23 June 2022
EMA/CHMP/587767/2022
Committee for Medicinal Products for Human Use (CHMP)

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

# Scemblix

asciminib

On 23 June 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Scemblix[2], intended for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase who have previously been treated with two or more tyrosine kinase inhibitors. The applicant for this medicinal product is Novartis Europharm Limited.

Scemblix will be available as 20 mg and 40 mg film-coated tablets. The active substance of Scemblix is asciminib, an antineoplastic agent (ATC code: L01EA), which is a potent inhibitor of BCR::ABL1 kinase activity.

The benefit of Scemblix is its ability to induce a major molecular response (MMR) at 24 and 96 weeks, as evaluated in a multicentre, randomised, active-controlled and open-label phase III study. The most common side effects are musculoskeletal pain, upper respiratory tract infections, thrombocytopenia, fatigue, headache, arthralgia, increased pancreatic enzymes, abdominal pain, diarrhoea and nausea.

The full indication is:

> Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors.

Scemblix should be prescribed by a physician experienced in the diagnosis and treatment of patients with leukaemia.

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 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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