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News Release

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The Journal of American Medical Association (JAMA) publishes Elinzanetant Phase III data

- OASIS 1 and 2 studies demonstrated positive results for investigational compound elinzanetant which met all primary endpoints by significantly reducing frequency and severity of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) over 12 weeks compared to placebo
 - Elinzanetant reduced the frequency of vasomotor symptoms (VMS) in OASIS 1 and 2 from baseline to week 4 by 55.9% and 57.9% respectively (compared to placebo with 31.4% and 35.7% respectively) and to week 12 by 65.2% and 67.0% respectively (compared to placebo with 42.2% and 45.9% respectively)
 - 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
 - Elinzanetant met its key secondary endpoints showing a statistically significant reduction in VMS frequency as early as week 1 as well as statistically significant improvements in sleep disturbances and menopause-related quality of life
 - The safety profile was favorable with the most frequently reported adverse events being headache and fatigue; no incidences of liver toxicity were observed with elinzanetant
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Berlin, August 22, 2024 – Data published in *The Journal of the American Medical Association (JAMA)* from the pivotal Phase III studies OASIS 1 and 2, evaluating the efficacy and safety of the investigational compound elinzanetant, has shown consistent results across both studies and are in line with the Phase II SWITCH study¹. This data reinforces the strong evidence of efficacy and safety of the compound. 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 vasomotor symptoms (VMS) associated with menopause, administered orally once daily.

Elinzanetant met all primary endpoints in the OASIS 1 and 2 studies, significantly reducing frequency and severity of moderate to severe VMS associated with menopause compared to placebo at weeks 4 and 12. In addition, elinzanetant met all key secondary endpoints showing a statistically significant reduction in the frequency of VMS from baseline to week 1 and statistically significant improvement of sleep disturbances and menopause related quality of life, compared to placebo.

In the OASIS 1 study, the frequency of VMS was reduced by 55.9% from baseline to week 4 and 65.2% to week 12, compared to reductions of 31.4% and 42.2% respectively for placebo. In the OASIS 2 study, similar results were seen with a reduction of 57.9% to week 4 and 67.0% to week 12, compared to reductions of 35.7% and 45.9% respectively in the placebo group.

By week 26, over 80% of participants had achieved at least a 50% reduction in VMS frequency in the elinzanetant group (81.6% and 81.5% in OASIS 1 and 2 respectively) and in those who switched from placebo to elinzanetant after week 12 (84.5% and 86.7% in OASIS 1 and 2 respectively). In addition, a statistically significant reduction was seen for VMS severity from baseline to weeks 4 and 12 with elinzanetant compared to placebo. In both studies elinzanetant showed a rapid onset of action as early as week 1 with statistically significant reduction in the frequency of VMS from baseline.

“Due to individual risk factors, medical contraindications or personal preference, there is an unmet need for additional safe and effective non-hormonal treatments for vasomotor symptoms associated with menopause that may also improve sleep disturbances and quality of life,” said JoAnn Pinkerton, M.D., Professor and Director of Midlife Health at UVA Health. “These positive results from OASIS 1 and 2 reinforce elinzanetant as a potential non-hormonal treatment option for women experiencing vasomotor symptoms in menopause.”

By meeting one of the key secondary endpoints, elinzanetant demonstrated significant reductions in sleep disturbances across both OASIS 1 and 2 studies. At baseline, participants on average experienced moderate sleep disturbances, highlighting the prevalence of this symptom for menopausal women. Following treatment with elinzanetant, the average scores were reduced to the normal range while scores in the placebo group fell within the mild sleep disturbance range. The range of normal, mild and

moderate sleep disturbances is according to classification in a reference population.²

These data reinforce that elinzanetant, as a dual NK-1 and 3 receptor antagonist, has the potential to improve sleep disturbances in menopausal women. Additionally, elinzanetant also improved menopause-related quality of life showing statistical significance compared to placebo.

Furthermore, reductions in frequency and severity of VMS as well as the improvements in sleep disturbances and menopause-related quality of life were maintained throughout the 26-week treatment period in the elinzanetant group. Improvements in these measures were similarly observed in the group that switched from placebo to elinzanetant after week 12.

“Women experiencing menopause need treatment options that can help reduce the impact of symptoms on their quality of life,” said James A. Simon, M.D., Clinical Professor of Obstetrics and Gynecology at George Washington University. “The results from OASIS 1 and 2 are very promising when looking to address the unmet needs many women may experience during the menopause transition.”

The safety profile of elinzanetant was favorable in both studies with headache and fatigue being the most frequently reported treatment emergent adverse events (TEAEs) within the elinzanetant groups. No liver toxicity was observed in the two studies. Additional safety data will be available from the 52-week placebo-controlled OASIS 3 Phase III study evaluating the efficacy and long-term safety of elinzanetant versus placebo, which Bayer announced positive topline results earlier this year.

Bayer has submitted a New Drug Application to the U.S. Food and Drug Association (FDA) for elinzanetant for the treatment of moderate to severe VMS associated with menopause based on positive results data from the OASIS 1, 2 and 3 studies. Bayer will submit applications for marketing authorizations of elinzanetant to additional health authorities as well.

About the OASIS 1, 2 and 3 studies

OASIS 1 and 2 (NCT05042362 and NCT05099159) 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 over 26 weeks. OASIS 1 and 2 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 (NCT05030584) is a double-blind, randomized, placebo-controlled multicenter study to investigate the efficacy and safety of elinzanetant for the treatment of vasomotor symptoms over 52 weeks in postmenopausal women. OASIS 3 randomized 628 postmenopausal women between 40 and 65 years across 83 sites in 9 countries.

About the Elinzanetant 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.

In addition to the OASIS program, Bayer is conducting NIRVANA (NCT06112756), 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 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 further evaluating the safety of elinzanetant.

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. 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 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. It can also be the result of surgical or medical treatment such as 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. 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 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. 26
- 2 Health Measures. PROMIS score cut points. Accessed (March 6, 2024). <https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis/promis-score-cut-points>