SUMMARY

fruquintinib

FRUZAQLA 5 mg and 1 mg

hard capsules

First listing

Adopted by the Transparency Committee on 20 November 2024

Summary of opinion

Favourable opinion for reimbursement of FRUZAQLA (fruquintinib) 5 mg and 1 mg (hard capsules) in the restricted indication "as monotherapy for the treatment of adult patients with metastatic colorectal cancer (mCRC) (ECOG score 0-1) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib".

Transparency Committee's conclusions

Clinical Benefit

- Metastatic colorectal cancer (mCRC) is a serious, life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is modest due to:
  - evidence of its efficacy in a randomised, double-blind phase 3 study (FRESCO-2 study), showing an effect of FRUZAQLA (fruquintinib) compared to placebo in terms of overall survival, with median survivals of 7.4 months and 4.8 months respectively in the FRUZAQLA (fruquintinib) and placebo groups (point estimate of the absolute difference in median survivals of +2.6 months),
  - the safety profile of this proprietary medicinal product (incidence of severe events (grades ≥ 3) recorded in 62.7% of patients),
  - the absence of robust data on quality of life in a context of advanced-line medical management of an advanced cancer disease.
- The heterogeneity of the population eligible for treatment under the specific indication (in particular patients for whom STIVARGA or LONSURF are a treatment option), and the comparator in the FRESCO-2 study (placebo) do not allow FRUZAQLA (fruquintinib) to be positioned within the therapeutic strategy.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the inadequately met medical need,
- the partial response to the identified need given:
  - the evidence of a low additional impact on mortality (point estimate of the absolute difference in median survivals of +2.6 months),
  - the lack of evidence of an impact on quality of life (exploratory endpoint),
  - the lack of evidence regarding the impact on healthcare organisation, as well as on the care and/or life pathway for patients or their families, in a context of medical management of an advanced cancer disease,

FRUZAQLA (fruquintinib) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of FRUZAQLA (fruquintinib) 5 mg and 1 mg hard capsules is moderate in the restricted indication "as monotherapy for the treatment of adult patients with metastatic colorectal cancer (mCRC) (ECOG score 0-1) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib".

The Committee issues a favourable opinion for inclusion of FRUZAQLA (fruquintinib) 5 mg and 1 mg hard capsules in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the restricted indication "as monotherapy for the treatment of adult patients with metastatic colorectal cancer (mCRC) (ECOG score 0-1) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib".

In the rest of the MA scope, the clinical benefit is insufficient to justify public funding.

Clinical Added Value

Considering:

- evidence of the superiority of fruquintinib compared to placebo in a randomised, comparative phase 3 study in terms of overall survival and progression-free survival, with a low effect size in terms of overall survival (point estimate of the absolute difference in median survivals of +2.6 months),
- the impossibility of drawing a formal conclusion with respect to quality of life (exploratory endpoint),
- the debatable choice of comparator due to a heterogeneous population for whom clinically relevant comparators are available (in particular patients for whom STIVARGA or LONSURF are a treatment option) and with exploratory data in the subgroup analyses depending on prior treatment (60% of the ITT population after LONSURF or STIVARGA alone and 40% after both LONSURF and STIVARGA),
- the absence of data in patients with an ECOG score > 1,

- the safety profile marked by the occurrence of grade ≥ 3 AEs in patients in the fruquintinib group (62.7% versus 50.4% in the placebo group) and AEs of particular interest in 80.7% of patients in the fruquintinib group versus 53% of patients in the placebo group,

the Committee deems that FRUZAQLA (fruquintinib) 5 mg and 1 mg hard capsules, provide no clinical added value (CAV V) in the current care pathway for adult patients with metastatic colorectal cancer (mCRC) (ECOG 0-1) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib.