HAUTE AUTORITÉ DE SANTÉ

# TRANSPARENCY COMMITTEE

## SUMMARY

## 3 MARCH 2021

*The legally binding text is the original French opinion version*

***niraparib***

**ZEJULA 100 mg hard capsules**

**New indication**

### Key points

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

### What therapeutic improvement?

Therapeutic improvement in the management of the disease.

### ◗ Role in the care pathway?

Following initial diagnostic and excision surgery, the standard first-line systemic chemotherapy for advanced stages (FIGO stages II to IV) is a combination of platinum and taxane (usually carboplatin and paclitaxel). Despite optimal initial surgery and the administration of paclitaxel-carboplatin chemotherapy, around 70% of patients will relapse within the first three years. For these women, the 5-year survival is estimated to be 30%.

The ESMO 2019 European guidelines and the NCCN 2020 American guidelines recommend the use of an anti-VEGF therapy, AVASTIN (bevacizumab), regardless of BRCA status, in combination with chemotherapy in patients with a poor prognosis (FIGO stage IV, sub-optimal surgery, large tumour mass, etc.). Maintenance therapy with an anti-VEGF alone may then be administered when this was initially prescribed. This treatment is administered for a maximum period of 15 months or until disease progression.

In the event of BRCA 1/2 mutation (germinal and/or somatic), maintenance treatment with olaparib is recommended.

**Role of ZEJULA (niraparib) in the care pathway:**

ZEJULA is a first-line maintenance treatment option for advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer in partial or complete response following first-line platinum-based chemotherapy.

In the absence of comparative data versus the management strategy incorporating bevacizumab in combination with chemotherapy then continued as maintenance therapy, its role compared to maintenance treatment with bevacizumab is not known. In addition, in the absence of comparative data, the role of niraparib compared to olaparib cannot be specified in the event of a BRCA 1/2 mutation.

In addition, the MA proposed two dosage regimens (200 mg per day or 300 mg per day) depending on weight (< or ≥ 77 kg) and platelet level (< or ≥ 150,000/µL); to date, no randomised studies having compared the efficacy of these two dosages in this indication are available.

## COMMITTEE'S CONCLUSIONS

## Clinical benefit

◗ Ovarian cancer is a life-threatening disease.
◗ This is a specific curative treatment for ovarian cancer.
◗ This proprietary medicinal product is part of a maintenance therapy regimen following platinum-based treatment.
◗ Its efficacy/adverse effects ratio is high.
◗ There are medicinal alternatives (see chapter on comparators).

**Public health impact**

Considering:
- the seriousness of the disease and its low incidence,
- the partially met medical need,
- the lack of response to the identified need considering the available data (improvement in progression-free survival under maintenance therapy with niraparib compared to the monitoring alone group, absence of impact on overall survival and quality of life as well as the safety profile),

consequently, as knowledge currently stands, no additional impact on public health is expected for the proprietary medicinal product ZEJULA (niraparib) in this indication.

**Considering all these elements, the Committee deems that the clinical benefit of ZEJULA (niraparib) is substantial in this new MA indication.**

**The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in this new indication and at the MA dosages.**

- **Recommended reimbursement rate: 100%**

## Clinical Added Value

**Considering:**

- **demonstration of an increase in median progression-free survival (primary endpoint) of +5.6 months in absolute value compared to placebo in an ITT population (13.8 months in the niraparib group versus 8.2 months in the placebo group]), in the randomised double-blind study,**

**despite:**

- **the absence of demonstration of an increase in overall survival, a non-ranked secondary endpoint (median overall survival: 30.3 months under niraparib and not reached under placebo),**
- **the absence of any formal conclusion that can be drawn based on the quality of life results,**
- **the safety profile of niraparib marked primarily by haematological events,**

**the Committee considers that ZEJULA (niraparib), like LYNPARZA (olaparib) provides a minor clinical added value (CAV IV) in the care pathway.**