10 December 2020
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Retsevmo

selpercatinib

On 10 December 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 Retsevmo, intended for the treatment of cancers that display rearranged during transfection (RET) gene alterations: *RET*-fusion positive non-small cell lung cancer (NSCLC), *RET*-fusion positive thyroid cancer and *RET*-mutant medullary-thyroid cancer (MTC). The applicant for this medicinal product is Eli Lilly Nederland B.V.

Retsevmo will be available as 40 and 80 mg hard capsules. The active substance of Retsevmo is selpercatinib, a RET receptor tyrosine kinase inhibitor (ATC code: L01EX22), inhibiting wild-type RET receptor tyrosine kinase and multiple mutated isoforms. Certain point mutations in *RET* or chromosomal rearrangements involving in-frame fusions of *RET* with various partners can result in constitutively activated chimeric RET fusion proteins that can act as oncogenic drivers by promoting cell proliferation of tumour cell lines.

The benefits with Retsevmo are its objective response rate and response duration in patients with RET-fusion positive NSCLC or thyroid cancer and RET-mutant MTC who have been previously treated. The most common side effects are increased aspartate transaminase, increased alanine transaminase, decreased lymphocyte count, dry mouth, increased creatinine, diarrhoea, fatigue, oedema and hypertension.

The full indication is:

> Retsevmo as monotherapy is indicated for the treatment of adults with:
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> – advanced *RET* fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy

[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.

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– advanced *RET* fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib.

Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced *RET* mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib.

Retsevmo should be initiated and supervised by physicians experienced in the use of anti-cancer 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.