Bayer expands development program for elinzanetant with Phase III study in breast cancer patients with vasomotor symptoms caused by endocrine therapy

- Study plans to investigate elinzanetant as non-hormonal treatment for vasomotor symptoms caused by endocrine therapy in breast cancer patients
- Elinzanetant is an innovative non-hormonal development compound in development for the treatment of vasomotor symptoms during menopause

Berlin, October 17, 2022 – Bayer, a global leader in women’s healthcare, announced today that it expands the Phase III clinical development program OASIS by initiating OASIS 4 – a Phase III study in breast cancer patients and women with high risk for breast cancer with vasomotor symptoms caused by endocrine therapy.

Breast cancer is the most frequent cancer in women globally with 2.3 million new cases in 2020. Almost 70% of breast cancers are hormone-receptor positive. The majority of these patients are receiving well-established adjuvant endocrine therapy (with the objective of reducing hormonal levels) for at least five years to reduce the recurrence of breast cancer and improving associated mortality. Endocrine therapy can also be used as primary prevention in women at high risk for developing breast cancer. Vasomotor symptoms (VMS; also referred to as hot flashes) is a known adverse reaction of endocrine therapy, which strongly impacts the quality of life and treatment continuation. The medical need for an effective non-hormonal treatment for VMS caused by endocrine therapy in breast cancer patients and women at high risk for developing breast cancer is high as currently no treatment options are available.

“For women treated with endocrine therapy for breast cancer – potentially for numerous years - vasomotor symptoms can intensively affect their quality of life and treatment continuation, which in turn might impact the effectiveness of their cancer therapy and...
“hence their survival”, said Dr. Christian Rommel, member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Global Head of Research and Development. “By adding OASIS 4 to our Phase III program with elinzanetant, we aim to help patients experiencing vasomotor symptoms caused by their endocrine therapy, to increase their quality of life.”

The OASIS 4 Phase III study intends to randomize approximately 400 patients at about 95 centers in 15 countries and is planned to investigate the efficacy and safety of elinzanetant 120 mg once daily in women at high risk for breast cancer and breast cancer patients with vasomotor symptoms caused by endocrine therapy.

In August 2021, the OASIS Phase III clinical development program started investigating the efficacy and safety of elinzanetant 120 mg once daily in menopausal women with vasomotor symptoms.

**About Vasomotor Symptoms**

Vasomotor symptoms (VMS; also referred to as hot flashes) is a result from hyperactivation of the thermoregulatory pathway mediated by hypertrophy of the KNDy neurons due to withdrawal of estradiol, which can result from progressive reduction of ovarian function due to natural menopause or medical intervention by bilateral oophorectomy or endocrine therapy.

VMS (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.

Vasomotor symptoms caused by endocrine therapy impact quality of life and treatment adherence and cannot currently be addressed as no treatment options are available.

**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 estrogen 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.

The clinical Phase III development program with elinzantant, OASIS, currently comprises four Phase III studies: OASIS 1,2,3 and 4.

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, which investigated the efficacy and safety of four different doses of elinzanetant compared to placebo in patients with vasomotor symptoms.

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 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 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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