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News Release

Not intended for U.S. and UK Media

19th World Congress on Menopause by the International Menopause Society (IMS):

Bayer to present latest research on impact and burden of menopause symptoms at IMS 2024

- Newest data on impact of sleep disturbances during menopausal transition to be presented at the 19th World Congress of the International Menopause Society (IMS)
 - 40% to 60% of women experience sleep disturbances during the menopausal transition which may have an impact on women's quality of life, work productivity as well as their physical and mental wellbeing
 - Additional presentations include pooled analysis as well as several subgroup analyses from the OASIS 1 and 2 Phase III studies of the investigational compound elinzanetant
 - These presentations reinforce Bayer's leadership and long-standing commitment in women's healthcare to address relevant unmet medical needs for women, including those who are experiencing menopause symptoms
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Berlin, October 17, 2024 – Bayer will present latest research results on menopause symptoms including sleep disturbances associated with menopause at the upcoming 19th World Congress on Menopause by the International Menopause Society (IMS) which takes place from October 19 – 22, in Melbourne, Australia. Data include the first release of results from the recently announced collaboration between Bayer and Samsung* to expand the knowledge base on sleep disturbances associated with menopause oral presentation "Exploring Sleep Disturbances Across Age and Sex with Wearable Smartwatches". The research to be presented demonstrates the continuous commitment of Bayer as a leader in women's healthcare to advance science and increase awareness and education around menopause as well as to broaden therapeutic choices in an area of high unmet need.

Bayer oral presentations include:

- Oral presentation: *“Vasomotor symptoms and the impact of sleep disturbance associated with menopause among postmenopausal women in Europe”*
 - Pauline Maki
 - Monday, October 21st, 2024: 15:50 to 17:20 AEST, Room 210
- Oral presentation: *“Exploring Sleep Disturbances Across Age and Sex with Wearable Smartwatches”*
 - Claudio Soares
 - Monday, October 21st, 2024: 15:50 to 17:20 AEST, Room 210

Additional Bayer presentations include:

- Scientific Symposia: *“Looking Beyond VMS: Sleep disturbances in the menopause”*
 - Claudio Soares, Susan Davis, Pauline Maki and Paula Briggs
 - Sunday, October 20th, 15:15 – 16:45 AEST, Room 203
- Poster # P037: *“Does sleep disturbance have an impact on depression and anxiety in perimenopausal and postmenopausal women? A Europe-based survey”*
 - Paula Briggs
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # P047: *“Frequency and co-occurrence of vasomotor symptoms, mood changes, and sleep disturbances across the menopausal transition: a descriptive study using secondary data from the Study of Women's Health Across the Nation (SWAN) study”*
 - Pauline Maki
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # P054: *“EMPOWER: Evaluating Menopausal symptom treatment Options and Women's preferences”*
 - Paula Briggs
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # P067: *“Proportion of participants achieving at least 50%, 75% or 100% reductions in VMS frequency with elinzanetant in a pooled analysis of OASIS 1 and 2”*

- Rosella Nappi
- Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # 070: *“Effect of elinzanetant for the treatment of vasomotor symptoms associated with menopause across race and ethnicity subgroups: pooled data from two Phase 3 studies”*
 - JoAnn V Pinkerton
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # 071: *“Effect of elinzanetant for the treatment of vasomotor symptoms associated with menopause across BMI and smoking history subgroups: pooled data from two Phase 3 studies”*
 - JoAnn V Pinkerton
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # P161: *“Design of the ESTeeM Study: Assessing the Burden, Treatment Patterns, and Unmet Needs of Sleep Disturbances in Menopausal Women”*
 - Senka Djordjevic
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # P163: *“Effect of elinzanetant, an NK-1/NK-3 receptor antagonist, on patient-reported sleep disturbance: findings from two pivotal phase 3 studies”*
 - Pauline Maki
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area
- Poster # P166: *“Impact of sleep disturbances on health-related quality of life in post-menopausal women”*
 - Claudio Soares
 - Sunday, October 20th, 2024, 19:40–21:00 AEST, Poster Area

Together with vasomotor symptoms (VMS, also known as hot flashes), sleep disturbances belong to the most frequent and disruptive symptoms associated with menopause.¹ 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 limit 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 in menopause which is highly relevant from both a healthcare and socio-economic perspective.

Bayer is developing elinzanetant, the first dual neurokinin-1 and 3 (NK-1 and 3) receptor antagonist in late-stage clinical development for the non-hormonal treatment of moderate to severe VMS associated with menopause. Results from the OASIS 1 and 2 studies were published in the Journal of the American Medical Association (*JAMA*)⁶ in August 2024. Detailed results of the Phase III study OASIS 3 were presented in September at The Menopause Society (TMS) annual meeting 2024, providing further additional efficacy data and sustained safety data of elinzanetant over 52 weeks, adding to the positive results of the OASIS 1 and 2 studies. Recently, the Health Authorities in Australia, Canada, Switzerland, UK as well as in the US accepted the company's New Drug Applications (NDAs) for elinzanetant for review. Bayer also submitted an EU application for marketing authorization for elinzanetant in the EU and is continuing to do so to further health authorities globally.

In addition to the Phase III clinical development program OASIS with elinzanetant, Bayer is conducting the Phase II study NIRVANA to explore efficacy and safety of investigational compound elinzanetant as a non-hormonal treatment for sleep disturbances associated with menopause.

*Bayer also entered earlier this year a strategic collaboration with Samsung Electronics America, Inc. to address data gaps on sleep disturbances associated with menopause using data provided by women through Samsung consumer devices.

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

About Elinzanetant

Elinzanetant is the first dual neurokinin-1 and 3 (NK-1 and 3) receptor antagonist, in late-stage clinical development for the non-hormonal treatment of moderate to severe VMS associated with menopause, administered orally once daily. Elinzanetant may address moderate to severe VMS by modulating a group of estrogen sensitive neurons in the hypothalamus region of the brain (the KNDy neurons) which, with the decrease of estrogen, become hypertrophic and lead to a hyperactivation of the thermoregulatory pathway, consequently disrupting body heat control mechanisms resulting in VMS. Based

on key secondary endpoints of OASIS 1 and 2, Elinzanetant may also decrease sleep disturbances associated with menopause.

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 transitional phase in women's lives, related to the progressive decline of ovarian function. It usually occurs in women during their 40s or early 50s. The hormonal decline can lead to various symptoms which can substantially affect a woman's health, quality of life, healthcare utilization and work productivity. The most frequently reported and disruptive symptoms during the menopausal transition are VMS, sleep disturbances and mood changes. Menopausal symptoms can also be the result of surgical or medical treatment. Addressing the 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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items 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.

References

- 1 Baker, FC; de Zambotti, M; Colrain, IM, et al. (2018). Sleep problems during the menopausal transition: prevalence, impact, and management challenges. *Nat Sci Sleep*; 10: 73–95.
- 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.
- 5 Proserpio, P ; Marra, S ; Campana, C ; Agostoni, E. C.; Palagini, L ; Nobili, L; Nappi, RE (2020) Insomnia and menopause: a narrative review on mechanisms and treatments, *Climacteric*, 23:6, 539-549
- 6 <https://jamanetwork.com/journals/jama/fullarticle/2822768>