25 April 2024
EMA/CHMP/169495/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rozlytrek

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Rozlytrek. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted a new pharmaceutical form, 50 mg film-coated granules, a new gastroenteral route of administration for the 100 and 200 mg hard capsules, and an extension to an existing indication for film-coated granules and hard capsules, as follows:[2]

Neurotrophic tyrosine receptor kinase (NTRK) gene fusion

> Rozlytrek as monotherapy is indicated for the treatment of adult and paediatric patients ~~12 years of age and~~ older **than 1 month** with solid tumours ~~expressing~~ **that have** 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 not received a prior *NTRK* inhibitor
> - who have no satisfactory treatment options (see sections 4.4 and 5.1).

For information, the full indications for Rozlytrek will be as follows:

> Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion
>
> Rozlytrek as monotherapy is indicated for the treatment of adult and paediatric patients older than 1 month with solid tumours that have a *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 not received a prior *NTRK* inhibitor

[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] New text in bold, removed text as strikethrough

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- who have no satisfactory treatment options (see sections 4.4 and 5.1).

ROS1 gene fusion

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.

Treatment with Rozlytrek should be prescribed by a physician experienced

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.