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News Release

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Elinzanetant recommended for approval in EU as treatment of moderate to severe vasomotor symptoms

- Positive opinion by the Committee for Medicinal Products for Human Use (CHMP) is based on the results from the clinical development Phase III studies OASIS 1-4
 - Recommended indication is treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause or caused by adjuvant endocrine therapy (AET) related to breast cancer
 - 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 for breast cancer
 - 67% of European women report vasomotor symptoms during menopause transition according to recent survey¹; up to 95% of women experience menopause symptoms while taking endocrine therapy for breast cancer²
 - Final decision of the European Commission is expected in the coming months
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Berlin, September 19, 2025 – The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended elinzanetant for marketing authorization in the European Union. The compound is recommended as 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 final decision of the European Commission on the marketing authorization is expected within the coming months. If approved, elinzanetant would be the first dual neurokinin (NK)-targeted therapy (NK-1 and NK-3 receptor antagonist) approved in these two indications in the EU. The compound is already approved under the brand name Lynkuet™ in Australia, Canada, the UK, and Switzerland for the treatment of VMS associated with menopause, and filings in other countries are underway

or planned. Currently there are no approved treatments for menopause symptoms induced by endocrine therapy for breast cancer.

“Menopause is a truly individual experience, with symptoms and severity varying widely from woman to woman,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, and Member of the Pharmaceutical Leadership Team at Bayer. “The positive CHMP opinion for elinzanetant marks a significant step forward in broadening treatment options for women across Europe. This milestone reflects our ongoing commitment to advancing innovative solutions that support better health outcomes and empower healthcare providers to offer more tailored care to meet the distinct needs of each woman.”

The CHMP opinion is based on positive results from the Phase III studies OASIS-1, -2, -3 and -4, evaluating the efficacy and safety profile of elinzanetant. Elinzanetant met all primary endpoints and key secondary endpoints in all four studies and demonstrated a favorable safety profile.

In OASIS-1 and -2, 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. Results from OASIS 1 and 2 were published in August 2024 in *The Journal of the American Medical Association (JAMA)*.³

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 treatment emergent adverse events with elinzanetant versus placebo being headache, fatigue and somnolence. Detailed results of the Phase III study OASIS 3 were published in *The Journal of the American Medical Association (JAMA) Internal Medicine* in September 2025.⁴

In OASIS-4, which investigated elinzanetant in women taking endocrine therapy for treatment or prevention of hormone receptor (HR+) breast cancer, the compound showed a statistically significant reduction in the frequency of moderate to severe VMS from baseline to weeks 4 and 12 compared to placebo. Key secondary endpoints showed statistically significant improvements of sleep disturbances and menopause-related quality of life from baseline to week 12 versus placebo. Additional secondary endpoints showed a reduction in VMS frequency at week 1 and improvements in VMS severity at weeks 4 and 12 versus placebo. The safety profile over 52 weeks observed in the OASIS-4 study was generally consistent with previously conducted studies and published data on elinzanetant in postmenopausal women with fatigue, somnolence and diarrhea being the most frequent treatment emergent adverse events (TEAEs) in the elinzanetant group. Data from OASIS-4 were published in the *New England Journal of Medicine (NEJM)* in June 2025.⁵

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.

Elinzanetant is approved under the brand name Lynkuet™ in Australia, Canada, the UK, and Switzerland for the treatment of VMS associated with menopause. Submissions for marketing authorizations for elinzanetant are also ongoing in the United States and 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 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 and are one of the leading causes for seeking medical attention during this phase of a woman's life. 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.

VMS may also be caused by endocrine therapy, for the treatment or prevention of breast cancer, impacting quality of life and treatment adherence. For these women, there are currently no approved treatment options.

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.

References:

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- 4 Panay N, et al. (2025). Elinzanetant for the treatment of vasomotor symptoms associated with menopause: a 52-week Phase 3 randomized trial (OASIS 3). *JAMA Internal Medicine*; DOI: /10.1001/jamainternmed.2025.442
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