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## News Release

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### **Bayer's Eliapixant significantly decreased cough frequency in Phase IIb trial in patients with refractory chronic cough**

- Significant improvement in 24-hour cough counts over placebo after 12 weeks of treatment and with a favorable safety and tolerability profile
  - Results from PAGANINI Phase IIb dose-finding study presented at the virtual European Respiratory Society (ERS) International Congress 2021
  - Currently no treatment approved for refractory chronic cough, a condition affecting one to five percent of people worldwide
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**Berlin, Germany, September 6, 2021** – Bayer today announced the results from PAGANINI, the Phase IIb dose-finding study evaluating the efficacy and safety of its investigational orally administered, potent and selective P2X3 receptor antagonist eliapixant (BAY1817080) in patients with refractory chronic cough (RCC). The primary efficacy outcome was met showing a statistically significant reduction in the 24-hour cough count (average hourly cough frequency based on 24-hour sound recordings) of up to 27% for eliapixant 75 mg twice daily over placebo after 12 weeks of treatment. In the study, eliapixant demonstrated a positive benefit-risk profile, with the vast majority of adverse events considered mild or moderate. Discontinuation of the study due to adverse events occurred in 8% of patients treated with eliapixant. Taste-related adverse events were reported in 24% of patients treated with the highest dose of eliapixant 150 mg twice daily and markedly less in patients receiving lower doses. Most were described as “a little” and “somewhat” bothersome, none described as “extremely” bothersome. The favourable tolerability of eliapixant in this trial is consistent with earlier clinical findings. As a result, eliapixant may have the potential for safe and effective long-term use.

RCC affects one to five percent of people worldwide and often has a debilitating effect on the quality of patients' lives. Currently, no treatment is approved for the therapy of RCC, and the medical need for new effective treatments is high.

“Given the high unmet medical need, we are very encouraged with the positive outcome of eliapixant in the chronic cough indication regarding efficacy and safety,” said Christian Rommel, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “The selective mechanism of action of eliapixant appears to be translating into improved tolerability in clinical trials. These results will guide us to advance our clinical development strategy of eliapixant.”

“Chronic cough is a common clinical condition with significant impact on quality of life and for which effective therapy remains an unmet clinical need. Over the past decade, there has been a major shift in how we approach this problem, driven by better appreciation of the clinical manifestation of chronic cough and an improved understanding of the associated neurobiology,” said Dr. Lorcan McGarvey, Professor of Respiratory Medicine, Wellcome-Wolfson Institute of Experimental Medicine, School of Medicine, Dentistry and Biomedical Sciences, Queen’s University Belfast. “The findings from the PAGANINI trial with eliapixant are very encouraging, showing a promising outcome to address this unmet need. Such advancements are needed to offer new treatment options to patients with refractory chronic cough who are often suffering for many years without a relief.”

The results of the eliapixant PAGANINI study were presented at the virtual European Respiratory Society (ERS) International Congress 2021 (Abstract #BA23231).

### **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, safety and tolerability of eliapixant compared to placebo in patients with RCC. In this study, 310 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 to document the symptoms subjectively. Blood samples were collected to monitor safety and measure the blood level of the study drug.

### **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. In addition to RCC, 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 Refractory Chronic Cough (RCC)**

The global prevalence of chronic cough is approximately 10 percent. The subtype of refractory chronic cough (RCC) affects one to five percent of all people worldwide. It does not serve as an airway-protective mechanism, like physiologic cough, 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 on average over 8 years. Currently, no treatment is approved for the therapy of RCC, 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](http://www.bayer.com).

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