SUMMARY

talquetamab

TALVEY 2 mg/ml and 40 mg/ml

solution for injection

First listing

Original French opinion adopted by the Transparency Committee on 26 June 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the indication "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.
- The efficacy/adverse effects ratio is moderate given a safety profile marked, in particular, by frequent mucocutaneous toxicity (dysgueusia, skin dryness and exfoliation).
- There are therapeutic alternatives in adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies.
- 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 considering:
  - the absence of evidence of an additional impact on morbidity and mortality or quality of life 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;

TALVEY (talquetamab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TALVEY (talquetamab) 2 mg/ml and 40 mg/ml is moderate in the MA indication.

The Committee issues a favourable opinion for inclusion of TALVEY (talquetamab) 2 mg/ml and 40 mg/ml in the list of covered drugs for inpatients approved for use in the MA indication 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 74.1% ($CI_{95\%}$: [66.1%; 81.1%]) for cohort A and 71.7% ($CI_{95\%}$: [63.7%; 78.9%]) for cohort C with a follow-up of 18.8 and 12.7 months respectively in a life-threatening situation;
- the absence of comparative data with an assessment based on a phase 1/2 study (Monumental-1), the results of which do not enable any robust conclusion to be reached with respect to the therapeutic contribution of talquetamab 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 talquetamab 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); frequent mucocutaneous toxicity should be noted for this bispecific antibody;
- 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;

the Committee deems that, on the basis of currently available data, TALVEY (talquetamab) 2 mg/ml and 40 mg/ml 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.