SUMMARY

brexucabtagene autoleucel
TECARTUS 0.4 - 2 x 10^8 cells
dispersion for infusion
Reassessment at the request of the CT

Adopted by the Transparency Committee on 6 November 2024

Summary of opinion

Favourable opinion for maintenance of reimbursement in the "treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor".

Transparency Committee's conclusions

Clinical Benefit

- Mantle cell lymphoma, is characterised by rapid progression, resistance to treatments and repeated relapses, and is the most aggressive form of indolent non-Hodgkin lymphoma. It is a serious disease that is rapidly life-threatening.
- The proprietary medicinal product TECARTUS (brexucabtagene autoleucel) is a specific curative treatment for mantle cell lymphoma.
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives (see section 5 of this opinion).
- TECARTUS (brexucabtagene autoleucel) is a third or later-line treatment for relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.

Public health benefit

Considering:

- the seriousness of the disease, particularly in relapsed patients or patients refractory to two or more lines of systemic therapy,
- its prevalence,
- the medical need considered to be partially met at this stage of the disease,
- the partial response to the identified need given:
  - an additional impact on morbidity and mortality in the short term, despite the absence of comparative data and uncertainties concerning the indirect comparisons made,
  - the lack of evidence of an impact on quality of life, due to the non-comparative nature of the studies,

    - uncertainties with respect to transposability given the potentially selected population in the ZUMA-2 study,
- the absence of an improvement in the care pathway of patients (as the dossier currently stands and given the short follow-up) due to:
    - hospitalisations, in some cases in the ICU (particularly during the first 7 days following infusion or in the event of the onset of early signs or symptoms of cytokine release syndrome and/or neurological effects),
    - hospitalisation of patients far from their homes,
    - the need to remain close to this hospital for monitoring for at least 4 weeks following infusion,
- and the impact on the organisation of care:
    - accreditation of hospitals based on precise criteria,
    - close coordination between the various departments of centres authorised to treat patients with CART cells (laboratories, internal pharmacy, clinical departments, etc.),

TECARTUS (brexucabtagene autoleucel) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of TECARTUS (brexucabtagene autoleucel) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion in the list of covered drugs for inpatients approved for use in the indication "treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor" and at the MA dosages.

Clinical Added Value

Considering:

- updated data from the ZUMA-2 study, after a median follow-up of 46.4 months, demonstrating a median overall survival of 46.5 months in the ITTm population and 43.9 months in the ITT population, in a life-threatening clinical situation;
- additional experience with respect to the real-world data for TECARTUS (brexucabtagene autoleucel) from the French DESCAR-T registry (27 activated centres, 152 treated patients, median follow-up of 14.2 months since eligibility);

and despite:

- updated data from the ZUMA-2 study, demonstrating differences with respect to real-world use data;
- a median overall survival of 43.9 months in the ZUMA-2 study (median follow-up of 46.4 months) versus 19.8 months for the DESCAR-T registry (median follow-up of 14.2 months);
- a median response duration of **28.2 months versus 12 months** for the DESCAR-T registry;
- uncertainties with respect to the transposability of the findings given the potentially selected population in the ZUMA-2 study;
- uncertainties relative to maintenance of efficacy in the long term;
- the safety profile marked by significant short-term toxicity;

the Committee considers that, on the basis of currently available data, TECARTUS (brexucabtagene autoleucel) provides a minor clinical added value (CAV IV) in terms of efficacy compared to the current treatment of relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.