21 March 2024
EMA/297074/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Retsevmo

selpercatinib

On 21 March 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 Retsevmo. The marketing authorisation holder for this medicinal product is Eli Lilly Nederland B.V.

The CHMP adopted a new indication as follows:

> Retsevmo as monotherapy is indicated for the treatment of adults with:
>
> – advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted (see sections 4.4 and 5.1).

For information, the full indications for Retsevmo will be as follows:[2]

> Retsevmo as monotherapy is indicated for the treatment of adults with:
>
> – advanced RET fusion positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor
> – **advanced RET fusion positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted (see sections 4.4 and 5.1)**
>
> Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with:
>
> – advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate)
> – advanced RET mutant medullary thyroid cancer (MTC).

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 will be available in all official European Union languages after a decision on this change to

[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**

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the marketing authorisation has been granted by the European Commission.