SUMMARY

alectinib

ALECENSA 150 mg

capsule

Indication extension

Adopted by the Transparency Committee on 23 October 2024

Summary of opinion

Favourable opinion for reimbursement "as monotherapy in the adjuvant treatment after complete tumour resection of adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) at high risk of recurrence"

Transparency Committee's conclusions

Clinical Benefit

- Non-small cell lung cancer (NSCLC) is a serious and life-threatening disease.
- This is a specific curative treatment for ALK+ NSCLC.
- The efficacy/adverse effects ratio is high.
- There are no medicinal products with this indication. However, non-specific chemotherapies are used following complete tumour resection.
- ALECENSA (alectinib) can be administered as a first-line adjuvant treatment after complete tumour resection in adults with ALK+ NSCLC.

Public health benefit

Considering:

- the seriousness of non-small cell lung cancer;
- the low prevalence of ALK+ NSCLC;
- the inadequately met medical need;
- the lack of evidence of an additional impact on morbidity and mortality and on quality of life;
- the lack of an expected impact on the organisation of care;

ALECENSA (alectinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ALECENSA (alectinib) is substantial as monotherapy in the adjuvant treatment after complete tumour resection of adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) at high risk of recurrence.

The Committee issues a favourable opinion for inclusion of ALECENSA (alectinib) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the above indication and at the MA dosages.

Clinical Added Value

Considering:

- demonstration of the superiority of ALECENSA (alectinib) compared to chemotherapy as an adjuvant treatment, in a randomised, open-label study on the risk of disease recurrence or death, a clinically relevant endpoint;
- with a substantial size effect, with a risk reduction of 76% (HR = 0.24; 95% CI [0.13; 0.45]), p<0.0001) in stage II-IIIA patients and in the stage IB-IIIA population (HR = 0.24; 95% CI [0.13; 0.43], p<0.0001);
- its acceptable safety profile, without any new safety signals in this indication;
- the inadequately met medical need in patients with ALK+ NSCLC at high risk of recurrence, after complete resection;

but in view of:

- an open-label study;
- a primary efficacy endpoint of disease-free survival as determined by the investigator (but 94% of the results were reviewed by an independent review committee);
- a lower effect reported when disease-free survival was assessed by the independent review committee than when it was assessed by the investigator, whereas the primary endpoint was assessment by the investigator;
- the lack of data relative to:
  - overall survival;
  - any recurrence after 2 years of treatment with alectinib;
  - the efficacy and safety of alectinib treatment in combination with chemotherapy;
  - quality of life, which are sufficiently robust;
  - resistance to alectinib;
  - concerning the optimal duration of adjuvant treatment with alectinib;
- a predominantly Asian study population (55.6%); no interaction test is available for this criterion, therefore a risk of heterogeneity of effect cannot be excluded;

  an unknown heterogeneity of the effect depending on stage, with only 26 stage Ib patients having been included.

the Committee deems that ALECENSA (alectinib) provides a minor clinical added value (CAV IV) in the care pathway in the adjuvant treatment after complete tumour resection of adult patients with ALK+ non-small cell lung cancer (NSCLC) at high risk of recurrence.