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News Release

Not intended for U.S. and UK Media

FDA approves FoundationOne®CDx as companion diagnostic for Vitrakvi™ (larotrectinib) to aid in identifying *NTRK* fusion-positive patients

- The companion diagnostic (CDx) approval is part of the global collaboration between Bayer and Foundation Medicine, Inc. for the development and commercialization of next-generation sequencing (NGS)-based companion diagnostics in oncology
 - Detection of genomic alterations that drive the growth and spread of the tumor can guide treatment decisions for cancer therapies, such as available biomarker driven therapies
 - FoundationOne®CDx analyzes substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes as well as select rearrangements and genomic signatures across all solid tumors, including the three *NTRK* gene fusions (*NTRK1*, *NTRK2* and *NTRK3*), to inform treatment decisions¹
 - Vitrakvi™ (larotrectinib) is the first and only TRK-specific inhibitor approved in the U.S. for adult and pediatric patients with TRK fusion cancer across all solid tumors and is under review in other markets around the world
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Berlin, October 23, 2020 – Bayer announced that the U.S. Food and Drug Administration (FDA) approved FoundationOne®CDx for use as the first companion diagnostic to help identify neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion-positive patients for whom treatment with Vitrakvi™ (larotrectinib) may be appropriate.^{1,2} FoundationOne CDx is an FDA approved comprehensive genomic profiling (CGP) test for all solid tumors that incorporates multiple companion diagnostic indications, which will advance broader biomarker testing access for the cancer community.¹

“Vitrakvi has a demonstrated clinical profile and is the only approved treatment specifically developed for patients with TRK fusion cancer,” said Robert LaCaze, Member of the Executive Committee of the Pharmaceuticals Division and Head of the Oncology Strategic Business Unit at Bayer. “The U.S. FDA approval of FoundationOne CDx for Vitrakvi

allows patients who may benefit from this treatment to be identified in a more precise way. We look forward to continuing our global collaboration with Foundation Medicine by expanding access to testing and determining the right treatment options for patients with cancer.”

Next-generation sequencing (NGS)-based CDx tests aim to unlock molecular information from each patient’s tumor genome to guide treatment decisions for cancer therapies.

Chugai Pharmaceuticals, a local partner of Foundation Medicine in Japan, recently filed an application with the Japanese Ministry of Health, Labour and Welfare (MHLW) for the expanded use of FoundationOne CDx as a companion diagnostic for Vitrakvi. Additional partnerships are underway to advance patient access to comprehensive genomic testing. In the U.S., Vitrakvi is approved for the treatment of adult and pediatric patients with solid tumors that have an *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. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

About Vitrakvi™ (larotrectinib)

Vitrakvi™ (larotrectinib), a first-in-class oral 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 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 42 countries, including the U.S., Canada, Brazil and the European Union (EU). 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. 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: Oncogenic Signaling, 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, 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 benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

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References

1. FoundationOne CDx Technical Information. Foundation Medicine, Inc.
https://info.foundationmedicine.com/hubfs/FMI%20Labels/FoundationOne_CDx_Label_Technical_Info.pdf.
2. VITRAKVI [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2019.