SUMMARY

dostarlimab

JEMPERLI 500 mg,

solution for dilution for infusion

Reassessment

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

- Endometrial cancer is a serious life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is not defined failing available robust comparative data to ensure the strength of conclusions on the effect of JEMPERLI (dostarlimab) treatment in view of the available alternatives.

  Indeed, the updated data provided in support of this application obtained from a non-comparative phase I study, do not remove the uncertainties raised by the Committee during the first assessment (opinion of 06 October 2021).

  In view of these uncertainties linked in particular with:
  - the preliminary nature of the efficacy data available,
  - the lack of comparative data, despite the existence of available clinically relevant comparators,
  - the significant toxicity which remains marked by severe adverse events (AEs) reported in 37.9% of patients and grade ≥ 3 AEs reported in more than one of every two patients (56.9%) after additional follow-up (+11.3 months of median follow-up).

  These data do not meet the Committee's minimum requirements to provide formal evidence of the clinical benefit of JEMPERLI (dostarlimab) in the treatment of patients with recurrent or advanced, dMMR/MSI-H endometrial cancer, progressing after or during a platinum salt-based chemotherapy regimen.
- JEMPERLI (dostarlimab) has no role in the therapeutic strategy.

➔ Public health benefit

In view of:

- the seriousness of the condition and its prevalence,
- the partially met medical need,
- the lack of response to the identified need,
- the lack of evidence of an additional impact on morbidity-mortality or quality of life, on account of the lack of direct or indirect comparative data based on good methodology in relation to clinically relevant comparators, despite being possible,
- the lack of evidence of an additional impact on delivery of care,
- the lack of evidence of an impact on the care and/or life pathway.

JEMPERLI (dostarlimab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of JEMPERLI 500 mg (dostarlimab), solution for dilution for infusion, is insufficient to justify public funding in view of the available alternatives in the marketing authorisation indication.

The Committee disapproves the inclusion of JEMPERLI 500 mg (dostarlimab), solution for dilution for infusion, in the list of covered drugs for inpatients for the indication and at the MA dosages.