



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

Not intended for U.S. and UK Media

Mirena® from Bayer approved in the US for extended duration of use in contraception

- Mirena®, Bayer's long-acting reversible intrauterine system, now approved by U.S. FDA for up to eight years in contraception
 - Mirena (52mg LNG IUS) now offers the longest contraceptive duration of use for any hormonal intrauterine system
 - The IUS is one of the most effective birth control methods
-

Berlin, August 18, 2022 – Bayer, a leader in women's healthcare, announced today that the supplemental New Drug Application (sNDA) for the extended use up to eight years in the indication, contraception was approved for its levonorgestrel (LNG) releasing intrauterine system (IUS) Mirena® by the U.S. Food and Drug Administration (FDA). This approval is based on the results of the Mirena Extension Trial evaluating the efficacy and safety of Mirena which demonstrated that contraceptive efficacy during years six to eight remains high.

"This label extension underlines Bayer's continued commitment to drive innovation in the area of women's healthcare and to offer women a broad variety of contraceptive methods during their reproductive life", said Dr. Michael Devoy, Chief Medical Officer at Bayer AG. "As every woman is different, the personal decision for a specific contraceptive option is taken on the individual needs of a woman in close consultation with her healthcare professional."

The duration of use for the second approved indication in the US (heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception) remains unchanged for up to five years.

At the beginning of 2022, Bayer also submitted the eight-year label extension for the indication contraception in the EU for the LNG-IUS Mirena.

LNG-IUS is one of the most effective birth control methods as it does not require user interventions 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. An 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 will be published in due course. 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 available in many countries over all continents. The approved indications in the US are contraception (prevention of pregnancy) for up to eight years of use and treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception for up to five years. 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.

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.

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](https://twitter.com/BayerPharma)

kw (2022-0127E)

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.