SUMMARY

mosunetuzumab

LUNSUMIO 1 mg and 30 mg,

solution for dilution for infusion

Initial inclusion

Original French opinion adopted by the Transparency Committee on 22 November 2023

The legally binding text is the original French opinion

Transparency Committee's Conclusions

Clinical Benefit

- Follicular lymphomas are life-threatening slow-growing non-Hodgkin's lymphomas.
- The proprietary medicinal product LUNSUMIO (mosunetuzumab) is a curative medicinal product.
  - The efficacy/adverse effects ratio of mosunetuzumab for this inclusion is poorly defined on account the insufficient level of evidence (phase I/Ib study followed by a multi-cohort phase I/II expansion phase) to determine the effect size of LUNSUMIO (mosunetuzumab) in the MA indication,
  - the lack of robust comparison in relation to the current treatment,
  - a safety profile particularly marked by a proportion of grade ≥3 adverse events of 70%, and serious adverse events reported in approximately half of patients (46.7%) with time-limited follow-up.

Based on the data currently available, LUNSUMIO (mosunetuzumab) has no role in the therapeutic strategy for adult patients presenting with relapsing or refractory follicular lymphoma after at least 2 lines of systemic treatment, in view of the therapies available.

➔ Public health benefit

In view of:

- the seriousness of the life-threatening condition and its incidence;
- the medical need partially met by the alternatives available,
- the lack of response to the identified medical need (lack of evidence of an additional impact on morbidity-mortality and on quality of life),
- the lack of additional impact on delivery of care.

LUNSUMIO (mosunetuzumab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LUNSUMIO 1 mg and 30 mg (mosunetuzumab), solutions for dilution for infusion, is insufficient, in view of the alternatives, to justify public funding in the MA indication.

The Committee disapproves the inclusion of LUNSUMIO 1 mg and 30 mg (mosunetuzumab), solutions for dilution for infusion, in the list of covered drugs for inpatients for the indication and at the MA dosages.