OPINION RELATIVE TO MEDICINAL PRODUCTS

olaparib

LYNPARZA 100 mg and 150 mg,

film-coated tablet

Reassessment at manufacturer's request

Original French opinion adopted by the Transparency Committee on 6 December 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Advanced high-grade ovarian, fallopian tube or primary peritoneal epithelial cancer is a life-threatening cancer.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- Medicinal alternatives are available.
- This is a maintenance treatment option after a first-line treatment for patients with a complete or partial response in view of the therapies available.

- **Public health benefit**

In view of:

- the seriousness of the condition and its incidence,
- the partially met medical need,
- the partial response to the identified need considering the improvement in progression-free survival and overall survival, with no evidence of improvement in quality of life,
- the lack of data allowing an assessment of the additional impact on delivery of care.

LYNPARZA (olaparib), in association with bevacizumab, is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LYNPARZA (olaparib), in association with bevacizumab, remains substantial in the MA indication.

The Committee approves continued inclusion of LYNPARZA (olaparib), in association with bevacizumab, in the list of drugs covered for outpatients and in the list of drugs covered for inpatients in the indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

In view of:

- the findings of the randomised, double-blind phase 3 study;
- providing evidence of the superiority of the association of olaparib + bevacizumab versus placebo + bevacizumab, in terms of:
  - investigator-assessed progression-free survival: HR=0.33 [95%CI: 0.25-0.45], with a median progression-free survival of 37.2 months [95%CI: 36.0-NE] in the olaparib + bevacizumab group versus 17.7 months [95%CI: 15.8-19.9] in the placebo + bevacizumab group, i.e. a point estimation of the absolute difference of 19.5 months;
  - overall survival: HR=0.62 [95%CI: 0.45-0.85], with a median overall survival of 75.2 months [95%CI: 73.3-NA] in the olaparib + bevacizumab group versus 57.3 months [95%CI: 51.6-NA] in the placebo + bevacizumab group, i.e. a point estimation of the absolute difference of 17.9 months;
- in subgroup analyses conducted on HRD+ patients for whom interaction tests between treatment effect and HRD status were significant, expressing a different effect of olaparib + bevacizumab on progression-free survival and overall survival according to HRD status.

and despite:

- the lack of stratification of randomisation on HRD status, liable to give rise to confounding bias in these estimations;

- the persistence of certain limitations highlighted in the initial opinion, such as the additional toxicity, the onset of myelodysplastic syndromes/acute myeloid leukaemia, and the lack of formal conclusion that can be drawn from the quality-of-life findings;

the Committee deems that LYNPARZA (olaparib) in association with bevacizumab provides moderate clinical added value (CAV III) in relation to bevacizumab monotherapy for the maintenance treatment of adult patients with advanced (FIGO stage III and IV) ovarian, fallopian tube or primary peritoneal epithelial cancer with a partial or complete response to a first line of treatment associating platinum-based chemotherapy with bevacizumab and whose cancer is associated with a positive homologous recombination deficiency (HRD) status, defined by a BRCA 1/2 gene mutation and/or genomic instability.