SUMMARY

pembrolizumab

KEYTRUDA 25 mg/mL

concentrate for solution for infusion

Indication extension

Adopted by the Transparency Committee on 25 September 2024

Summary of opinion

Favourable opinion for reimbursement in the indication "in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction-adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1"

Transparency Committee's conclusions

Clinical Benefit

- Advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinomas are serious, life-threatening diseases.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- KEYTRUDA (pembrolizumab), in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, is a first-line treatment for locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1.

Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the partial response to the identified need, due to an impact on morbidity and mortality, with an improvement in overall survival and progression-free survival, but without evidence of an impact on quality of life,
- the lack of evidence of an impact on the organisation of care, with, however, the addition of an infusion of pembrolizumab every 3 weeks to an already substantial protocol composed of two chemotherapy drugs and an anti-HER2 therapy,

KEYTRUDA (pembrolizumab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of KEYTRUDA (pembrolizumab) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of KEYTRUDA (pembrolizumab) in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering, on the one hand:

- demonstration in a phase 3, double-blind study of a superiority of KEYTRUDA (pembrolizumab), in combination with trastuzumab, fluoropyrimidine and dual platinum-containing chemotherapy, compared with trastuzumab combined with dual chemotherapy alone, in the ITT population including 85% patients with a CPS ≥ 1 in terms of:
  - overall survival: HR = 0.80 ($CI_{95\%}$ [0.67; 0.94]) with a difference in median of +3.2 months;
  - progression-free survival: HR = 0.73 ($CI_{95\%}$ [0.61; 0.87]) with a difference in median of +1.9 months;

but, on the other hand:

- the absence of robust data on quality of life,
- an effect size judged to be modest in terms of progression-free survival and overall survival,
- its safety profile marked, in particular by immune-mediated adverse effects,

the Transparency Committee deems that KEYTRUDA (pembrolizumab), in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, as first-line treatment for locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1 provides a minor clinical added value (CAV IV) compared to platinum-containing chemotherapy and fluoropyrimidine.