Opdivo® (nivolumab) – Expanded indication

- On October 13, 2023, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.
    - Opdivo was previously approved for the adjuvant treatment of adult and pediatric patients 12 years and older with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
- In addition to adjuvant treatment of melanoma, Opdivo is approved for 12 additional indications. Refer to the Opdivo drug label for a complete listing of indications and uses.
- The approval of Opdivo for the expanded indication was based on CHECKMATE-76K, a randomized, double-blind study in 790 patients with completely resected Stage IIB/C melanoma. Patients received Opdivo or placebo for up to 1 year or until disease recurrence or unacceptable toxicity. The major outcome measure was recurrence-free survival (RFS), defined as the time between the date of randomization and the date of first recurrence (local, regional, or distant metastasis), new primary melanoma, or death, from any cause.
    - Opdivo reduced the risk of recurrence, new primary melanoma, or death in patients with completely resected Stage IIB or IIC melanoma by 58% compared to placebo (hazard ratio [HR] 0.42; 95% CI: 0.30, 0.59; $p < 0.0001$).
- The recommended dose of Opdivo for the adjuvant treatment of melanoma in adult patients and pediatric patients age 12 years and older and weighing 40 kg or more is 240 mg every 2 weeks or 480 mg every 4 weeks. The dose in pediatric patients age 12 years and older and weighing less than 40 kg is 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks. The duration of therapy is until disease recurrence or unacceptable toxicity for up to 1 year.
- Refer to the Opdivo drug label for dosing for all its other indications.