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Investor News

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American Association for Cancer Research (AACR) Special Conference on Pediatric Cancer Research:

Updated larotrectinib pediatric clinical trial data demonstrate continued durability of response in TRK fusion cancers

- 93 percent overall response rate in 17 pediatric patients with TRK fusion cancers
- 94 percent of all patients remain on larotrectinib or received surgery with curative intent, four patients have been followed greater than one year and 12 have been followed greater than six months
- Larotrectinib demonstrates central nervous system activity in first-ever TRK fusion glioblastoma response with a TRK inhibitor

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Leverkusen, Germany, December 4, 2017 – Bayer and Loxo Oncology, Inc., a biopharmaceutical company based in Stamford, Connecticut, US, (NASDAQ: LOXO), today announced updated clinical data from the larotrectinib (LOXO-101) pediatric Phase I SCOUT trial (NCT02637687). These data are being presented today at the American Association for Cancer Research (AACR) Special Conference on Pediatric Cancer Research in Atlanta, US. Bayer and Loxo Oncology are jointly developing larotrectinib, an investigational compound being studied globally for the treatment of patients with cancers harboring tropomyosin receptor kinase (TRK) gene fusions, which are genetic alterations present across a wide range of tumors resulting in uncontrolled TRK signaling and tumor growth.

“Targeted therapy success stories in pediatric oncology are uncommon, and larotrectinib has invigorated the pediatric oncology community,” said Brian Turpin, D.O., the presenting SCOUT principal investigator and assistant professor in the division of oncology at Cincinnati Children’s Hospital. “Larotrectinib’s near universal response rate and compelling durability of response in pediatric patients with TRK fusion cancers is likely to be practice changing. Furthermore, the first-ever TRK inhibitor response in a TRK

fusion glioblastoma patient highlights the potential for larotrectinib in TRK fusion central nervous system tumors."

"These data confirm that larotrectinib – a highly differentiated compound – can deliver consistent and durable responses in TRK fusion patients across age groups and multiple tumor types," said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer. We hope these data continue to support future milestones that will ultimately improve outcomes and change the course of cancer care for TRK fusion patients and their families."

As of the July 17, 2017 data cut-off date, 24 pediatric patients were enrolled, including 17 patients with TRK fusion cancers. TRK fusion patients carried primary diagnoses of infantile fibrosarcoma, thyroid cancer, and various soft tissue sarcomas. The Overall Response Rate (ORR = PR + CR, Partial Response + Complete Response) in the TRK fusion patients was 93 percent as assessed by both the investigators and an independent review committee. Among the 17 patients with TRK fusion cancers, 94% either remain on drug or received surgery with curative intent; four patients have been followed greater than one year and 12 have been followed greater than six months.
The larotrectinib adverse event profile is consistent with data previously presented publicly. The most common treatment-related adverse events at the dose given in the Phase II, included increased liver function tests, neutropenia and nausea, all largely grade 1.

These data are being presented in a poster session on December 4, 2017 and an oral presentation on December 5, 2017. The poster and presentation will be available online at https://www.loxooncology.com/focus/publications-abstracts at the time of their scheduled presentations.

About Larotrectinib (LOXO-101)
Larotrectinib (LOXO-101) is a potent, oral and selective investigational new drug in clinical development for the treatment of patients across a wide range of cancers that harbor abnormalities involving the tropomyosin receptor kinases (TRKs). Growing research suggests that the NTRK genes, which encode for TRKs, can become abnormally fused to other genes, resulting in growth signals that can lead to cancer in many sites of the body.

In an analysis of 55 adult and pediatric patients with TRK fusion cancers that were evaluable according to RECIST, larotrectinib demonstrated a 75 percent independently-reviewed confirmed overall response rate (ORR) and an 80 percent investigator-assessed confirmed ORR, across many different types of solid tumors. Larotrectinib received Orphan Drug Designation (ODD) in the US for the treatment of solid tumors harboring NTRK-fusion proteins and in Europe for soft tissue sarcoma. Additionally, the FDA granted breakthrough therapy designation to larotrectinib for the treatment of unresectable or metastatic solid tumors with NTRK-fusion proteins in adult and pediatric patients who require systemic therapy and who have either progressed following prior treatment or who have no acceptable alternative treatments.

For additional information about the larotrectinib or LOXO-195 clinical trials, please refer to www.clinicaltrials.gov or visit www.loxooncologytrials.com. Neither larotrectinib nor LOXO-195 are approved by the U.S. Food and Drug Administration, the European Medicines Agency or any other health authority.

In November 2017, Bayer and Loxo Oncology entered into an exclusive global collaboration on the development and commercialization of larotrectinib and LOXO-195, a next-generation TRK inhibitor. Bayer and Loxo Oncology will jointly develop the two products, larotrectinib and LOXO-195, and Bayer will lead ex-U.S. regulatory activities as well as worldwide commercial activities. In the U.S. Bayer and Loxo Oncology will co-promote the products. Loxo Oncology will remain responsible for the filing in the U.S.

About TRK Fusion Cancer

TRK fusions are chromosomal abnormalities that occur when one of the NTRK genes (*NTRK1, NTRK2, NTRK3*) becomes abnormally connected to another, unrelated gene (*e.g. ETV6, LMNA, TPM3*). This abnormality results in uncontrolled TRK signaling that can lead to cancer. TRK fusions occur rarely but broadly in various adult and pediatric solid tumors, including appendiceal cancer, breast cancer, cholangiocarcinoma, colorectal cancer, GIST, infantile fibrosarcoma, lung cancer, mammary analogue secretory carcinoma of the salivary gland, melanoma, pancreatic cancer, thyroid cancer, and various sarcomas. TRK fusions can be identified through various diagnostic tests, including targeted next-generation sequencing (NGS), immunohistochemistry (IHC), polymerase chain reaction (PCR), and fluorescent in situ hybridization (FISH). For more information, please visit www.TRKtesting.com.

Cancers Harboring Genetic Alterations

Scientists have long been working to better understand how a normal cell becomes a cancer cell to deliver better therapies with fewer side effects. Some people develop cancers that are caused by a single inappropriate DNA change, known as “oncogenic drivers.” When a genetic test identifies a patient with an oncogenic driver, there is the potential for use of highly selective drugs that inhibit oncogenic drivers in cancer. While there has been made notable progress in improving outcomes for people living with cancer over the last several decades, there has been a growing interest in developing highly targeted medicines to treat cancer, to further maximize the patients’ clinical benefit. This development is supported by the increasing use of genetic testing in cancer clinical medicine and improving chemistry approaches to building highly selective inhibitors against single targets in the cancer cell.

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 four marketed products and several other compounds 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.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 99,600 people and had sales of EUR 34.9 billion. Capital expenditures amounted to EUR 2.2 billion, R&D expenses to EUR 4.4 billion. For more information, go to www.bayer.com.

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