SUMMARY

abemaciclib

VERZENIOS 50, 100 and 150 mg

film-coated tablets

Indication extension

Original French opinion adopted by the Transparency Committee on 24 May 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- HR-positive/HER2-negative early breast cancer is a serious life-threatening condition.
- This is a curative medicinal product.
- Considering:
  - demonstration of a superiority of abemaciclib in combination with standard endocrine therapy compared to standard endocrine therapy alone in terms of invasive disease-free survival (IDFS) only, with a modest difference of 5.6 points and an effect on distant recurrences primarily; but the impossibility of considering this outcome measure as a substitute for an overall survival endpoint as knowledge currently stands;
  - the safety profile, marked by a higher frequency of treatment discontinuations for adverse events with this combination compared to standard endocrine therapy alone: (18.5% versus 6.4%).

  The efficacy/adverse effects ratio is modest.
- This is a first-line treatment in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence.

- **Public health benefit**

Considering:

- the seriousness of the disease, which is life-threatening;

- the high prevalence of HR-positive/HER2-negative early breast cancer;
- the medical need partially met by endocrine therapies, but for which there is still a medical need for effective and well-tolerated medicinal products;
- 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 lack of evidence to support an absence of deterioration in the organisation of care and the care pathway;

VERZENIOS (abemaciclib) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of VERZENIOS (abemaciclib) is moderate in the MA indication.

The Committee issues a favourable opinion for inclusion of VERZENIOS (abemaciclib) 50, 100 and 150 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: 30%**

Clinical Added Value

Considering:

- demonstration of a superiority of abemaciclib in combination with standard endocrine therapy compared to standard endocrine therapy alone in terms of invasive disease-free survival (IDFS) in the primary analysis and the suggested maintenance of the effect after a median follow-up of 42 months, with a modest difference of 5.6 points and an effect on distant recurrences primarily; but the impossibility of considering this outcome measure as a substitute for an overall survival endpoint as knowledge currently stands;
- the lack of evidence of an improvement in overall survival to date (immature data for this endpoint);
- the safety profile, characterised by gastrointestinal disorders, thromboembolic events and infections, particularly at the start of treatment;

the Committee deems that VERZENIOS (abemaciclib) provides no clinical added value (CAV V) compared with standard endocrine therapy alone.