**SUMMARY**

zanubrutinib

# BRUKINSA 80 mg

**hard capsules**

Indication extension

**Original French opinion adopted by the Transparency Committee on 17 July 2024**

**The legally binding text is the original French opinion version**

## Summary of opinion

**Unfavourable opinion for reimbursement in the indication "BRUKINSA in combination with obinutuzumab is indicated for the treatment of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies"**

# Transparency Committee's conclusions

## Clinical Benefit

- Follicular lymphomas are slow-progressing indolent non-Hodgkin lymphomas that are life-threatening.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio has not been adequately established given:
  - a poor quality of the research evidence, linked, in particular, to a control arm judged to be suboptimal, which cannot eliminate the possibility of a loss of opportunity for patients with refractory or relapsed follicular lymphoma (FL) in third or later-line treatment,
  - the safety profile marked by excess grade 3 adverse effects (62.9% versus 47.9%) and SAEs (40.6% versus 31.0%).
- As the dossier currently stands, BRUKINSA (zanubrutinib) has no role in the care pathway of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies, in view of the therapies available.

### Public health benefit

Considering:

- the seriousness of the condition and its prevalence/incidence,
- the partially met medical need,

- the lack of response to the identified need with the lack of evidence of an additional impact of BRUKINSA (zanubrutinib) on morbidity and mortality or on quality of life, given the exploratory nature of the results for these endpoints in the phase 2 study,
- the lack of evidence of an additional impact on the organisation of care in the absence of data.

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 insufficient to justify public funding cover in the MA indication in view of the available alternatives.**

**The Committee issues an unfavourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.**