SUMMARY

idecabtagene vicleucel

ABECMA 260-500 x 10^6 cells

dispersion for infusion

Reassessment

Original French opinion adopted by the Transparency Committee on 21 June 2023

The legally binding text is the original French opinion version

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.
- There are therapeutic alternatives.
- 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 the condition,
- the partially met medical need,
- the partial response to the identified need:
  - a 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,

- an expected impact on the healthcare system, given treatment in a qualified 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) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of ABECMA (idecabtagene vicleucel) in the hospital formulary list of reimbursed proprietary medicinal products 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 standard-of-care therapy chosen by the investigator (from five different protocols), in terms of:
  - progression-free survival assessed by an independent committee according to IMWG criteria: HR = 0.49 [CI95%: 0.38-0.65];
  - overall survival rate assessed by an independent committee according to IMWG criteria: OR = 3.5 [CI95%: 2.1-5.9];
- subgroup analyses, performed in patients having received three or four prior therapies, partly corresponding to the current MA population, having suggested similar results, particularly in terms of progression-free survival: HR = 0.49 [CI95%: 0.36-0.67], median of 11.9 months (min-max: 9.2-14.1) in the ABECMA (idecabtagene vicleucel) group, and 4.2 months (min-max: 3.1-5.9) in the investigator's choice treatment group, i.e. a point estimate of an absolute difference of 7.7 months;

and despite:

- the exploratory nature of this subgroup analysis;
- the open-label design of the study;
- the limits of the control group, since patients could have already received prior therapy;
- the lack of evidence of an impact on overall survival, on the basis of currently available data;
- the absence of any formal conclusion that can be drawn based on the quality-of-life findings;
- the absence of data in patient having received more than four prior therapies, despite these being included in the MA indications;
- the safety profile marked by significant toxicity,

the Committee considers that, as the dossier currently stands, ABECMA (idecabtagene vicleucel) provides a minor clinical added value (CAV IV) in the current care pathway, excluding CARVYKTI (ciltacabtagene autoleucel) and bispecific antibodies (teclistamab and elranatanab).