SUMMARY

durvalumab

IMFINZI 50 mg/ml,

concentrate for solution for infusion

New indication(s)

Original French opinion adopted by the Transparency Committee on 21 June 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Biliary tract cancer is a rare cancer with an estimated annual incidence in France of 2,965 new cases excluding intrahepatic cholangiocarcinoma and 1,328 to 1,825 new cases of intrahepatic cholangiocarcinoma. Diagnosis is often delayed due to clinical signs present at an advanced stage of the disease. Consequently, the prognosis is poor, particularly for intrahepatic cholangiocarcinoma.
- The medicinal product IMFINZI (durvalumab) is a curative medicinal product.
- The efficacy/adverse effects ratio is high due to:
  - a statistically significant absolute difference in median overall survival (primary efficacy endpoint) of 1.3 months and in progression-free survival (secondary efficacy endpoint) of 1.5 months, in favour of the durvalumab + gemcitabine and cisplatin group following a median follow-up of 13 months;
  - a safety profile deemed to be acceptable;
  - the absence of any formal conclusion that can drawn based on the quality of life results given their exploratory nature;
- This is a first-line treatment in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the partial response to the identified need:

- an inadequately demonstrated additional impact on morbidity and mortality due to demonstration of a modest improvement in overall survival and progression-free survival with the durvalumab + gemcitabine/cisplatin combination, and the lack of demonstrated impact on quality of life;
- the lack of demonstration of an additional impact on the organisation of care and the care pathway;

IMFINZI (durvalumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of IMFINZI (durvalumab) 50 mg/mL concentrate for solution for infusion is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of IMFINZI (durvalumab) 50 mg/mL concentrate for solution for infusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- demonstration of the superiority of durvalumab combined with gemcitabine and cisplatin compared to the gemcitabine and cisplatin combination alone, in a randomised, double-blind study, in terms of overall survival (OS, primary endpoint) and progression-free survival (PFS, ranked secondary endpoint),
- the effect size deemed to be modest but significant, with an absolute difference for median OS of 1.3 months, with an HR= 0.80; $CI_{97\%}$ [0.64; 0.99]),
- the lack of formal conclusions that can be drawn from the exploratory results of the secondary endpoints, including quality of life,
- a safety profile deemed to be acceptable,
- the medical need partially met by the available alternatives and the evolution of guidelines for the management of advanced biliary tract cancer,

the Committee deems that IMFINZI (durvalumab) 50 mg/mL concentrate for solution for infusion provides a minor clinical added value (CAV IV) compared to gemcitabine + cisplatin chemotherapy in the first-line treatment of adults with unresectable or metastatic biliary tract cancer (BTC).