Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

durvalumab

IMFINZI 50 mg/ml

concentrate for solution for infusion

Indication extension

Adopted by the Transparency Committee on 15 January 2025

Summary of opinion

Favourable opinion for reimbursement in the following indication: "IMFINZI in combination with platinum-based chemotherapy, followed by IMFINZI as monotherapy, is indicated for the first-line treatment of adults with advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR)."

The assessment of durvalumab is based on data from a comparative DUO-E study (No. NCT04269200) conducted in patients with primary advanced/metastatic (stage III or IV) or recurrent endometrial cancer, the results of which are described hereafter. It should be noted that this study included an assessment of the effect of durvalumab in combination with olaparib for maintenance therapy following induction therapy with durvalumab in combination with carboplatin + paclitaxel chemotherapy in these patients.

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 of IMFINZI (durvalumab) is high.
- There are therapeutic alternatives with a MA.
- The proprietary medicinal product IMFINZI (durvalumab) is a first-line treatment in the indication: IMFINZI (durvalumab) in combination with carboplatin + paclitaxel chemotherapy in the induction phase, followed by maintenance therapy with IMFINZI (durvalumab) as monotherapy for the treatment of adult patients with mismatch repair proficient (pMMR)/microsatellite instability-high (MSS) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the inadequately met medical need,
- the response to the identified need, with:
  - an established additional impact on morbidity despite an established efficacy of IMFINZI (durvalumab) only in the ITT population (broader population than the MA population concerned by this assessment);
  - the lack of evidence of an additional impact on mortality;
  - 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,

IMFINZI (durvalumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of IMFINZI (durvalumab) concentrate for solution for infusion is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion of IMFINZI (durvalumab) concentrate for solution for infusion in the list of covered drugs for inpatients approved for use in the indication and at the MA dosage.

Clinical Added Value

Considering:

- evidence of a superiority in the phase 3 DUO-E study of durvalumab in combination with paclitaxel + carboplatin chemotherapy in the induction phase, followed by maintenance therapy with durvalumab as monotherapy in terms of radiological progression-free survival in the ITT population with an HR_{BvsA}= 0.71 ($CI_{95\%}$ = [0.57; 0.89]; p = 0.003). The median progression-free survival was 10.2 months ($CI_{95\%}$ = [9.7; 14.7]) in the durvalumab group versus 9.6 months, ($CI_{95\%}$ = [9.0; 9.9]) in the control group, i.e. an absolute difference of 0.6 months;

and despite:

- the lack of evidence of a superiority of durvalumab in combination with paclitaxel + carboplatin chemotherapy in the induction phase, followed by maintenance therapy with durvalumab in combination with olaparib, in terms of overall survival, in the ITT population (including 20% dMMR/MSI-H patients) assessed via an interim analysis;
- the absence of an overall survival analysis specifically scheduled in the protocol for the dMMR/MSI-H patient subgroup in the DUO-E study;
- an excess toxicity compared to the other groups concerning grade 3 or 4 AEs, which are reported in around 50% of patients (primarily anaemia and neutropenia, but also syncope and gastrointestinal disorders);
- the absence of any formal conclusion that can be drawn on quality of life (exploratory endpoint);

the Committee deems that IMFINZI (durvalumab) concentrate for solution for infusion provides a minor clinical added value (CAV IV) compared to the carboplatin + paclitaxel combination in the treatment of adult patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer (EC).