Lonsurf® (trifluridine/tipiracil) – New indication

- On Februarys 25, 2019, Taiho Oncology announced the FDA approval of Lonsurf (trifluridine/tipiracil), for the treatment of 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.

- Lonsurf is also approved for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

- Gastric cancer is the fifteenth most commonly diagnosed cancer in the U.S. In 2018, there were an estimated 26,240 new cases and 10,800 deaths in the U.S. Approximately 35% of U.S. patients with gastric cancer are diagnosed at the distant or metastasized stage and metastatic gastric cancer is associated with a five-year survival rate of about 5%.

- The approval of Lonsurf's new indication was based on TAGS, a double-blind study in 507 patients with metastatic gastric or GEJ adenocarcinoma previously treated with at least 2 prior regimens for advanced disease. Patients were randomized to receive Lonsurf or placebo until disease progression or unacceptable toxicity. The major efficacy outcome measure was overall survival (OS) and an additional outcome measure was progression-free survival (PFS).

    — Median OS was 5.7 months (95% CI: 4.8, 6.2) for Lonsurf vs. 3.6 months (95% CI: 3.1, 4.1) for placebo (Hazard Ratio [HR]: 0.69; 95% CI: 0.56, 0.85; p = 0.0006).
    — There was also a statistically significant improvement in PFS with Lonsurf vs. placebo (HR: 0.56; 95% CI: 0.46, 0.68; p < 0.0001).

- The recommended dosage of Lonsurf for both indications is 35 mg/m^2 up to a maximum of 80 mg per dose (based on the trifluridine component) orally twice daily with food on days 1 through 5 and days 8 through 12 of each 28-day cycle until disease progression or unacceptable toxicity.

    — The dose should be rounded to the nearest 5 mg increment.
    — Refer to the Lonsurf drug label for additional dosing recommendations.