CDx to identify NTRK fusions in solid tumors approved

written by CAP TODAY
January 19, 2021

January 2021—The Food and Drug Administration approved the next -generation sequencing–based FoundationOne CDx test (Foundation Medicine) as a companion diagnostic to identify fusions in neurotrophic receptor tyrosine kinase 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).

Larotrectinib was granted accelerated approval on Nov. 26, 2018 for adult and pediatric patients with solid tumors that have an *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.

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