SUMMARY

idecabtagene vicleucel

ABECMA 260 - 500 x 10^6 cells

dispersion for infusion

Indication extension

Original French opinion adopted by the Transparency Committee on 17 July 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in "the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI) and an anti-CD38 antibody and have demonstrated disease progression on the last therapy"

Transparency Committee's conclusions

Clinical Benefit

- Multiple myeloma is a serious, life-threatening blood disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a treatment for adult patients who have received at least two 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 the disease,
- the partially met medical need,
- the partial response to the identified need given:
  - the demonstrated additional impact on morbidity,
  - with no demonstrated impact on overall survival or quality of life,
  - the lack of data enabling assessment of a potential additional impact on the care and/or life pathway,
  - the expected additional impact on the healthcare system, given treatment in an authorised facility,

ABECMA (idecabtagene vicleucel) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ABECMA (idecabtagene vicleucel) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of ABECMA (idecabtagene vicleucel) in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- demonstration in an open-label, randomised phase 3 study of the superiority of ABECMA (idecabtagene vicleucel) compared to the investigator's choice treatment, from five different regimens, in terms of:
  - progression-free survival assessed by an independent review committee according to IMWG criteria: HR = 0.49 [95% CI: 0.38-0.65], with a median of 13.3 months (min-max: 11.8-16.1) in the ABECMA (idecabtagene vicleucel) group, and 4.4 months (min-max: 3.4-5.9) in the investigator's choice treatment group, i.e. a point estimate of the absolute difference of 8.9 months;
  - the overall response rate assessed by an independent review committee according to IMWG criteria: OR = 3.5 [95% CI: 2.1-5.9];

and despite:

- the open-label implementation of the study, having led to possible assessment biases, particularly in terms of assessment of treatment decisions;
- the fact that patients from the investigator's choice treatment group could receive a previously administered treatment (except the last treatment received);
- the lack of clinical relevance of the overall response rate in this context, particularly given the lack of evidence of its transposability to overall survival time or improvement of quality of life;
- the lack of evidence, as the dossier currently stands, of an impact on overall survival, in an advanced disease with an unfavourable prognosis;
- the absence of any formal conclusion that can be drawn based on the quality-of-life findings;
- the safety profile marked, in particular, by significant toxicity;

the Committee deems that ABECMA (idecabtagene vicleucel) provides a minor clinical added value (CAV IV) in the current care pathway, which includes the relevant comparators.