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News Release

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Bayer's investigational P2X3 antagonist meets primary efficacy endpoint and shows favorable safety and tolerability profile

Positive Phase IIb results for eliapixant in patients with refractory chronic cough

Berlin, Germany, August 3, 2021 – Bayer today announced positive results from the Phase IIb clinical trial evaluating the efficacy and safety of its investigational orally administered, potent and selective P2X3 receptor antagonist eliapixant (BAY1817080) in patients with refractory chronic cough. The primary efficacy outcome was met showing a statistically significant improvement in 24-hour cough counts per hour (average hourly cough frequency based on 24-hour sound recordings) over placebo after 12 weeks of treatment. The data showed a favorable safety and tolerability profile.

“Refractory chronic cough has a debilitating effect on patients’ lives, and there is a high medical need for new effective treatment options that are well tolerated, where currently no approved treatments are available,” said Christian Rommel, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “We are pleased with the positive outcome of eliapixant in the chronic cough indication regarding efficacy, safety and differentiation. We look forward to sharing the data at an upcoming scientific meeting.”

In addition to refractory chronic cough, eliapixant is currently being evaluated in Phase II clinical trials for the treatment of endometriosis, overactive bladder and neuropathic pain. The P2X3 receptor antagonist was derived from Bayer’s former strategic alliance with Evotec SE, a global drug discovery and development company.

About the Phase IIb Study

The Phase IIb study (PAGANINI, NCT04562155) is an international placebo controlled, randomized, double-blind, parallel group, dose-finding study to evaluate the efficacy and

safety of eliapixant compared to placebo in patients with refractory chronic cough. In this study, more than 300 participants received either 25, 75 or 150 mg of eliapixant or placebo tablets twice daily for 12 weeks. Observation for each participant lasted about 18 weeks in total. Participants were asked to wear a digital device to record the cough and to complete questionnaires every day to document the symptoms subjectively. Blood samples were collected to monitor the safety and measure the blood level of the study drug. Detailed efficacy and safety analyses from this study will be presented at an upcoming scientific congress.

About Eliapixant

Eliapixant (BAY1817080) is an investigational orally administered, potent and selective P2X3 receptor antagonist. The P2X3 receptor is a key modulator of afferent nerve fiber signaling, thus considered to play a central role in diseases with nerve hypersensitization such as cough hypersensitivity syndrome. P2X3 receptor antagonists block the receptor aiming to decrease peripheral nerve fiber sensitivity. Eliapixant is currently evaluated in clinical studies for the treatment of refractory chronic cough, endometriosis, overactive bladder and neuropathic pain. The P2X3 receptor antagonist was derived from a former strategic research alliance with Evotec SE with an initial focus on endometriosis.

About Refractory Chronic Cough

The global prevalence of chronic cough is approximately 10 percent. Refractory chronic cough (RCC) affects 1-5 percent of all people worldwide. It does not serve as an airway-protective mechanism but is driven by a cough hypersensitivity syndrome. RCC disrupts patients' daily life, causing them to cough between 10 to 100 times per hour without any external trigger and has a major impact on physical and psychological aspects of quality of life. Many times, the condition comes with a long patient journey and time-to-diagnosis is in average over 8 years. Currently, there are only limited treatment options available to manage this condition, and the medical need for new effective treatments is high.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands

for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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