SUMMARY

talazoparib

TALZENNA 0.1 and 0.25 mg,

hard capsules

Indication extension and initial inclusion

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: "TALZENNA (talazoparib) is indicated in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated"

Transparency Committee's Conclusions

Clinical Benefit

- Seriousness of the disease: metastatic castration-resistant prostate cancer (mCRPC) is a serious and life-threatening condition.
- The proprietary medicinal product TALZENNA (talazoparib) is a curative and symptomatic medicinal product.
- The efficacy/adverse effects ratio of TALZENNA (talazoparib) is high.
- Availability of an alternative: there are therapeutic alternatives (see Clinically relevant comparators).
- The proprietary medicinal product TALZENNA (talazoparib) is a treatment option indicated in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. For mCRPC patients, niraparib + abiraterone and olaparib + abiraterone in combination with prednisone or prednisolone is also a treatment option for eligible patients. In the absence of comparative data, it is not possible to specify the role of the TALZENNA (talazoparib) + enzalutamide combination, in particular in the subpopulation of patients with BRCA1/2 mutations.

➔ Public health benefit

In view of:

- the seriousness of the disease and its incidence;
- the partially met medical need;
- the partial response to the identified need, with:
  - an established additional impact on morbidity and mortality despite the established efficacy of TALZENNA (talazoparib) only versus placebo;
  - the lack of evidence of an additional impact on mortality and quality of life;
  - In addition, a presumed expected simplification of the care pathway with TALZENNA (talazoparib) given that there is no test prior to setting up treatment (BRCA 1/2);

TALZENNA (talazoparib) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit (CB) of TALZENNA (talazoparib) is substantial to justify public funding for the extension of the marketing authorisation indication.

The Committee approves inclusion in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for the indication extension 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 superiority in relation to enzalutamide in terms of radiological progression-free survival (rPFS), the primary outcome measure in the TALAPRO-2 phase III study; with 151/402 (37.6%) events in the talazoparib + enzalutamide group versus 191/403 (47.4%) in the placebo + enzalutamide group, HR=0.63; 95% CI [0.51 - 0.78]; p < 0.0001.

  The median rPFS was not reached (95% CI [27.5; NE]) in the talazoparib + enzalutamide group and was 21.9 months (95% CI [16.6; 25.1]) in the placebo + enzalutamide group.

and despite:

- the lack of evidence of superiority on overall survival in the TALAPRO-2 phase III study of the talazoparib + enzalutamide combination in relation to the placebo + enzalutamide,
- an additional toxicity primarily concerning grade > 3 adverse events reported in 75.2% of the patients in the talazoparib + enzalutamide group and 45.1% of the patients in the placebo + enzalutamide group;
- the risk of myelodysplastic syndrome (MDS) or acute myeloid leukaemia (AML), identified as a potential substantial risk in the Risk Management Plan (RMP) and in a context of treatment at an advanced stage of the disease,
- the lack of formal conclusion that can be drawn on quality of life (exploratory outcome measure),

the Committee deems that TALZENNA (talazoparib) provides minor clinical added value (CAV IV) versus enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.