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# Investor News

**Not intended for U.S. and UK media**

## Bayer receives approval for new long-term contraceptive Skyla™ in the U.S.

- New low dose levonorgestrel-releasing intrauterine system (IUS)
- Longterm contraception for up to three years

**Leverkusen, Germany, January 10, 2013** – Bayer HealthCare has received approval from the U.S. Food and Drug Administration (FDA) for its new low dose levonorgestrel-releasing intrauterine system (IUS) called Skyla™ in the U.S.. The new IUS is placed in the uterus for the prevention of pregnancy for up to three years.

“The approval of Skyla in the U.S. highlights Bayer’s continued commitment to drive innovation and empower women with a variety of birth control options at different reproductive stages of their lives,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We are pleased to provide women who are seeking contraception with a new and effective option to consider with their healthcare providers in the U.S..”

Skyla is a small, flexible plastic T-shaped device containing 13.5mg of a hormone called levonorgestrel. The size of the Skyla T-body is 28mm x 30mm, and its placement tube has a diameter of 3.8mm. It slowly releases a low dose of 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 reliable 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.

In December 2012 Bayer HealthCare successfully concluded the European registration procedure for this new low dose levonorgestrel-releasing intrauterine system. Bayer HealthCare plans to market the new IUS under the brandname “Jaydess” in the EU.

**About the Clinical Development Program for Skyla**

The approval of Skyla is supported by data from a Phase 3 trial of 2,884 women aged 18-35. There were 1,432 women who received Skyla, of which 39 percent (556) had not yet had a child. The study was a multicenter, multi-national randomized open-label study conducted 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 Skyla is more than 99 percent effective in preventing pregnancy.

Skyla was generally well tolerated, with no unexpected adverse events (AE) reported. Low incidences of ectopic pregnancy, pelvic inflammatory disease (PID), expulsion of the device from the uterus and uterine perforation were seen.

The results of this study have been presented at 68$^{th}$ 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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