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Vitrakvi receives first tumor-agnostic approval in EU

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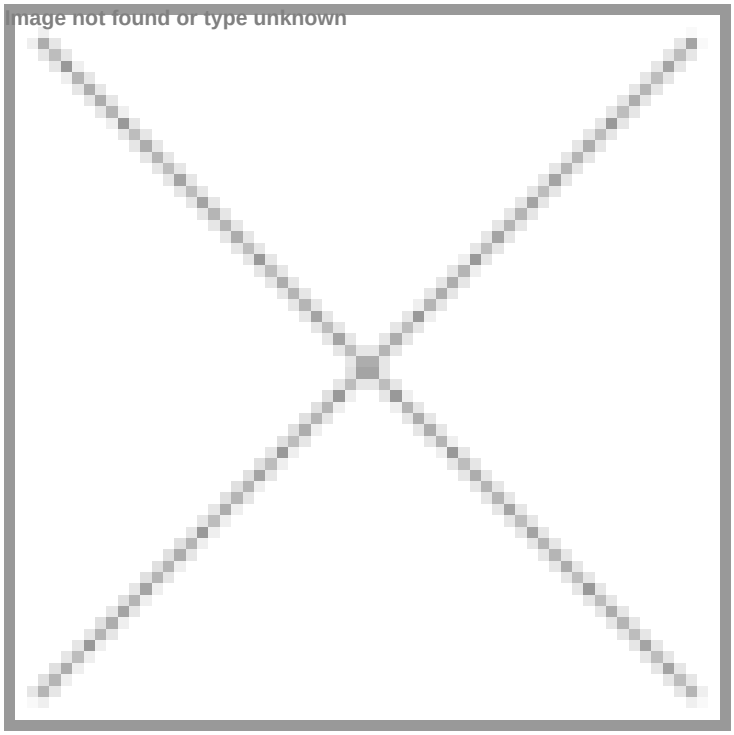
Precision oncology treatment Vitrakvi® (larotrectinib) approved for the treatment of adults and children with locally advanced or metastatic solid tumors that have a rare genomic alteration called an NTRK gene fusion



Bayer has announced that the European Commission has granted marketing authorization in the European Union (EU) for the precision oncology treatment Vitrakvi® (larotrectinib). The drug is indicated for the treatment of adult and pediatric patients with solid tumors that display a Neurotrophic Tyrosine Receptor Kinase (*NTRK*) gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory treatment options.

Vitrakvi, a first-in-class oral TRK inhibitor exclusively designed to treat tumors that have an*NTRK* gene fusion, is the first treatment in the EU to receive a tumor-agnostic indication. Vitrakvi has demonstrated high response rates and durable responses in adults and children with TRK fusion cancer, including central nervous system (CNS) tumors. It is already approved in the U.S., Brazil and Canada.

“With this first-ever tumor-agnostic approval in the EU, physicians in Europe now have the option to replace less tailored treatment approaches with a precision oncology treatment exclusively designed to treat tumors that have an*NTRK* gene fusion – a rare cancer which affects both children and adults and occurs in varying frequencies across various tumor types,” said Prof. Jesus Garcia-Foncillas, Director of the University Cancer Institute and the Department of Oncology at the University Hospital “Fundacion Jimenez Diaz” and Professor of Oncology at the Autonomous University of Madrid, Director of

the Translational Oncology Division at the Health Research Institute FJD-UAM and Coordinator of the Comprehensive Cancer Program of four University Hospitals in Madrid.

“Existing therapies commonly used to treat TRK fusion cancer patients such as chemotherapy or immuno-oncology therapies have shown limited efficacy, and may have significant side effects. With Vitrakvi, we have seen rapid, robust and durable responses with a consistent and manageable safety profile in patients with TRK fusion cancer, regardless of the age of the patient or where in the body the tumor is located.”

TRK fusion cancer is rare overall, affecting no more than a few thousand patients across Europe annually. It affects both children and adults and occurs in varying frequencies across various tumor types. TRK fusion cancer occurs when an*NTRK* gene fuses with another unrelated gene, producing an altered TRK protein. The altered protein, or TRK fusion protein, becomes constitutively active or overexpressed, triggering a signaling cascade. These TRK fusion proteins act as oncogenic drivers that fuel the spread and growth of the patients’ cancer, regardless of where it originates in the body.

Larotrectinib, an oral, highly selective TRK inhibitor, was investigated in clinical trials across 29 different histologies of solid tumors including lung, thyroid, melanoma, gastrointestinal stromal tumors, colon, soft tissue sarcomas, salivary gland and infantile fibrosarcoma. The compound has shown efficacy in primary CNS tumors as well as patients with brain metastases, across age or tumor histology.

“The approval of Vitrakvi® in the EU, a first-of-its-kind treatment exclusively designed for adults and children with TRK fusion cancer, represents a meaningful advancement in the fight against cancer, as it treats the oncogenic driver that causes tumor spread and growth, rather than where the tumor originates in the body,” said Robert LaCaze, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of the Oncology Strategic Business Unit. “Cancer care is currently undergoing a paradigm shift and as this new era of precision oncology treatment unfolds, we are continuing our effort of delivering innovative medicines such as Vitrakvi, which can provide value to patients and their treating physicians around the world.”

“As researchers learn more about tumor genomics, precision oncology treatments that directly address the genomic abnormality driving tumor growth become increasingly relevant for patients. We now have the tools to move beyond a one-size fits all treatment approach,” said Marcia K. Horn, President and CEO of ICAN, the International Cancer Advocacy Network. “We welcome the approval of Vitrakvi for patients with TRK fusion cancer in the EU, which also underscores the importance of implementing consistent, widespread high quality molecular testing into the clinical practice to identify more patients through genomic insights and ultimately benefit their care.”