HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
20 MARCH 2020

osimertinib
TAGRISSO 40 and 80 mg film-coated tablets

New indication

Key points

Favourable opinion for reimbursement as monotherapy in the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.

What therapeutic improvement?

TAGRISSO provides a therapeutic improvement compared to other anti-EGFR TKIs in the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with mutations (EGFR).

Role in the care pathway?

In the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations, when the use of an anti-EGFR TKI isconsidered, osimertinib is the first-line treatment of choice due to demonstration of an improvement in overall survival compared to erlotinib and gefitinib with a safety profile judged to be acceptable.

The Committee reiterates that patients with EGFR mutations other than exon 19 deletion or exon 21 (L858R) activating mutations (in particular the T790M mutation for which osimertinib has an MA and a

specific Committee opinion) were not assessed in the FLAURA study. Exons 19 or 21 mutations represent the majority of all EGFR mutations (85%)[1] [2]

1 Leduc C, Merlio JP, Besse B et al. Clinical and molecular characteristics of non-small-cell lung cancer (NSCLC) harboring EGFR mutation: results of the nationwide French Cooperative Thoracic Intergroup (IFCT) program. Ann Oncol 2017; 28(11): 2715-2724.

2 *Mutations de l'EGFR dans le cancer du poumon : mise en évidence d'une cible moléculaire permettant un accès spécifique aux thérapies ciblées* [EGFR mutations in lung cancer: detection of a molecular target enabling specific access to targeted therapies], INCa, Boulogne-Billancourt, February 2010.

01 COMMITTEE'S CONCLUSIONS

01.1 Clinical benefit

◗ Non-small cell lung cancer (NSCLC) is a serious, life-threatening condition.
◗ The proprietary medicinal product TAGRISSO (osimertinib) is part of a specific curative NSCLC treatment.
◗ Its efficacy/adverse effects ratio is high.
◗ There are medicinal alternatives.
◗ TAGRISSO is a first-line treatment.

Public health impact

Considering:

- the severity of locally advanced or metastatic NSCLC with EGFR mutation and the low prevalence of EGFR mutation (around 10%),
- the medical need, which is considered to be partially met,
- the demonstrated impact on morbidity and mortality compared to current alternatives,
- the absence of conclusive quality of life data,
- the absence of data enabling assessment of the impact on the care organisation (hospitalisations avoided, transfer of care to consultations), which is not documented,

TAGRISSO (osimertinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TAGRISSO (osimertinib) is substantial in this MA indication extension.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication(s) and dosages.

01.2 Clinical Added Value

Considering:

- **the demonstration of the superiority of osimertinib compared to the anti-EGFR TKIs erlotinib or gefitinib in terms of:**
  - **progression-free survival evaluated by the investigator (median survival of 18.9 months in the osimertinib group vs 10.2 months in the comparator group; HR=0.46; 95% CI [0.37; 0.57]; p < 0.0001) and,**
  - **overall survival (median survival of 38.6 months in the osimertinib group vs 31.8 months in the comparator group; HR=0.799, $CI_{95.05\%}$ [0.64; 0.99]; p= 0.0462),**
- **the acceptable safety profile of osimertinib compared to the anti-EGFR TKIs erlotinib or gefitinib,**
- **the absence of any formal conclusion that can be drawn based on the quality of life results,**

the Committee considers that TAGRISSO (osimertinib) provides a moderate clinical added value (CAV III) compared to the anti-EGFR TKIs TARCEVA (erlotinib) and IRESSA (gefitinib) in the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutations.