**SUMMARY**

nivolumab

# OPDIVO 10 mg/ml,

**solution for infusion**

Indication extension

**Original French opinion adopted by the Transparency Committee on 20 December 2023**

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

## Transparency Committee's Conclusions

### Clinical Benefit

- Melanoma is a serious life-threatening disease.
- OPDIVO (nivolumab) is a proprietary medicinal product intended to prevent recurrence.
- The efficacy/adverse effects ratio is high.
- There are alternative medications at this stage of treatment (KEYTRUDA (pembrolizumab)).
- This product is a first-line treatment in the context of adjuvant therapy to surgery.

#### Public health benefit

In view of:

- the seriousness of the condition and its incidence;
- the partially met medical need;
- the response to the identified need;
- evidence of an additional impact on morbidity. With, however, immature overall survival and exploratory quality-of-life data;
- the additional impact on the delivery of care, the care and/or life pathway which has not been studied;

OPDIVO (nivolumab) is unlikely to have an additional impact on public health.

**Considering all of these elements, the Committee deems that the clinical benefit of OPDIVO (nivolumab) is substantial in the indication: as monotherapy for the adjuvant treatment of adult and adolescent patients aged 12 years and over, with completed resected stage IIB or IIC melanoma.**

**The Committee approves inclusion in the list of covered drugs for inpatients of OPDIVO (nivolumab) as monotherapy for the adjuvant treatment of adult and adolescent patients aged 12 years and over, with completely resected stage IIB, IIC melanoma.**

## Clinical Added Value

Taking into account:

- evidence in a randomised study *versus* placebo of superiority of nivolumab on the primary outcome measure, recurrence-free survival where HR=0.42 ($CI_{95\%}$ [0.30; 0.59]);
- the lack of evidence of a gain in overall survival (immaturity of the data available (ranked secondary outcome measure));
- treatment considered to be similar for both adults and adolescents, The efficacy findings of the CheckMate76k study did not include any patients aged ≤ 18 years, the efficacy data for adults were accepted as suitable for extrapolation to adolescents aged 12 years and over,

**the Committee deems that, based on the data currently available, OPDIVO (nivolumab) provides, like KEYTRUDA (pembrolizumab), minor clinical added value (CAV IV) as monotherapy for the adjuvant treatment of adult and adolescent patients aged 12 years and over, with completely resected stage IIB, IIC melanoma.**