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Investor News

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Bayer receives green light for new long-term contraceptive in the EU

- Company plans to market the new low dose levonorgestrel-releasing intrauterine system under the brand name “Jaydess”
- Product provides reliable contraception for up to three years

Leverkusen, Germany, December 5, 2012 – Bayer HealthCare has successfully concluded the European registration procedure for its new low dose levonorgestrel-releasing intrauterine system (IUS). This long-term contraceptive is placed in the uterus for the prevention of pregnancy for up to three years. Sweden served as Reference Member State for the Decentralized Procedure to gain EU-wide marketing authorization for the new IUS. Based on the positive conclusion, the Health Authorities of the EU Member States will grant national approvals in the coming weeks and months. First launches of the product in the EU are expected in the second quarter of 2013.

“Our new intrauterine system has been primarily developed for women who are looking for a reliable, convenient long-term contraceptive option with a very low hormonal dose”, said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The new IUS is a small, flexible plastic T-shaped device - the size of the T-body is 28mm x 30mm, and its placement tube is 3.8mm. It slowly releases a low dose of a hormone called levonorgestrel locally in the uterus and therefore only small amounts of the hormone enter the bloodstream.

Compared to oral contraceptives the new IUS is a contraceptive option for women that do not want to take a pill every day. It also offers rapid return to a woman’s usual level of fertility after removal.

Once approved, Bayer HealthCare plans to market the new intrauterine system under the brand name "Jaydess“ in the EU.

In December 2011 Bayer HealthCare has also submitted an application for marketing authorization in the U.S. for the new low dose levonorgestrel-releasing intrauterine system.

About the Clinical Development Program

The application for marketing approval of the new IUS is supported by data from a Phase 3 trial of 1,432 women aged 18-35, of which 39 percent (556) had not yet had a child. The study was a multicenter, multi-national randomized open-label study evaluating the new IUS (LNG-IUS12). It was carried out in 11 countries in Europe, Latin America, the U.S. and Canada.

The Pearl Index was the primary efficacy endpoint used to assess contraceptive reliability. The data showed that the new IUS is more than 99 percent effective in preventing pregnancy.

The new IUS 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.

The results of this study have been presented at 68th Meeting of the American Society for Reproductive Medicine in San Diego, California, in October 2012.

To learn more about contraception, please visit:
www.bayerpharma.de/contraception

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), 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 55,700 employees (Dec

31, 2011) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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