9 November 2023
EMA/CHMP/483198/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Omjjara

momelotinib

On 9 November 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Omjjara[2], intended for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate-to-severe anaemia who have primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis.

The applicant for this medicinal product is Glaxosmithkline Trading Services Limited.

Omjjara will be available as 100 mg, 150 mg and 200 mg film-coated tablets. The active substance of Omjjara is momelotinib, an antineoplastic protein kinase inhibitor (ATC code: Not yet assigned). 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 benefit of Omjjara is its ability to achieve reductions of 50% or greater in disease-related symptoms and 35% or more in spleen volume in the indication population. The most common side effects are diarrhoea, thrombocytopenia and nausea.

The full indication is:

> Omjjara is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

Omjjara should be prescribed by physicians experienced in the in the use of anti-cancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product

[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 an 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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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.