FDA Approves Opdivo for Esophageal Cancer

Checkpoint inhibitor extended survival by about three months compared with chemotherapy.

June 12, 2020 By Food and Drug Administration (FDA)

FDA approves nivolumab for esophageal squamous cell carcinoma

On June 10, 2020, the Food and Drug Administration approved nivolumab (OPDIVO, Bristol-Myers Squibb Co.) for patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.

Efficacy was investigated in ATTRACTION-3 (NCT02569242), a multicenter, randomized (1:1), active-controlled, open-label trial in 419 patients with unresectable advanced, recurrent, or metastatic ESCC. Patients who were refractory or intolerant to at least one fluoropyrimidine- and platinum-based regimen received nivolumab 240 mg by intravenous infusion over 30 minutes every 2 weeks (n=210), or investigator's choice of taxane chemotherapy consisting of docetaxel (75 mg/m^2 intravenously every 3 weeks) or paclitaxel (100 mg/m^2 intravenously once a week for 6 weeks followed by 1 week off) (n=209).

The major efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures were overall response rate (ORR), response duration, and progression-free survival (PFS) as assessed by the investigator using RECIST 1.1.

The trial demonstrated a statistically significant improvement in OS. Median OS for patients receiving nivolumab was 10.9 months (95% CI: 9.2, 13.3) compared with 8.4 months (95% CI: 7.2, 9.9) for patients receiving investigator's choice of taxane chemotherapy (HR: 0.77; 95% CI: 0.62, 0.96; p=0.0189). OS benefit was observed regardless of tumor PD-L1 expression level.

The ORR was 19.3% (95% CI: 13.7, 26) in the nivolumab arm versus 21.5% (95% CI: 15.4, 28.8) in the taxane chemotherapy arm, with median response duration of 6.9 months (95% CI: 5.4, 11.1) and 3.9 months (95% CI: 2.8, 4.2), respectively. The trial did not demonstrate an improvement in PFS (HR: 1.1; 95% CI: 0.9, 1.3).

The most common adverse reactions in [at least] 10% of patients receiving nivolumab were rash, decreased appetite, diarrhea, constipation, musculoskeletal pain, upper respiratory tract infection, cough, pyrexia, pneumonia, anemia, fatigue, pruritus, nausea, and hypothyroidism.

The recommended nivolumab dose for ESCC is 240 mg every 2 weeks or 480 mg every 4 weeks.

View full prescribing information for OPDIVO.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

Nivolumab was granted priority review and orphan drug designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.
