FDA Approves Lonsurf for Recurrent, Metastatic Gastric Cancer

Median overall survival was 5.7 months for patients receiving Lonsurf and 3.6 months for those receiving placebo.

February 22, 2019 By Food and Drug Administration (FDA)

On February 22, 2019, the Food and Drug Administration approved trifluridine/ tipiracil tablets (LONSURF, Taiho Pharmaceutical Co., Ltd.)—a fixed combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor—for adult patients with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

Approval was based on TAGS (NCT02500043), an international, randomized, double-blind, placebo-controlled trial in 507 patients with metastatic gastric or GEJ adenocarcinoma previously treated with at least two prior lines of chemotherapy. Patients were randomized 2:1 to receive Lonsurf (n=337) 35 mg/m2 orally twice daily on Days 1-5 and 8-12 of each 28-day cycle with best supportive care (BSC) or matching placebo (n=170) with BSC until disease progression or unacceptable toxicity.

Median overall survival was 5.7 months (4.8, 6.2) for patients receiving Lonsurf and 3.6 months (3.1, 4.1) for those receiving placebo (hazard ratio: 0.69; 95% CI: 0.56, 0.85; p=0.0006). Progression-free survival was also longer in patients randomized to the Lonsurf arm (hazard ratio 0.56; 95% CI: 0.46, 0.68; p<0.0001).

In the TAGS trial, the most common adverse reactions or laboratory abnormalities (≥10% incidence) in patients treated with Lonsurf occurring at a higher rate than in patients receiving placebo were neutropenia, anemia, nausea, decreased appetite, thrombocytopenia, vomiting, and diarrhea.

The recommended Lonsurf dose and schedule is 35 mg/m2/dose orally twice daily with food on Days 1 through 5 and Days 8 through 12 of each 28-day cycle.

View full prescribing information for LONSURF.

FDA granted this application 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.

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