



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2024
EMA/CHMP/525856/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Rybrevant amivantamab

On 14 November 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 Rybrevant. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.

The CHMP adopted a new indication as follows:

Rybrevant is indicated:

- in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations.

For information, the full indications for Rybrevant will be as follows:²

Rybrevant is indicated:

- **in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations.**
- in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced ~~non-small cell lung cancers (NSCLC)~~ with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI).
- in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced 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.

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



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.