SUMMARY

sotorasib

LUMYKRAS 120 mg,

film-coated tablets

Reassessment

Original French opinion adopted by the Transparency Committee on 19 July 2023

The legally binding text is the original French opinion version

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 and with the absence of a specific treatment (before the availability of LUMYKRAS (sotorasib).
- It is a treatment option in patients who have progressed after at least one prior line of systemic therapy.

- **Public health benefit**

Considering:

- the seriousness of the condition,
- the partially met medical need,
- the lack of response to the identified need,
  - with no demonstrated additional 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,

LUMYKRAS (sotorasib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LUMYKRAS (sotorasib) remains low in the marketing authorization (MA) indication.

The Committee issues a favourable opinion for maintenance of inclusion of LUMYKRAS (sotorasib) 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: 100%**

Clinical Added Value

LUMYKRAS (sotorasib) 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 around 1 month;
- the open-label implementation of the study, having led to possible assessment biases, particularly in terms of treatment decisions;
- the uncertain reproducibility of measurement of progression-free survival in this study;
- the lack of demonstration 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 results;
- the safety profile of sotorasib, which does not appear to be more favourable than that of docetaxel;

the Committee deems that LUMYKRAS (sotorasib) provides no clinical added value (CAV V) compared with docetaxel.