FDA Approves Keytruda for HER2-Positive Stomach Cancer

75% of people treated with a combination of immunotherapy, targeted therapy and chemotherapy saw their tumors shrink.

May 6, 2021 By Food and Drug Administration (FDA)

FDA grants accelerated approval to pembrolizumab for HER2-positive gastric cancer

On May 5, 2021, the Food and Drug Administration granted accelerated approval to pembrolizumab (Keytruda, Merck & Co.) in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.

Approval was based on the prespecified interim analysis of the first 264 patients of the ongoing KEYNOTE-811 (NCT03615326) trial, a multicenter, randomized, double-blind, placebo-controlled trial in patients with HER2-positive advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma who had not previously received systemic therapy for metastatic disease.

Patients were randomized (1:1) to receive pembrolizumab 200 mg or placebo every 3 weeks, in combination with trastuzumab and either fluorouracil plus cisplatin or capecitabine plus oxaliplatin.

The main efficacy measure for this analysis was overall response rate (ORR) assessed by blinded independent review committee. The ORR was 74% (95% CI 66, 82) in the pembrolizumab arm and 52% (95% CI 43, 61) in the placebo arm (one-sided p-value< 0.0001, statistically significant). The median duration of response (DoR) was 10.6 months (range 1.1+, 16.5+) for patients treated with pembrolizumab and 9.5 months (range 1.4+, 15.4+) for those in the placebo arm.

The adverse reaction profile observed in patients receiving pembrolizumab in Study KEYNOTE-811 is consistent with the known pembrolizumab safety profile.

The recommended pembrolizumab dose for adult patients with locally advanced unresectable or metastatic HER2 positive gastric or GEJ adenocarcinoma in combination with trastuzumab and chemotherapy is 200 mg every 3 weeks or 400 mg every 6 weeks.

View full prescribing information for Keytruda.

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.

This application was granted priority review. 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.

This announcement was published on the Food and Drug Administration website on May 5, 2021.
