SUMMARY

palbociclib

IBRANCE 75 mg, 100 mg and 125 mg

hard capsules, tablets

Reassessment

Original French opinion adopted by the Transparency Committee on 18 October 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- HR-positive/HER2-negative breast cancer, at the locally advanced or metastatic stage, is a serious, life-threatening disease.
- This is a specific curative cancer treatment.
- Efficacy/adverse effects ratio:
  - High in combination with letrozole,
  - High in combination with fulvestrant.
- There are therapeutic alternatives.
- In combination with letrozole and in combination with fulvestrant, it is a first-line treatment (see paragraph 5.1).
- The combination of palbociclib with fulvestrant is a treatment option only in patients who have received prior endocrine therapy (at the advanced stage or during adjuvant treatment for early progressions, see paragraph 5.1).

Public health benefit

Considering:

- the seriousness of HR-positive/HER2-negative locally advanced or metastatic breast cancer, which is life-threatening, and its high prevalence,
- the medical need partially met by other CDK 4/6 inhibitors,
- the partial response to the identified need given:

- a demonstrated additional impact on morbidity,
- the lack of any demonstrated impact to date on mortality and quality of life,
- the absence of data supporting a positive or negative impact on the organisation of care and the care pathway,

IBRANCE (palbociclib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of IBRANCE (palbociclib) 75 mg, 100 mg and 125 mg hard capsules and tablets is substantial only:

- **in combination with letrozole in women having received no prior therapy for the advanced stage of the disease and not previously treated with a nonsteroidal aromatase inhibitor (letrozole or anastrazole) in the context of adjuvant therapy in the prior 12 months;**
- **in combination with fulvestrant in women who have received prior endocrine therapy (at the advanced stage or during adjuvant treatment for early progressions).**

The Committee issues a favourable opinion for maintenance of inclusion of IBRANCE (palbociclib) 75 mg, 100 mg and 125 mg hard capsules and tablets in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication retained and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 100%**

Clinical Added Value

➔ **In combination with letrozole**

Considering:

- demonstration of the superiority of pablociclib in combination with letrozole compared to letrozole alone in terms of progression-free survival, with a difference in medians of 10.3 months in a randomised, double-blind phase 3 study (PALOMA 2);
- but the lack of evidence of an increase in overall survival (the Committee highlights that the proprietary medicinal product KISQALI (ribociclib) has demonstrated a benefit in terms of overall survival in this context);
- the absence of a relevant clinical benefit in terms of quality of life assessed in exploratory analyses;
- and the safety profile marked by a high risk of haematotoxicity;

the Committee deems that IBRANCE (palbociclib) 75 mg, 100 mg and 125 mg hard capsules and tablets, in combination with letrozole, provides no clinical added value (CAV V) compared to letrozole alone as first-line therapy during the metastatic stage of HR-positive/HER2-negative breast cancer in postmenopausal women, not previously treated with a nonsteroidal aromatase inhibitor (letrozole or anastrazole) in the context of adjuvant therapy in the prior 12 months, in the absence of short-term life-threatening symptomatic visceral involvement.

➔ In combination with fulvestrant

Considering:

- demonstration of the superiority of pablociclib in combination with fulvestrant compared to fulvestrant alone in terms of progression-free survival, with a difference of 5.4 months in a randomised, double-blind phase 3 study (PALOMA 3);
- but the lack of evidence of an increase in overall survival;
- the absence of a relevant clinical benefit in terms of quality of life in exploratory analyses;
- and the safety profile marked by a high risk of haematotoxicity;

the Committee deems that IBRANCE (palbociclib) 75 mg, 100 mg and 125 mg hard capsules and tablets, in combination with fulvestrant, provides no clinical added value (CAV V) compared to fulvestrant alone as first-line therapy in the event of early progression (less than 12 months after the end of adjuvant therapy) or as a second and later-line treatment in postmenopausal women with HR-positive, HER2-negative breast cancer, who have received prior endocrine therapy and in the absence of short-term life-threatening symptomatic visceral involvement.