**SUMMARY**

cemiplimab

# LIBTAYO 350 mg,

**concentrate for solution for infusion**

New indication(s)

**Original French opinion adopted by the Transparency Committee on 5 April 2023**

**The legally binding text is the original French opinion version**

## Key points

Favourable opinion on reimbursement solely in patients with recurrent or metastatic cervical cancer and with disease progression during or after platinum-based chemotherapy without the addition of pembrolizumab.

## What therapeutic improvement?

LIBTAYO (cemiplimab), in monotherapy, is a second-line treatment for recurrent or metastatic cervical cancer with disease progression during or after platinum-based chemotherapy without the addition of pembrolizumab.

# Transparency Committee's Conclusions

## Clinical Benefit

- Recurrent or metastatic cervical cancer is a serious disease that is life-threatening.
- It is a curative medicinal product.
- The efficacy/adverse effect ratio is significant.
- It is a second-line treatment in patients with recurrent or metastatic cervical cancer with disease progression during or after platinum-based chemotherapy without the addition of pembrolizumab.

### Public health benefit

In view of:

- the gravity of the disease and its incidence;
- the partially met medical need;
- the partial response to the need identified:
  - an additional proven impact on morbidity and mortality in the subpopulation selected for reimbursement. The impact on quality of life has not been demonstrated to date;
  - the absence of additional impact on the organisation of care;
  - the absence of impact on the care pathway and life course;

LIBTAYO (cemiplimab) is not liable to have an additional impact on public health.

**In view of all of these elements, the Committee considers that the clinical benefit provided by LIBTAYO 350 mg (cemiplimab), concentrate for solution for infusion is significant solely in patients with recurrent or metastatic cervical cancer with disease progression during or after platinum-based chemotherapy without the addition of pembrolizumab.**

**In the remainder of the indication, the Committee considers that the clinical benefit provided is insufficient.**

**The Committee gives a favourable opinion on the inclusion of LIBTAYO 350mg (cemiplimab), concentrate for solution for infusion on the list of medicinal products approved for the use of communities solely in patients with recurrent or metastatic cervical cancer with disease progression during or after platinum-based chemotherapy without the addition of pembrolizumab.**

## Clinical Added Value

In view of:

- the demonstration in a phase III, comparative, randomised open study of the superiority of cemiplimab compared to chemotherapy left to the choice of the investigator, in the treatment of recurrent, persistent or metastatic cervical cancer, that has progressed or recurred after treatment with platinum salts ± bevacizumab, in terms of overall survival (OS) with a median difference of 3.5 months and an HR = 0.685, 95% CI = [0.560; 0.838] in the overall study population;
- the profile of patients in the EMPOWER 1676 study who were not exposed to pembrolizumab, even though this immunotherapy has recently been incorporated into the first-line therapeutic strategy for eligible patients;
- the acceptable tolerance profile.

**the Committee considers that LIBTAYO (cemiplimab) provides moderate clinical added value (CAV III) compared to monochemotherapies (pemetrexed, gemcitabine, irinotecan, topotecan and vinorelbine) solely in patients with recurrent or metastatic cervical cancer with disease progression during or after platinum-based chemotherapy without the addition of pembrolizumab.**