Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

adagrasib

KRAZATI 200 mg

film-coated tablets

Inclusion on list

Adopted by the Transparency Committee on 29 January 2025

Summary of opinion

Favourable opinion for reimbursement in "KRAZATI as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation and disease progression after at least one prior systemic therapy."

Transparency Committee's Conclusions

Clinical Benefit

- Advanced non-small cell lung cancer with KRAS G12C mutation is a serious life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is low.
- There are therapeutic alternatives not specific to the KRAS G12C mutation, in a context in which the prognostic and predictive value of this mutation is inadequately defined.
- It is a treatment option in patients who have progressed after at least one prior line of systemic therapy, in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease,
- the partially met medical need,
- the lack of response to the identified need given:
  - the lack of evidence of an 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 lack of data supporting a potential additional impact on the care and/or life pathway,

KRAZATI (adagrasib) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of KRAZATI 200 mg (adagrasib) film-coated tablets is low in the MA indication.

The Committee issues a favourable opinion for inclusion of KRAZATI 200 mg (adagrasib) 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 at the MA dosages.

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

Clinical Added Value

KRAZATI (adagrasib) demonstrated a statistically significant superiority in terms of progression-free survival and objective response rate assessed by an independent review committee in a randomised, open-label phase 3 study versus docetaxel.

However, this result is limited by:

- the lack of clinical relevance of the absolute difference in progression-free survival medians, of 1,65 month;
- the open-label implementation of the study, having led to possible assessment biases, particularly in terms of treatment decisions;
- the lack of evidence of an effect on overall survival, in a context of advanced disease with an unfavourable prognosis;
- the lack of clinical relevance of the objective response rate in this context;
- the absence of any formal conclusion that can be drawn based on the quality of life findings;
- the safety profile of adagrasib, which does not appear to be more favourable than that of docetaxel;

the Committee deems that KRAZATI 200 mg (adagrasib) film-coated tablets provides no clinical added value (CAV V) compared with docetaxel.