SUMMARY

selpercatinib

RETSEVMO 40 mg and 80 mg

hard capsules

Indication extension

Original French opinion adopted by the Transparency Committee on 24 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement "as monotherapy for the first-line treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC)".

Transparency Committee's conclusions

Clinical Benefit

As first-line treatment:

- Medullary thyroid cancer (MTC) is a serious disease that is life-threatening.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high. RETSEVMO (selpercatinib) has demonstrated a superiority in terms of progression-free survival compared to vandetanib or cabozantinib, with no demonstration of an improvement in overall survival.
- This is a first-line treatment for advanced RET-mutant medullary thyroid cancer (MTC), with regard to the available therapies.

Public health benefit

Considering:

- the seriousness of the disease and its rarity,
- the partially met medical need,
- the demonstrated superiority in terms of progression-free survival compared to the investigator's choice treatment (vandetanib or cabozantinib), in a phase 3, randomised, open-label trial,
- the lack of a demonstrated additional impact on mortality or quality of life,
- the lack of data enabling assessment of an additional impact on the care and/or life pathway,

RETSEVMO (selpercatinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of RETSEVMO (selpercatinib) 40 mg and 80 mg hard capsules is substantial in the indication "as monotherapy for the first-line treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC)".

The Committee issues a favourable opinion for inclusion of RETSEVMO (selpercatinib) 40 mg and 80 mg hard capsules in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use as monotherapy for the first-line treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC), and at the MA dosages.

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

Clinical Added Value

As first-line treatment, considering:

- demonstration of a superiority of RETSEVMO (selpercatinib) compared to cabozantinib or vandetanib in terms of progression-free survival assessed by an independent review committee (HR = 0.280; $CI_{95\%}$ [0.165; 0.475], p<0.0001), in a phase 3, randomised, open-label trial (LIBRETTO-531);
- a safety judged to be favourable;
- management considered to be similar for adults and adolescents. Since the studies (LIBRETTO-001 and LIBRETTO-531) only included three adolescents, the efficacy data in adults were accepted as being extrapolable to adolescents 12 years and older;

and despite:

- the lack of evidence of an improvement in overall survival (non-ranked secondary endpoint) following the interim analysis, in a context of advanced disease with an unfavourable prognosis;
- the absence of any formal conclusion that can be drawn based on the exploratory quality of life findings;
- results available with a short follow-up period (median follow-up of 1 year on the interim analysis, which became the primary analysis);

the Committee deems that RETSEVMO (selpercatinib) provides a minor clinical added value (CAV IV) compared to vandetanib or cabozantinib in the first-line treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC).