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Investor News

Not intended for U.S. and UK Media

Bayer announces initiation of rolling submission of new drug application in the U.S. for Larotrectinib for the treatment of TRK fusion cancers

Completion of NDA submission expected in early 2018

Leverkusen, Germany, December 20, 2017 – Bayer today announced that its collaboration partner Loxo Oncology, Inc. (Nasdaq: LOXO), a biopharmaceutical company based in Stamford, CT, has initiated the submission of a rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for larotrectinib. The NDA is being submitted 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. 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. Loxo Oncology expects to complete the NDA submission in early 2018.

“The initiation of the rolling submission in the U.S. by Loxo Oncology is an important milestone, as it brings us one step closer to potentially being able to offer a much needed new treatment option for patients with TRK fusion cancers in the near future,” said Robert LaCaze, Member of the Executive Committee at Bayer AG’s Pharmaceuticals Division and Head of the Oncology Strategic Business Unit.

About Larotrectinib (LOXO-101)

Larotrectinib is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with 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 RECIST-evaluable TRK fusion adult and pediatric patients, larotrectinib demonstrated an 80 percent investigator-assessed overall response rate (ORR) and a 75 percent independently-reviewed confirmed ORR, across many different types of solid tumors. Larotrectinib has been granted Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation by the U.S. FDA. For additional information about the larotrectinib clinical trials, please refer to www.clinicaltrials.gov. Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123 or visit www.loxooncologytrials.com.

In November 2017, Loxo Oncology and Bayer entered into an exclusive global collaboration for the development and commercialization of larotrectinib and LOXO-195, a next-generation TRK inhibitor. Loxo Oncology leads worldwide development and U.S. regulatory activities. Bayer leads ex-U.S. regulatory activities and worldwide commercial activities. In the U.S., Loxo Oncology and Bayer will co-promote the products.

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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