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News Release

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Late-breaking data from pivotal Phase III studies OASIS 1 and 2 to be presented at 2024 ACOG Annual Meeting:

Elinzanetant significantly reduces frequency and severity of moderate to severe hot flashes associated with menopause

- Pivotal OASIS 1 and 2 Phase III studies of investigational compound elinzanetant achieved a statistically significant reduction in frequency and severity of vasomotor symptoms (VMS; also known as hot flashes) over 12 weeks compared to placebo
 - Consistent benefits were also seen across both studies in all three key secondary endpoints, with significant reduction in frequency of VMS at week 1, improvement in sleep disturbances and menopause-related quality of life
 - The safety profile in both studies was favorable
 - These late-breaking data will be presented for the first time during a scientific symposium at the 2024 American College of Obstetricians and Gynecologists (ACOG) annual meeting
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Berlin, May 16, 2024 – Bayer will present detailed results from the pivotal Phase III studies OASIS 1 and 2, showing that the investigational compound elinzanetant significantly reduced frequency and severity of moderate to severe vasomotor symptoms (VMS; also known as hot flashes) associated with menopause compared to placebo. In addition, elinzanetant met its key secondary endpoints showing a statistically significant reduction in the frequency of VMS from baseline to week 1 and improved sleep disturbances and menopause related quality of life compared to placebo. These data will be presented at the 2024 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical & Scientific Meeting taking place from May 17 – 19 in San Francisco, CA, USA.

Elinzanetant successfully met all four primary endpoints in both studies demonstrating statistically significant reductions in the frequency and severity of moderate to severe VMS from baseline to week 4 and 12 compared to placebo. Elinzanetant showed in OASIS 1 significant mean reductions versus placebo for *frequency* at week 4 with -3.29 ($p<0.0001$) and week 12 with -3.22 ($p<0.0001$) and for *severity* at week 4 with -0.33 ($p<0.0001$) and week 12 with -0.40 ($p<0.0001$). In OASIS 2, elinzanetant demonstrated significant mean reductions versus placebo for *frequency* at week 4 with -3.04 ($p<0.0001$) and at week 12 with -3.24 ($p<0.0001$) and for *severity* at week 4 with -0.22 ($p=0.0003$) and at week 12 with -0.29 ($p<0.0001$). The safety profile of elinzanetant was favorable in both studies with headache and fatigue being the most frequent treatment emergent adverse events (TEAEs) within the elinzanetant groups.

“There are limited approved non-hormonal treatments for bothersome menopausal symptoms, such as hot flashes and sleep disturbances. Consequently, many women experience discomfort for months or even years, with the majority of symptoms left untreated,” said JoAnn Pinkerton, M.D., Professor and Director of Midlife Health at UVA Health. “These results are exciting news for women who suffer from moderate to severe hot flashes and build on our confidence that elinzanetant may be a potential non-hormonal solution for them.”

Both studies also achieved for all three key secondary endpoints a statistically significant reduction in the frequency of VMS from baseline to week 1 ($p<0.0001$ and $p=0.0013$, respectively), as well as statistically significant improvements in sleep disturbances ($p<0.0001$ in both studies) and menopause-related quality of life ($p<0.0001$ and $p=0.0059$, respectively) compared to placebo.

“The robust efficacy and favorable safety profile of elinzanetant reinforces its potential as a non-hormonal treatment for women experiencing menopause,” said Dr. Christian Rommel, member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Global Head of Research and Development. “We look forward to submitting applications to health authorities for marketing authorizations of elinzanetant to treat moderate to severe VMS associated with menopause, building upon our extensive legacy and commitment to women’s healthcare.”

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.

Earlier in March 2024, Bayer announced positive topline results for the third Phase III study OASIS 3 in the OASIS clinical development program evaluating the efficacy and long-term safety of the investigational compound elinzanetant versus placebo. In this study, elinzanetant successfully met the primary endpoint demonstrating a statistically significant reduction in the frequency of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) from baseline to week 12 compared to placebo. The long-term safety profile observed over 52 weeks in the OASIS 3 study is overall consistent with previously conducted studies and published data^{1,2} on elinzanetant. These results will be presented at upcoming scientific congresses.

Bayer will submit the data from the OASIS 1, 2 and 3 studies to health authorities for approval of marketing authorizations of elinzanetant for the treatment of moderate to severe VMS associated with menopause.

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 started 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-1,3 (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 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 Trower, M; Anderson, RA; Ballantyne, E, et al. (2020). Effects of NT-814, a dual neurokinin 1 and 3 receptor antagonist, on vasomotor symptoms in postmenopausal women: a placebo-controlled, randomized trial. *Menopause*; 27 (5): 498–505.