Not intended for U.S. and UK Media

Annual Meeting of the American Society of Clinical Oncology (ASCO) 2019

New data for larotrectinib show overall response rates of 94% in children and 76% in adults with TRK fusion cancer; clinical benefit demonstrated in patients with primary central nervous system tumors and brain metastases

- In children with TRK fusion cancer (n=34), the overall response rate (ORR) was 94% and durable, with median duration of response (DOR) not reached
- In adults with TRK fusion cancer (n=74), the ORR was 76% and durable, with median DOR not reached
- In evaluable patients with brain metastases (n=5), ORR was 60%
- Improvements in quality of life were shown with larotrectinib treatment in both children and adults
- Majority of adverse events were grade 1 or 2, as reported in prior publications

---

Abstracts: 10010; 3122; 2006; 6602

Leverkusen, May 15, 2019 – Bayer today announced findings from new analyses for larotrectinib, showing an overall response rate (ORR) of 94% in children with TRK fusion cancer, with median duration of response (DOR) not reached at the time of data cut-off (July 30, 2018). In adult patients, a high response rate of 76% was seen, with the median DOR not reached at the time of data cut-off (July 30, 2018; median follow-up of 17.2 months per investigator assessment). New data on patients with primary central nervous system (CNS) tumors of various histologies or brain metastases confirm the activity of larotrectinib in these patients. In an analysis on quality of life, clinically meaningful improvements were seen with larotrectinib treatment in both children and adults with TRK fusion cancer. Safety data were consistent with previous publications, with the majority of adverse events (AEs) being grade 1 or 2. The full data from these analyses will be

presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) 2019, taking place in Chicago, Illinois (U.S.) from May 31 – June 4, 2019.

“These data further confirm the efficacy and safety of larotrectinib in patients with TRK fusion cancer, regardless of tumor type and age, including those who present with brain metastases or primary CNS tumors,” said Douglas S. Hawkins, M.D., hematology/oncology division chief at Seattle Children’s Hospital and professor of pediatrics at the University of Washington School of Medicine. “It underscores the urgency for widespread genomic testing to identify patients.”

Larotrectinib is CNS active, and has been exclusively designed to treat TRK fusion cancer in adults and children with an *NTRK* gene fusion.

“These latest data add to the body of evidence for larotrectinib in patients with TRK fusion cancer,” said Scott Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer’s Pharmaceutical Division. “With our commitment to developing treatments like larotrectinib as well as the investigational TRK inhibitor BAY 2731954, we are demonstrating our commitment to researching and advancing the future of cancer care, while providing true value for patients and physicians.”

Larotrectinib Presentations and Posters

Data from the subset of children taken from the expanded dataset show an overall response rate (ORR) of 94% (n=34) with larotrectinib, including 12 complete responses (CR), 18 confirmed partial responses (PR) and 2 PR pending confirmation. At the time of data cut-off (July 30, 2018), the median duration of response (DOR) had not been reached (range 1.6+ to 26.7+ months); with an estimated 84% of responding patients benefiting for longer than one year. (*Oral Presentation 10010, Session: Pediatric Oncology II; Sunday, June 2, 8:12AM – 8:24AM (CDT), Room: S504)*

In an analysis of the adult subset from the expanded dataset, larotrectinib demonstrated an ORR of 76% by investigator assessment (INV) (n=74) across 14 tumor types with a 9% CR rate, and an ORR of 68% (n=65) by independent review committee (IRC), including a 17% CR rate. At the time of data cut-off (July 30, 2018), the median duration of response had not been reached. *(Poster Presentation 3122, Session: Developmental*

Therapeutics and Tumor Biology (Nonimmuno); Saturday, June 1, 8:00AM – 11:00AM (CDT), Room: Hall A)

An analysis across clinical trials of patients with brain metastases (n=6) shows a partial response (PR) for 60% of patients (n=3), stable disease (SD) of 20% (n=1), with one patient not evaluable. In the 9 patients with primary CNS tumors, disease control was achieved in all evaluable patients. Additional data will be provided in an oral presentation at ASCO on June 3, 2019. (*Oral Presentation 2006, Session: Central Nervous System Tumors; Monday, June 3, 3:15PM – 3:27PM (CDT), Room: S102)*

In a new evaluation on patient-reported outcomes, children and adults (n=37) reported meaningful early improvement in quality of life following treatment with larotrectinib. Improvements versus baseline were observed quickly (within three to five cycles) and were sustained in the majority of patients. (*Poster Presentation 6602, Session: Health Services Research, Clinical Informatics, and Quality of Care; Saturday, June 1, 1:15PM – 4:15PM (CDT), Room: Hall A)*

About Larotrectinib

Larotrectinib (Vitrakvi®) was approved by the U.S. Food and Drug Administration (FDA) in November 2018 for the treatment of adult and pediatric patients with an *NTRK* gene fusion without a known acquired resistance mutation that are either metastatic or where surgical resection will likely result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment. In the U.S., larotrectinib was 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. Bayer has submitted a Marketing Authorization Application (MAA) in the European Union and additional 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 BAY 2731954 (previously LOXO-195) 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 of 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 includes five 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 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

Bayer Investor Relations Team

Bayer AG
Investor Relations
51368 Leverkusen, Germany
E-mail: ir@bayer.com
Internet: http://www.investor.bayer.com

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.