SUMMARY

amivantamab

RYBREVANT 350 mg,

concentrate for solution for infusion

Reassessment

Adopted by the Transparency Committee on 5 April 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on reimbursement “as monotherapy in the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based therapy.“

Role in the care pathway?

Despite the low level of proof of the data, and while waiting for new data on efficacy and safety, the Committee considers that RYBREVANT (amivantamab), in monotherapy, is a treatment option in the management of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations, after failure of platinum-based therapy.

Considering the absence of comparative data with acceptable methodological quality, the role of RYBREVANT (amivantamab) in relation to the available therapeutic alternatives (chemotherapy) cannot be specified. It should be emphasized that, in this context, the introduction of this medicinal product into the therapeutic strategy is associated with a greater risk than for medicinal products for which their efficacy has been based on a comparison made using an appropriate methodology.

Transparency Committee's Conclusions

Clinical benefit

- Non-small-cell lung cancer is a severe disease which is life-threatening. The disabling nature of this disease has been corroborated by a patient advocacy group.
- The medicinal product RYBREVANT (amivantamab) has a curative intent.
- Its efficacy/adverse effect ratio is poorly established due to:
  - The absence of robust comparative data while clinically relevant comparators were available;
  - The weakness of its demonstration of efficacy: preliminary data derived from a phase I/II single arm study;
  - Adverse events of grades ≥ 3 occurring in more than 40% of patients.
- There are therapeutic alternatives.
- It is a treatment option in adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations, after failure of platinum-based therapy.

Public health benefits

In view of:

- the severity of non-small-cell lung cancer and its incidence;
- the very partially met medical need;
- the absence of response to the medical need identified (no proven impact to date on morbidity and mortality or on patients' quality of life);
- the absence of data that would allow an assessment of any additional impact on the care pathway and /or life course;

RYBREVANT (amivantamab) is not considered to have an additional public health impact.

In view of all of these elements, the Committee considers that the clinical benefit (CB) provided by RYBREVANT (amivantamab) is low in the MA indication.

The Committee gives a favourable opinion on inclusion on the list of medicinal products approved for the use of communities in the MA indication and at the MA doses.

The Committee conditions that this medicinal product will keep the low CB obtained as part of the reassessment within a maximum time frame of one year from the date of this opinion, based on the submission of the results of the phase III study in the first-line treatment of patients with advanced or metastatic NSCLC with activating EGFR Exon 20 insertion mutations (PAPILLON, results expected on March 31st 2024 at the latest).

Clinical Added Value

In view of:

- the poor demonstration of efficacy of RYBREVANT (amivantamab), based on data from a phase I/II single-arm study;
- the uncertainty regarding the relative efficacy of RYBREVANT, considering the absence of a direct comparison and of the methodological weakness of the indirect comparison provided, in a context where a direct comparison with an available therapeutic alternative with a robust methodology was possible ;
- the safety profile, marked by an incidence of adverse events of grades ≥ 3 noted in 41.8 % of patients;
- the medical need highlighted by experts;

the Transparency Committee considers that in the current state of the dossier, RYBREVANT (amivantamab) provides no clinical added value (CAV V) in the management of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations, after failure of platinum-based therapy.