SUMMARY

rucaparib

RUBRACA 200 mg, 250 mg and 300 mg,

film-coated tablets

Indication extension

Original French opinion Adopted by the Transparency Committee on 27 March 2024

The legally binding text is the original French opinion version

Summary of opinion

Approval of reimbursement for the indication: "as monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy"

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.
- There are therapeutic alternatives.
- This is a first-line maintenance treatment option for advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer patients who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Public health benefit

In view of:

- the seriousness of the disease and its low incidence,
- the partially met medical need,

- the lack of response to the identified need considering the data available (improvement in progression-free survival, and accounting for additional toxicity) and:
  - the lack of evidence of an impact on mortality and quality of life;
  - the lack of evidence of an additional impact on delivery of care, or on the care and/or life pathway for the patient or her family circle.

RUBRACA (rucaparib) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of RUBRACA (rucaparib) 200 mg, 250 mg and 300 mg, film-coated tablets, is substantial in the marketing authorisation indication.

The Committee approves inclusion RUBRACA (rucaparib) 200 mg, 250 mg and 300 mg, film-coated tablets, in the list of covered drugs for outpatients and in the list of covered drugs for inpatients in the indication and at the dosages of the marketing authorisation.

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

Clinical Added Value

In view of:

- the evidence of the superiority of rucaparib monotherapy versus placebo, in a randomised double-blind study, in terms of investigator-assessed progression-free survival:
  - HRD subpopulation: HR = 0.47; 95% CI [0.31-0.72]; p = 0.0005; with a median progression-free survival of 28.7 months of rucaparib + IV placebo group and 11.3 months in the oral placebo + IV placebo group;
  - ITT population: HR = 0.52; 95% CI [0.40-0.68]; p < 0.0001; with a median progression-free survival of 20.2 months of rucaparib + IV placebo group and 11.0 months in the oral placebo + IV placebo group;
- the lack of evidence of superiority on overall survival in the HRD subpopulation and the ITT population in an interim analysis;
- limited follow-up of the efficacy of rucaparib with a median follow-up of approximately 26 months;
- the lack of formal conclusion that can be drawn from the quality-of-life findings;
- the safety profile of rucaparib marked in particular by a high incidence of grade ≥ 3 (61% and 23%) adverse events (AEs), serious AEs (21% and 6%) and by the onset of myelodysplastic syndromes/acute myeloid leukaemia;
- the context of the current strategy which includes one available treatment (olaparib/bevacizumab) with evidence of an improvement in overall survival as maintenance treatment for patients with a tumour positive for homologous recombination deficiency (HRD).

the Committee deems that, based on the data currently available, RUBRACA (rucaparib) 200 mg, 250 mg and 300 mg, film-coated tablets, in the same way as ZEJULA (niraparib), provides minor clinical added value (CAV IV) for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary

peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.