28 May 2020
EMA/CHMP/279960/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rozlytrek

entrectinib

On 28 May 2020, 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 Rozlytrek, intended for the treatment of patients whose solid tumours have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, or patients with ROS1-positive advanced non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Roche Registration GmbH.

Rozlytrek will be available as hard capsules (100 and 200 mg). The active substance of Rozlytrek is entrectinib, a tropomyosin receptor kinase (TRK) inhibitor (ATC code L01XE56). It targets cells with constitutive activation of TRK proteins resulting from gene fusions and the proto-oncogene tyrosine-protein kinase ROS (ROS1).

The benefits with Rozlytrek are considered to be its objective response rate and response duration both in patients with locally advanced, metastatic solid tumours that display a NTRK gene fusion who have no satisfactory treatment options, and in patients with ROS1-positive advanced NSCLC. The most common side effects are fatigue, constipation, dysgeusia, oedema, dizziness, diarrhoea, nausea, dysaesthesia, dyspnoea, anaemia, increased weight, increased blood creatinine, pain, cognitive disorders, vomiting, cough, and pyrexia.

The full indication is:

> Rozlytrek as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older, with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion,
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> - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
> - - who have not received a prior *NTRK* inhibitor
> - who have no satisfactory treatment options (see sections 4.4 and 5.1).

[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 more comprehensive data at a later stage.

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Rozlytrek as monotherapy is indicated for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.

It is proposed that Rozlytrek be prescribed by physicians experienced in the use of anticancer therapies.

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.