HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
06 OCTOBER 2021

The legally binding text is the original French opinion version

cemiplimab
LIBTAYO 350 mg concentrate for solution for infusion

New indication

Key points

Favourable opinion for reimbursement as monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC and who are not candidates for definitive chemoradiation, or metastatic NSCLC.

What therapeutic improvement?

No clinical added value in the current therapeutic strategy including pembrolizumab.

◗ Role in the care pathway?

The current first-line management for metastatic non-small cell lung cancer expressing PD-L1 (in ≥ 50% tumour cells), in the absence of molecular abnormalities (EGFR mutations, or ALK or ROS-1 rearrangements), is based on immunotherapy, for eligible patients.

Pembrolizumab is a first-line treatment:

- as monotherapy,
- in combination with chemotherapy (irrespective of PD-L1 expression status):
  - in combination with pemetrexed and platinum chemotherapy, in non-squamous NSCLC,
  - in combination with carboplatin and paclitaxel (or nab-paclitaxel) chemotherapy, in squamous NSCLC.

In the event of contraindication to immunotherapy, or to one of the chemotherapy drugs combined with pembrolizumab, chemotherapy is indicated. This involves dual therapy combining a platinum (cisplatin or carboplatin) with one of the following substances: vinorelbine, gemcitabine, docetaxel, paclitaxel or pemetrexed (only in non-squamous NSCLC for the latter), irrespective of PD-L1 expression status. The nivolumab/ipilimumab can be combined with two cycles of chemotherapy in the absence of contraindications in metastatic NSCLC, irrespective of PD-L1 expression status. In non-squamous NSCLC, bevacizumab can be added to the dual chemotherapy regimen, in the absence of contraindications; and atezolizumab can be combined with bevacizumab + paclitaxel + carboplatin, irrespective of PD-L1 expression status.

Role of the medicinal product in the care pathway

LIBTAYO (cemiplimab) as monotherapy is a first-line treatment option for adult patients with non-small cell lung cancer expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC and who are not candidates for definitive chemoradiation, or metastatic NSCLC.

However, the Committee regrets the absence of data enabling the role of LIBTAYO (cemiplimab) to be positioned compared to the current standard of care therapy, i.e., pembrolizumab as monotherapy, only if PD-L1 ≥ 50%. Consequently, as knowledge currently stands, the role of cemiplimab as monotherapy compared to pembrolizumab monotherapy is not known.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

◗ Non-small cell lung cancer (NSCLC) is a serious, life-threatening disease.

◗ The proprietary medicinal product LIBTAYO (cemiplimab) is a curative medicinal product specific to NSCLC.

◗ Its efficacy/adverse effects ratio is high.

◗ There are therapeutic alternatives, in particular pembrolizumab (as monotherapy), which has demonstrated its superiority compared to chemotherapy in terms of overall survival, with an acceptable safety profile.

◗ LIBTAYO (cemiplimab) as monotherapy is a first-line treatment option for adult patients with non-small cell lung cancer expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC and who are not candidates for definitive chemoradiation, or metastatic NSCLC. The role of the combination compared to pembrolizumab cannot be specified as the dossier currently stands, in the absence of direct comparative data.

Public health impact

Considering:

- the seriousness of advanced or metastatic NSCLC expressing PD-L1 in ≥ 50% tumour cells,
- the partially met medical need,
- an annual incidence of around 7,800 cases,
- the partial response provided by cemiplimab to the identified need, given:
    - a demonstrated short-term additional impact on morbidity and mortality versus a comparator that was already not the standard of care on the date that the study started,
    - a non-demonstrated impact on quality of life due to a lack of demonstrative data,
- a lack of expected impact on the care pathway,

LIBTAYO (cemiplimab) is unlikely to have an additional impact on public health.

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

The Committee issues a favourable opinion for inclusion 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 cemiplimab as monotherapy compared to chemotherapy in terms of overall survival (HR=0.68 [CI95%: 0.52-0.87], with an individual estimate of a median absolute improvement of 7.8 months, deemed clinically relevant), in an open-label, randomised phase 3 study;**

and despite:

- **the absence of robust comparative data versus pembrolizumab, the current standard of care therapy;**
- **the lack of demonstrated impact on health-related quality of life;**

the Transparency Committee considers that LIBTAYO (cemiplimab), as monotherapy, provides no clinical added value (CAV V) in the care pathway including pembrolizumab, in the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC and who are not candidates for definitive chemoradiation, or metastatic NSCLC.