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News Release

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Elinzanetant meets all primary and secondary endpoints in Phase III study OASIS 4 for treatment of moderate to severe vasomotor symptoms caused by breast cancer treatments

- In OASIS 4, a Phase III study conducted outside of the US, the investigational compound elinzanetant met all primary endpoints demonstrating a statistically significant reduction in frequency of moderate to severe vasomotor symptoms (VMS) caused by adjuvant endocrine therapy compared to placebo in women with or at high risk of developing hormone receptor positive breast cancer.
- The study also met all secondary endpoints with a reduction in severity of VMS at weeks 4 and 12, a reduction in frequency of VMS at week 1 as well as improvements in sleep disturbances and menopause related quality of life
- The safety profile over 52 weeks is generally consistent with previously published data in postmenopausal women with VMS.
- Positive topline results from OASIS 4, the first pivotal international Phase III study addressing this population of unmet medical need, add to the positive results of OASIS 1,2 and 3 and further support the efficacy and safety of elinzanetant
- Elinzanetant is the first dual neurokinin-1 and 3 (NK-1,3) receptor antagonist in development for the non-hormonal treatment of moderate to severe VMS associated with menopause or caused by adjuvant endocrine therapy, administered orally once daily

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Berlin, January 9, 2025 – Bayer today announced positive topline results of the Phase III study OASIS 4 investigating elinzanetant as non-hormonal treatment for moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy in women with breast cancer or at high risk of developing breast cancer. Elinzanetant successfully met the primary endpoints of the study demonstrating statistically significant reductions in the frequency of moderate to severe vasomotor symptoms (VMS, also known as hot flashes) from baseline to week 4 and 12 compared to placebo.

The study also achieved all secondary endpoints demonstrating reductions in severity of VMS at week 4 and 12, VMS frequency reduction at week 1 as well as maintaining the effects over the study period. Elinzanetant also showed improvements of sleep disturbances and menopause-related quality of life at week 12 compared to placebo. The safety profile over 52 weeks observed in the OASIS 4 study is generally consistent with previously conducted studies and published data[1,2,3] on elinzanetant in postmenopausal women with VMS.

“Elinzanetant has consistently demonstrated positive results across all four Phase III clinical trials that assessed the efficacy and safety for the treatment moderate to severe vasomotor symptoms associated with menopause or caused by adjuvant endocrine therapy,” said Dr. Christian Rommel, Head of Research and Development and Member of the Executive Committee of Bayer’s Pharmaceuticals Division. “Importantly, OASIS 4 is the first pivotal international study to assess the safety and efficacy of a non-hormonal treatment approach for women with or at high risk of breast cancer who are suffering from VMS caused by adjuvant endocrine therapy, reaffirming our commitment at Bayer to advancing innovative treatments for the different needs of women and their health.”

Breast cancer is the most frequent cancer in women globally with 2.3 million new cases in 2020, with nearly 70% of tumors being hormone-receptor positive. Adjuvant endocrine therapy is well established in guidelines worldwide and routinely prescribed to all women with hormone-positive breast cancer. Treatment with adjuvant endocrine therapy (such as tamoxifen or aromatase inhibitors) for up to 10 years substantially reduces the breast cancer mortality rate throughout the 2 decades after diagnosis.[4] Adjuvant endocrine therapy can also be used as primary prevention, in women at high risk of developing breast cancer. VMS (also referred to as hot flashes) is a common adverse reaction of the adjuvant endocrine therapy, which may affect quality of life and treatment compliance, with potential impact on recurrence and long term outcomes[5]. There is unmet medical need for an effective non-hormonal treatment for VMS caused by adjuvant endocrine therapy as currently no approved treatment options are available.

“For women undergoing endocrine therapy against breast cancer, menopausal symptoms like VMS and sleep disturbances are very common and can significantly affect quality of life, potentially impacting treatment adherence,” said Dr. Fatima Cardoso, Principal Investigator of OASIS 4, from Lisbon, Portugal. “The positive results from OASIS 4 bring

us one step closer to a much-needed non-hormonal option for managing VMS in breast cancer patients and women at risk of breast cancer."

Elinzanetant is the first dual neurokinin-1 and 3 (NK-1,3) 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 for breast cancer, administered orally once daily. OASIS 4 (NCT05587296) is the first pivotal international Phase III study to assess the safety and efficacy of a non-hormonal treatment of moderate to severe VMS caused by adjuvant endocrine therapy. It is the fourth Phase III study in the OASIS clinical development program with positive topline results, with details planned to be presented at upcoming scientific congresses. Data from OASIS 1 and 2 were published in the Journal of the American Medical Association (*JAMA*)[3] 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. Based on the positive results from the Phase III clinical development program, submissions for marketing authorizations for elinzanetant are ongoing in the US, EU and other markets around the world.

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 associated with menopause over 52 weeks and randomized 628 postmenopausal women between 40 and 65 years across 83 sites in 9 countries. OASIS 4 is a double-blind, randomized, placebo-controlled multicenter study to investigate efficacy and safety of elinzanetant for the treatment of vasomotor symptoms caused by adjuvant endocrine therapy, over 52 weeks and optionally for an additional 2 years in women with, or at high risk for developing hormone-receptor positive breast cancer. 474 patients at 90 centers in 16 countries (excluding the US) were randomized.

About Elinzanetant

Elinzanetant is the first dual neurokinin-1 and 3 (NK-1, 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.

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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, Bolognese J, Caetano C, Joffe H, Kerr M, Panay N, Seitz C, Seymore S, Trower M, Zuurman L, Pawsey S. Efficacy and safety of elinzanetant, a selective neurokinin-1,3 receptor antagonist for vasomotor symptoms: a dose-finding clinical trial (SWITCH-1). Menopause. 2023 Mar 1;30(3):239-246.
2 Trower M, et al. Effects of NT-814, a dual neurokinin 1 and 3 receptor antagonist, on vasomotor symptoms in postmenopausal women: a placebo-controlled, randomized trial. Menopause: The Journal of The North American Menopause Society. 2020; 27 (5): 498-505.
3 https://jamanetwork.com/journals/jama/fullarticle/2822766
4 Davies et al. Lancet 2013
5 Pistilli et al. J Clin Oncol 38:2762-2772