SUMMARY

elacestrant

ORSERDU 86 mg and 345 mg

film-coated tablets

First listing

Original French opinion adopted by the Transparency Committee on 26 June 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the indication as monotherapy "for the treatment of postmenopausal women, and men, with oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have disease progression following at least one line of endocrine therapy including a CDK 4/6 inhibitor".

Transparency Committee's conclusions

Clinical Benefit

- Locally advanced or metastatic breast cancer is a life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is modest, given a poor quality of the demonstration (infra-therapeutic control arm).
- There are medicinal alternatives.
- This is treatment option in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease and its incidence,
- the partially met medical need,
- the lack of response to the identified need:
  - with no evidence of an additional impact on morbidity and mortality (low point estimate of the absolute difference in terms of progression-free survival and with no clinical relevance retained, with an absence of demonstrated improvement in overall survival) or on quality of life,

- the absence of data enabling assessment of the additional impact on the organisation of care,

ORSERDU (elacestrant) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ORSERDU (elacestrant) film-coated tablets is moderate in the MA indication.

The Committee issues a favourable opinion for inclusion of ORSERDU (elacestrant) film-coated tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and dosages.

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

Clinical Added Value

ORSERDU (elacestrant) demonstrated a statistically significant superiority in terms of progression-free survival assessed by an independent review committee in a randomised, open-label phase 3 study versus endocrine therapy alone.

However, considering the following limitations:

- The low clinical relevance of this finding, given the point estimate of an absolute difference in median progression-free survival of less than 2 months, combined with the lack of evidence of an effect on overall survival in the final analysis, in a context of advanced disease with an unfavourable prognosis;
- The infra-therapeutic nature of the control group. The Committee considers that:
  - other clinically relevant comparators, which were available on the date of study and have a greater efficacy, could have been used (expert opinion);
  - a high proportion of patients in the control group who received an aromatase inhibitor (60%) had already received prior therapy with a drug from this therapeutic class. Retreatment following prior failure of this therapeutic class can be considered to be a loss of opportunity compared to the other available comparators (expert opinion);
- The absence of any formal conclusion that can be drawn based on the quality of life findings;

the Committee deems that ORSERDU (elacestrant) film-coated tablets provides no clinical added value (CAV V) compared to endocrine therapy alone.