HAUTE AUTORITÉ DE SANTÉ

ASSESS HEALTH TECHNOLOGIES

OPINION ON MEDICINAL PRODUCTS

abemaciclib

VERZENIOS 50, 100 mg and 150 mg

film-coated tablets

New indication

Adopted by the Transparency Committee on 14 September 2022

SUMMARY

The legally binding text is the original French opinion version

- **Breast cancer**
- **Sectors: Community and Hospital**

Key points

Disapproval of reimbursement for the following indication:

VERZENIOS (abemaciclib) in association with hormone therapy is indicated for adult patients in adjuvant treatment of early-onset hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer, with lymph node involvement, and high risk of recurrence.

For pre/perimenopausal women, aromatase inhibitor hormone therapy must be associated with a luteinising hormone-releasing hormone (LHRH) agonist.

Role in therapeutic strategy?

Role of VERZENIOS (abemaciclib) in the therapeutic strategy:

Considering:

- the evidence, despite being statistically significant, of the superiority of abemaciclib in association with standard hormone therapy versus standard hormone therapy alone in terms of invasive disease-free survival, which has limitations as to the effect size which remains clinical small on this outcome measure in terms of absolute gain (95.2% vs 93.4%; Δ = 1.8 points), and the unsuitability of this outcome measure as a substitute for overall survival based on current knowledge;
- the lack of data on overall survival considering the duration of the study;
- the safety profile, characterised by gastrointestinal disorders, thromboembolic events and infections, similar to that observed in advanced breast cancer. However, the acceptability of adverse effects is lower in this context of early-stage adjuvant treatment;

The Committee deems, based on the data currently available, that VERZENIOS (abemaciclib) has no role in the therapeutic strategy in association with hormone therapy in the adjuvant treatment of adult early-onset HR+/HER2- breast cancer patients, with lymph node involvement and high risk of recurrence.

Committee's conclusions

Actual Clinical Benefit

- Early-onset HR+/HER2- breast cancer is a serious life-threatening condition.
- The proprietary medicinal product VERZENIOS (abemaciclib) is a curative medicinal product.
- Considering:
  - the evidence of a small effect size (95.2% vs 93.4%; Δ = 1.8 points) of adding abemaciclib to standard hormone therapy versus the same treatment alone, despite being statistically significant, on invasive disease-free survival;
  - the unsuitability of this outcome measure as a substitute for overall survival based on current knowledge;
  - the lack of data on overall survival considering the duration of the study;
  - the safety profile, characterised by gastrointestinal disorders, thromboembolic events and infections, similar to that observed in advanced breast cancer. However, the acceptability of adverse effects is lower in this context of early-stage adjuvant treatment.
  - In addition, the data furnished do not support a lack of degradation of the delivery of care and the care pathway for VERZENIOS (abemaciclib).

  The efficacy/adverse effect ratio is poorly defined.
- The existence of therapeutic alternatives (see Section 5 of this opinion)
- VERZENIOS (abemaciclib) has no role in the therapeutic strategy in association with hormone therapy in the adjuvant treatment of adult early-onset HR+/HER2- breast cancer patients, with lymph node involvement and high risk of recurrence.

Public health benefit

Considering:

- the severity of the life-threatening disease;
- the high prevalence of early-onset HR+/HER2- breast cancer;
- the medical need partially met by hormone therapy treatments, but for which there is still a medical need for effective and well-tolerated medicinal products;
- the lack of response to the identified need considering:
  - the lack of evidence to date of an additional impact on morbidity-mortality and on quality of life in view of the evidence, despite being statistically significant, of the superiority of abemaciclib in association with standard hormone therapy versus standard hormone therapy alone in terms of invasive disease-free survival, which has limitations as to the effect size which remains clinical small on this outcome measure in terms of absolute gain (95.2% vs 93.4%; Δ = 1.8 points), and the unsuitability of this outcome measure as a substitute for overall survival based on current knowledge;
  - the lack of data on overall survival considering the duration of the study;
  - the lack of data supporting a lack of degradation of the delivery of care and the care pathway;

VERZENIOS (abemaciclib) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of VERZENIOS (abemaciclib) is insufficient to justify public funding in view in the marketing authorisation indication

The Committee disapproves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the marketing authorisation indication and at the marketing authorisation dosages.