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News Release

Not intended for U.S. and UK Media

Bayer receives approval for Vitrakvi™ in Japan

- Precision oncology treatment Vitrakvi™ (larotrectinib) approved for the treatment of NTRK fusion-positive advanced or recurrent solid tumors
 - In clinical studies, larotrectinib demonstrated high response rates and durable responses in adults and children with TRK fusion cancer, including responses and a high disease control rate in primary central nervous system (CNS) tumors
 - The Japanese marketing authorization of Vitrakvi follows the approval of the expanded use of FoundationOne®CDx, a comprehensive genomic profiling (CGP) test, in Japan for use as a companion diagnostic (CDx) to identify patients with TRK fusion cancer who could benefit from treatment with Vitrakvi
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Berlin, March 23, 2021 – Bayer announced today that the Japanese Ministry of Health, Labor and Welfare (MHLW) has granted marketing authorization for larotrectinib, under the brand name Vitrakvi™, for the treatment of Neurotrophic Tyrosine Receptor Kinase (NTRK) fusion-positive advanced or recurrent solid tumors. Vitrakvi is a highly selective TRK inhibitor exclusively designed to treat tumors that have an NTRK gene fusion. Vitrakvi has demonstrated high response rates, durable responses and a favorable safety profile in adults and children with TRK fusion cancer. For those patients with primary central nervous system (CNS) tumors and with CNS metastases, responses and a high disease control rate have been observed. It is already approved in the U.S., countries of the European Union (EU), the UK and other markets around the world.

“There remains a high unmet need for new and innovative cancer treatments in Japan. The approval of Vitrakvi marks an important step towards treating TRK fusion cancer based on the oncogenic driver rather than the site or origin in the body,” said Makoto Tahara, MD., Ph.D. Chief, Department of Head and Neck Medical Oncology, National Cancer Center Hospital East. “Clinicians now have the option to replace less tailored treatment approaches with a precision oncology treatment specifically designed to treat patients with TRK fusion cancer.”

The marketing authorization of Vitrakvi follows the approval of the expanded use of FoundationOne®CDx, a comprehensive genomic profiling (CGP) test, in Japan for use as a companion diagnostic (CDx) to identify patients with TRK fusion cancer who are expected to benefit from treatment with Vitrakvi. The CDx approval is part of the global collaboration between Bayer and Foundation Medicine, Inc. (FMI), for which Chugai is the local development partner of FMI.

“Treatments that directly address the genomic abnormality driving tumor growth, such as Vitrakvi, can provide value to patients and physicians in Japan with the potential to significantly improve treatment outcomes regardless of tumor type or patient age,” said Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division. “This approval further underscores the importance of high quality and accessible genomic testing to allow more precise identification of patients who are most likely to benefit from a treatment specifically designed to treat tumors with an *NTRK* gene fusion. It supports clinicians to get the right treatment, that is efficacious and has a favorable safety profile, to the right patient at the right time.”

The approval of Vitrakvi in Japan is based on data from 125 patients from the Phase II NAVIGATE trial in adult and adolescent patients and the Phase I/II pediatric SCOUT trial. Results analyzed from the NAVIGATE trial population showed an overall response rate (ORR) of 65.2% with a complete response (CR) rate of 16.9% and in SCOUT an ORR of 88.9% with a CR rate of 22.2%. Larotrectinib showed a favorable safety profile based on the safety data from 116 patients in the NAVIGATE trial and 73 patients in the SCOUT trial.

TRK fusion cancer is rare overall, affecting 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. Vitrakvi, an oral, highly selective TRK inhibitor, was investigated in clinical trials across multiple different histologies of solid tumors including lung and thyroid cancer, melanoma, gastrointestinal stromal tumors, colon and breast cancer, soft tissue sarcomas, salivary gland cancer and infantile fibrosarcoma. It has shown remarkable efficacy and tolerability

across tumor types regardless of patient age in clinical trials with a follow-up time of more than three years in adults and children with TRK fusion cancer, including central nervous system (CNS) tumors.

About Vitrakvi™ (Larotrectinib)

Vitrakvi™ (larotrectinib), a highly selective TRK inhibitor, was exclusively designed to treat tumors that have a *NTRK* gene fusion. The compound has demonstrated high response rates and durable responses over three years in adults and children with TRK fusion cancer, including responses and a high disease control rate in central nervous system (CNS) tumors. It has the largest dataset and longest follow-up data of any TRK inhibitor. The dataset of 159 patients was published in *The Lancet Oncology* and additional updates were presented at the ESMO Virtual Congress 2020.

Vitrakvi is approved in more than 40 countries, including the U.S., countries of the European Union (EU), the UK and other markets around the world. Additional filings in other regions are underway or planned.

Following the acquisition of Loxo Oncology by Eli Lilly and Company in February 2019, Bayer now possesses the exclusive rights to develop and commercialize larotrectinib worldwide, and also has exclusive rights to the investigational TRK inhibitor selitrectinib (BAY 2731954) which is currently in clinical development.

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. We have 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: Oncogenic Signaling, Targeted Alpha Therapies, and Immuno-Oncology. A 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, and another TRK inhibitor advancing through the pipeline. 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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