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News Release

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Positive topline results from Phase III long-term study OASIS 3 support submissions for marketing authorization for Bayer's elinzanetant

- OASIS 3 study provides additional supporting efficacy data as well as long-term safety data of elinzanetant, complementing positive topline results of OASIS 1 and 2 studies
 - Bayer will submit data from OASIS 1, 2 and 3 studies to health authorities for approval of marketing authorizations of elinzanetant for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause
 - 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
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Berlin, March 19, 2024 – Bayer today announced positive topline results of the Phase III study OASIS 3 evaluating the efficacy and long-term safety of the investigational compound elinzanetant versus placebo. In this study, elinzanetant successfully met the primary endpoint demonstrating 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.

“OASIS 3 was designed to address the important question of the long-term profile of elinzanetant. With the positive topline results of OASIS 3 adding to the existing evidence from OASIS 1 and 2, elinzanetant has consistently shown positive data across all Phase III clinical trials in the treatment of moderate to severe VMS associated with menopause,” said Dr. Christian Rommel, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Global Head of Research and Development. “We are looking

forward to sharing the full data at upcoming medical conferences as we move towards submitting to health authorities.”

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.

“It is critical that we continue to broaden therapeutic options that will effectively meet the significant needs of menopausal women,” said Nick Panay, Principal Investigator for OASIS 3, Consultant Gynaecologist, Imperial College Healthcare NHS Trust, Professor of Practice, Imperial College London and President of International Menopause Society. “These results, coupled with the recent announcement of topline data for OASIS 1 and OASIS 2, strengthen our confidence in the proposed efficacy and safety of elinzanetant as a potential novel non-hormonal solution for women experiencing menopause-related symptoms.”

OASIS 3 (NCT05030584) is the third Phase III study in the OASIS clinical development program with positive topline results. In early 2024, Bayer announced topline data of the first two Phase III studies OASIS 1 and 2 (NCT05042362 and NCT05099159) which met all primary and key secondary endpoints. The results of all three studies 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 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 OASIS 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.

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 world population of women experiencing menopause is projected to increase to 1.2 billion, with 47 million new women entering this phase each year. Menopause is a transitional phase in women's lives, related to the progressive decline of ovarian function, and which usually occurs in women during their 40s or early 50s. It can also be the result of surgical or medical treatment, for example 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 and 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.