

# The Medical Letter<sup>®</sup>

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### IN BRIEF

#### Trifluridine/Tipiracil (*Lonsurf*) for Metastatic Colorectal Cancer

The FDA has approved *Lonsurf* (Taiho Oncology), a combination of the thymidine-based nucleoside analog trifluridine and the thymidine phosphorylase inhibitor tipiracil, for oral treatment of metastatic colorectal cancer. Trifluridine is incorporated into DNA, interfering with DNA synthesis and inhibiting cell proliferation. Tipiracil inhibits the metabolism of trifluridine. The combination is only approved for use in patients who were previously treated with a fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin, irinotecan, an anti-VEGF biological such as bevacizumab, and, if the tumor is RAS wild-type, an anti-EGFR agent (cetuximab or panitumumab). The median survival of patients with metastatic colorectal cancer treated with these drugs is about 30 months.

FDA approval of trifluridine/tipiracil was based on the results of a randomized, double-blind, placebo-controlled trial in 800 patients with metastatic colorectal cancer who had previously been treated with chemotherapy and biological therapy. Median overall survival, the primary endpoint, was significantly longer with trifluridine/tipiracil compared to placebo (7.1 months vs 5.3 months). Median progression-free survival, a secondary endpoint, was 1.7 months with placebo and 2.0 months with trifluridine/tipiracil. The most common adverse effects of the combination included nausea, vomiting, diarrhea, fatigue, neutropenia, anemia, and leukopenia. Among 533 patients treated with the combination, only one treatment-related death occurred (from septic shock).<sup>1</sup>

*Lonsurf* is available in tablets containing 15 mg of trifluridine and 6.14 mg of tipiracil or 20 mg of trifluridine and 8.19 mg of tipiracil. The recommended dosage is 35 mg/m<sup>2</sup> (based on the trifluridine component) orally twice daily on days 1-5 and 8-12 of each 28-day cycle until disease progression or unacceptable toxicity occurs. *Lonsurf* should be taken within one hour after meals. The cost of one treatment cycle (sixty 20 mg/8.19 mg tablets) is \$10,947.70.<sup>2</sup>

1. RJ Mayer et al. Randomized trial of TAS-102 for refractory metastatic colorectal cancer. *N Engl J Med* 2015; 372:1909.

2. Approximate WAC for a patient with a 1.7 m<sup>2</sup> surface area. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. May 5, 2016. Reprinted with permission by First Databank, Inc. All rights reserved. ©2016. [www.fdbhealth.com/policies/drug-pricing-policy](http://www.fdbhealth.com/policies/drug-pricing-policy).

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