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News Release

Not intended for U.S. and UK Media

Bayer provides regulatory update on elinzanetant in the U.S.

Berlin, July 25, 2025 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has notified the company that it has extended the review period for the New Drug Application (NDA) for elinzanetant, the first neurokinin 1 and neurokinin 3 receptor antagonist for the treatment of moderate to severe vasomotor symptoms (VMS; also known as hot flashes) due to menopause.

The FDA has determined additional time is needed for a full review of the NDA submission, including information provided to support the application. The extension to the PDUFA review period is up to 90 days. The FDA did not raise any concern regarding the general approvability of elinzanetant in its correspondence.

“With the consistent positive results from our clinical Phase III program assessing the efficacy and safety of elinzanetant, we remain confident about elinzanetant’s potential as a new treatment option for moderate to severe vasomotor symptoms associated with menopause”, said Dr. Christian Rommel, member of the Executive Committee of Bayer’s Pharmaceuticals Division and Global Head of Research and Development. “As we continue to work with the FDA during the ongoing review, we are fully committed to making elinzanetant available to women in the U.S. as soon as we receive FDA approval.”

The NDA is based on the positive results from the Phase III studies OASIS 1, 2 and 3 evaluating the efficacy and safety of the investigational compound elinzanetant versus placebo. Results from OASIS 1 and 2 were published in August 2024 in *The Journal of the American Medical Association (JAMA)*. Detailed results of the Phase III study OASIS 3 providing supporting efficacy and additional long-term safety data were presented at The Menopause Society (TMS) annual meeting in September 2024.

In the last 30 days, elinzanetant was approved under the brand name Lynkuet™ in the United Kingdom and Canada. Submissions for marketing authorizations for elinzanetant are also ongoing in the European Union and other markets around the world.

About Women's Healthcare at Bayer

Women's Health is in Bayer's DNA. As a global leader in women's healthcare Bayer has a long-standing commitment to delivering science for a better life by advancing a portfolio of innovative treatments. Bayer offers a wide range of effective short- and long-acting birth control methods as well as therapies for menopause management and gynecological diseases. Bayer is also focusing on innovative options to address the unmet medical needs of women worldwide and to broadening treatment choices such as in menopause. Additionally, Bayer intends to provide 100 million women per year in low-and-middle income countries by 2030 with access to family planning by funding multi-stakeholder aid programs for capacity building and by ensuring the supply of affordable modern contraceptives. This is part of the comprehensive sustainability measures and commitments from 2020 onwards and in line with the Sustainable Development Goals of the United Nations.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating 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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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