16 September 2021
EMA/CHMP/338054/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion1 (initial authorisation)

Qinlock
ripretinib

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Qinlock2, intended for the treatment of advanced gastrointestinal stromal tumour (GIST) in patients who have received prior treatment with three or more kinase inhibitors.

The applicant for this medicinal product is Deciphera Pharmaceuticals (Netherlands) B.V.

Qinlock will be available as 50 mg tablets. The active substance of Qinlock is ripretinib, an antineoplastic agent and protein kinase inhibitor (ATC code: L01EX19). Qinlock is designed to selectively block the oncogenic KIT and PDGFRA kinases by blocking their active conformation.

The benefits of Qinlock are its ability to prolong the time until disease progression in patients with GIST. The most common side effects are fatigue, alopecia, nausea, myalgia, constipation, diarrhoea, palmar-plantar erythrodysaesthesia syndrome, weight loss and vomiting.

The full indication is:

Qinlock is indicated for the treatment of adult patients with advanced gastrointestinal stromal tumour (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib.

Qinlock should be prescribed by physicians experienced in the administration of anticancer therapy.

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