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Opdivo (nivolumab) Injection
Clinical Update

Clinical Update: FDA Approves Opdivo (nivolumab) for the Treatment of Patients with Advanced Esophageal Squamous Cell Carcinoma (ESCC) After Prior Fluoropyrimidine- and Platinum-based Chemotherapy.
FDA approval date: June 10, 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) is indicated for the treatment of patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.

ATTRACTION-3 (NCT02569242) is a Phase 3, multicenter, randomized, active-controlled, open-label global study evaluating Opdivo versus taxane chemotherapy (investigator's choice of docetaxel or paclitaxel) in patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma, refractory or intolerant to at least one prior fluoropyrimidine- and platinum-based regimen. The trial included patients regardless of tumor PD-L1 status, but tumor specimens were evaluated prospectively using the PD-L1 IHC 28-8 pharmDx assay at a central laboratory.
This application was granted Priority Review Designation by the FDA, and the approval is based on the Phase 3 ATTRACTION-3 trial in which Opdivo (n=210) demonstrated superior overall survival (OS) versus taxane chemotherapy (n=209) (investigator's choice of docetaxel or paclitaxel) (hazard ratio [HR] 0.77; 95% confidence interval [CI]: 0.62 to 0.96; p=0.0189).1,2 The median OS was 10.9 months (95% CI: 9.2 to 13.3) for Opdivo compared to 8.4 months (95% CI: 7.2 to 9.9) for docetaxel or paclitaxel.1 Opdivo is the first approved immunotherapy in this setting regardless of tumor PD-L1 expression level. The trial excluded patients who were refractory or intolerant to taxane therapy, had brain metastases that were symptomatic or required treatment, had autoimmune disease, used systemic corticosteroids or immunosuppressants or had apparent tumor invasion of organs adjacent to the esophageal tumor or had stents in the esophagus or respiratory tract. The major efficacy outcome measure was OS.1 Additional efficacy outcome measures included overall response rate (ORR) and progression-free survival (PFS) as assessed by the investigator using RECIST v1.1 and duration of response (DOR).

In the United States, it is estimated that approximately 18,440 new cases of esophageal cancer will be diagnosed and approximately 16,170 deaths will result from the disease this year alone. Esophageal cancer is a type of gastrointestinal cancer that starts in the inner layer of the esophagus (the mucosa) and grows.