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Investor Relations
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Investor News

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Bayer receives green light for new five-year contraceptive in the EU

- New low dose levonorgestrel-releasing intrauterine system will be named "Kyleena™"
 - Introduction in Europe is scheduled to start in January 2017
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Leverkusen, Germany, October 4, 2016 – Bayer has successfully concluded the European registration procedure to gain EU-wide marketing authorization for its new low-dose levonorgestrel-releasing intrauterine system (LNG-IUS). Only in September 2016 the U.S. Food and Drug Administration (FDA) granted this new Bayer product marketing authorization. The new IUS releases the lowest daily dose of the hormone levonorgestrel in an intrauterine system (IUS) made for up to five years of effective protection against pregnancy, using the smallest T-body in an IUS available today. Based on the positive conclusion, it is expected that the Health Authorities of the EU Member States will grant national marketing authorizations in the coming weeks and months. Once approved, Bayer plans to introduce the new five-year contraceptive also in the EU under the brand name "Kyleena™".

"Long-acting reversible methods have a significant advantage, because a woman does not need to take daily action to make it work. Our scientists and clinicians have intensely worked on new low-dose long-acting contraceptives in the last decades as more and more women worldwide seek this form of contraception. Bayer is very pleased to soon be able to offer women in the EU our latest innovation in this field," said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceuticals Division and Head of Development.

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.

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 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

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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