Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

Not intended for UK Media

Bayer submits New Drug Application to U.S. FDA for elinzanetant for the treatment of moderate to severe vasomotor symptoms associated with menopause

- The New Drug Application (NDA) includes data from the Phase III studies OASIS 1, 2 and 3 - showing elinzanetant significantly reduced the frequency and severity of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) over 12 weeks compared to placebo
- 80% of U.S. women will experience hot flashes during the menopause transition with many remaining untreated[1]
- Elinzanetant is the first dual neurokinin-1 and 3 (NK-1 and NK-3) receptor antagonist in late-stage clinical development for the non-hormonal treatment of moderate to severe VMS associated with menopause

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Berlin, August 1, 2024 – Bayer today announced that a New Drug Application (NDA) for the investigational compound elinzanetant has been submitted to the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) associated with menopause. The submission is based on the positive results from the Phase III OASIS 1, 2 and 3 studies.

“Half of the world’s population will experience menopause, with 27 million women in the U.S. currently experiencing this transition. Despite the impact menopausal symptoms may have on women’s health and quality of life, many go without treatment due to gaps in awareness, education, and limitations of treatment options available”, said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, Member of the Pharmaceutical Leadership Team at Bayer. “The FDA submission for elinzanetant marks a significant milestone in our efforts to offer a new non-hormonal option for women. This further underscores our position as leaders in Women's Health and our dedication to addressing the unmet medical needs of women globally.”

The submission is based on positive results from the OASIS 1, 2 and 3 Phase III studies evaluating the efficacy and safety of the investigational compound elinzanetant versus placebo. Findings showed that elinzanetant (120 mg orally once daily) significantly reduced the frequency and severity of moderate-to-severe VMS and demonstrated a favorable safety profile with headache and fatigue being the most frequent treatment emergent adverse events (TEAEs) within the elinzanetant groups. Consistent improvements were also seen across OASIS 1 and 2 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 full results of OASIS 1 and 2 were recently presented at the 2024 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical & Scientific Meeting. Positive topline results for the Phase III study OASIS 3 were announced in March 2024, providing additional supporting efficacy data as well as safety data of elinzanetant over 52 weeks, with details being presented at an upcoming scientific meeting.

Hot flashes are among the most frequently reported symptoms of menopause, a transitional phase in a woman's life expected to affect 1.2 billion women worldwide by 2030.[2] Hot flashes have also been shown to negatively impact women's quality of life and are one of the leading causes for women to seek medical attention.[1,3] It is important that additional options become available to give women a choice on how to address these symptoms.

Bayer will submit applications for marketing authorizations of elinzanetant for the treatment of moderate to severe VMS associated with menopause to other health authorities as well.

About the OASIS 1, 2 and 3 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 over 26 weeks. OASIS 1 and 2 randomized 396 and 400 postmenopausal women between 40 and 65 years across 184 sites in 15 countries. OASIS 3 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.

Based on results from a large and diverse longitudinal study of menopausal transition in the US, 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.

Contact for global media inquiries:
Anna Koch, phone +49 30 221541595
Email: anna.koch@bayer.com

Contact for US media inquiries:
Courtney Ambrosi, phone 1 (908) 798-1107
Email: courtney.ambrosi@bayer.com

Contact for investor inquiries:
Bayer Investor Relations Team, phone +49 214 30-72704
Email: ir@bayer.com
www.bayer.com/en/investors/ir-team

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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.

1 Thurston RC, Joffe H. Obstet Gynecol Clin North Am. 2011 Sep;38(3): 489–501
2 Hill, Maturitas 1996 Mar;23(2):113-27.
3 Biglia N, et al. ecancer2019;13:909.