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News Release

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Bayer starts Phase III clinical development program OASIS with Elinzanetant

Elinzanetant is an innovative non-hormonal development compound investigated for the treatment of vasomotor symptoms during menopause

Berlin, August 31, 2021 – Bayer, a global leader in women’s healthcare, announced today that it started the Phase III clinical development program OASIS, which aims to evaluate the efficacy and safety of elinzanetant for the treatment of vasomotor symptoms during menopause. Elinzanetant is a first in class, non-hormonal, once-daily, oral, dual neurokinin-1,3 receptor antagonist under investigation.

Vasomotor symptoms (hot flashes) are reported by up to 80% of women at some point during the menopausal transition and the leading cause for seeking medical attention during this particular phase of a woman’s life. Over 1/3 of women report severe symptoms, which can last 10 years or more after the last menstrual period. Vasomotor symptoms may have a negative impact on sleep, mood and quality of life.

“Based on the positive Phase II data, we are very pleased to now start the Phase III program with elinzanetant targeting the most frequent and bothersome menopausal symptoms”, said Dr. Christian Rommel, member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Global Head of Research and Development. “With our OASIS clinical development program, we are addressing an important unmet medical need in women’s health as currently a vast majority of women is not receiving treatment for their menopausal symptoms. Our clear goal therefore is to develop a non-hormonal treatment option that will improve women’s quality of life during menopause.”

The OASIS Phase III clinical development program is investigating the efficacy and safety of elinzanetant 120mg once daily in menopausal women with vasomotor symptoms. The

program intends to enroll approximately 1,300 patients at more than 200 centers in over 20 countries.

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) demonstrating good efficacy for elinzanetant with a favorable safety profile. RELENT-1 was a Phase Ib/IIa study investigating the safety, pharmacokinetics and preliminary efficacy of elinzanetant. SWITCH-1 was a Phase IIb study, which investigated the efficacy and safety of four different doses of elinzanetant compared to placebo in patients with vasomotor symptoms. Results have been presented at the 2020 virtual annual meeting of the North American Menopause Society (NAMS).

In September 2020, Bayer completed the acquisition of KaNDy Therapeutics Ltd., a UK clinical-stage biotech company, and fully integrated elinzanetant into its women's healthcare development pipeline.

About Menopause

By 2030, the world population of menopausal and postmenopausal women is projected to increase to 1.2 billion, with 47 million new entrants each year. Menopause is an inevitable process due to ovarian ageing which usually occurs in women in their late 40s or early 50s. The decline in hormone production by the ovaries can lead to various symptoms, which can dramatically affect a woman's health, quality of life, consumption of healthcare and work productivity. The most frequently reported and bothersome symptoms during the menopausal transition are hot flashes, sleep disturbances and mood changes. With increased longevity, menopause management is of growing importance since this is a period where women are at the peak of their life's activity, personally and professionally. For this reason, maintaining functional ability and good quality of life is extremely relevant from both a healthcare and socio-economic perspective.

About Elinzanetant

Elinzanetant is a first-in-class, non-hormonal, orally administered, dual neurokinin-1,3 receptor antagonist currently in clinical development for the treatment of vasomotor symptoms during menopause. Elinzanetant addresses vasomotor symptoms by modulating a group of oestrogen sensitive neurons in the hypothalamus in the brain (the KNDy neurons), that due to the absence of oestrogen, become hyperactive in

menopausal women and consequently disrupt body heat control mechanisms resulting in the debilitating vasomotor symptoms of hot flashes.

About Women's Healthcare at Bayer

Bayer is a recognized leader in the area of women's healthcare, with 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. Today, Bayer's research and development efforts focus on finding new treatment options for menopause as well as gynecological diseases and includes several compounds in various stages of pre-clinical and clinical development. Together, these projects reflect the company's approach to research, which prioritizes targets and pathways with the potential to alter the way that gynecological diseases are treated. Additionally, Bayer intends to provide 100 million women in low-and-middle income countries by 2030 with access to family planning by funding multi-stakeholder aid programs 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. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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kw (2021-0161E)

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