



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 April 2024  
EMA/CHMP/174588/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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# Rybrevent

## amivantamab

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 Rybrevent. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.

The CHMP adopted a new indication as first-line combination therapy for non-small cell lung cancer.

For information, the full indications for Rybrevent will therefore be as follows:<sup>2</sup>

Rybrevent is indicated:

**-in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating EGFR Exon 20 insertion mutations.**

-as monotherapy for treatment of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations, after failure of platinum-based therapy.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold

