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News Release

Not intended for U.S. and UK Media

Mirena[®] approved in Europe for extended duration of use in contraception

- Mirena[®] (52mg LNG IUS), Bayer's long-acting reversible intrauterine system, received regulatory approval in the European Workshare Procedure for up to eight years in contraception, now offering the longest contraceptive duration of use for any hormonal intrauterine system – national approvals expected in Q4
 - The IUS is one of the most effective birth control methods
 - Mirena was also approved for the treatment of idiopathic menorrhagia (heavy menstrual bleeding) for up to eight years if symptoms have not returned earlier
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Berlin, October 14 , 2022 – Bayer, a leader in women's healthcare, announced today that it has positively concluded the European Workshare Procedure extending the duration of use for up to eight years in contraception of its levonorgestrel (LNG) releasing intrauterine system (IUS) Mirena[®] for countries in Europe. This regulatory approval in Europe is based on the results of the Mirena Extension Trial evaluating the efficacy and safety of Mirena which demonstrated that contraceptive efficacy remains high with greater than 99% during years six to eight of use. Following the completion of the European Workshare procedure the first national approvals in the EU are expected in Q4 2022.

“With the positive clearance of the approval process in Europe we are pleased to be able to offer soon the extended label also to women in Europe and with this enriching the range of contraceptive methods as individual contraceptive needs are changing throughout the reproductive life”, said Dr. Michael Devoy, Chief Medical Officer at Bayer AG.

The European approval also includes symptom driven extended use for the indication idiopathic menorrhagia (heavy menstrual bleeding) for up to eight years or until symptoms return. The IUS should be removed or replaced after eight years at the latest.

In August 2022, Bayer received U.S. approval for the extended duration of use for up to eight years in the contraception indication for its levonorgestrel (LNG) releasing intrauterine system (IUS) Mirena.

A LNG-IUS is one of the most effective birth control methods as it does not require user compliance such as daily dosing or monthly re-fills. It can be removed by the doctor at any time and offers a rapid return to a woman's natural level of fertility after removal. A LNG-IUS should only be inserted after a comprehensive discussion and evaluation of all contraceptive options and the individual woman's needs.

About the Contraceptive Efficacy & Mirena Extension Trial

The contraceptive efficacy of Mirena for up to five years has been studied in five large clinical trials involving 3,330 women. The Pearl Index was about 0.2 in the first year and cumulatively, contraception failed by about 0.7% over five years. The contraceptive effectiveness of Mirena after more than five years (including years six to eight) was studied in the Mirena Extension Trial. Based on 2 pregnancies (1 in Year 6 and 1 in Year 7) and 10,216 exposure cycles, the cumulative pregnancy rate at the end of the 3-year period of extended use (Years 6, 7 and 8) was 0.68% with a 95% upper confidence limit of 2.71%. The study confirmed a positive benefit risk profile with no new or unexpected safety findings. The eight-year data from the extension trial were published in abstract form at the American College of Obstetricians and Gynecologists (ACOG) in 2022. The full paper is published in the American Journal of Obstetrics and Gynecology at <https://doi.org/10.1016/j.ajog.2022.09.007>. Information about this trial can be found at <https://clinicaltrials.gov/ct2/show/study/NCT02985541>.

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. Mirena is available in many countries over all continents.

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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