FDA Approves Fruzaqla for Refractory Metastatic Colorectal Cancer

Fruquintinib improved progression-free and overall survival for patients who did not respond to chemotherapy.

November 9, 2023 By Food and Drug Administration (FDA)

On November 8, 2023, the Food and Drug Administration approved fruquintinib (Fruzaqla, Takeda Pharmaceuticals, Inc.) for adult patients with metastatic colorectal cancer (mCRC) who received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

View full prescribing information for fruquintinib.

Efficacy was evaluated in FRESCO-2 (NCT04322539) and FRESCO (NCT02314819). FRESCO-2 (NCT04322539), an international, multicenter, randomized, double-blind, placebo-controlled trial, evaluated 691 patients with mCRC who had disease progression during or after prior fluoropyrimidine-, oxaliplatin-, irinotecan-based chemotherapy, an anti-VEGF biological therapy an anti-EGFR biological therapy if RAS wild type, and at least one of trifluridine/tipiracil or regorafenib. FRESCO, a multicenter, placebo-controlled trial conducted in China, evaluated 416 patients with metastatic colorectal cancer who had disease progression during or after prior fluoropyrimidine-, oxaliplatin, and irinotecan-based chemotherapy.

In both trials patients were randomly allocated (2:1) to either fruquintinib 5 mg orally once daily or placebo for the first 21 days of each 28-day cycle plus best supportive care. Patients received therapy until disease progression or unacceptable toxicity.

Overall survival (OS) was the major efficacy outcome in both trials. In FRESCO-2, median OS was 7.4 months (95% CI: 6.7, 8.2) for those treated with fruquintinib and 4.8 months (95% CI: 4.0, 5.8) in the placebo group (HR 0.66 [95% CI: 0.55, 0.80] p-value < 0.001). In FRESCO, median OS was 9.3 months (95% CI: 8.2, 10.5) and 6.6 months (95% CI: 5.9, 8.1) in the respective treatment arms (HR 0.65 [95% CI: 0.51, 0.83] p-value < 0.001).

The most common adverse reactions (reported in ≥20% of patients) were hypertension, palmar-plantar erythrodysesthesia, proteinuria, dysphonia, abdominal pain, diarrhea, and asthenia.

The recommended fruquintinib dose is 5 mg orally once daily, with or without food, for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

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, Singapore's Health Sciences Authority (HSA), Switzerland's Swissmedic, and United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). The application reviews are ongoing at the other regulatory agencies.

This application was granted priority review. FDA expedited programs are described 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 by the Food and Drug Administration on November 8, 2023.
