SUMMARY

tabelecleucel

EBVALLO 2.8 × 10^7 – 7.3 × 10^7 cells/ml,

dispersion for injection

Initial inclusion

Original French opinion adopted by the Transparency Committee on 7 June 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) following prior therapy is a severe and rare blood disease that is life-threatening.
- EBVALLO (tabelecleucel) is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a second or later-line treatment in adult and paediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy.

Public health benefit

Considering:

- the seriousness of relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) following prior therapy and its low incidence,
- the unmet medical need,
- the lack of response to the identified need (additional impact on morbidity and mortality and/or on quality of life not demonstrated),
- the absence of an improvement in the care pathway of patients (as the dossier currently stands and given the short follow-up),

EBVALLO (tabelecleucel) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of EBVALLO 2.8 × 10^7 - 7.3 × 10^7 cells/ml (tabelecleucel) dispersion for injection is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of EBVALLO 2.8 × 10^7 - 7.3 × 10^7 cells/ml (tabelecleucel) dispersion for injection 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:

- efficacy data from a non-comparative study, with an overall response rate of 51.7% ($CI_{95\%}$ [32.5; 70.6]) in the Solid organ transplant cohort (including 6 Complete Responses and 9 Partial Responses) and 50% ($CI_{95\%}$ [23; 77]) in the Haematopoietic stem cell transplant population (FAS population – analysed on 05/11/2021);
- results from the indirect comparison between data from the ALLELE study and data from retrospective observational study RS002, suggesting an improvement in overall survival in the treated group (ALLELE study) with an HR=0.37 ($CI_{95\%}$ [0.20; 0.71]);
- the benefit of having access to a medicinal product having been assessed following the failure of prior therapy including rituximab and/or chemotherapy, with a safety profile deemed to be acceptable;

and despite:

- the lack of experience with this therapy, in terms of both efficacy and safety;

the Committee deems that, on the basis of currently available data, and pending the final results of the ALLELE study in particular, EBVALLO 2.8 × 10^7 - 7.3 × 10^7 cells/ml (tabelecleucel) dispersion for injection provides a minor clinical added value (CAV IV) in the current care pathway, i.e. in adult and paediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy.