14 November 2024
EMA/CHMP/490671/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Augtyro

repotrectinib

On 14 November 2024, 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 Augtyro, 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 Bristol-Myers Squibb Pharma EEIG.

Augtyro will be available as 40 mg and 160 mg hard capsules. The active substance of Augtyro is repotrectinib, a tropomyosin receptor kinase (TRK) inhibitor (ATC code L01EX28). It targets cells with constitutive activation of TRK proteins resulting from gene fusions and the proto-oncogene tyrosine-protein kinase ROS (ROS1).

The benefits of Augtyro are its objective response rate and response duration, both in patients with locally advanced, metastatic solid tumours that display a NTRK gene fusion who were or were not previously treated with a NTRK inhibitor and in patients with ROS1-positive advanced NSCLC, as observed in a single arm trial. The most common side effects are dizziness, dysgeusia, constipation, paraesthesia, anaemia, and dyspnoea.

The full indication is:

> Augtyro as monotherapy is indicated for the treatment of adult patients with *ROS1*-positive advanced non-small cell lung cancer (NSCLC).
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> Augtyro as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with advanced solid tumours expressing a *NTRK* gene fusion, and
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> - who have received a prior NTRK inhibitor, or
> - have not received a prior NTRK inhibitor and treatment options not targeting NTRK

[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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provide limited clinical benefit, or have been exhausted

Augtyro should be prescribed by physicians experienced in the use of anticancer medicinal products.

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.