INAHTA Brief

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Title KEYTRUDA (cancer du rein) – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2982864/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 in the indication in combination with axitinib in the first-line treatment of advanced, clear-cell renal cell carcinoma or with a clear-cell component.

Conclusions of Transparency Committee

Clinical Benefit

- Clear-cell renal cell cancer is a serious, life-threatening disease.
- This is a specific curative treatment for clear-cell renal cell carcinoma or with a clear-cell component.
- The short-term efficacy/adverse effects ratio of the KEYTRUDA (pembrolizumab)/axitinib combination is high in purely clear-cell renal cell carcinoma or with a clear-cell component.
- There are therapeutic alternatives.
- It is a first-line treatment.
- The KEYTRUDA (pembrolizumab)/axitinib combination is unlikely to have an impact on public health.

Considering all of the above, the clinical benefit of KEYTRUDA (pembrolizumab) in combination with axitinib is substantial in the first-line treatment of advanced clear-cell renal cell carcinoma or with a clear-cell component.

Clinical Added Value
Considering:
- demonstration of the superiority of the KEYTRUDA (avelumab) plus axitinib combination compared to sunitinib, considered to be an acceptable comparator, on the two primary endpoints in an interim analysis and with a short median follow-up of 12.8 months:
  - progression-free survival assessed by an independent review committee (median of 15.1 months vs. 11.1 months; HR=0.69; 95%CI [0.57; 0.84], p= 0.00014),
  - overall survival: HR=0.53 95%CI [0.38; 0.74]; p=0.00005, with, nonetheless, an uncertainty for the subgroup with a favourable prognosis,

despite:
- the additional toxicity of this combination compared to sunitinib with, in particular, a higher frequency of serious adverse events (40.3% vs. 31.3%), grade ≥ 3 events (75.8% vs. 70.6%) or events leading to discontinuation of treatment (30.5% vs. 13.9%),
- the absence of any data on quality-of-life with a demonstrative value,
- uncertainties, particularly with respect to the respective contributions of each of the components of the pembrolizumab/axitinib combination,

the KEYTRUDA (pembrolizumab)/axitinib combination provides moderate Clinical Added Value (CAV III) compared to sunitinib in the first-line treatment of advanced clear-cell renal cell carcinoma or with a clear-cell component.

Recommendations

The Transparency Committee issued its approval for the funding of KEYTRUDA (pembrolizumab) by the French national health insurance system (hospital only) in the indication in combination with axitinib in the first-line treatment of advanced, clear-cell renal cell carcinoma or with a clear-cell component.

Methods

The assessment of KEYTRUDA (pembrolizumab) was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

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