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News Release

Not intended for U.S. and UK Media

Bayer to highlight clinical data on Vitrakvi™ (larotrectinib) and research on investigational AhR inhibitor at AACR 2020 Virtual Meeting

- Additional analyses from clinical trials may further aid in identifying the appropriate patients for Vitrakvi™ (larotrectinib), including a presentation on patient outcomes by prior therapy and performance status
 - Featured research includes an oral presentation in the Plenary Session on efficacy and safety outcomes in patients with NTRK gene fusions or other alterations
 - Structure and functional characterization of investigational small molecule aryl hydrocarbon receptor (AhR) inhibitor, BAY 2416964, in immunotherapy
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Abstracts: CT199, 10363, DDT01-02

Berlin, April 23, 2020 – Bayer announced additional clinical trial results for Vitrakvi™ (larotrectinib) and latest research on its investigational small molecule aryl hydrocarbon receptor (AhR) inhibitor BAY 2416964 to be presented at the upcoming American Association for Cancer Research (AACR) 2020 Virtual Annual Meeting I from April 27-28, 2020. Data at this meeting underscore Bayer's continued efforts to explore the potential of clinical stage projects in oncology from the laboratory to clinical practice and share the latest study progress with the scientific community. The original AACR program will be presented in segments in two AACR Virtual Annual Meetings, with the first part taking place from April 27-28. Access to AACR Virtual Annual Meeting I will be made freely available. More details can be found [here](#). The abstracts of these proffered paper presentations will be posted online at 12:01 a.m. EDT (U.S.) / 6:01 a.m. CET (EU) on Monday, April 27.

“We are committed to making our potentially practice-changing research on treatment approaches available to doctors and to people living with cancer,” said Scott Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division. “Bayer’s approach to cancer research includes investing in drug development and testing programs designed to help ensure that the right patients get the right treatment. At AACR, we will share important clinical trial analyses that help inform the selection of patients who may be eligible for our TRK inhibitor Vitrakvi. In addition, Bayer will also share research on a potential new approach in immuno-oncology.”

Two analyses from the Vitrakvi clinical trials will be shared. The first analysis includes a Plenary Session presentation on Vitrakvi efficacy and safety data based on the presence of neurotrophic receptor tyrosine kinase (*NTRK*) gene fusions or other alterations, and the second includes data on outcomes in patients with TRK fusion cancer by prior therapy and performance status. Vitrakvi is approved in the U.S., Canada, Brazil and the European Union (EU). While local labels might differ, the product indication spans across all solid tumors that harbor an *NTRK* gene fusion. Additional filings in other regions are underway or planned.

At the virtual meeting, for the first time, the structure and functional characterization of the investigational small molecule AhR inhibitor BAY 2416964 will be presented. The AhR receptor is expressed in many different immune cells and is considered to play an important role in immuno-suppression within the tumor microenvironment. An AhR inhibitor such as BAY 2416964 is thought to reactivate anti-tumor immune responses in a manner distinct from currently approved checkpoint inhibitors, and thus may provide a new approach for cancer immunotherapy. BAY 2416964 is currently investigated in a first-in-human, Phase I trial in patients with advanced solid malignancies. Immuno-oncology (IO) is a key area of research for Bayer.

Presentations for the Virtual Annual Meeting I are listed below:

Presentations:

- *Efficacy and safety of larotrectinib in patients with cancer and NTRK gene fusions or other alterations*
 - Virtual Plenary Session: VCTPL06 - Targeted Therapy
 - Abstract: 10363
 - April 28, 2020, 4:20 – 4:30 pm (EDT) / 10:20 – 10:30 pm (CET)

- *Larotrectinib in TRK fusion cancer patients: outcomes by prior therapy and performance status*
 - Virtual Poster Session: VPO.CT02 - Phase II Clinical Trials
 - Abstract: CT199
 - April 27, 2020, 9:00 am – 6:00 pm (EDT) / 3:00 pm – 12:00 am (CET)

- *BAY 2416964: The first Aryl Hydrocarbon Receptor (AhR) inhibitor to enter phase I clinical development as a novel cancer immunotherapy*
 - Virtual Symposium: VSY.DDT01 - New Drugs on the Horizon: Part 1
 - Abstract: DDT01-02
 - April 27, 2020 5:17 – 5:37 pm (EDT) / 11:17 – 11:37 pm (CET)

About Vitrakvi™ (Larotrectinib)

Larotrectinib was approved in September 2019 in the European Union under the brand name Vitrakvi™ 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 has also received regulatory approval in the U.S, Brazil and Canada. Filings in other regions are underway or planned.

Following the acquisition of Loxo Oncology by Eli Lilly and Company in February 2019, Bayer has obtained the exclusive licensing rights for the global development and

commercialization, including in the U.S., for larotrectinib and the investigational TRK inhibitor selitrectinib (BAY 2731954) progressing through clinical development.

About TRK Fusion Cancer

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 promoting cell growth and survival, leading to TRK fusion cancer, regardless to where it originates in the body. 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, GI cancers (colon, cholangiocarcinoma, pancreatic and appendiceal), sarcoma, CNS cancers (glioma and glioblastoma), salivary gland cancers (mammary analogue secretory carcinoma) and pediatric cancers (infantile fibrosarcoma and soft tissue sarcoma).

About Bayer's Oncology Research Platforms

Bayer focuses its research activities on first-in-class innovations across the following scientific platforms: Oncogenic Signaling, Targeted Alpha Therapies, and Immuno-Oncology. In the field of Oncogenic Signaling the company is developing small molecules and other modalities to target crucial pathways of intracellular tumor signaling that are responsible for the development and survival of cancer in well-defined patient populations identified using selection biomarker. In regard to Targeted Alpha Therapies drug candidates are being developed using the company's proprietary Thorium-227 platform for delivering high-energy alpha-radiation via different targeting molecules such as antibodies to tumor cells. In Immuno-Oncology Bayer is developing next-generation treatments that intervene at different levels of the cancer immunity cycle specifically addressing patients not responding to immune checkpoint inhibitors.

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now expands to six marketed products and several other assets in various stages of clinical development. Together,

these products reflect the company's approach to research, which 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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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.