01XE57E) . Its antineoplastic activity is linked to the selective inhibition of the Janus associated kinases (JAKs) involved in the signalling mediation of a number of cytokines and growth factors that are important for haematopoiesis and immune function.

The benefits with Inrebic are its ability to reduce the size of the spleen by at least 35% and to treat other symptoms in adults with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), and myelofibrosis following polycythaemia vera or essential thrombocythaemia. The most common side effects are diarrhoea, nausea, vomiting, thrombocytopenia, anaemia and bleeding.

The full indication is:

> Inrebic is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are JAK inhibitor naïve or who have been treated with ruxolitinib.

Inrebic should be prescribed by physicians experienced in the administration of anti-cancer agents.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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