FDA Approves Companion Diagnostic Test for Vitrakvi

The FoundationOne CDx test identifies solid tumors with NTRK fusions.

October 26, 2020 By Food and Drug Administration (FDA)

On October 23, 2020, the Food and Drug Administration approved the next-generation sequencing (NGS)-based FoundationOne CDx test (Foundation Medicine, Inc.) as a companion diagnostic to identify fusions in neurotrophic receptor tyrosine kinase (NTRK) genes, NTRK1, NTRK2, and NTRK3, in DNA isolated from tumor tissue specimens from patients with solid tumors eligible for treatment with larotrectinib (VITRAKVI, Bayer Healthcare Pharmaceuticals, Inc.).

Larotrectinib was granted accelerated approval on November 26, 2018, for adult and pediatric patients with solid tumors that have a NTRK gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment.

Approval of larotrectinib was based on data from three multicenter, open-label, single-arm clinical trials: LOXO-TRK-14001 (NCT02122913), SCOUT (NCT02637687), and NAVIGATE (NCT02576431). Identification of positive NTRK gene fusion status was prospectively determined in local laboratories using NGS, fluorescence in situ hybridization (FISH), and reverse transcriptase-polymerase chain reaction (RT-PCR) methods. NTRK gene fusions were inferred in three pediatric patients with infantile fibrosarcoma who had a documented ETV6 translocation by FISH. The major efficacy outcome measures were overall response rate (ORR) and response duration, as determined by a blinded independent review committee according to RECIST 1.1.

The FoundationOne CDx assay (F1CDx) approval as a companion diagnostic for larotrectinib was based on the retrospective testing with F1CDx of available tumor tissue samples from patients enrolled in the three clinical trials that supported the accelerated approval of larotrectinib. Efficacy for larotrectinib was shown to be maintained in patients with confirmed NTRK fusion positive results by the F1CDx. F1CDx is a NGS based in vitro diagnostic device that is capable of detecting several mutations in addition to NTRK gene fusions.

View the Summary of Safety and Effectiveness for the FoundationOne CDx test (P170019/S017).

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.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

This announcement was originally published on the Food and Drug Administration website on October 23, 2020.

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