SUMMARY

glofitamab

COLUMVI 2.5 and 10 mg,

solution for dilution for infusion

Initial inclusion

Original French opinion adopted by the Transparency Committee on 20 December 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Diffuse large B cell lymphoma (DLBCL) is a serious life-threatening condition.
- This is a curative medicinal product.
- Pending the findings of the STARGLO phase III study, the efficacy/adverse effects ratio of COLUMVI (glofitamab) is moderate considering the lack of comparative data in relation to the available alternatives in the target population and the insufficient follow-up in terms of safety.
- There is one therapeutic alternative as a third-line treatment for patients who have failed to respond to or are ineligible for CAR-T therapy; it is the proprietary medicinal product MINJUVI (tafasitamab)
- **COLUMVI (glofitamab) is a therapeutic alternative as a third-line treatment** for relapsed or refractory adult patients after at least two lines of treatment and **who have failed to respond to or are ineligible for CAR-T cell-based treatments**.

Public health benefit

In view of:

- the seriousness and the low prevalence of diffuse large B cell lymphoma,
- the partially met medical need,
- the lack of response to the identified need with **an additional impact of COLUMVI (glofitamab) on morbidity-mortality and on quality of life, for which there is no evidence to date**,
- the lack of evidence of an additional impact on delivery of care in the absence of data,

COLUMVI (glofitamab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of COLUMVI (glofitamab), solution for dilution for infusion at the dosages of 2.5 mg and 10 mg, is:

- **substantial only as monotherapy for the treatment of adult patients with refractory or relapsed diffuse large B cell lymphoma (DLBCL), after at least two lines of systemic treatment and who have failed to respond to or are ineligible for CAR-T cell-based medicinal products;**
- **insufficient to justify public funding in the other clinical contexts of the marketing authorisation.**

The Committee approves the inclusion of COLUMVI (glofitamab), solution for dilution for infusion at the dosages of 2.5 mg and 10 mg, in the list of covered drugs for inpatients only as monotherapy for the treatment of adult patients with refractory or relapsed diffuse large B cell lymphoma (DLBCL), after at least two lines of systemic treatment and who have failed to respond to or are ineligible for CAR-T cell-based medicinal products and at the marketing authorisation dosages,

The Committee disapproves the inclusion of COLUMVI (glofitamab), solution for dilution for infusion at the dosages of 2.5 mg and 10 mg, in the list of covered drugs for inpatients in the other clinical contexts of the MA.

Clinical Added Value

In view of:

- the lack of comparative data and the consideration of two phase II studies (NP30179 and BiCAR), the findings of which do not allow any conclusions to be drawn as to the therapeutic improvement of glofitamab compared to the available alternatives for adult patients with relapsed or refractory DLBCL after at least two lines of systemic treatment;
- limited follow-up on the safety data of glofitamab with a median follow-up of less than 2 years in the NP30179 study and 5.85 months in the BiCAR study and a safety profile particularly marked by the frequent onset of cytokine release syndrome (CRS), grade 3-4 neutropenia and severe infection;
- a partially met medical need with a benefit of having an additional alternative for relapsed or refractory patients after at least two lines of DLBCL treatment;
- and pending the findings of the phase III study comparing glofitamab in association with gemcitabine and oxaliplatin (GemOx) to the R-GemOx (rituximab, gemcitabine, oxaliplatin) regimen, in relapsed or refractory DLBCL patients after at least 1 line of systemic treatment (STARGLO study);

the Committee deems that, based on the current data, and pending the findings of the STARGLO phase III study, **COLUMVI (glofitamab) monotherapy provides no clinical added value (CAV V)** in the therapeutic strategy of adult patients with refractory or relapsed diffuse large B cell lymphoma (DLBCL), after at least two lines of systemic treatment and who have failed to respond to or are ineligible for CAR-T cell-based medicinal products.