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News Release

Not intended for U.S. and UK Media

Lynkuet™ (elinzanetant) approved in the EU for the treatment of moderate to severe vasomotor symptoms associated with menopause or endocrine therapy for breast cancer

- Elinzanetant, now approved in the EU under the brand name Lynkuet™ is a dual neurokinin (NK)-targeted therapy (NK-1 and NK-3 receptor antagonist) and the only hormone-free treatment for moderate to severe vasomotor symptoms (VMS; also known as hot flashes) associated with menopause or caused by adjuvant endocrine therapy (AET) related to breast cancer
- European approval in these two indications is based on positive results from the OASIS Phase III program, comprising four clinical studies (OASIS-1-4), in which elinzanetant significantly reduced the frequency and severity of moderate to severe VMS in women experiencing menopause or receiving endocrine therapy for breast cancer and demonstrated a favorable safety profile

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Berlin, November 19, 2025 – The European Commission has granted marketing authorization in the European Union (EU) for elinzanetant, under the brand name Lynkuet™. The compound is approved for the treatment of moderate to severe vasomotor symptoms (VMS; also known as hot flashes) associated with menopause or caused by adjuvant endocrine therapy (AET) related to breast cancer.

“The European approval of Lynkuet™ brings a new option to women whose daily lives are disrupted by vasomotor symptoms,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, and Member of the Pharmaceutical Leadership Team at Bayer. “We understand how challenging and isolating these symptoms can be, often interfering with daily rhythm, personal productivity, and overall quality of life. Our commitment is to support women with solutions that truly address their needs, helping them feel like them themselves again by supporting health and wellbeing at every stage.”

By 2030, it is estimated that 1.2 billion women globally will be experiencing menopause.[1] VMS affect up to 80% of women during the menopausal transition.[2] In Europe, approximately 40% of women report moderate to severe VMS,[3] highlighting the substantial burden of these symptoms on daily life and overall well-being.

“Menopause symptoms, including hot flashes, can greatly affect women's quality of life,” said Nick Panay, Principal Investigator for OASIS-3, Consultant Gynecologist, Imperial College Healthcare NHS Trust, Professor of Practice, Imperial College London and Immediate Past President of the International Menopause Society. “This approval is an important milestone in the area of menopause care as it expands therapeutic options for women experiencing distressing menopause symptoms with a novel targeted hormone-free treatment and facilitates healthcare professionals to achieve more personalized treatment.”

VMS may also be caused by endocrine therapy, for the treatment or prevention of breast cancer. Breast cancer remains the most common cancer diagnosed in women worldwide, with approximately 70% of cases categorized as hormone-receptor positive (HR+).[4,5] Endocrine therapy, an established treatment for women with HR+ breast cancer, can often result in VMS[6,7] impacting quality of life and treatment adherence.

“Menopausal symptoms are common side effects of endocrine therapy for breast cancer, frequently leading to treatment discontinuation, which highlights the importance of managing these symptoms in breast cancer care,” said Dr. Fatima Cardoso, Principal Investigator of OASIS-4, from Lisbon, Portugal. “With the approval of this hormone-free therapy, we now have the first approved treatment option for this indication that will help in addressing an important unmet medical need of women and improve their quality of life during this challenging time.”

The approval of elinzanetant in the EU is based on the positive results from the OASIS Phase III clinical development program, comprising OASIS-1, -2, -3 and -4, which met all primary endpoints and key secondary endpoints in all four studies and demonstrated a favorable safety profile. Data have been published in diverse medical journals: OASIS-1 and –2 in August 2024 in *The Journal of the American Medical Association* (JAMA)[8], OASIS-3 in *The Journal of the American Medical Association (JAMA) Internal Medicine* in September 2025[9] and OASIS-4 in the *New England Journal of Medicine* (NEJM) in June 2025.[10]

About elinzanetant (Lynkuet™)

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 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 disturbances.

Elinzanetant is approved under the brand name Lynkuet™ in Australia, Canada, the UK, the U.S., and Switzerland for the treatment of VMS associated with menopause and in the EU for the treatment of moderate to severe VMS associated with menopause or caused by adjuvant endocrine therapy (AET) related to breast cancer. Submissions for marketing authorizations for elinzanetant are also ongoing in other markets around the world.

About the Elinzanetant clinical development program

The Phase III clinical development program of elinzanetant, OASIS, comprises four Phase III studies: OASIS-1, -2, -3 and -4. OASIS-1 and -2 investigated the efficacy and safety 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 of elinzanetant for the treatment of vasomotor symptoms associated with menopause over 52 weeks and randomized 628 postmenopausal women between 40 and 65 years across 83 sites in 9 countries. OASIS-4 is a double-blind, randomized, placebo-controlled multicenter study to investigate the efficacy and safety of elinzanetant for the treatment of vasomotor symptoms associated with endocrine therapy for treatment or prevention of hormone receptor positive (HR+) breast cancer over 52 weeks and optionally for an additional 2 years in women taking endocrine therapy, for treatment of

breast cancer. 474 patients at 90 centers in 16 countries (excluding the US) were randomized.

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 usually occurring in their late 40s or early 50s. 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. 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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