Bayer HealthCare

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News Release

U.S. FDA APPROVES BAYER'S SKYLA™ (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 13.5 mg FOR PREVENTION OF PREGNANCY FOR UP TO THREE YEARS

First new IUD (intrauterine device) to enter market in more than a decade

Approval of Skyla expands Bayer's IUD portfolio

Wayne, NJ, January 9, 2013 – Bayer HealthCare Pharmaceuticals Inc. today announced that the U.S. Food and Drug Administration (FDA) approved Skyla™ (levonorgestrel-releasing intrauterine system) 13.5 mg, a new hormone-releasing system that is placed in the uterus for the prevention of pregnancy for up to three years.[1]

"Research shows that nearly 50 percent of pregnancies in the U.S. are unintended,[2] which emphasizes the need for increased education and access to effective birth control options," said Anita L. Nelson, M.D., Professor of Obstetrics and Gynecology at Harbor-UCLA Medical Center, Torrance, CA. "Skyla is more than 99 percent effective at preventing pregnancy and may be appropriate for women who want a birth control method that they do not have to take daily. Further, Skyla may be used by women whether or not they have ever had a child, representing an important new choice for women who don't want to become pregnant for up to three years."

Skyla is a small, flexible plastic T-shaped device containing 13.5 mg of a progestin hormone called levonorgestrel. The size of the Skyla T-body is 28mm x 30mm and the outer diameter of the placement tube is 3.8mm. Because Skyla slowly releases levonorgestrel into the uterus, only small amounts of the hormone enter the blood. During the first three to six months of using Skyla, women may experience irregular periods and an increase in the number of bleeding days. Women may also have frequent spotting or light bleeding. Some women may have heavy bleeding during

this time. After using Skyla for a while, the number of bleeding and spotting days is likely to lessen, and there is a small chance that periods may stop altogether.[1,3]
Women can have Skyla placed by a healthcare provider during an in-office visit. Skyla is intended for long-term use for up to three years but may be removed by a healthcare provider at any time. Women could become pregnant as soon as Skyla is removed, so they should use another method of birth control if they do not want to become pregnant. About 77% of women who want to become pregnant will become pregnant sometime in the first year after Skyla is removed.[3]

“The approval of Skyla expands Bayer’s IUD portfolio and highlights our continued commitment to empower women with a variety of birth control options at different reproductive stages of their lives,” said Pamela A. Cyrus, M.D., Vice President and Head of U.S. Medical Affairs, Bayer HealthCare Pharmaceuticals. “We are pleased to bring the first new IUD to market in the U.S. in 12 years, and to provide women who are seeking contraception with an important new and effective option to consider with their healthcare providers.”

Skyla (levonorgestrel-releasing intrauterine system) 13.5 mg will be available by prescription the week of February 11.

About the Clinical Trial for Skyla[1]

The approval of Skyla is supported by data from a Phase 3 trial that included 1,432 women aged 18-35 who received Skyla, of which 38.8% (556) had not yet had a child. The trial was a multicenter, multinational, randomized open-label study conducted in 11 countries in Europe, Latin America, the U.S. and Canada. Women less than six weeks postpartum, with a history of ectopic pregnancy, with clinically significant ovarian cysts or with HIV or otherwise at high risk for sexually transmitted infections were excluded from the trial.

The pregnancy rate calculated as the Pearl Index (PI) in women aged 18-35 years was the primary efficacy endpoint used to assess contraceptive reliability. The PI was calculated based on 28-day equivalent exposure cycles; evaluable cycles excluded those in which back-up contraception was used unless a pregnancy occurred in that cycle. Skyla-treated women provided 15,763 evaluable 28-day cycle equivalents in the first year and 39,368 evaluable cycles over the three-year treatment period. The PI estimate for the first year of use based on the five pregnancies that occurred after the onset of treatment and within seven days after Skyla removal or expulsion was 0.41 with a 95% upper confidence limit of 0.96. The cumulative three-year pregnancy rate, based on 10 pregnancies, estimated by the Kaplan-Meier method was 0.9 per 100 women or 0.9%, with a 95% upper confidence limit of 1.7%.

Of Skyla-treated women, 21.9% discontinued the study treatment due to an adverse event. Most common adverse reactions (occurring in ≥ 5% users) were vulvovaginitis (20.2%), abdominal/pelvic pain (18.9%), acne/seborrhea (15.0%), ovarian cyst (13.2%), headache (12.4%), dysmenorrhea (8.6%), breast pain/discomfort (8.6%), increased bleeding (7.8%) and nausea (5.5%).

Other serious adverse reactions were also observed, including ectopic/intrauterine pregnancy, life-threatening infections, pelvic inflammatory disease (PID), perforation and expulsion.

Important Safety Information for Skyla (levonorgestrel-releasing intrauterine system) 13.5 mg
If you have a pelvic infection, get infections easily, or have certain cancers, don't use Skyla. Less than 1% of users get a serious infection called pelvic inflammatory disease.

If you have persistent pelvic or stomach pain or if Skyla comes out, tell your doctor. If Skyla comes out, use back-up birth control. Skyla may attach to or go through the uterus and cause other problems.

Pregnancy while using Skyla is uncommon but can be life threatening and may result in loss of pregnancy or fertility. Ovarian cysts may occur but usually disappear.

Bleeding and spotting may increase in the first few months, and remain irregular. Over time, periods are likely to become shorter and lighter, or may stop.

Skyla does not protect against HIV or STDs.

Only you and your healthcare provider can decide if Skyla is right for you. Skyla is available by prescription only.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For additional information about Skyla, please see full prescribing information at www.skyla-us.com.

About Bayer HealthCare Pharmaceuticals Inc.
Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities

of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare Pharmaceuticals provides products for Diagnostic Imaging, General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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Forward-Looking Statement

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[1] Skyla Prescribing Information, January 2013

[2] Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. National Center for Health Statistics. Vital Health Stat 23(29). 2010. "Introduction" Available at http://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf. Accessed on 1/2/13.

[3] Skyla Patient Prescribing Information, January 2013