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# News Release

**Not intended for UK Media**

## Bayer's elinzanetant meets all primary and key secondary endpoints in pivotal OASIS 1 and 2 Phase III studies

- OASIS 1 and 2 pivotal studies evaluating investigational compound elinzanetant met all primary endpoints demonstrating a statistically significant reduction in frequency and severity of moderate to severe vasomotor symptoms (VMS) compared to placebo in postmenopausal women
- Both studies also showed superiority over placebo for all key secondary endpoints with a statistically significant reduction in frequency of VMS at week 1, as well as improvement of sleep disturbances and menopause-related quality of life
- The safety profile observed in both studies is overall consistent with previously published data on elinzanetant
- OASIS 1 and 2 are two of three Phase III clinical studies investigating the efficacy and safety of elinzanetant, a first dual neurokinin-1,3 (NK-1,3) receptor antagonist, as a non-hormonal treatment of moderate to severe VMS associated with menopause, administered orally once daily

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**Berlin, January 8, 2024** – Bayer today announced positive top-line results of the pivotal Phase III studies OASIS 1 and 2 evaluating the efficacy and safety of the investigational compound elinzanetant versus placebo. Elinzanetant successfully met all four primary endpoints in both studies demonstrating statistically significant reductions in the frequency and severity of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) from baseline to week 4 and 12 compared to placebo.

Both studies also achieved all three key secondary endpoints showing a statistically significant 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. The safety profile observed in the OASIS 1 and 2 studies is overall consistent with previously published data[1,2] on elinzanetant.

“We are excited about the positive results of these two pivotal Phase III studies for elinzanetant, reinforcing its potential as a non-hormonal treatment option in menopause management,” said Dr. Christian Rommel, member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Global Head of Research and Development. "We want to thank the women participating in the OASIS studies, their families, and all study investigators as well as their clinical and nursing staff for their time and commitment to advance menopause research."

Elinzanetant is a first dual neurokinin-1,3 (NK-1,3) receptor antagonist, in late-stage clinical development for the non-hormonal treatment of moderate to severe VMS associated with menopause, administered orally once daily.

“Menopausal symptoms such as hot flashes and sleep disturbances can be highly disruptive and broadly impact health and quality of life, still many women cope in silence and remain untreated,” said JoAnn Pinkerton, M.D., Professor and Director of Midlife Health at UVA Health. “It’s important that we continue to research for solutions that address the unmet needs of women, and I am looking forward to the unveiling of the full results.”

OASIS 1 and 2 (NCT05042362 and NCT05099159) are the first two Phase III studies in the OASIS clinical development program with results, and the details are planned to be presented at upcoming scientific congresses. The results of the third Phase III study OASIS 3 (NCT05030584) are expected in the coming months. Bayer plans to submit data from the OASIS 1, 2 and 3 studies to health authorities for approval of marketing authorizations for treatment of moderate to severe VMS associated with menopause.

**About the OASIS 1 and 2 studies**

OASIS 1 and 2 are double-blind, randomized, placebo-controlled multicenter studies investigating the efficacy and safety of elinzanetant administered orally once daily in women with moderate to severe VMS associated with menopause. OASIS 1 and 2 randomized 396 and 400 postmenopausal women between 40 and 65 years across 184 sites in 15 countries.

**About the OASIS Clinical Development Program**

The Phase III clinical development program of elinzanetant, OASIS, currently comprises four Phase III studies: OASIS 1, 2, 3 and 4. The OASIS 1, 2 and 3 studies investigate the efficacy and safety of elinzanetant 120 mg in women with moderate to severe VMS associated with menopause. The OASIS 4 study is an expansion of the clinical phase III program and investigates the efficacy and safety of elinzanetant in women with moderate to severe VMS caused by endocrine therapy for treatment or prevention of breast cancer.

The design and dosing of the Phase III clinical development program is based on the positive data from two Phase II studies (RELENT-1 and SWITCH-1). RELENT-1 was a Phase Ib/IIa study investigating the safety, pharmacokinetics and preliminary efficacy of elinzanetant. SWITCH-1 was a Phase IIb study investigating the efficacy and safety of four different doses of elinzanetant compared to placebo in women with VMS.

**About Elinzanetant**

Elinzanetant is a first dual neurokinin-1,3 (NK-1,3) 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. Elinzanetant may also decrease sleep disturbances associated with menopause.

**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 endocrine therapy.

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 world population of women experiencing menopause is projected to increase to 1.2 billion, with 47 million new women entering this phase each year. Menopause is a transitional phase in women's lives, related to the progressive decline of ovarian function, and which usually occurs in women during their 40s or early 50s. It can also be the result of surgical or medical treatment, for example breast cancer treatment. 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. Addressing these 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.

**About Women's Healthcare at Bayer**

Women's Health is in Bayer's DNA and 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. Its 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items 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:*
1 Simon JA, Anderson RA, Ballantyne E, Bolognese J, Caetano C, Joffe H, Kerr M, Panay N, Seitz C, Seymore S, Trower M, Zuurman L, Pawsey S. Efficacy and safety of elinzanetant, a selective neurokinin-1,3 receptor antagonist for vasomotor symptoms: a dose-finding clinical trial (SWITCH-1). Menopause. 2023 Mar 1;30(3):239-246.
2 Trower M, et al. Effects of NT-814, a dual neurokinin 1 and 3 receptor antagonist, on vasomotor symptoms in postmenopausal women: a placebo-controlled, randomized trial. Menopause: The Journal of The North American Menopause Society. 2020; 27 (5): 498-505.