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Investor News

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Bayer exercised option to obtain full licensing rights for larotrectinib and BAY 2731954 (LOXO-195)

- Bayer exercised option under change-in-control clause in it's agreement with Loxo Oncology to obtain full licensing rights for the two TRK inhibitor agents
 - Bayer to be solely responsible for the global development and commercialization of both larotrectinib and BAY 2731954 (LOXO-195)
 - Co-Promotion in the U.S. to be converted into exclusive commercialization by Bayer
 - Larotrectinib was approved in November 2018 in the U.S. under the brand name Vitrakvi® as the first TRK inhibitor for patients with advanced solid tumors harboring an NTRK gene fusion; filings in Europe and other regions underway
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Leverkusen, Germany, February 15, 2019 – Bayer has exercised its option, under a change-in-control clause in the collaboration agreement with Loxo Oncology, to obtain the exclusive licensing rights for the global development and commercialization, including the U.S., for larotrectinib (Vitrakvi®) and BAY 2731954 (LOXO-195). Both compounds are being developed globally for the treatment of adult and pediatric patients with advanced solid tumors harboring NTRK gene fusions. The option was triggered by the acquisition of Loxo Oncology by Eli Lilly and Company which became effective today.

“Bayer is dedicated to improving the lives of cancer patients, and precision oncology is a promising area that has the potential to redefine the way cancer patients are treated. Our partnership with Loxo Oncology was an important milestone and with the opportunity to exercise our option on larotrectinib and BAY 2731954, we are taking the next step in our efforts to advance the future of cancer care and strengthen our leadership in this field,” said Robert LaCaze, Member of the Executive Committee of Bayer’s Pharmaceuticals Division and Head of the Oncology Strategic Business Unit at Bayer. “With the first-ever approved TRK inhibitor, larotrectinib, and BAY 2731954 progressing through clinical development, we have two very promising compounds in our precision oncology portfolio

and we are committed to expanding this portfolio by bringing forward highly differentiated and promising additional projects.”

In November 2017, Bayer and Loxo Oncology entered into a global collaboration for the joint development and commercialization of the TRK inhibitors larotrectinib and BAY 2731954 (LOXO-195). Following the change of control, Bayer will be solely responsible for the global development and commercialization of both larotrectinib and BAY 2731954. Bayer is already leading ex-US regulatory activities, and worldwide commercial activities. When the new exclusive licensing arrangement takes effect, the co-promotion in the U.S. will be converted into an exclusive commercialization by Bayer and the sharing of commercial costs and profits on a 50/50 basis for the U.S. market will be replaced by royalties to be paid by Bayer. Bayer will continue to pay royalties on future net sales outside the U.S.

In addition, in connection with Bayer’s exercise of the option, certain licenses granted by Loxo to Bayer will become exclusive following anti-trust clearance in the US.

About Larotrectinib and BAY 2731954 (LOXO-195)

Larotrectinib was approved in November 2018 in the US under the brand name Vitrekvi® for the treatment of adult and pediatric patients with solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation that are either metastatic or where surgical resection will likely result in severe morbidity, and have no satisfactory alternative treatments or have progressed following treatment. Larotrectinib is the first treatment to receive a tumor-agnostic indication at the time of initial FDA approval. In clinical trials of patients with TRK fusion cancer, larotrectinib demonstrated an ORR of 75 percent (N=55) (95% CI: 61, 85%), including a 22 percent complete response (CR) rate.

BAY 2731954 (LOXO-195) is an, oral and selective investigational new drug in clinical development rationally designed for the treatment of patients with cancers that have acquired resistance to initial TRK therapy. 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.

NTRK gene fusions are genomic alterations that result in constitutively-activated chimeric TRK fusion proteins, which act as an oncogenic driver, promoting cell proliferation and survival in tumor cell lines. Larotrectinib is a CNS active TRK inhibitor designed to inhibit

these proteins. TRK fusions can be found in many types of solid tumors and affect both children and adults. In the clinical trials that were the basis for this approval, larotrectinib showed clinical benefit across numerous unique tumor types, including lung, thyroid, melanoma, GIST, colon, soft tissue sarcoma, salivary gland and infantile fibrosarcoma.

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 five 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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Forward-Looking Statements

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