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

Approval of reimbursement for "monotherapy for the first-line treatment of adult and adolescent patients 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, life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high. RETSEVMO (selpercatinib) has shown superiority in terms of progression-free survival in relation to vandetanib and cabozantinib, with no evidence of an improvement in overall survival
- This is a first-line treatment of advanced-stage RET-mutant medullary thyroid cancer (MTC) in view of the therapies available.

Public health benefit

In view of:

- the seriousness of the disease and its rarity,
- the partially met medical need,
- the evidence of superiority in terms of progression-free survival compared to the standard-of-care therapy chosen by the investigator (vandetanib or cabozantinib), in a randomised, open-label phase III study,
- the lack of evidence of an additional impact on mortality or quality of life,
- the lack of data allowing an 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 of these elements, the Committee deems that the clinical benefit of RETSEVMO (selpercatinib) 40 mg and 80 mg, hard capsules, is substantial for the indication "as monotherapy for the first-line treatment of adult and adolescent patients 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC)".

The Committee approves inclusion of RETSEVMO (selpercatinib) 40 mg and 80 mg, hard capsules, in the list of covered drugs for outpatients and in the list of covered drugs for inpatients as monotherapy for the first-line treatment of adult and adolescent patients from 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) and at the dosages of the marketing authorisation.

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

Clinical Added Value

As first-line treatment, in view of:

- evidence of superiority of RETSEVMO (selpercatinib) in relation to cabozantinib or vandetanib in terms of progression-free survival assessed by an independent review committee (HR = 0.280; 95% CI [0.165; 0.475], p<0.0001), in a randomised, open-label phase III study (LIBRETTO-531);
- safety deemed to be favourable;
- treatment considered to be similar for both adults and adolescents. As the studies (LIBRETTO and LIBRETTO-531) only included 3 adolescents, the efficacy data for adults have been accepted as suitable for extrapolation to adolescents 12 years and older,

and despite:

- the lack of evidence of an improvement in overall survival (non-ranked secondary outcome measure) during the interim analysis, in a context of advanced-stage disease with an unfavourable prognosis;
- the lack of formal conclusions that can be drawn from the exploratory quality-of-life findings;
- the findings available with a short follow-up period (median follow-up of 1 year at the interim analysis that has become the primary analysis);

the Committee deems that RETSEVMO (selpercatinib) 40 mg and 80 mg, hard capsules, provides minor clinical added value (CAV IV) in relation to vandetanib or cabozantinib, for the first-line treatment of adult and adolescent patients 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC).