FDA Approves Opdivo for Resected Esophageal Cancer

Checkpoint inhibitor doubled disease-free survival time after surgery.

May 24, 2021 By Food and Drug Administration (FDA)

FDA approves nivolumab for resected esophageal or GEJ cancer

On May 20, 2021, the Food and Drug Administration approved nivolumab (Opdivo, Bristol-Myers Squibb Company) for patients with completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy.

Efficacy was evaluated in CheckMate-577 (NCT02743494), a randomized, multicenter, double-blind trial in 794 patients with completely resected (negative margins) esophageal or GEJ cancers who had residual pathologic disease following concurrent chemoradiotherapy. Patients were randomized (2:1) to receive either nivolumab 240 mg or placebo every 2 weeks for 16 weeks followed by 480 mg of nivolumab or placebo every 4 weeks beginning at week 17 for up to one year of treatment.

The main efficacy outcome measure was disease-free survival (DFS), defined as the time between randomization date and the first recurrence (local, regional, or distant from the primary resected site) date, or death, from any cause, as assessed by the investigator prior to subsequent anti-cancer therapy.

CheckMate-577 demonstrated a statistically significant improvement in DFS for patients receiving nivolumab as compared to those on the placebo arm. The median DFS was 22.4 months (95% CI: 16.6, 34.0) versus 11 months (95% CI: 8.3, 14.3), respectively (HR 0.69; 95% CI: 0.56, 0.85; p=0.0003). The DFS benefit was observed regardless of tumor PD-L1 expression and histology.

The most common adverse reactions (incidence ≥20%) in patients receiving nivolumab are fatigue, rash, musculoskeletal pain, pruritus, diarrhea, nausea, asthenia, cough, dyspnea, constipation, decreased appetite, back pain, arthralgia, upper respiratory tract infection, pyrexia, headache, abdominal pain, and vomiting.

The recommended nivolumab dose for adjuvant treatment of resected esophageal or GEJ cancer is 240 mg every 2 weeks or 480 mg every 4 weeks for a total treatment duration of 1 year. Both doses are administered as 30-minute intravenous infusions.

View full prescribing information for Opdivo.

This review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this review, FDA collaborated with the Australian Therapeutic Goods Administration (TGA), Health Canada, and Switzerland's Swissmedic. The application reviews are ongoing at the other regulatory agencies.

This review used the Real-Time Oncology Review (RTOR) pilot program, which streamlined data submission prior to the filing of the entire clinical application, and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. Nivolumab received orphan drug designation for this indication. 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.

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