



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

News Release

Not intended for UK Media

Late-breaking data from Phase III long-term study OASIS 3 presented at 2024 TMS Annual Meeting:

Data from Phase III study OASIS 3 support efficacy and long-term safety of investigational compound elinzanetant in the treatment of moderate to severe vasomotor symptoms associated with menopause

- Results from the Phase III OASIS 3 study further support efficacy data and sustained safety data of elinzanetant over 52 weeks, adding to the positive results of the OASIS 1 and 2 studies
 - The long-term safety was consistent with previous findings, further confirming the favorable safety profile; no incidences of endometrial hyperplasia or endometrial malignant neoplasms; no signal of hepatotoxicity was observed
 - These late-breaking data will be presented for the first time at the 2024 annual meeting of The Menopause Society (TMS)
 - 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
-

Berlin, September 10, 2024 –Bayer will present detailed results from the Phase III study OASIS 3, providing supporting efficacy data and sustained safety data over 52 weeks for the investigational compound elinzanetant, adding to the positive results of the OASIS 1 and 2 studies. These data will be presented at the 2024 annual meeting of The Menopause Society (TMS) taking place from September 10-14, in Chicago, IL, USA.

OASIS 3 is a Phase III efficacy and long-term safety study of elinzanetant for the treatment of vasomotor symptoms (VMS, also known as hot flashes) associated with menopause.

The data to be presented shows that elinzanetant successfully met the primary endpoint demonstrating a statistically significant reduction in the frequency of moderate to severe vasomotor symptoms from baseline to week 12 compared to placebo. Improvements in the elinzanetant arm were also seen in key secondary endpoints with a mean change from baseline in sleep disturbances and menopause related quality of life as shown by the total score over time.

There was no minimum threshold of moderate to severe VMS for inclusion in the study, and at baseline women had a mean of 6.7 VMS (standard deviation, SD 7.2) in the elinzanetant group and 6.8 in the placebo group (SD 6.2). After 12 weeks of treatment, the number of VMS was reduced to 1.6 (SD 2.5) in the elinzanetant group and 3.4 (SD 4.2) in the placebo group. The VMS reductions were maintained throughout the study duration. In addition, improvements were seen in measures of sleep disturbances and menopause-related quality of life with elinzanetant use over 52 weeks, based on descriptive analyses.

“To see the tolerability of elinzanetant in OASIS 3 remain consistent with earlier studies is very promising,” said James A. Simon, M.D., clinical professor of obstetrics and gynecology at The George Washington University School of Medicine, Founder of IntimMedicine Specialists. “With a longer study duration and in a population with a VMS profile potentially more representative of that seen in clinical practice suggests, if approved, elinzanetant may be another option for women suffering from moderate to severe VMS.”

The safety profile of elinzanetant over 52 weeks was favorable and consistent with findings from the 26-week OASIS 1 and OASIS 2 studies, which were recently published in the *Journal of the American Medical Association (JAMA)*¹. In OASIS 3, headache and COVID-19 were the most frequently reported treatment emergent adverse events (TEAEs) within the elinzanetant group. No incidences of endometrial hyperplasia, endometrial malignant neoplasms, and no liver toxicity signal were observed with elinzanetant.

“The detailed results of OASIS 3 are complementing the positive results of OASIS 1 and 2, addressing the question on its long-term profile and indicating the potential of elinzanetant to treat moderate to severe VMS associated with menopause,” said Dr.

Christian Rommel, Global Head of Research and Development at Bayer AG's Pharmaceuticals Division. "We look forward to continuing our discussions with health authorities around the world regarding marketing authorizations for this 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 VMS associated with menopause, administered orally once daily.

OASIS 3 (NCT05030584) is the third Phase III study in the OASIS clinical development program with positive results. Results from the first two Phase III studies OASIS 1 and 2 (NCT05042362 and NCT05099159) were recently published in the *Journal of the American Medical Association (JAMA)*. Based on positive results from OASIS 1, 2 and 3, Bayer has submitted a New Drug Application to the U.S. FDA for elinzanetant for the treatment of moderate to severe VMS associated with menopause. Bayer is continuing to submit applications for marketing authorizations of elinzanetant to further 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 (SDM) 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. Based on key secondary endpoints of OASIS 1 and 2, 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.

Contact for global media inquiries:

Katja Wiggers, phone +49 30 221541614

Email: katja.wiggers@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

Find more information at <https://pharma.bayer.com/>

Follow us on Facebook: <http://www.facebook.com/bayer>

Follow us on LinkedIn: [Bayer | Pharmaceuticals](#)

kw (2024-0121E)

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 <https://jamanetwork.com/journals/jama/fullarticle/2822766>