SUMMARY

Quizartinib

VANFLYTA 17.7 mg and 26.5 mg,

film-coated tablets

First listing

Original French opinion adopted by the Transparency Committee on 29 May 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the indication "VANFLYTA (quizartinib) is indicated in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by VANFLYTA single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) that is FLT3-ITD positive".

Transparency Committee's conclusions

Clinical Benefit

- Acute myeloid leukaemias (AML) include various malignant blood diseases characterised by the clonal proliferation of abnormal myeloid precursors and impairment of normal haematopoiesis. It is a life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease and its low incidence,
- the partially met medical need,
- the partial response to the identified need given:

- an expected additional impact, in terms of mortality, of adding VANFLYTA (quizartinib) to chemotherapies in the induction and consolidation phases followed by VANFLYTA (quizartinib) single-agent maintenance therapy, compared to chemotherapies alone in the induction and consolidation phases. The additional impact on morbidity has not been demonstrated to date.
- the absence of demonstrated impact on quality of life,
- the absence of an impact on the organisation of care,

VANFLYTA (quizartinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VANFLYTA 17.7 mg and 26.5 mg (quizartinib) film-coated tablets is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of VANFLYTA 17.7 mg and 26.5 mg (quizartinib) 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

Considering:

- demonstration of the superiority of VANFLYTA (quizartinib) compared to placebo, administered in combination with standard chemotherapy during the induction and consolidation phases and as single-agent maintenance therapy, in terms of overall survival (HR = 0.776, $CI_{95\%}$ = [0.615; 0.979]; p = 0.032),

and despite:

- the absence of a demonstrated improvement in terms of event-free survival,
- the absence of robust data enabling specific determination of the contribution of VANFLYTA (quizartinib) to the different treatment phases and, in particular, with respect to the effect of allogeneic HSCT,
- the lack of robust data enabling differentiation between the contribution of VANFLYTA (quizartinib) in the maintenance phase in patients having received allogeneic HSCT and those who did not, in the absence of randomisation before the initiation of maintenance therapy,
- a safety profile marked by the high frequency of early deaths (in the first 30 to 60 days), primarily related to an excess bone marrow toxicity following the addition of VANFLYTA (quizartinib) to intensive chemotherapy,
- the exploratory nature of the quality of life data,
- the impossibility of determining the role of VANFLYTA (quizartinib) compared to RYDAPT (midostaurine), given their concomitant development,

the Committee deems that VANFLYTA 17.7 mg and 26.5 mg (quizartinib) film-coated tablets, in combination with chemotherapies during the induction and consolidation phases and as single-agent maintenance therapy, provides a minor clinical added value (CAV IV), in the

same way as RYDAPT (midostaurine), compared to induction and consolidation chemotherapies administered alone and without a maintenance phase.