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News Release

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World Sleep congress 2025:

Bayer to present research on sleep disturbances associated with menopause at the World Sleep congress 2025

- First results from the exploratory phase II study NIRVANA investigating elinzanetant in women having sleep disturbances associated with menopause
 - Presentation of new results from global smartwatch-based study SONAR in collaboration with Samsung identifying sleep parameters in women across five countries
 - Interim results from the observational study ESTeeM quantifying the burden of menopause-related sleep disturbances, quality of life, and work productivity to be presented
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Berlin, September 2, 2025 – Bayer will present latest research on sleep disturbances associated with menopause at the upcoming World Sleep congress 2025, which takes place from September 5-10 in Singapore. Together with vasomotor symptoms (VMS, also known as hot flashes), sleep disturbances belong to the most frequent and disruptive symptoms associated with menopause.¹ The research to be presented demonstrates the continuous commitment of Bayer as a leader in women's healthcare to advance science, increase awareness and education around menopause as well as to broaden therapeutic options in an area of high unmet medical need.

Approximately 40% to 60% of women experience sleep disturbances during the menopausal transition, which may include trouble falling asleep or staying asleep potentially causing a negative impact on women's quality of life and limiting their daily activities, including performance at work.^{2,3} Sleep disturbances associated with menopause may also be associated with negative effects on metabolism, body fat gain, poor cardiovascular health in later life, cognitive health decline, and depressive

symptoms.^{4,5} Addressing these menopause symptoms is key to maintaining functional ability and quality of life which is highly relevant from both a healthcare and socio-economic perspective.

For the first time, full results from the Phase II exploratory NIRVANA study (NCT06112756) with elinzanetant on menopause-associated sleep disturbances will be presented. The results and post-hoc analyses include the effect of elinzanetant in reducing wakefulness after sleep onset (WASO), assessed by polysomnography, the consistency in effect of elinzanetant on WASO across different objective and subjective methods, and the effect of elinzanetant on sleep continuity and sleep patterns. Further poster presentations evaluate the monitoring of sleep with a contactless home-based sleep monitor, namely Sleepiz One+, compared to onsite polysomnography (PSG), a gold standard measure used routinely in clinical studies for assessing sleep disorders.

Additional results to be presented at the congress assess the burden of sleep disturbances associated with menopause. Data from the global smartwatch-based study SONAR, which is part of a collaboration between Bayer and Samsung, will be discussed, identifying associations of age, BMI, physical activity and country with sleep parameters in women will be discussed. Furthermore, interim data from the observational study EsTeeM (NCT06728332) on the burden of menopause-related sleep disturbances, quality of life, and work productivity, will also be presented as a poster.

Key presentations from Bayer at World Sleep 2025 (**all times in local event time UTC + 8 hours**):

Oral presentations:

- “Identifying sleep associations in women across five countries: a global smartwatch-based study”
 - o **Claudio Soares**, *Pauline Maki, Fiona Baker, Ricky Choi, Jongmin Choi, Minsoeng Kim, Donghyun Lee, Jungwon Lee, Hon Pak, Nils Schoof, Julie Dorey, Elif Inan Eroglu, Elaina Bolinger, Cecilia Caetano, Carsten Moeller, Carina Dinkel-Keuthage*
 - o *Tuesday, September 9, 09:00 AM – 10:30 AM, Room 328*

Poster presentations:

- “Effect of elinzanetant in reducing polysomnographic wakefulness after sleep onset in postmenopausal women: Results from the Phase II NIRVANA exploratory study”
*Hadine Joffe, Claudio Soares, **Fiona Baker**, Pauline Maki, Malek Bajbouj, Gary Zammit, Cecilia Caetano, Ulrike Krahn, Huda Shalhoub, Frank Kramer, Hoi-Shen Radcliffe, Christian Seitz*
 - o 242: Monday, September 8, 06:30 PM – 07:30 PM, Hall 405
- “Effect of elinzanetant on wakefulness after sleep onset across subjective and objective measures: post hoc analysis of the NIRVANA phase II pilot study in postmenopausal women with sleep disturbances”
 - o **Rossella Nappi**, Claudio Soares, Gary Zammit, Fiona Baker, Hadine Joffe, Pauline Maki, Cecilia Caetano, Hoi-Shen Radcliffe, Ulrike Krahn, Huda Shalhoub, Frank Kramer, Christian Seitz
 - o 508: Monday, September 8, 06:30 PM – 07:30 PM, Hall 405
- “Effect of elinzanetant on sleep continuity and sleep architecture in postmenopausal women with sleep disturbances: post hoc analysis of the Phase II pilot study NIRVANA”
 - o **Claudio Soares**, Hadine Joffe, Fiona Baker, Pauline Maki, Malek Bajbouj, Gary Zammit, Cecilia Caetano, Hoi-Shen Radcliffe, Ulrike Krahn, Huda Shalhoub, Frank Kramer, Christian Seitz
 - o 238: Monday, September 8, 06:30 PM – 07:30 PM, Hall 405
- “Head-to-head comparison of a contactless home sleep monitor with polysomnography in women with menopause-associated sleep disturbances”
 - o **Frank Kramer**, Andrew Trigg, Hoi-Shen Redcliffe, Ulrike Krahn, Christian Seitz, Marc Rullan, Harsha Umesh Babu, Jonas Kraus
 - o 415: Tuesday, September 9, 04:45 PM – 05:45 PM, Hall 405
- “ESTeeM: Burden of Menopause-Related Sleep Disturbances, Quality of Life, and Work Productivity in a Real-World Setting”
 - o Pauline Maki, Claudio N. Soares, **Fiona Baker**, Lisa Larkin, Ruth D. Holzmann, Julie Dorey, Ioanna Gkioni, Carina Dinkel-Keuthage, Nils Schoof, Marcelo Graziano, Huda Shalhoub, Ekta Kapoor
 - o 480: Tuesday, September 9, 04:45 PM – 05:45 PM, Hall 405

To view the complete program, please visit the [World Sleep congress website](#).

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 and Canada in July 2025, and in Switzerland in August 2025 for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) associated with menopause. It is under regulatory review in the United States, countries of the European Union 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 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. OASIS-4 is a double-blind, randomized, placebo-controlled multicenter study to investigate the efficacy and safety of elinzanetant for the treatment of VMS 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.

Data from OASIS-1 and -2 were published in the Journal of the American Medical Association (JAMA) in August 2024. Detailed results of the Phase III study OASIS 3 providing additional efficacy and safety data over 52 weeks were presented at The Menopause Society (TMS) annual meeting in September 2024. Detailed results of OASIS-4 the first pivotal international Phase III study to assess the safety and efficacy of elinzanetant in moderate to severe VMS associated with endocrine therapy for breast cancer were presented for the first time at the American Society of Clinical Oncology (ASCO) in June 2025 as well as simultaneously published in the New England Journal of Medicine (NEJM). NIRVANA is an exploratory Phase II randomized, parallel-group treatment, double-blind study. The primary objective is to explore the efficacy of elinzanetant on sleep disturbances associated with menopause (SDM) as determined by polysomnography (PSG). PSG is a validated method to study sleep and underlying causes of sleep disturbances. Additional objectives include exploring the efficacy of elinzanetant on SDM as determined by patient-reported outcomes and evaluating the safety of elinzanetant for the treatment of SDM. More information can be found at <https://clinicaltrials.gov/study/NCT06112756>.

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. 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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- 2 Simon, JA; Anderson, RA; Ballantyne, E, et al. (2023). Efficacy and safety of elinzanetant, a selective neurokinin-1,3 receptor antagonist for vasomotor symptoms: a dose-finding clinical trial (SWITCH-1). *Menopause*; 30 (3): 239–246.
- 3 Nappi, RE; Kroll, R; Siddiqui, E, et al. (2021). Global cross-sectional survey of women with vasomotor symptoms associated with menopause: prevalence and quality of life burden. *Menopause*; 28 (8): 875–882.
- 4 Nappi, RE; Simoncini, T (2021). Menopause transition: a golden age to prevent cardiovascular disease. *Lancet Diabetes Endocrinol*; 9 (3): 135–137.
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