



Bayer AG
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Investor News

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Bayer's new five-year-contraceptive submitted for EU and US Marketing Authorization

Clinical studies demonstrated efficacy of new long-acting contraceptive with lowest available daily hormone dose for five years of contraception

Leverkusen, Germany, November 20, 2015 – Bayer has submitted an application for marketing authorization in both the European Union and in the United States for LCS-16, a new low-dose levonorgestrel-releasing intrauterine system (LNG-IUS) which is directly placed in the uterus for contraception for up to five years. Long-acting contraception is one of the most effective methods of birth control. An LNG-IUS can be removed at any time and offers rapid return to a woman's usual level of fertility after removal.

"As a leader in Women's Healthcare we are committed to continuously advance our portfolio of innovative contraceptive methods to meet the needs of a broad range of women", said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "An intrauterine system does not only bring the advantage that women do not have to think about their contraception every day, but also that it contains fewer hormones than other hormonal contraceptive options like the pill or implant. With the application for marketing authorization for LCS-16, we hope we will be able to offer women an additional option of a reliable and convenient long-acting reversible contraception that contains the lowest available dose of hormones for up to five years."

Data from Phase III clinical trials, including 574 nulliparous and 878 parous women from North America and several European countries have demonstrated that LCS-16 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. The data showed that the new IUS is more than 98.5 percent effective in preventing pregnancy. Moreover, LCS-16 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 and uterine perforation were seen.

About LCS-16:

LCS-16 is a small, flexible plastic T-shaped device. Once placed in the uterus, it releases a low dose of the progestogen levonorgestrel directly into the uterus and provides effective birth control for up to five years. It also offers rapid return to a woman's usual level of fertility after removal.

With a Pearl-Index of 0.31 after three years and 0.29 after five years based on reported efficacy in clinical trials, LCS-16 provides highly effective, long-acting contraception for women who desire a low-dose contraceptive option for up to five years.

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.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care and agriculture. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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