SUMMARY

zanubrutinib

BRUKINSA 80 mg,

hard capsules

Initial inclusion

Original French opinion adopted by the Transparency Committee on 19 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Marginal zone lymphoma is a rare, life-threatening blood disease.
- This is a curative medicinal product.
- Considering the absence of formal conclusions concerning the effect size of the proprietary medicinal product for progression-free survival and overall survival versus a clinically relevant comparator and a safety profile marked by a certain toxicity, the efficacy/adverse effects ratio has not been adequately established.
- There are therapeutic alternatives (see paragraph 2.2 Management) to treatment with BRUKINSA (zanubrutinib).

It is a treatment option in patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy.

- **Public health benefit**

Considering:

- the seriousness of the disease and its incidence (2,790 new cases of MZL per year in France),
- the inadequately met medical need,
- the lack of additional response to the identified need, on morbidity and mortality as well as quality of life,
- the absence of an additional impact on the organisation of care,
- the lack of impact on the patient's care and/or life pathway,

BRUKINSA (zanubrutinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BRUKINSA (zanubrutinib) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of BRUKINSA (zanubrutinib) in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 100%**

Clinical Added Value

Considering:

- the impossibility of drawing formal conclusions concerning the effect size of the treatment compared to the available alternatives given:
  - the weakness of demonstration of its efficacy (data from a phase II, non-comparative study), with a primary endpoint (overall response rate) that is not the most relevant in the context of an indolent disease;
  - the small size of the study populations (n = 66), associated with a limited median follow-up period;
  - the absence of a formal conclusion that can be drawn from the results for progression-free survival, overall survival and quality of life given their exploratory and non-comparative nature;
- the safety profile of BRUKINSA (zanubrutinib) marked by grade 3 and more adverse reactions in 48.5% of patients and serious adverse reactions reported in 41.1% of patients;
- interpretation limitations surrounding the indirect comparison provided;

the Committee deems that BRUKINSA (zanubrutinib) provides no clinical added value (CAV V) in the current care pathway in adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy.