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American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program):

Efficacy of Vitrakvi™ (larotrectinib) further established with continued high response rates and durable response in updated analyses in adult patients and quality of life data in adult and pediatric patients with TRK fusion cancer

- 71% overall response rate (ORR) per investigator assessment and median duration of response of 35.2 months shown in expanded data set of 116 adult patients with TRK fusion cancer
- Among patients with brain metastases, ORR was also 71%
- Majority of adverse events (AEs) were grade 1 or 2, no new unexpected grade 3 or 4 AEs were reported
- New analysis demonstrates clinically meaningful and sustained improvements in quality of life (QoL) in adult and pediatric patients

Abstracts: 3610, 3614

Leverkusen, May 29, 2020 – Updated clinical data for Vitrakvi™ (larotrectinib) show continued high response rates and duration of response with longer follow-up and favorable safety in an expanded data set of 116 adult patients with TRK fusion cancer, including those with brain metastases. A separate analysis demonstrated clinically meaningful improvements in quality of life (QoL) for adult and pediatric patients, including infants younger than 2 years, using clinical questionnaires. These findings are being presented at the [American Society of Clinical Oncology \(ASCO\) 2020 Virtual Scientific Program](#), held May 29-31, 2020.

“With more patients added and a longer follow-up, we continue to see efficacy and a consistent safety profile for larotrectinib, regardless of tumor types, in adult patients with solid tumors harboring a TRK fusion. In addition, new data provide an understanding of

quality of life results for the majority of adults, children and infants with TRK fusion-positive cancers treated with larotrectinib,” said Alexander Drilon, M.D. Acting Chief of Early Drug Development Service at Memorial Sloan Kettering Cancer Center, New York, USA. “These data underscore the importance of routine genomic testing for people diagnosed with cancer, so that we can identify and match appropriate patients with the right treatment approach.”

Updated data with a cut-off of July 15, 2019 in 116 adult patients with TRK fusion cancer across 17 tumor types showed an overall response rate (ORR) per investigator assessment of 71% (95% CI 62–79) with 10% complete responses. For patients with brain metastases (n=14), the ORR was 71% (95% CI 42–92) with 10 patients having partial responses. The median duration of response was 35.2 months (95% CI 21.6–not estimable [NE]) at a median follow-up of 17.4 months. The median progression-free survival was 25.8 months (95% CI 15.2–NE) at a median follow-up of 14.6 months. The rate of overall survival (OS) at ≥ 12 months was 87 percent.

“These analyses add to the breadth of data including long-term follow-up with Vitrakvi, supporting its use as an efficacious treatment for adults and children with TRK fusion cancer,” said Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division. “Our continued study of cancers caused by genomic alterations underscores our commitment to developing treatments like Vitrakvi for patients and the physicians who serve them.”

The safety profile was consistent with that of the overall safety population previously reported. The majority of adverse events (AE) reported were grade 1 or 2. One patient (1%) discontinued due to a larotrectinib-related AE. No treatment-related grade 3 or 4 AEs occurred in more than 3% of patients and no treatment-related deaths were reported.

In an additional analysis, QoL data were collected from the larotrectinib trials using EORTC QLQ-C30 (adults) and PedsQL (children) questionnaires, which were analyzed descriptively and longitudinally. The proportion of patients above 2 years with normal or above and below normal QoL scores, compared to values in the literature for the U.S. general population, was also calculated. The majority of adults and most of the children and infants with TRK fusion cancer treated with larotrectinib had rapid, clinically meaningful, and sustained improvements in QoL. QoL scores for most patients ≥ 2 years

were either maintained within or moved into the normal range during larotrectinib treatment.

Data for both these analyses presented at ASCO were pooled from three larotrectinib clinical trials (NCT02122913, NCT02576431 and NCT02637687) in adult and pediatric patients with TRK fusion cancer.

Dr. Alexander Drilon has provided compensated advisory services to Bayer.

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 trials are still ongoing, with the latest dataset published in *The Lancet Oncology* and additional updates planned to be presented at upcoming scientific meetings.

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 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

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