SUMMARY

trastuzumab deruxtecan

ENHERTU 100 mg

powder for concentrate for solution for infusion

Indication extension

Original French opinion adopted by the Transparency Committee on 26 June 2024

The legally binding text is the original French opinion version

Summary of opinion

Unfavourable opinion for reimbursement in "the treatment of adult patients with NSCLC whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy"

Transparency Committee's conclusions

Clinical Benefit

- Non-small cell lung cancer (NSCLC) with activating HER2 mutation is a life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio has not been adequately established given the absence of direct comparative data versus clinically relevant comparators, even though a randomised controlled trial would have been possible, and the major methodological limitations of the indirect comparisons provided;
- There are medicinal alternatives.
- Consequently, the Committee considers that ENHERTU (trastuzumab deruxtecan) has no role in the care pathway.
- **Public health benefit**

Considering:

- the seriousness of the disease and its incidence,
- the partially met medical need,
- the lack of response to the identified need given the absence of evidence of an additional impact on morbidity and mortality or on quality of life,
- the absence of data enabling assessment of the additional impact on the organisation of care,

ENHERTU (trastuzumab deruxtecan) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ENHERTU (trastuzumab deruxtecan) 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 of ENHERTU (trastuzumab deruxtecan) in the list of covered drugs for inpatients approved for use in the MA indication.