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News Release

Not intended for U.S. and UK Media

Bayer's Lynkuet™ (elinzanetant) granted priority review by U.S. FDA for additional indication

- Priority review granted for treatment of moderate to severe vasomotor symptoms (VMS; also known as hot flashes) in women undergoing endocrine therapy for hormone receptor positive breast cancer
- Lynkuet™ (elinzanetant) also became the first therapy indicated for the treatment of moderate to severe VMS caused by adjuvant endocrine therapy (AET) for breast cancer in the UK, Switzerland and Canada, in addition to the initial indication of treatment of VMS associated with menopause
- For many women receiving endocrine therapy for hormone receptor-positive breast cancer, VMS are a common side effect which can affect quality of life and treatment adherence
- Regulatory submission in the U.S. as well as the indication expansions around the world are based on results from the Phase III OASIS-4 study in women receiving AET for the treatment or prevention of hormone receptor positive (HR+) breast cancer, which demonstrated significant reductions in VMS and showed additional benefits in sleep disturbances and menopause-related quality of life in these patients

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Berlin, September 28, 2026 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental new drug application (sNDA) and granted Priority Review designation for Lynkuet™ (elinzanetant) for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) in women receiving endocrine therapy for the treatment or prevention of hormone receptor positive (HR+) breast cancer.

Elinzanetant was first approved in the U.S. in October 2025 for the treatment of moderate to severe VMS due to menopause, supported by data from three Phase III clinical trials (OASIS-1, OASIS-2 and OASIS-3). Being the first dual neurokinin (NK)-targeted therapy

(NK-1 and NK-3 receptor antagonist), the compound is globally developed for the treatment of moderate to severe VMS associated with menopause or caused by adjuvant endocrine therapy (AET) for breast cancer, administered orally once daily.

Lynkuet also became the first therapy indicated for the treatment of moderate to severe VMS caused by AET for breast cancer in the UK, Switzerland and Canada, in addition to the initial indication of treatment of VMS associated with menopause.

In the EU, the compound had been approved in November 2025 for the treatment of moderate to severe VMS associated with menopause or caused by AET related to breast cancer.

“Endocrine therapy is a standard of care for many women facing HR+ breast cancer, which can commonly cause side effects such as vasomotor symptoms,” said OASIS-4 Primary Investigator Fatima Cardoso, MD, FESMO Director Breast Unit, Centre Antoine Lacassagne and Advanced Breast Cancer (ABC) Global Alliance, Nice, France. “It’s important that we continue to learn more about vasomotor symptoms due to endocrine therapy as part of supporting women throughout their breast cancer care journey.”

The sNDA for Lynkuet in the U.S., the indication extensions in Canada, Switzerland and the UK and the respective approval in the EU are based on results of the Phase III OASIS-4 trial. Key details and findings from the study[1]:

- The OASIS-4 study was a 52-week, double-blind, randomized placebo-controlled Phase III interventional study conducted at 90 sites outside of the US. A total of 474 women 18 to 70 years of age with moderate to severe VMS caused by AET for HR+ breast cancer or its prevention were randomized 2:1 to elinzanetant (n=316) for 52 weeks or placebo for 12 weeks, followed by elinzanetant for 40 weeks (n=158).
- Lynkuet successfully met the primary endpoints demonstrating statistically significant reductions in the frequency of moderate to severe VMS from baseline to week 4 and 12 compared to placebo, in women receiving endocrine therapy for treatment or prevention of HR+ breast cancer.
- The study also achieved all secondary endpoints demonstrating reductions in severity of VMS at week 4 and 12, VMS frequency reduction at week 1, as well as improvements of sleep disturbances and menopause-related quality of life from

baseline to week 12 versus placebo and maintaining the effects over the study period.
- The key findings were presented at ASCO 2025 and simultaneously published in the New England Journal of Medicine (NEJM) in June 2025.

“At Bayer, we believe women deserve treatment choices that reflect the complexity of their health needs and experiences. The positive results from the OASIS-4 study further support the potential of elinzanetant to address unmet needs in menopause care, including for women facing vasomotor symptoms associated with breast cancer treatment. This confirms the potential of elinzanetant in broadening treatment options for women across different life stages and health circumstances,” said Cecilia Caetano, M.D., Vice President, Global Medical Affairs and Evidence Generation Lead Women’s Health, Bayer Pharmaceuticals Division.

Breast cancer remains the most commonly diagnosed cancer among women globally. In 2022, approximately 2.3 million women were diagnosed with breast cancer, accounting for 30% of all cancers in women. Nearly 70% of these cases are hormone receptor-positive (HR+).[2] AET is an established standard of care for treating HR+ breast cancer, with duration of use varying between 5 and 10 years based on cancer type and other clinical considerations.[3] Treatment with AET for up to 10 years has been shown to substantially reduce breast cancer mortality rate over the two decades after diagnosis.[4] Hot flashes are a common side effect of AET treatment, and due to the HR+ diagnosis – many women are discouraged from using hormone-releasing medicines.[5]

Earlier this year, the National Comprehensive Cancer Network updated its survivorship guidelines listing Lynkuet as a preferred non-hormonal pharmacologic treatment in the selective NK-1 and/or NK-3 receptor antagonists category for treatment of moderate to severe VMS due to medically and surgically induced menopause.[6]

Elinzanetant is approved under the brand name Lynkuet™ in several countries around the world, including Australia and the U.S., for the treatment of VMS associated with menopause and in the EU, UK, Switzerland and Canada for the treatment of moderate to severe VMS associated with menopause or caused by AET related to breast cancer. Submissions for marketing authorizations for elinzanetant are also ongoing in further countries 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 caused by 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 disturbances.

About Menopause

By 2030, nearly 500 million women will be in the menopausal transition years.[7]
The Menopausal transition is a phase in women's lives, related to the cessation of menstrual cycles 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.[7-9] 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 longstanding 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 broaden 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 multistakeholder aid programs for capacity building and by ensuring the supply of affordable modern contraceptives.

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 support efforts to master major challenges presented by a growing and aging global population and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 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.

Bayer AG is a holding company with operating subsidiaries worldwide. References to “Bayer” or “the company” herein may refer to one or more subsidiaries as context requires.

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