SUMMARY

darolutamide

NUBEQA 300 mg,

film-coated tablet

First assessment

Original French opinion adopted by the Transparency Committee on 8 November 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Seriousness of the condition: metastatic hormone-sensitive prostate cancer is a serious life-threatening condition.
- The proprietary medicinal product NUBEQA (darolutamide) is a curative medicinal product.
- The efficacy/adverse effects ratio of NUBEQA (darolutamide) is high.
- Availability of an alternative: there are therapeutic alternatives (see Clinically relevant comparators).
- The proprietary medicinal product NUBEQA (darolutamide) is a first-line treatment in association with androgen suppression and taxane-based chemotherapy.

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, with:
  - an established additional impact of NUBEQA (darolutamide) + docetaxel + ADT compared to docetaxel + ADT on mortality in terms of overall survival;
  - the lack of evidence of an impact on quality of life;
  - the presumed lack of a simplification of the care pathway with NUBEQA (darolutamide).

NUBEQA (darolutamide) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit (CB) of NUBEQA (darolutamide) in association with docetaxel is substantial in the MA indication extension.

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 MA dosages.

➔ **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 the ARASENS phase III study of the association of darolutamide + docetaxel + ADT versus placebo + docetaxel + ADT, in terms of overall survival with an inestimable median OS versus 48.9 months in the comparator group and HR= 0.675; 95% CI [0.568 - 0.801]; p< 0.0001,

and despite:

- the lack of formal conclusion that can be drawn on quality of life (exploratory outcome measure),

the Committee deems that NUBEQA (darolutamide) in association with docetaxel and androgen suppression provides moderate clinical added value (CAV III) versus docetaxel combined with androgen suppression for the treatment of adult metastatic hormone-sensitive prostate cancer (mHSPC) patients.