OPINION ON MEDICINAL PRODUCTS

cemiplimab
LIBTAYO 350 mg

solution for dilution for infusion

New indication

Adopted by the Transparency Committee on 14 September 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Approval of the reimbursement of LIBTAYO (cemiplimab) monotherapy for the treatment of adult patients with locally advanced or metastatic basocellular carcinoma (laBCC or mBCC), whose condition has progressed or who are exhibiting Hedgehog pathway inhibitor (HPI) intolerance.

Therapeutic improvement?

No therapeutic improvement, based on the data available.

Role in therapeutic strategy?

The first-line treatment of these advanced forms of basocellular carcinoma (BCC) is based on the use of Sonic Hedgehog pathway inhibitors, Vismodegib or Sonidegib. Indeed, most cases of BCC express mutations of this pathway, making them accessible to this type of targeted therapy. The oral medicinal products, Vismodegib and Sonidegib, make it possible to obtain high objective response rates. For Vismodegib, the objective response rates are in the region of 43% in locally advanced BCC (laBCC), and 30% in metastatic BCC (mBCC). For Sonidegib, the objective response rates are 56% in laBCC, and 8% in mBCC. These Sonic Hedgehog pathway inhibitors are frequently associated with side-effects that may limit their use, particularly in older patients: weight loss, anorexia and ageusia, vomiting, fatigue, etc.

In cases of failure to respond to these treatments or of intolerance making it impossible to continue treatment, no appropriate treatment was hitherto available. Chemotherapy is very ineffective on this type of tumour and also poorly tolerated in the older cohort.

Role of the medicinal product:

LIBTAYO (cemiplimab) is a second-line treatment indicated for adult patients with locally advanced or metastatic basocellular carcinoma, that has progressed or is exhibiting Hedgehog pathway inhibitor (HPI) intolerance.

Committee's conclusions

Clinical Benefit

- Locally advanced basocellular carcinoma is a severe life-threatening disease.
- The proprietary medicinal product LIBTAYO (cemiplimab) is a curative medicinal product.
- The efficacy/adverse effect ratio is moderate.
- There is no alternative medication with an acceptable level of evidence at this stage of the disease.
- It is a second-line treatment (patients whose condition has progressed or who are exhibiting Hedgehog pathway inhibitor (HPI) intolerance).

Public health benefit

Considering:

- The severity of the disease,
- Its low prevalence and incidence,
- The unmet medical need,
- The preliminary non-comparative data showing an overall response rate in the region of 24 to 28% according to the cohort assessed, not statistically significantly different from the historic values selected in frequency calculations (set at 15% and 20% respectively) (primary outcome measure),
- The lack of comparative studies defining the effect size,
- The lack of evidence of an additional impact on delivery of care,

LIBTAYO (cemiplimab) is not likely to have a public health benefit for adult patients with locally advanced or metastatic basocellular carcinoma, whose condition has progressed or who are exhibiting Hedgehog pathway inhibitor (HPI) intolerance.

HAS - Evaluation and Access to Innovation Department

Considering all of these elements, the Committee deems that the actual clinical benefit of LIBTAYO (cemiplimab) is moderate in the marketing authorisation indication.

The Committee approves inclusion in the list of proprietary medicinal products approved for community use in the extension of indication: "LIBTAYO (cemiplimab) is indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic basocellular carcinoma (laBCC or mBCC), whose condition has progressed or who are exhibiting Hedgehog pathway inhibitor (HPI) intolerance".

Clinical Added Value

Considering:

- **The non-comparative phase II study data based on an overall response rate in the region of 24 to 28% according to the cohort assessed, with however an inconclusive statistical test with respect to the historic values selected in the frequency calculation,**
- **The lack of comparative data, particularly versus supportive care,**

The Committee deems that, based on the data currently available, LIBTAYO (cemiplimab) provides no clinical added value (CAV V) for the treatment of adult patients with locally advanced or metastatic basocellular carcinoma (laBCC or mBCC), whose condition has progressed or who are exhibiting Hedgehog pathway inhibitor (HPI) intolerance.