RXADVANCE
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# Opdivo (nivolumab) Injection Clinical Update

Clinical Update: FDA Approves Opdivo (nivolumab) + Yervoy (ipilimumab) as First-Line Treatment of Patients with Metastatic Non-Small Cell Lung Cancer Whose Tumors Express PD-L1≥1%.
FDA approval date: May 15, 2020

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of advanced melanoma, advanced non-small cell lung cancer, advanced small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma.

Opdivo (nivolumab) 3 mg/kg plus Yervoy (ipilimumab) 1 mg/kg (injections for intravenous use) was approved by the U.S. Food and Drug Administration (FDA) for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. This approval is based on Part 1a of the Phase 3 CheckMate -227 trial in which Opdivo + Yervoy (n=396) demonstrated superior overall survival (OS) versus chemotherapy (n=397) (hazard ratio [HR] 0.79; 95% confidence interval [CI]: 0.67 to 0.94; P=0.0066) regardless of tumor histology with a minimum follow up of 29.3 months. Opdivo + Yervoy is a unique combination of two immune checkpoint inhibitors that features a potentially synergistic mechanism of action, targeting two different checkpoints (PD-1 and CTLA-4) to help destroy tumor cells: Yervoy helps activate and proliferate T cells, while Opdivo helps existing T cells discover the tumor. Some of the T cells stimulated by Yervoy can become memory T cells, which may allow for a long-term immune response. Targeting of normal cells can also occur and result in immune-mediated adverse reactions, which can be severe and potentially fatal. Please see the Important Safety Information section, including Boxed WARNING for Yervoy (ipilimumab) regarding immune-mediated adverse reactions.