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News Release

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Bayer receives approval for precision oncology treatment Vitrakvi™ in China

- Precision oncology treatment Vitrakvi™ (larotrectinib) approved for the treatment of *NTRK* fusion-positive advanced or recurrent solid tumors in adult and pediatric patients in China
- In clinical studies of patients with TRK fusion solid tumors, larotrectinib demonstrated powerful efficacy with high response rates and durable responses across tumor types as well as a favorable safety profile
- Vitrakvi, which is exclusively designed to treat TRK fusion solid tumors, is the first therapy in China with a tumor-agnostic indication
- Vitrakvi will be available in China in oral capsules for adults and children. The Center of Drug Evaluation of China's National Medical Products Administration is currently reviewing its regulatory application as a liquid formulation

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Berlin, April 13, 2022 – Bayer today announced that the Center of Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) approved larotrectinib, under the brand name Vitrakvi™, for the treatment of adult and pediatric patients with advanced solid tumors that harbor a Neurotrophic Tyrosine Receptor Kinase (*NTRK*) gene fusion. *NTRK* gene fusions should be identified by a sufficiently validated test. Larotrectinib is a first-in-class, highly selective TRK inhibitor exclusively designed to treat solid tumors that have an *NTRK* gene fusion, also known as TRK fusion solid tumors. This precision oncology treatment has demonstrated high response rates, durable responses and a favorable safety profile in adults and children with TRK fusion solid tumors. Vitrakvi is already approved in the U.S., Japan, countries of the European Union (EU), the UK and other markets around the world.

"These clinically meaningful high response rates and durable responses as well as the favorable safety profile seen in larotrectinib trials involving patients from China and

worldwide, support its efficacy and safety in adults and children," said Prof. Xu Ruihua, MD, PhD, President of Sun Yat-sen University Cancer Center. "A high unmet need remains for new and innovative cancer treatments in China. Advancements in precision therapies, like larotrectinib, demonstrate the importance of comprehensive genomic testing to uncover actionable oncogenic drivers and identify patients most likely to benefit from a targeted treatment approach."

"The approval of larotrectinib in China represents a meaningful advancement in cancer care with a highly innovative treatment option that addresses the genomic alteration driving solid tumor growth, regardless of the location where the tumor originates," said Christine Roth, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of Bayer's Oncology Strategic Business Unit. "This approval further demonstrates Bayer's commitment to delivering next-generation precision medicines to appropriate patients and clinicians."

The approval of larotrectinib in China is based on data from 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. In these trials, larotrectinib was investigated across more than 20 different histologies of solid tumors including lung cancer, thyroid cancer and colorectal cancer as well as salivary gland cancer and soft tissue sarcomas including infantile fibrosarcoma and gastrointestinal stromal tumors. The compound has shown powerful efficacy with high response rates and durable responses as well as a favorable safety profile across tumor types in adults and children with TRK fusion solid tumors. The clinical activity has been shown across multiple tumor types including primary central nervous system (CNS) tumors and brain metastases.

TRK fusion cancer is rare overall. 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 a chimeric TRK protein. The altered protein, or TRK fusion protein, becomes constitutively active or overexpressed, triggering the activation of an intercellular signaling cascade leading to tumor growth and spread.

Larotrectinib will be available in China in oral capsules for adults and children. The CDE of China's NMPA is currently reviewing its regulatory application as a liquid formulation.

About Vitrakvi™ (larotrectinib)

Vitrakvi™ (larotrectinib), a first-in-class oral TRK inhibitor, was exclusively designed to treat tumors that have an *NTRK* gene fusion. The compound has demonstrated high response rates and highly durable responses of over four years in adults and children with TRK fusion cancer, including central nervous system (CNS) tumors. To date, it has the largest dataset and longest follow-up data of any TRK inhibitor. The trials are still ongoing, with the latest dataset presented at the European Society for Medical Oncology (ESMO) Congress 2021 and additional updates planned to be presented at upcoming scientific meetings.

Larotrectinib is approved under the brand name Vitrakvi™ in more than 40 countries around the world, including the U.S., countries of the European Union (EU), and most recently in China. Filings in other regions are underway or planned. In the EU, the product is approved for the treatment of adult and pediatric patients with solid tumors that harbor 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.

About TRK Fusion Cancer

TRK fusion cancer occurs when an *NTRK* gene fuses with another unrelated gene, producing a chimeric TRK protein. The altered protein, or TRK fusion protein, becomes constitutively active or overexpressed, triggering a signaling cascade. These TRK fusion proteins are oncogenic drivers promoting cell growth and survival, leading to TRK fusion cancer. TRK fusion cancer is not limited to certain types of tissues and can occur in any part of the body. TRK fusion cancer occurs in various adult and pediatric solid tumors with varying frequency, including lung, thyroid, gastrointestinal (GI) cancers (colon, cholangiocarcinoma, pancreatic and appendiceal), sarcoma, CNS cancers (glioma and glioblastoma), salivary gland cancers (including secretory carcinoma of the salivary gland) and pediatric cancers (infantile fibrosarcoma and other soft tissue sarcomas).

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop innovative medicines that help improve and extend the lives of people living with cancer. The oncology franchise at Bayer includes six marketed products across various

indications and several compounds in different stages of clinical development. Bayer focuses its research activities on first-in-class innovations across the following scientific platforms: Precision Molecular Oncology, Targeted Alpha Therapies, and Immuno-Oncology. Across the areas of focus, we have several prostate cancer treatments on the market or in development, with the goal of extending survival while limiting side effects of treatment throughout the different stages of the disease. Another key focus at Bayer is on innovative precision oncology treatments, with an approved TRK inhibitor exclusively designed to treat tumors that have an *NTRK* gene fusion, the oncogenic driver of tumor growth and spread. The company's approach to research prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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