SUMMARY

relugolix

ORGOVYX 120 mg,

film-coated tablets

First assessment

Adopted by the Transparency Committee on 26 April 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for reimbursement in the “treatment of adult patients with advanced hormone-sensitive prostate cancer”.

Role in the care pathway?

ORGOVYX (relugolix) is an **additional therapeutic option in the first-line treatment of advanced hormone-sensitive prostate cancer**, in the same way as the other GnRH agonist or antagonist medicinal products already available.

Transparency Committee's conclusions

Clinical Benefit

- Prostate cancer, particularly in the event of metastatic forms, is a life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in view of the therapies available (see 5.1).

Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the medical need partially met by GnRH analogues and degarelix (GnRH antagonist),
- the lack of response to the identified need, due to the absence of data supporting the additional impact on morbidity and mortality and quality of life,
- the absence of an additional impact on the organisation of care,

ORGOVYX (relugolix) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ORGOVYX (relugolix) 120 mg film-coated tablets is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of ORGOVYX (relugolix) 120 mg film-coated tablets in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%

Clinical Added Value

Considering:

- demonstration of a non-inferiority of relugolix compared to leuprorelin:
  - on an acceptable endpoint, which is the achievement and maintenance of androgen suppression;
  - in a study context favourable to treatment compliance;
- the safety profile, which is deemed to be acceptable versus clinically relevant comparators;

and despite:

- the open-label nature of the HERO study leading to an assessment and follow-up bias, whereas double-blinding was feasible;
- the inclusion of a heterogeneous population with, in particular, more than a third of the patients included not corresponding to the scope of the MA (28.0% localised form and 9.8% not classifiable) i.e. advanced hormone-sensitive prostate cancer, grouping together metastatic and locally advanced stages;

- the absence of an efficacy analysis performed in the study subpopulation corresponding to the MA, i.e. patients with advanced hormone-sensitive prostate cancer;
- the profile of the patients with a metastatic form included in the HERO study, which does not correspond to those immediately treated in current clinical practice with the combination of a GnRH agonist or antagonist (androgen deprivation) with second-generation hormone therapy (only enzalutamide could be added during the study in the event of PSA progression);

the Committee deems that ORGOVYX (relugolix) 120 mg film-coated tablets provide no clinical added value (CAV V) in the current care pathway.