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News Release

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Bayer starts Phase III study with Mirena® (52mg LNG- IUS) for treatment of nonatypical endometrial hyperplasia

- Expansion of robust clinical development program of Bayer's long-acting reversible intrauterine system Mirena® (52mg LNG IUS)
 - Nonatypical endometrial hyperplasia (NAEH) is benign form of endometrium thickening
 - Number of new cases annually ranges from 121 to 270 per 100.000 women depending on the population.^{1,2,3} Currently, there are no approved medical treatment options for NAEH
 - 52mg LNG-IUS is globally available and in more than 120 countries approved in several indications: prevention of pregnancy, heavy menstrual bleeding, endometrial protection during estrogen therapy for menopausal symptoms and for menstrual pain
 - Reinforcing Bayer's leading position and commitment to understanding and advancing women's healthcare in areas of unmet medical need
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Berlin, December 2, 2025 – Bayer, a global leader in women's healthcare, announced today the clinical Phase III study SUNFLOWER (**Study of Understanding NAEH - treatment Efficacy of Levonorgestrel – IUS in Women Electing non-surgical options**) with its 52mg levonorgestrel-releasing intrauterine system (LNG-IUS) Mirena®. The study will investigate the efficacy and safety of the 52mg LNG-IUS in the treatment of nonatypical endometrial hyperplasia (NAEH) in women.

Nonatypical endometrial hyperplasia (NAEH) is an abnormal thickening of the lining of the uterus, known as endometrium, due to an imbalance between estrogen and progesterone levels. This condition is classified as nonatypical as the cells in the endometrium do not show signs of cancer. It can be silent, or present with heavy or abnormal bleeding, or bleeding after menopause. If untreated, this condition may lead to uterine cancer. The annual incidence of nonatypical endometrial hyperplasia (NAEH) ranges from 121 to 270

per 100.000 women depending on the geography, age and menopause status. Currently, there are no approved medical treatment options for this condition presenting a high unmet medical need given its potential to progress to an atypical form or even to uterine cancer.

“Having a leading position in global women’s health we are committed to advance science focusing on innovative options to address the unmet medical need of women globally. With this new Phase III study, we are now expanding our broad clinical development program for intrauterine systems to be able to support women suffering from nonatypical endometrial hyperplasia with an effective treatment”, said Christian Rommel, Ph.D., Head of Research and Development at Bayer’s Pharmaceuticals Division.

About SUNFLOWER study

The planned Phase III clinical study SUNFLOWER (**S**tudy of **U**nderstanding **N**AEH - **t**reatment **E**fficacy of **L**evon**O**rgestrel – IUS in **W**omen **E**lecting non-su**R**gical options) will evaluate the treatment of nonatypical endometrial hyperplasia (NAEH) with 52mg LNG IUS versus Oral Progestin (OP) and aims to enroll 207 patients at about 90 centers in 3 countries. The study is anticipated to take around 1.5 years until completion. Previous studies^{4,5,6} have tested the use of 52mg LNG-IUS for the treatment of this condition indicate good response based on the type of hormone present in the IUS and the direct effect inside the uterus helping to bring the endometrium back to normal state in most cases. The aim of this study is to assess how 52mg LNG-IUS is treating NAEH in a controlled clinical study.

About Mirena®

Mirena is a T-shaped device containing 52 mg of synthetic levonorgestrel. Once placed in the uterus, it continuously releases small amounts of levonorgestrel directly into the uterus. Mirena is a long-acting reversible contraceptive (LARC) and can be removed at any time by a healthcare provider if a woman’s plans change. The current approved indications which may vary from country to country are contraception (prevention of pregnancy), idiopathic menorrhagia/ heavy menstrual bleeding (HMB), endometrial protection during estrogen therapy for menopause and dysmenorrhea (painful periods). Mirena is available in more than 120 countries.

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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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