**SUMMARY**

erdafitinib

# BALVERSA 3 mg, 4 mg and 5 mg

**film-coated tablets**

First listing

**Adopted by the Transparency Committee on 15 January 2025**

## Summary of opinion

**Favourable opinion for reimbursement only "as monotherapy for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received chemotherapy based on platinum salts and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting"**

**Unfavourable opinion for reimbursement in the other situations covered by the MA indication.**

# Transparency Committee's conclusions

## Clinical Benefit

- Unresectable or metastatic urothelial carcinoma is a serious, life-threatening disease.
- The proprietary medicinal product BALVERSA (erdafitinib) is a curative medicinal product.
- Its efficacy/adverse effect ratio is high, considering:
  - evidence of superiority versus chemotherapy, particularly in terms of overall survival, with, however,
  - a toxicity profile marked by the development of central serous retinopathy, skin and mucosal reactions (hand-foot syndrome, stomatitis and onycholysis), serious hyponatraemia and hyperphosphataemia, requiring dose reductions below the MA dosage (in 51.1% of patients in the pivotal study) to manage toxicity.
- Alternative medications are available for patients who have previously received chemotherapy based on platinum salts and an anti-PD-1 or anti-L1 drug, PADCEV (enfortumab vedotin) and JAVLOR (vinflunine).
- This therapy is a third-line treatment after a chemotherapy regimen based on platinum salts and an anti-PD-1 or anti-PD-L1 drug, or a second-line treatment following maintenance therapy with BAVENCIO (avelumab) in adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations.

- **Public health benefit**

Considering:

- the seriousness and prevalence of urothelial carcinoma,
- the partially met medical need,
- the partial response to the identified need given:
  - evidence of an additional impact on mortality in the pivotal study. However, concerns remain, primarily regarding ocular and skin toxicities;
  - the lack of evidence of an additional impact on quality of life;
  - the lack of data making it possible to assess the additional impact on the organisation of care, but taking into account the dosage requiring a daily oral dose;

BALVERSA (erdafitinib) is unlikely to have an additional impact on public health.

**Considering all of these elements, the Committee deems that the clinical benefit of BALVERSA 3 mg, 4 mg, 5 mg (erdafitinib) film-coated tablets is:**

- **substantial only "as monotherapy for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received chemotherapy based on platinum salts and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting";**
- **insufficient to justify public funding in the other MA situations.**

**The Committee issues the following opinions:**

- **a favourable opinion for inclusion of BALVERSA 3 mg, 4 mg, 5 mg (erdafitinib) film-coated tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages;**
- **an unfavourable opinion for inclusion of BALVERSA 3 mg, 4 mg, 5 mg (erdafitinib) 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 other situations covered by the MA indication.**

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

## Clinical Added Value

Considering:

- evidence of the superiority of BALVERSA (erdafitinib) compared to chemotherapy (docetaxel or vinflunine), in a randomised, open-label phase 3 study in terms of overall survival, with an HR = 0.64; CI95% [0.47; 0.88]) and progression-free survival (HR = 0.58; CI95% [0.44; 0.78]);
- the medical need partially met by the available alternatives;

and despite:

- a toxicity profile marked by the development of central serous retinopathy, skin and mucosal reactions (hand-foot syndrome, stomatitis and onycholysis), serious hyponatraemia and hyperphosphataemia;
- a lack of evidence of an improvement in quality of life;

- the lack of robust comparative data versus enfortumab vedotin, a medicinal product already available in the treatment of adult patients with locally advanced or metastatic urothelial carcinoma, who have previously received chemotherapy based on platinum salts and an anti-PD-1 drug or an anti-PD-L1 drug. However, the absence of a direct comparison is justified on the date of the present assessment given their concomitant development;

**the Committee deems that BALVERSA 3 mg, 4 mg, 5 mg (erdafitinib) film-coated tablets provides a minor clinical added value (CAV IV) compared to chemotherapy in the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received chemotherapy based on platinum salts and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting.**

**In the other situations of the MA: not applicable.**