SUMMARY

dostarlimab

JEMPERLI 500 mg

concentrate for solution for infusion

First listing

Adopted by the Transparency Committee on 18 December 2024

Summary of opinion

Favourable opinion for reimbursement in the following indication: “in combination with carboplatin and paclitaxel for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

Transparency Committee’s conclusions

Clinical Benefit

- Endometrial cancer is a serious life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effect ratio of JEMPERLI (dostarlimab) is high.
- There are therapeutic alternatives with an MA but which had not been assessed by the Transparency Committee on the date of the present opinion (see paragraph 2.2: Clinically relevant comparators).
- The proprietary medicinal product JEMPERLI (dostarlimab) is a first-line treatment indicated in combination with carboplatin + paclitaxel chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy.

This document and its bibliographic reference are available to download at www.has-sante.fr

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➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the inadequately met medical need,
- the partial response to the identified need, with:
  - an established additional impact on morbidity;
  - an expected additional impact on mortality despite an established efficacy of JEMPERLI (dostarlimab) only in the ITT population (broader population than the MA population, which represented around a quarter of the patients enrolled in the RUBY study); with, nonetheless, the existence of a significant quantitative interaction for MMR status concerning the end-points (PFS and OS), indicating a greater effect of dostarlimab in patients with a dMMR status than in those with a pMMR status;
  - the lack of evidence of an additional impact on quality of life;
  - the lack of evidence of an additional impact on the organisation 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 provided by JEMPERLI 500 mg (dostarlimab) concentrate for solution for infusion is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of JEMPERLI 500 mg (dostarlimab) concentrate for solution for infusion in the list of covered drugs for inpatients in the indication and at the MA dosage.

Clinical Added Value

Considering:

- evidence of a superiority in the phase 3 RUBY study of dostarlimab in combination with paclitaxel + carboplatin chemotherapy in the induction phase, followed by maintenance therapy with dostarlimab, in terms of radiological progression-free survival, with:
  - **in patients with dMMR/MSI-H tumour status, an HR = 0.28 (95% CI = [0.162; 0.495]; and a median PFS: not reached [11.8; NA] versus 7.7 months [5.6; 9.7]) in the comparator group;**
  - **in the ITT population an HR = 0.64 (95% CI = [0.507; 0.800] and a median PFS of: 11.8 months [9.6; 17.1] versus 7.9 months [7.6; 9.5] in the comparator group;**
- evidence of superiority of dostarlimab in combination with paclitaxel + carboplatin chemotherapy in the induction phase, followed by maintenance therapy with dostarlimab, in terms of overall survival, in the ITT population (including 23% dMMR/MSI-H patients) via an interim analysis;
- the existence of a significant quantitative interaction for MMR status concerning the endpoints (PFS and OS) indicating a greater effect of dostarlimab in patients with a dMMR tumour status than in those with a pMMR tumour status;

and despite:

- the absence of an overall survival analysis specifically scheduled in the protocol for the dMMR/MSI-H patient subgroup in the RUBY study;

- an excess toxicity primarily concerning adverse events of grades ≥ 3, with 72.2% in the dostarlimab group versus 60.2% in the placebo group, immunological AEs (58.5% and 37.0%), and serious AEs (39.8% and 28.0%);
- the absence of any formal conclusion that can be drawn on quality of life (exploratory endpoint);

the Committee deems that JEMPERLI (dostarlimab) in combination with carboplatin and paclitaxel in the induction phase, followed by maintenance treatment with JEMPERLI (dostarlimab) as monotherapy provides a moderate clinical added value (CAV III) compared to the carboplatin + paclitaxel combination in the treatment of adult patients with dMMR/ MSI-H primary advanced or recurrent endometrial cancer (EC).