



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

News Release

Not intended for U.S. and UK Media

Bayer submits EU marketing authorization application for elinzanetant to treat moderate to severe vasomotor symptoms

- 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, administered orally once daily
 - EMA submission is based on data from Phase III OASIS development program for elinzanetant
 - Recent survey showed that 67% of European women reported vasomotor symptoms during menopause transition¹
-

Berlin, October 15, 2024 – Bayer has submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for elinzanetant for the treatment of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) associated with menopause or caused by adjuvant endocrine therapy.

“Menopausal symptoms can differ significantly from one woman to another in both their nature and intensity,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, Member of the Pharmaceutical Leadership Team at Bayer. “With this submission, Bayer is seeking to expand treatment choices so that clinicians can offer more personalized care that addresses the unique needs of each woman.”

The EMA submission is based on results from the Phase III development program OASIS. Data from OASIS 1 and 2 were published in the Journal of the American Medical Association (JAMA)² in August 2024. Detailed results of the Phase III study OASIS 3 providing additional efficacy and safety data over 52 weeks were presented at The Menopause Society (TMS) annual meeting in September 2024.

Recently, the Health Authorities in Australia, Canada, Switzerland, UK as well as in the US accepted the company's New Drug Applications (NDAs) for elinzanetant for review. Bayer is continuing to submit applications for marketing authorizations of elinzanetant to further health authorities globally.

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. OASIS 1 and 2 investigated the efficacy and safety of elinzanetant administered orally once daily in women with moderate to severe VMS associated with menopause over 26 weeks and 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 investigated the efficacy and safety of elinzanetant for the treatment of vasomotor symptoms over 52 weeks in postmenopausal women and randomized 628 postmenopausal women between 40 and 65 years across 83 sites in 9 countries. The OASIS 4 study investigates the efficacy and safety of elinzanetant in women with moderate to severe VMS caused by adjuvant endocrine therapy for treatment or prevention of breast cancer. This study intends to randomize approximately 400 patients at about 95 centers in 15 countries.

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 or caused by adjuvant endocrine therapy, 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 adjuvant 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 adjuvant 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. 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. Menopausal symptoms can also be the result of surgical or medical treatment. Addressing the symptoms is key to maintaining functional ability and quality of life 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 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

(2024-0164E)

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 Nappi RE, et al. Global cross-sectional survey of women with vasomotor symptoms associated with menopause: prevalence and quality of life burden. *Menopause*. 2021;28 (8): 875–882.

² Elinzanetant for the Treatment of Vasomotor Symptoms Associated With Menopause: OASIS 1 and 2 Randomized Clinical Trials | Gynecology | JAMA | JAMA Network