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Investor News

Not intended for U.S. and UK Media

Bayer announces completion of rolling submission of New Drug Application in the U.S. for larotrectinib for the treatment of TRK fusion cancer

Leverkusen, Germany, March 26, 2018 – Bayer today announced that its collaboration partner Loxo Oncology, Inc., (NASDAQ: LOXO), a biopharmaceutical company based in Stamford, Connecticut (US), has completed the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for larotrectinib for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. The rolling submission had been initiated in December 2017. NTRK gene fusions are genetic alterations present across a wide range of tumors resulting in uncontrolled tropomyosin receptor kinase (TRK) signaling and tumor growth. Larotrectinib was designed to directly target TRK, turning off the signaling pathway that allows TRK fusion cancer to grow.

“This NDA submission in the U.S. marks an important milestone in bringing us one step closer to providing larotrectinib as a potential treatment option for patients with TRK fusion cancer,” said Scott Fields, MD, Bayer’s senior vice president and head of Oncology Development at Bayer’s Pharmaceutical Division. “NTRK gene fusions, while rare, are present in various pediatric and adult cancers. We are committed to working with the FDA and the oncology community to bring larotrectinib to patients as soon as possible.”

Bayer and Loxo Oncology are jointly developing larotrectinib, an investigational compound being studied globally for the treatment of patients across a wide range of cancers that harbor an NTRK gene fusion. Bayer plans to submit a Marketing Authorization Application (MAA) in the European Union in 2018.

About larotrectinib (LOXO-101)

Larotrectinib is a potent, oral and highly selective tropomyosin receptor kinase (TRK) inhibitor. The investigational new drug is in clinical development for the treatment of

patients with cancers that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. 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 clinical trials, larotrectinib demonstrated marked and durable anti-tumor activity in TRK fusion cancer regardless of patient age or tumor type. In an analysis of 55 RECIST-evaluable adult and pediatric patients with NTRK gene fusions, larotrectinib demonstrated an 80% investigator-assessed overall response rate (ORR) and a 75% centrally-assessed confirmed ORR, across many different types of solid tumors. Larotrectinib was well tolerated; the majority of all adverse events were grade 1 or 2. There were no treatment-related grade 4 or 5 events, and no treatment-related grade 3 adverse events occurred in more than 5% of patients.

Larotrectinib has been granted Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation by the U.S. FDA.

In November 2017, Bayer and Loxo Oncology entered into an exclusive global collaboration for the development and commercialization of larotrectinib and LOXO-195, a novel TRK inhibitor. Bayer and Loxo Oncology will jointly develop the two products with Loxo Oncology leading the ongoing clinical studies as well as the filing in the U.S., and Bayer leading ex-U.S. regulatory activities and worldwide commercial activities. In the U.S., Bayer and Loxo Oncology will co-promote the products.

For additional information about the larotrectinib clinical trials, please refer to www.clinicaltrials.gov/ or www.loxooncologytrials.com.

About TRK fusion cancers

Neurotrophic tyrosine receptor kinase (NTRK) gene 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 tropomyosin receptor kinase (TRK) signaling that can lead to cancer. NTRK gene 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. NTRK gene fusions can be identified through various diagnostic tests, including targeted next-generation sequencing (NGS), polymerase chain reaction

(PCR), fluorescent in situ hybridization (FISH) or by immunohistochemistry (IHC), to detect TRK protein. For more information, please visit www.trkcancer.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.

About Bayer

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 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

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