SUMMARY

elranatamab

ELREXFIO 40 mg/mL

solution for injection

First listing

Original French opinion adopted by the Transparency Committee on 24 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Transparency Committee's conclusions

Clinical Benefit

- Multiple myeloma is a blood disease that is almost always fatal, with a short median survival time (3 to 5 years).
- This is a curative medicinal product.
- There are therapeutic alternatives in adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies.
- Pending the results of the phase 3 MagnetisMM-5 trial, the efficacy/adverse effects ratio of ELREXFIO (elranatamab) is high and remains to be confirmed given the absence of comparative data versus the available alternatives in the target population and the insufficient follow-up in terms of safety.
- This is a treatment for adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

➔ Public health benefit

Considering:

- the seriousness of multiple myeloma and its incidence,
- the medical need partially met by available drugs,
- the lack of response to the identified need:
  - the additional impact on morbidity and mortality and on quality of life not demonstrated to date;
  - the absence of an additional impact on the organisation of care;
  - the lack of any expected additional impact on the care pathway in the absence of robust data supporting this;

ELREXFIO (elranatamab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ELREXFIO (elranatamab) 40 mg/mL solution for injection is substantial as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

The Committee issues a favourable opinion for inclusion of ELREXFIO (elranatamab) 40 mg/mL solution for injection in the list of covered drugs for inpatients approved for use as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy, and at the MA dosages.

Clinical Added Value

Considering:

- efficacy data from a non-comparative phase 1/2 trial, with an overall response rate (primary endpoint) of 61% ($CI_{95\%}$ [51.8; 69.6]) in a life-threatening situation;
- the absence of comparative data with an assessment based on a phase 2 study (MagnetisMM-3), the results of which do not enable any robust conclusion to be reached with respect to the therapeutic contribution of elranatamab compared to the available alternatives in adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody;
- limited follow-up on the safety data of elranatamab, with a median follow-up of 14.7 months in the MagnetisMM-3 trial, and a profile marked, in particular, by the frequent occurrence of adverse events of particular interest, of low grade in the majority of cases, such as cytokine release syndrome (CRS) and neurotoxicity (ICANS);
- a partially met medical need with a benefit of having an additional alternative in patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody;
- and pending the results of the phase 3 trial (MagnetisMM-5) comparing elranatamab as monotherapy or in combination with daratumumab versus daratumumab + pomalidomide + dexamethasone in patients with relapsed or refractory multiple myeloma who have received at

least one prior treatment line, and a maximum of three prior treatment lines, including lenalidomide and a proteasome inhibitor;

the Committee deems that, on the basis of currently available data, and pending the results of the phase 3 MagnetisMM-5 trial, **ELREXFIO (elranatamab) as monotherapy provides no clinical added value (CAV V)** in the care pathway for adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

The Committee considers that the ELREXFIO (elranatamab) development plan proposed by the operating company is likely to provide data that will enable its assessment to be updated. It certifies that this development plan is ongoing, incorporating a phase 3 clinical trial (MagnetisMM-5). The results are expected before 31 December 2024 by the Committee, which will reassess this proprietary medicinal product in the light of these data in 2025.