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Investor News

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U.S. FDA accepts larotrectinib New Drug Application and grants priority review

Leverkusen, Germany, May 29, 2018 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) submitted by its collaboration partner Loxo Oncology, Inc. (NASDAQ: LOXO), a biopharmaceutical company based in Stamford, Connecticut (U.S.), and granted Priority Review 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 FDA has set a target action date of November 26, 2018, under the Prescription Drug User Fee Act (PDUFA).

NTRK gene fusions are genetic alterations that result in uncontrolled production of tropomyosin receptor kinase (TRK) fusion proteins, and lead to tumor growth. Bayer and Loxo Oncology are jointly developing larotrectinib, which is being studied globally for the treatment of patients across a wide range of cancers that harbor a NTRK gene fusion. Bayer plans to submit a Marketing Authorization Application (MAA) in the European Union in 2018.

“TRK fusion cancer is not limited to any organ or site of the body and occurs in both adults and children,” said Scott Fields, MD, senior vice president and head of Oncology Development at Bayer’s Pharmaceutical Division. “The Priority Review designation for larotrectinib may help bring this treatment option to patients, facing a high unmet medical need, as soon as possible.”

The FDA grants Priority Review for the applications of medicines that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Larotrectinib has also been granted Breakthrough Therapy Designation, which is a

process designed to expedite the development and review of drugs that are intended to treat a serious condition and may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Additionally, Rare Pediatric Disease Designation and Orphan Drug Designation were granted by the U.S. FDA.

About larotrectinib (LOXO-101)
Larotrectinib is an investigational tropomyosin receptor kinase (TRK) inhibitor 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 can become abnormally fused to other genes, producing a TRK fusion protein that can lead to the development of solid tumors across multiple sites of the body. In clinical trials, larotrectinib demonstrated an 80 percent investigator-assessed confirmed overall response rate (ORR) and a 75 percent centrally-assessed confirmed ORR, across many different types of solid tumors. The majority of all adverse events were grade 1 or 2.

In November 2017, Bayer and Loxo Oncology entered into an exclusive global collaboration for the development and commercialization of larotrectinib and LOXO-195, a TRK inhibitor in clinical development. 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. Larotrectinib has not been approved by the U.S. Food and Drug Administration, the European Medicines Agency or any other health authority.

About TRK fusion cancer
TRK fusion cancer occurs when a neurotrophic tyrosine receptor kinase (*NTRK)* gene fuses with another unrelated gene, producing an altered tropomyosin receptor kinase (TRK) protein. The altered protein, or TRK fusion protein, is constantly active, triggering a permanent signal cascade. These proteins become the primary driver of the spread and growth of tumors in patients with TRK fusion cancer. TRK fusion cancer is not limited to certain types of cells or tissues, which means it can occur in any part of the body. TRK fusion cancer occurs in various adult and pediatric solid tumors with varying prevalence, 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. It may affect greater than 60 percent of both adult and pediatric patients with certain rare tumor types, such as secretory breast, secretory salivary gland and infantile fibrosarcoma. Only sensitive and specific tests can reliably detect TRK fusion cancer. Next-generation sequencing (NGS) can provide a comprehensive view of genomic alterations across a large number of genes. Fluorescence in situ hybridization (FISH) can also be used to test for TRK fusion cancer and Immunohistochemistry (IHC) can be used to detect the presence of TRK protein.

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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