Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version.

SUMMARY

zolbetuximab

VYLOY 100 mg

powder for concentrate for solution for infusion

Inclusion on list

Adopted by the Transparency Committee on 15 January 2025

Summary of opinion

Favourable opinion for reimbursement in the indication "VYLOY, in combination with fluoropyrimidine- and platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive (see section 4.2 of the SmPC)".

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.
- VYLOY, in combination with fluoropyrimidine- and platinum-based chemotherapy, is a first-line treatment in adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.

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,

VYLOY (zolbetuximab) 100 mg powder for concentrate for solution for infusion is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of VYLOY (zolbetuximab) 100 mg powder for concentrate for solution for infusion is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of VYLOY (zolbetuximab) 100 mg powder for concentrate for solution for infusion 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:

- evidence in two double-blind, phase 3 studies of a superiority of VYLOY (zolbetuximab) in combination with dual fluoropyrimidine- and platinum-based chemotherapy compared with dual chemotherapy alone, in the ITT population in terms of:
  - overall survival: HR=0.784; $CI_{95\%}$ [0.644; 0.954] (SPOTLIGHT study) and HR=0.763; $CI_{95\%}$ [0.622; 0.936] (GLOW study);
  - progression-free survival: HR= 0.751; $CI_{95\%}$ [0.598; 0.942] (SPOTLIGHT study) and HR= 0.687; $CI_{95\%}$ [0.544; 0.866] (GLOW study);

but, on the other hand:

- methodological limitations concerning the analysis of the time to confirmed deterioration (TTCD) with non-demonstration of non-inferiority in the SPOTLIGHT study and a non-inferiority only for the physical function scale (first endpoint in the ranked sequence) in the GLOW study despite a ranked analysis scheduled in the protocols of the two studies;
- an effect size judged to be modest in terms of progression-free survival and overall survival,
- its safety profile marked, in particular, by an increase in nausea and vomiting,
- the problem of the transposability of the results to the French population (around 30% Asian patients in the SPOTLIGHT study and 60% in the GLOW study);

the Committee considers that VYLOY (zolbetuximab) 100 mg powder for concentrate for solution for infusion provides a minor clinical added value (CAV IV) compared to fluoropyrimidine- and platinum-based chemotherapy in the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.