FDA approves larotrectinib

February 2019—The FDA granted accelerated approval to larotrectinib (Vitrakvi, Loxo Oncology) for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation, are metastatic, or where surgical resection is likely to result in severe morbidity and have no satisfactory alternative treatments or that have progressed following treatment.

“This new site-agnostic oncology therapy isn’t specific to a cancer arising in a particular body organ, such as breast or colon cancer. Its approval reflects advances in the use of biomarkers to guide drug development and the more targeted delivery of medicine,” said FDA Commissioner Scott Gottlieb, MD, in a statement released by the FDA.

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