9 November 2023
EMA/492226/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Krazati

adagrasib

On 9 November 2023, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion recommending the granting of a conditional[2] marketing authorisation for the medicinal product Krazati, intended for the treatment of patients with *KRAS* G12C mutation non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Mirati Therapeutics B.V.

Krazati will be available as 200 mg film-coated tablets. The active substance of Krazati is adagrasib, a *KRAS* G12C (Kirsten rat sarcoma viral oncogene homolog) inhibitor (ATC ode: L01XX77) which covalently and irreversibly binds to the unique cysteine of *KRAS* G12C. Inactivation of *KRAS* G12C by adagrasib blocks tumour cell signalling and survival, inhibits cell growth and promotes apoptosis selectively in tumours harbouring *KRAS* G12C, an oncogenic driver of tumourigenesis.

The benefits of Krazati are its objective response rate and response duration in patients with *KRAS* G12C-mutated NSCLC who had disease progression after receiving prior therapy. The most common side effects are diarrhoea, nausea, vomiting, fatigue, hepatotoxicity and anaemia.

The full indication is:

> KRAZATI as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with *KRAS* G12C mutation and disease progression after at least one prior systemic therapy.

Krazati should be prescribed by physicians experienced in the use of anti-cancer medicinal product.

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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.

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