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News Release

Not intended for U.S. and UK Media

Bayer's Lynkuet™ (elinzanetant) approved in the U.S. for treatment of moderate to severe vasomotor symptoms due to menopause

- This approval is supported by data from the Phase III OASIS clinical program evaluating Lynkuet™ (elinzanetant) for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes), due to menopause[1]
- In OASIS 1 and 2, elinzanetant met the co-primary endpoints of reduction in number and severity of moderate to severe hot flashes day and night at weeks 4 and 12 from baseline[1]
- Hot flashes are a common symptom of menopause[2] and one of the main reasons women seek treatment[3], hot flashes may impact women differently[4] and some can be disruptive[5]
- Elinzanetant is the first dual neurokinin (NK) targeted therapy,[1] NK1 and NK3 receptor antagonist

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Berlin, October 24, 2025 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has approved elinzanetant as the first dual neurokinin (NK) targeted therapy[1], neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist, under the brand name Lynkuet™ for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) due to menopause. Inhibition of Substance P and Neurokinin B through antagonism of NK1 and NK3 receptor signaling on kisspeptin/neurokinin B/dynorphin (KNDy) neurons with elinzanetant can modulate neuronal activity in the thermoregulation associated with hot flashes.[1] The FDA approval is supported by data from three Phase III clinical studies (OASIS 1, OASIS 2 and OASIS 3) that evaluated the efficacy and safety of elinzanetant for the treatment of moderate to severe VMS due to menopause.

"For more than a century, Bayer has been dedicated to pioneering advances in women's health, and this FDA approval represents a bold step forward – our first hormone-free

treatment for alleviating vasomotor symptoms of menopause," said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. "There is a need for more individualized approaches to menopause care, and Lynkuet™ addresses a significant gap in treatment options. The approval in the U.S. reflects our unwavering commitment to delivering science-driven solutions that meet women's evolving healthcare needs and empower them to take charge of their health at every stage of life."

The efficacy of elinzanetant for the treatment of moderate to severe VMS due to menopause was demonstrated in the first 12 weeks of two randomized, double-blind, placebo-controlled, multicenter clinical trials, OASIS 1 and OASIS 2, in 796 menopausal women.[1] The co-primary efficacy endpoints in both trials were the mean change in frequency and severity of moderate to severe VMS from baselines to weeks 4 and 12, including day and night hot flashes.[1] The safety of elinzanetant was evaluated in three randomized, double-blind, placebo-controlled, multicenter clinical trials (OASIS 1, OASIS 2 and OASIS 3) in 1420 women. In OASIS 3, 627 women received elinzanetant or placebo for up to 52 weeks to evaluate long-term safety.[1]

"These three studies investigated the safety and efficacy of elinzanetant for the treatment of moderate to severe hot flashes due to menopause," said JoAnn Pinkerton, M.D., Professor and Director of Midlife Health at UVA Health and Lead Investigator on the OASIS 2 trial. "Hot flashes, particularly when severe, can have an impact on women's daily lives and this approval provides healthcare providers with a new treatment option that can be used first-line for moderate to severe hot flashes due to menopause."

Hot flashes are a common symptom of menopause[2] that may impact women differently[4]. Hot flashes can be disruptive[5] and are a common reason for which women in menopause seek treatment[3].

"It's important that women know they have choices for treating moderate to severe hot flashes due to menopause, and today's approval further expands a woman's options for treating these symptoms," said Claire Gill, President and Founder of the National Menopause Foundation.

Elinzanetant is expected to be available in the U.S. beginning in November 2025.

About elinzanetant

Elinzanetant is the first dual neurokinin (NK) targeted therapy,[1] neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist, approved in the U.S. for the treatment of moderate to severe VMS due to menopause.[1]

The compound is being developed globally for the treatment of moderate to severe vasomotor symptoms (VMS; also known as hot flashes) associated with menopause or endocrine therapy (ET) for breast cancer, administered orally once daily. Increasing evidence indicates that hypothalamic neurons called kisspeptin, neurokinin B, and dynorphin (KNDy) neurons, expressing both NK-1 and NK-3 receptors and their ligands Substance P and NKB, play a role in thermoregulation. Declining estrogenic activity due to natural menopause or endocrine therapy leads to hyperactivity of KNDy neurons and dysregulation of the thermoregulatory center, resulting in VMS. NK-1 receptors may also have a role in the cooling response through sweating and peripheral vasodilatation as well as on sleep disturbance.

Elinzanetant has been approved under the brand name Lynkuet™ in the U.S. as well as in Australia, Canada, the UK, and Switzerland. It is pending approval in the European Union and under review in other markets around the world.

About Menopause

By 2030, the global population of women experiencing menopause is projected to increase to 1.2 billion, with 47 million women entering this phase each year. Menopause is a phase in women's lives, related to the progressive decline of ovarian function. It usually occurs in women during their 40s or early 50s. Menopause symptoms can also be a consequence of surgical (such as bilateral oophorectomy) or medical treatment (such as endocrine therapy for breast cancer). The most frequently reported and disruptive symptoms during the menopausal transition are VMS, sleep disturbances and mood changes.[6-8]Addressing these symptoms is key to maintaining functional ability and quality of life in menopause which is highly relevant from both a healthcare and socio-economic perspective.

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
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

References:

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