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Bayer gets EU CHMP nod for precision oncology treatment larotrectinib

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Upon approval, larotrectinib would be the first therapy in Europe with a tumor-agnostic indication



The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended Bayer's precision oncology treatment larotrectinib for marketing authorization in the European Union (EU). The recommended indication is 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. The final decision of the European Commission on the marketing authorization is expected in the coming months. Larotrectinib, a first-in-class oral TRK inhibitor specifically developed to treat tumors that have an *NTRK* gene fusion, will be the first treatment to receive a tumor-agnostic indication in the EU. Larotrectinib is already approved in the U.S. as well as in Brazil and Canada.

The CHMP recommendation is based on pooled clinical trial data of 102 patients (93 patients from the primary analysis population and an additional 9 patients with primary central nervous [CNS] tumors) across the Phase I trial of adult patients, the Phase II NAVIGATE trial in adult and adolescent patients and the Phase I/II pediatric SCOUT trial, showing a high response rate with durable and rapid responses for larotrectinib.

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. In clinical trials, larotrectinib was investigated across 29 different histologies of solid tumors including lung, thyroid, melanoma, gastrointestinal stromal tumors, colon, soft tissue sarcomas, salivary gland and infantile fibrosarcoma. Larotrectinib is an oral, highly selective TRK inhibitor that targets TRK proteins that fuel the spread and growth of the patients' cancer, regardless of where it originates in the body. Larotrectinib has shown efficacy in primary central nervous system (CNS) tumors as well as patients with brain metastases, across age or tumor histology.

"This positive CHMP recommendation for the first-ever tumor agnostic indication in Europe marks an important step towards delivering a first-of -its -kind precision medicine for children and adults with TRK fusion cancer in Europe," said Dr Scott Z Fields, Senior Vice President and Head of Oncology Development at Bayer. "Larotrectinib was specifically developed to treat patients with TRK fusion cancer, and has the potential to significantly improve treatment outcomes, regardless of tumor type or age. As researchers learn more about tumor genomics, it becomes all the more important to ensure broad access to genomic testing to allow patients that have the potential to benefit from precision medicines to be identified and treated, moving us beyond a one-size fits all therapeutic approach."

High quality *NTRK* testing is key to identifying those patients who are most likely to benefit from larotrectinib. Only specific tests can identify *NTRK* gene fusions or TRK fusion proteins. Immunohistochemistry (IHC) is a useful screening tool. However, IHC detects both the expression of the wildtype TRK protein as well as the TRK fusion protein; therefore, positive results need to be confirmed by more specific tests such as next-generation sequencing. Patients eligible for treatment with larotrectinib should be selected based on the presence of an *NTRK* gene fusion in their tumor.