OPINION ON MEDICINAL PRODUCTS

polatuzumab vedotin
POLIVY 30 mg and 140 mg,

powder for solution for dilution for infusion

New indication

Adopted by the Transparency Committee on 7 December 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Disapproval of reimbursement of POLIVY (polatuzumab vedotin), in association with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of previously untreated adult diffuse large B cell lymphoma patients.

Role in therapeutic strategy?

The therapeutic management of diffuse large B cell lymphoma (DLBCL) patients involves, as a first-line treatment, an association of chemotherapy with an anti-CD20 monoclonal antibody, namely the R-CHOP regimen, leading to complete remission in two-thirds of cases. Despite existing first-line therapeutic options (immunochemotherapy), 30 to 40% of DLBCL patients have refractory or relapsed disease with an unfavourable prognosis.

Role of the medicinal product

Considering:

- the effect size deemed to be modest on progression-free survival in the POLARIX randomised, double-blind, phase III study, assessing polatuzumab Vedotin in association with rituximab/cyclophosphamide/prednisone/doxorubicin versus the current conventional treatment (R-CHOP): HR = 0.73; $CI_{95\%}$ = [0.57; 0.95] and the medians not yet reached in both groups compared,
- the lack of evidence of superiority in terms of complete response assessed by an independent review committee by PET-CT (ranked secondary outcome measure),
- the lack of evidence of a benefit on overall survival (other ranked secondary outcome measure), on the date of analysis,

- the lack of formal evidence of lower toxicity or of improvement in terms of quality of life considering the exploratory nature of the data,

the Committee deems that, based on the data currently available, POLIVY (polatuzumab vedotin), in association with rituximab/cyclophosphamide/doxorubicin/prednisone, has no role in the therapeutic strategy for the treatment of previously untreated adult diffuse large B cell lymphoma patients.

Committee's conclusions

Clinical Benefit

- Diffuse large B cell lymphoma, in particular in relapsed or refractory patients, not eligible for haematopoietic stem cell transplantation, is a serious life-threatening disease.
- This proprietary medicinal product is a curative treatment of diffuse large B cell lymphoma.
- The efficacy/adverse effect ratio of POLIVY (polatuzumab vedotin) is poorly defined on account of a modest effect size on progression-free survival and the lack of evidence of superiority of POLIVY (polatuzumab vedotin), in association with rituximab/cyclophosphamide/doxorubicin/prednisone versus the current conventional treatment (R-CHOP) in terms of complete response rate and overall survival. Moreover, there is no evidence of a benefit in terms of safety or quality of life.
- Therapeutic alternatives are available (see Section 5. Clinically relevant comparators)
- POLIVY (polatuzumab vedotin), in association with rituximab/cyclophosphamide/doxorubicin/prednisone, has no role in the therapeutic strategy for the treatment of previously untreated adult diffuse large B cell lymphoma patients.

Public health benefit

Considering:

- the severity of diffuse large B cell lymphoma (DLBCL) which is life-threatening in the short term,
- the prevalence and incidence of the disease,
- the medical need partially met by existing alternatives,
- the lack of response to the identified need with the lack of evidence of an additional impact on morbidity-mortality or on quality of life considering the efficacy and safety data available from the POLARIX phase III study,
- the lack of demonstrated impact on delivery of care,

POLIVY (polatuzumab vedotin) in association with rituximab/cyclophosphamide/doxorubicin/prednisone is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of POLIVY (polatuzumab vedotin) is insufficient to justify public funding in view of the marketing authorisation indication and in view of the alternatives available.

The Committee disapproves inclusion in the list of proprietary medicinal products approved for community use for the marketing authorisation indication and dosages.