Bayer to present latest research results on real-world evidence of menopausal symptoms and their treatment in women at EMAS 2023

- Poster presentation on the EMPOWER study, a qualitative analysis from interviews with menopausal women, shows the importance of vasomotor symptoms (VMS), as well as potential treatment side effects on the women's treatment decisions
- Poster presentation from the real-world REALISE study assessing menopausal symptom burden and quality of life in women with breast cancer on endocrine adjuvant (EA) therapy demonstrates the need for awareness of EA-related VMS and concomitant symptoms on breast cancer care
- Another poster presentation from the real-world REALISE study analyzes treatment patterns of menopausal women by vasomotor symptom severity and concomitant symptoms, indicating a need for broadening treatment choices according to symptom burden and severity

Berlin, May 2, 2023 – Bayer will present latest real-world evidence on menopause symptoms and menopause management in general as well as menopausal symptom burden and quality of life (QoL) in women with breast cancer on endocrine adjuvant therapy at the upcoming 14th European Congress by the European Menopause and Andropause Society (EMAS). The research presented showcases the commitment of Bayer as a leader in women’s healthcare to broaden therapeutic choices and to increase awareness and education around menopausal symptoms. As part of this commitment, the company is investigating new approaches including the late-stage asset elinzanetant to broaden its menopause portfolio, to address an important unmet medical need in menopause management as currently a vast majority of women is not receiving treatment
for their menopause symptoms. The EMAS congress takes place from May 3 – 5, in Florence, Italy.

Data presented will include key findings from the EMPOWER study focusing on the perceptions of menopausal symptoms and their treatment demonstrating that menopausal women consider a range of benefit and risk attributes when making treatment decisions to manage menopausal symptoms, often leading to not using prescribed treatments. Findings from the REALISE study, a real-world evaluation on vasomotor and other symptoms in menopausal women, show that women who experience vasomotor symptoms (VMS) while receiving endocrine adjuvant (EA) therapy for breast cancer experience a high VMS and concomitant symptom burden including mood and sleep symptoms, which affects their daily activities and quality of life. As EA treatment side effects can contribute to therapy discontinuation and worse outcomes, clinicians should be aware of EA-related VMS and concomitant symptoms to improve breast cancer care. In a separate analysis from REALISE, assessing menopause treatment patterns for women in the US and Europe, it was shown that treatment rates remain low with about one quarter of all menopausal women consulting physicians with vasomotor symptoms (VMS) remaining untreated, despite the impact on quality of life.

Bayer’s presentations at EMAS 2023 are:

- **EMPOWER Perceptions of Menopausal Symptoms and Their Treatment: Qualitative Evidence from Interviews with Menopausal Women in the US, the UK, and Germany**
  Paula Briggs, Katrin Schaudig, Hadine Joffe, Diane Bitner, Victoria Banks, Carsten Moeller, Nariman Nashaat, Cecilia Caetano, Cecile Janssenswillen, Nils Schoof, Jenny A Whitty, Tommi Tervonen, Hannah Collacott

- **Menopausal symptom burden and quality of life in women with breast cancer on endocrine adjuvant therapy: findings from the REALISE study**
  Tommaso Simoncini, Nils Schoof, Siir Su Saydem, Cecilia Caetano, Cecile Janssenswillen, Megan Scott, Carsten Moeller, Katrin Schaudig, Mia Harvey, Victoria Banks

- **Menopause management: real-world analysis of treatment patterns by vasomotor symptom severity and concomitant symptoms from the US and Europe**
  Cecile Janssenswillen, Sheryl Kingsberg, Lauren Lee, Megan Scott, Lisa Halvorson, Victoria Banks
The poster session will be held on Wednesday, 3 May 2023 18:45 – 19:45 CEST. To view the complete abstracts, please visit the EMAS congress website. All abstracts will be also published in the journal Maturitas July 2023 issue (printed and online).

About Vasomotor Symptoms
Vasomotor symptoms (VMS; also referred to as hot flashes) are 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 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, with relevant impact in quality of life.

Vasomotor symptoms can also be caused by endocrine therapy for treatment or prevention of breast cancer 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 women in the menopause phase is projected to increase to 1.2 billion, with 47 million new entrants each year. Menopause is a natural phase in women’s lives, related to progressive decline of ovarian function, which usually occurs in women in their late 40s or early 50s. It can also be the result of surgical or medical treatment, for example for breast cancer. 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 VMS, 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 vasomotor symptoms of hot flashes.

The clinical Phase III development program with elinzanetant, OASIS, currently comprises four Phase III studies: OASIS 1,2,3 and 4. The initial OASIS Phase III clinical development program (OASIS 1,2,3) investigates the efficacy and safety of elinzanetant 120 mg once daily in menopausal women with vasomotor symptoms.

The OASIS 4 study is an expansion of the clinical phase III program and investigates 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.

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 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 such as in the area of 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 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to www.bayer.com.

**Contact for media inquiries:**
Katja Wiggers, phone +49 30 221541614
Email: katja.wiggers@bayer.com

Find more information at https://pharma.bayer.com/
Follow us on Facebook: http://www.facebook.com/bayer
Follow us on Twitter: @BayerPharma

**kw** (2023-0077)

**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.