Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Bayer and Loxo Oncology to develop and commercialize two novel oncology therapies selectively targeting genetic drivers of cancer

- Larotrectinib (LOXO-101) and LOXO-195 target tropomyosin receptor kinase (TRK) fusion proteins, which are a product of genetic alterations that occur across a range of different tumors
- Co-Promotion of the products in the U.S.
- Bayer solely responsible for the commercialization of both products outside the U.S.
- U.S. filing of larotrectinib planned for late 2017 or early 2018

Leverkusen, Germany, November 14, 2017 – Bayer today announced that the company has entered into an exclusive global collaboration with Loxo Oncology, Inc., a biopharmaceutical company based in Stamford, Connecticut, US, (NASDAQ: LOXO) for the development and commercialization of larotrectinib (LOXO-101) and LOXO-195. Both compounds are being investigated in global studies for the treatment of patients with cancers harboring tropomyosin receptor kinase (TRK) gene fusions, which are genetic alterations across a wide range of tumors resulting in uncontrolled TRK signaling and tumor growth.

“The collaboration with Loxo Oncology represents another milestone in our endeavor to strengthen our oncology presence and underlines our commitment to this therapeutic area”, said Dieter Weinand, Member of the Board of Management of Bayer AG and President of the Pharmaceuticals Division. “Loxo Oncology’s very innovative approach complements Bayer’s oncology pipeline with highly differentiated compounds across different treatment modalities, which are being developed to make a meaningful difference for patients suffering from various types of cancer.”

Larotrectinib is an oral, potent and highly selective TRK inhibitor. LOXO-195 is a next-generation, selective TRK inhibitor capable of addressing potential mechanisms of acquired resistance that may emerge in patients receiving larotrectinib or multikinase

inhibitors with anti-TRK activity. Larotrectinib is currently the only selective TRK inhibitor in clinical development with the comprised clinical data set showing clinically meaningful and durable responses with an overall response rate of 75 percent, confirmed by an independent review committee, regardless of tumor type and age. The first filing for larotrectinib is planned in the U.S. in late 2017 or early 2018, with the EU filing expected in 2018.

“We see great potential in larotrectinib and moreover the follow-on compound LOXO-195 which has the potential to provide additional benefit for patients who might progress on an initial TRK inhibition therapy. These agents have the potential to fullfil the promise of precision medicine, where tumor genetics rather than tumor site of origin define the treatment approach for patients”, said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer.

“This is a transformational collaboration for the company as we prepare for commercialization,” said Jacob Van Naarden, chief business officer of Loxo Oncology. “Bayer has a history of successful co-promotion efforts with emerging biopharmaceutical companies and we are confident that their oncology team has the global reach and expertise, including an existing field force dedicated to cancer, to complement our existing commercial plans. We look forward to working with Bayer and believe that together we can bring our TRK inhibitors to more patients more quickly.”

Under the terms of the agreement, Loxo Oncology will receive an upfront payment of USD 400 million and is eligible for USD 450 million in milestone payments upon larotrectinib regulatory approvals and first commercial sale events in certain major markets and an additional USD 200 million in milestone payments upon LOXO-195 regulatory approvals and first commercial sale events in certain major markets. Bayer and Loxo Oncology will jointly develop the two products, larotrectinib and LOXO-195, and share development costs on a 50/50 basis. Bayer will lead ex-U.S. regulatory activities, and worldwide commercial activities. In the U.S., where Bayer and Loxo Oncology will co-promote the products, the parties will share commercial costs and profits on a 50/50 basis. Loxo Oncology will remain responsible for the filing in the U.S. Bayer will pay Loxo Oncology tiered double-digit percentage royalties on future net sales outside of the U.S. and U.S. and ex-U.S. sales milestones totaling USD 500 million.

About Larotrectinib (LOXO-101) and LOXO-195

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 RECIST-evaluable TRK fusion adult and pediatric patients, 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 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.

LOXO-195 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that have acquired resistance to initial TRK therapy such as larotrectinib. Though drugs such as larotrectinib can induce durable responses in these patients, the cancer may eventually begin to grow again. This phenomenon is called “acquired resistance,” in that the cancer has acquired features conferring resistance to the initial therapy that was once effective. Emerging data in the field of TRK inhibition suggest that acquired resistance may emerge due to TRK kinase point mutations. LOXO-195 was designed to address these new point mutations and induce a new response in the patient’s cancer. In July 2017, a multi-center Phase I/II trial in patients with TRK fusion cancers who have progressed while receiving another TRK inhibitor or are intolerant to another TRK inhibitor was initiated.

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.

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.

About Loxo Oncology

Loxo Oncology is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single

drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, thereby delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible. For more information, please visit the company's website at www.loxooncology.com.

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.

Bayer AG, Investor Relations contacts:

Oliver Maier (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)