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News Release

Not intended for U.S. and UK Media

Bayer receives first approval worldwide for Lynkuet™ (elinzanetant) in the UK as treatment of moderate to severe vasomotor symptoms associated with menopause

- The first approval worldwide for elinzanetant, under the brand name Lynkuet™ (Lynkuet®▼ in the UK), for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) associated with menopause is based on results from the three pivotal trials in the OASIS Phase III clinical development program[1]
- Elinzanetant is the first dual neurokinin (NK)-targeted therapy (NK-1 and NK-3 receptor antagonist) and has demonstrated a significant mean reduction in the frequency and severity of moderate to severe VMS
- Up to 80% of women will experience hot flashes during the menopause transition[2], yet almost two thirds remain untreated[3]

Berlin, July 10, 2025 – Bayer today announced that the Medicines and Healthcare products Regulatory Agency (MHRA, regulatory authority in the UK) has authorized the use of elinzanetant, the first dual neurokinin NK)-targeted therapy (NK-1 and NK-3 receptor antagonist) under the brand name Lynkuet™ (Lynkuet®▼ in UK) for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) associated with menopause in the United Kingdom.[1]

“This first approval worldwide marks a significant milestone for our hormone-free treatment elinzanetant to manage some of the most disruptive menopausal symptoms,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “It highlights Bayer’s longstanding commitment to advance women’s health, and we are looking forward to bringing this option to many more women around the world.”

“Menopausal symptoms, such as hot flashes, can have a profound impact on the quality of life for women. They are not just physical discomforts; they can significantly disrupt daily activities, sleep and emotional well-being,” said Dr Paula Briggs, Consultant Gynaecologist in Sexual and Reproductive Health in Liverpool Women’s NHS Foundation Trust, Immediate Past Chair of the British Menopause Society. “I welcome expanded therapeutic options that address the diverse needs and preferences of women going through menopause. Physicians now have a new hormone-free treatment option that offers an alternative for tailoring treatment plans, helping women manage their symptoms and potentially enhance their overall quality of life during this important transition.”

The marketing authorization in the UK is the first approval worldwide and based on positive results from the Phase III studies OASIS-1, -2 and -3 evaluating the efficacy and safety profile of elinzanetant. Elinzanetant met all primary endpoints in all three studies and demonstrated a favorable safety profile.[1]

In OASIS-1 and -2[4], elinzanetant significantly reduced mean frequency and severity of moderate to severe VMS associated with menopause compared to placebo at weeks 4 and 12. Efficacy was maintained with over 80% of participants in the elinzanetant group achieving at least a 50% reduction in VMS frequency by week 26, including those who switched from placebo to elinzanetant after week 12. Both trials also achieved all three key secondary endpoints showing a statistically significant mean reduction in the frequency of VMS from baseline to week 1, as well as statistically significant improvements in sleep disturbances and menopause-related quality of life compared to placebo.

In OASIS-3, elinzanetant demonstrated a statistically significant mean reduction in the frequency of moderate to severe VMS from baseline to week 12 compared to placebo. The VMS reductions were maintained throughout the study duration. OASIS-3 reinforced the findings from OASIS-1 and -2, reporting a sustained benefit and safety profile over 52 weeks with the most frequently reported adverse with elinzanetant versus placebo being headache, fatigue and somnolence (also known as drowsiness).

Based on the positive results from the Phase III clinical development program, submissions for marketing authorizations for elinzanetant are also ongoing in the US, the EU and other markets around the world.

About elinzanetant

Elinzanetant is the first dual neurokinin (NK)-targeted therapy, (NK-1 and NK- 3 receptor antagonist), globally developed 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, expressing both NK-1 and NK-3 receptors and their ligands, called kisspeptin, neurokinin B, and dynorphin (KNDy) neurons play a role in thermoregulation. Declining estrogenic activity due to natural menopause or ET 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.

The compound has been authorized under the brand name Lynkuet™ in the UK in July 2025.[1] It is under regulatory review in the Unites States, countries of the European Union and other markets around the world.

About the Phase III OASIS-1, -2 and -3 studies in elinzanetant

The UK approval of elinzanetant is supported by three Phase III clinical studies – OASIS-1, -2 and -3. OASIS11 and -2 investigated the efficacy and safety profile of elinzanetant administered orally once daily in women with moderate to severe VMS associated with menopause over 26 weeks and randomized 396 and 400 postmenopausal women between 40 and 65 years across 184 sites in 15 countries. Patients in the elinzanetant arm received a 120 mg dose of elinzanetant once daily for 26 weeks and patients in the control arm received a matching placebo once daily for 12 weeks, followed by elinzanetant 120 mg dose for 14 weeks. OASIS-3 investigated the efficacy and safety profile of elinzanetant versus placebo for the treatment of moderate to severe VMS associated with menopause over 52 weeks in postmenopausal women, without a minimum number of VMS for inclusion. 628 postmenopausal women between 40 and 65 years across 83 sites in 9 countries were randomized.

About Vasomotor Symptoms

Vasomotor symptoms (VMS; also referred to as hot flashes) result from hyperactivation of the thermoregulatory pathway mediated by hypertrophy of the KNDy neurons. This is due to a decrease of estrogen, which can result from the progressive reduction of ovarian function due to natural menopause or medical intervention by bilateral oophorectomy or medical treatment such as endocrine therapy for breast cancer.

VMS are reported by up to 80% of women at some point during the menopausal transition[2] and are one of the leading causes for seeking medical attention during this phase of a woman's life.[2] Over one-third of menopausal women report severe symptoms, which can last 10 years or more after the last menstrual period, with relevant impact on quality of life.[2,5]

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.[6] Menopause is a phase in women's lives, related to the progressive decline of ovarian function usually occurring in their late 40s or early 50s.[7] Menopause symptoms can also be a consequence of surgical or medical treatment such as breast cancer treatment. The most frequently reported and disruptive menopause symptoms are VMS and sleep disturbances, which can substantially affect a woman's health, quality of life and work productivity.[8] Addressing disruptive menopause symptoms is key to maintaining functional ability and quality of life 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.

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▼ In the UK, this medicine is subject to additional monitoring. This will allow quick identification of new safety information. Side effects will be reported directly via the MHRA Yellow Card Scheme at https://yellowcard.mhra.gov.uk/. By reporting side effects, more information on the safety of this medicine can be provided.