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Investor News

Not intended for U.S. and UK Media

FDA approves new five-year-contraceptive of Bayer

Leverkusen, Germany, September 19, 2016 – The U.S. Food and Drug Administration (FDA) has approved Bayer AG's new low dose levonorgestrel-releasing intrauterine system (LNG-IUS) which will be marketed in the US under the brand name Kyleena™. Kyleena releases the lowest daily dose of the hormone levonorgestrel in an intrauterine system for up to five years of effective protection against pregnancy, using the smallest T-shaped body in an IUS available today. Long-acting contraception is one of the most effective methods of birth control as it does not require user interventions such as daily dosing or monthly re-fills. An LNG-IUS can be removed at any time and offers rapid return to a woman's natural level of fertility after removal.

"The approval of Kyleena in the U.S. highlights Bayer's continued commitment to drive innovation and empower women with a broad range of birth control options at different reproductive stages of their lives," said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. "Kyleena provides women with an additional reliable and reversible contraceptive option as it does not require daily user intervention to work."

Unintended pregnancies remain high globally, with 54% of these ending in abortion in developed countries¹. Unintended pregnancies are particularly high among younger women due to their higher fecundity, compounded by the issue that they frequently do not use their contraceptives correctly^{2,3,4,5,6,7,8}. Women should talk to their healthcare professional in order to find the most suitable contraceptive method for them within the wide contraceptive portfolio.

The launch of Kyleena in the US is planned for October 2016.

In November 2015 Bayer has also submitted an application for the marketing authorization in the EU for this new low dose levonorgestrel-releasing intrauterine system.

About Kyleena

Kyleena is a small, soft and flexible plastic T-shaped device containing 19.5mg of a synthetic hormone called levonorgestrel. The size of the Kyleena T-body is 28mm x 30mm, and its placement tube has a diameter of 3.8mm. Once placed in the uterus, Kyleena continuously releases a low dose of the progestogen levonorgestrel directly into the uterus. Kyleena provides effective birth control for up to five years and also offers rapid return to a woman's natural level of fertility after removal.

About the Clinical Development Program for Kyleena

The approval of Kyleena is based on data from a Phase III clinical trial, including 574 nulliparous and 878 parous women from North America, Latin America and several European countries, which has demonstrated that Kyleena is highly effective and well tolerated regardless of age and parity.

The primary endpoint of the Phase III clinical trial program was contraceptive efficacy assessed by the Pearl index. With a Pearl-Index of 0.29 after five years in clinical trials, Kyleena is more than 99 percent effective for each year of use in preventing pregnancy for women who desire a low-dose, long-acting contraceptive option for up to five years.

Moreover, Kyleena was generally well tolerated, with no unexpected adverse events reported. Low incidences of ectopic pregnancy, pelvic inflammatory disease, expulsion of the device from the uterus or uterine perforation were seen.

About Bayer in Women's Healthcare

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. With a long heritage in Women's Healthcare, Bayer offers a wide range of effective short- and long-acting birth control methods as well as therapies for menopause management and gynecological diseases with several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way how women's health related conditions are treated.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and

improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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