INAHTA Brief

Issue 2020/003

Title KEYTRUDA – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/p_3112911/fr/keytruda

Aim

Assessment of KEYTRUDA (pembrolizumab) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies with a view to setting of its price by the French Healthcare Products Pricing Committee (CEPS) in the context of a new indication: in combination with carboplatin and either paclitaxel or nab-paclitaxel, in the first-line treatment of metastatic squamous non-small cell lung carcinoma (NSCLC) in adults.

Conclusions of Transparency Committee

Substantial clinical benefit in patients (ECOG performance status of 0 or 1) in the indication, considering:

- Squamous non-small cell lung carcinoma (NSCLC) is a serious, life-threatening disease.
- KEYTRUDA is a curative treatment.
- The efficacy/adverse effects ratio of KEYTRUDA in combination with chemotherapy with carboplatin and either paclitaxel or nab-paclitaxel is high.
- There are medicinal alternatives.
- KEYTRUDA, in combination with chemotherapy with carboplatin and either paclitaxel or nab-paclitaxel, is a first-line treatment for adult patients (ECOG performance status of 0 or 1) with metastatic squamous NSCLC.
- Public health impact

Considering:
- the seriousness of the disease,
- its incidence,
- the medical need to have access to alternatives at the metastatic stage of the disease,
- the partial response to the identified partially met medical need given the impact on morbidity and mortality due to the superiority of KEYTRUDA in combination with carboplatin + paclitaxel/nab-paclitaxel compared to carboplatin + paclitaxel/nab-paclitaxel demonstrated in terms of progression-free survival and overall survival following an interim analysis with a median follow-up of 8.3 months in the pembrolizumab group and 7.4 months in the placebo group,
- the absence of data enabling assessment of the additional impact on the organisation of care,
- the absence of a demonstrated impact on quality of life (exploratory data supplied), KEYTRUDA is not liable to have an additional impact on public health.

Considering:
- the demonstration of the superiority of the combination of pembrolizumab (KEYTRUDA) plus chemotherapy with carboplatin and paclitaxel or nab-paclitaxel compared to the same chemotherapy administered alone in terms of progression-free survival and overall survival (joint primary endpoints) following an interim analysis scheduled in the protocol,
- the substantial improvement in overall survival (+ 4.6 months), observed following an interim analysis after a median follow-up of 8.3 months in the pembrolizumab group and 7.4 months in the placebo group,
- the limited transposability of data from the KEYNOTE-407 study to the French population given that 40% of patients received the nab-paclitaxel + carboplatin combination, not cited in French national recommendations,
- the absence of robust quality of life data,

KEYTRUDA, in combination with chemotherapy with carboplatin and either paclitaxel or nab-paclitaxel, provides a moderate clinical added value (CAV III) compared to the combination of carboplatin and either paclitaxel or nab-paclitaxel in the first-line treatment of adult patients (ECOG performance status of 0 or 1) with metastatic squamous NSCLC.

Recommendations

The Transparency Committee issued its approval for the funding of KEYTRUDA by the French national health insurance system (hospital use only) in this new indication.

Methods

The assessment of KEYTRUDA was founded on evidence-based medicine with a critical analysis of the clinical data. The assessment of the efficacy and safety of KEYTRUDA is based on clinical data.

Written by

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