Generic Name:
Larotrectinib
Trade Name:
Vitrakvi
Company:
Loxo Oncology
Notes:

FDA granted accelerated approval to larotrectinib, a treatment for adult and pediatric patients whose cancers have a specific genetic biomarker.

This is the second time the agency has approved a cancer treatment based on a common biomarker across different types of tumors rather than the location in the body where the tumor originated. The approval marks a new paradigm in the development of cancer drugs that are ?tissue agnostic,? said FDA in a news release. It follows the policies that the FDA developed in a guidance document released earlier this year.

Larotrectinib is indicated for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) 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.

Research has shown that the NTRK genes, which encode for TRK proteins, can become fused to other genes abnormally, resulting in growth signals that support the growth of tumors. NTRK fusions are rare but occur in cancers arising in many sites of the body. Prior to today?s approval, there had been no treatment for cancers that frequently express this mutation, like mammary analogue secretory carcinoma, cellular or mixed congenital mesoblastic nephroma, and infantile fibrosarcoma.

Efficacy of larotrectinib was studied in three clinical trials that included 55 pediatric and adult patients with solid tumors that had an identified NTRK gene fusion without a resistance mutation and were metastatic or where surgical resection was likely to result in severe morbidity. These patients had no satisfactory alternative treatments or had cancer that progressed following treatment.

Larotrectinib demonstrated a 75% overall response rate across different types of solid tumors. These responses were durable, with 73% of responses lasting at least 6 months, and 39% lasting 1 year or more at the time results were analyzed. Examples of tumor types with an NTRK fusion that responded to larotrectinib include soft tissue sarcoma, salivary gland cancer, infantile fibrosarcoma, thyroid cancer, and lung cancer.

Larotrectinib received an accelerated approval, which enables FDA to approve drugs for serious conditions to fill an unmet medical need using clinical trial data that is thought to predict a clinical benefit to patients. Further clinical trials are required to confirm the agent's clinical benefit. The sponsor is conducting or plans to conduct these studies.

Common adverse effects in clinical trials included fatigue, nausea, cough, constipation, diarrhea, dizziness, vomiting, and increased AST and ALT enzyme blood levels in the liver. Health care providers are advised to monitor patient ALT and AST liver tests every 2 weeks during the first month of treatment, then monthly and as clinically indicated. Women who are pregnant or breastfeeding should not take larotrectinib because it may cause harm to a developing fetus or newborn baby. Patients should report signs of neurologic reactions such as dizziness.

Medication Monitor Categories:
New Drug Approvals
