16 September 2021
EMA/CHMP/210600/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Gavreto

pralsetinib

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Gavreto, intended for the treatment of patients with rearranged during transfection (RET)-fusion positive non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Roche Registration GmbH.

Gavreto will be available as 100 mg hard capsules. The active substance of Gavreto is pralsetinib, a RET receptor tyrosine kinase inhibitor (ATC code: L01EX23), targeting oncogenic RET fusion proteins (KIF5B-RET and CCDC6-RET). Certain point mutations in *RET* or chromosomal rearrangements involving in-frame fusions of *RET* with various partners can result in constitutively activated chimeric RET fusion proteins that can act as oncogenic drivers by promoting cell proliferation of tumour cell lines.

The benefits of Gavreto are its objective response rate and response duration in patients with RET-fusion positive NSCLC as observed in a pivotal phase I/II, open-label, multi-cohort, single-arm study. The most common side effects are anaemia, increased aspartate aminotransferase, neutropenia, constipation, musculoskeletal pain, fatigue, leukopenia, increased alanine aminotransferase and hypertension.

The full indication is:

> Gavreto is indicated as monotherapy for the treatment of adult patients with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

Gavreto should be initiated by a physician experienced in the administration of anticancer medicinal products.

[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 likely to provide comprehensive clinical data at a later stage.

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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.