25 July 2019
EMA/CHMP/413258/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vitrakvi

larotrectinib

On 25 July 2019, 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 Vitrakvi, intended for the treatment of patients with solid tumours that display a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. The applicant for this medicinal product is Bayer AG.

Vitrakvi will be available as an oral solution (20 mg/ml) and hard capsules (25 and 100 mg). The active substance of Vitrakvi is larotrectinib, a tropomyosin receptor kinase (TRK) inhibitor (ATC code L01XE53). It targets cells with constitutive activation of TRK proteins resulting from gene fusions.

The benefits with Vitrakvi are considered to be its objective response rate and response duration in patients with locally advanced, metastatic solid tumours that display a NTRK gene fusion and who have no satisfactory treatment options. The most common side effects are fatigue, increased alanine transaminase, dizziness, increased aspartate transaminase, constipation, nausea, anaemia, and vomiting.

The full indication is:

"Vitrakvi as monotherapy is indicated for the treatment of adult and paediatric patients with solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion,

- who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
- who have no satisfactory treatment options (see sections 4.4 and 5.1)."

It is proposed that Vitrakvi be initiated by physicians experienced in the administration 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

[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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