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FDA Approves New Indication For Mirena(R) to Treat Heavy Menstrual Bleeding in IUD Users

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-- the need to change sanitary protection during the night(2)

"Many women with heavy periods often suffer privately with their symptoms. And because approved effective non-surgical treatment options are limited, women who do seek treatment for heavy periods often face the choice of having surgical procedures, such as hysterectomies" said Dr. Andrew Kaunitz, M.D., FACOG, Professor and Associate Chairman, Department of Obstetrics and Gynecology, University of Florida College of Medicine-Jacksonville. "In a clinical trial, nearly nine out of 10 women were treated successfully for heavy menstrual bleeding with Mirena -- meaning it reduced monthly blood loss by more than 50 percent from baseline and to below 80 milliliters. This makes it an effective, nonsurgical first-line option."

"Mirena has a proven track-record as an effective contraceptive that lasts for up to five years. We are pleased to now also offer Mirena as a treatment option for women with heavy menstrual bleeding who choose to use an IUD for contraception," said Stefan Oelrich, Vice President and General Manager, Women's Health Care, Bayer HealthCare Pharmaceuticals. "Today's announcement demonstrates our continuing efforts to improve women's health."

Only a woman and her healthcare provider can decide if Mirena is right for her. Mirena is recommended for women who have had a child. Mirena should not be used by a woman who has a pelvic infection, gets infections easily or has certain cancers. Less than 1% of users get a serious infection called pelvic inflammatory disease. A woman should talk to her healthcare provider about problems related to this condition. Mirena may attach to or go through the wall of the uterus and cause other problems. If Mirena comes out, a woman should use back-up birth control and call her healthcare provider. In the uncommon event a woman gets pregnant while using Mirena, she should seek emergency care because pregnancy with an intrauterine device may result in loss of pregnancy or loss of fertility. Pelvic and/or abdominal pain may occur. If persistent, women should talk to their healthcare provider. Ovarian cysts may occur and usually disappear. Bleeding and spotting may increase in the first few months and continue to be irregular. Periods may become shorter, lighter or even stop. *Mirena does not protect against HIV or STDs.*

About the Heavy Menstrual Bleeding Study

FDA approval is based on data from a randomized, open-label, active-control, parallel-group clinical trial of 160 healthy women of reproductive age who had confirmed heavy menstrual bleeding and did not have any medical conditions known to cause HMB, with the exception of small uterine fibroids in some patients. Heavy menstrual bleeding, defined as menstrual blood loss (MBL) of greater than or equal to 80 mL, was determined using the alkaline hematin method. In the study, Mirena (n=79) was compared to an approved first-line hormonal therapy, medroxyprogesterone acetate (n=81), over six menstrual cycles. Successful treatment was defined when two outcomes were met: 1) a proportion of subjects with end-of-study MBL < 80 mL and 2) a greater than or equal to 50% decrease in MBL from baseline to end-of-study. Mirena demonstrated a significantly superior reduction in MBL. Additionally, a greater number of women in the Mirena arm achieved successful treatment vs. those in the medroxyprogesterone acetate arm (85% vs. 22%; respectively, $p < 0.001$). The study excluded women with organic or systemic conditions that may cause heavy uterine bleeding (except fibroids, with total volume not > 5 mL). The most common reported adverse events for Mirena in the study were uterine bleeding/spotting at irregular intervals, headache, ovarian cysts, vaginitis, pain during menstruation (dysmenorrhea), pelvic pain, and breast tenderness.

About Mirena

Mirena (levonorgestrel-releasing intrauterine system) is a removable intrauterine contraceptive that delivers small amounts of hormone directly to the uterus. It is among the most efficacious forms of birth control and works for up to five years. Mirena received FDA approval for the prevention of pregnancy in December 2000. It is currently used by approximately two million women in the U.S. and has been used by more than 15 million women worldwide.(3)

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals operation of Bayer HealthCare LLC, a division of Bayer AG. One of the world's leading, innovative companies in the healthcare and medical products industry, Bayer HealthCare combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the United States, Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, Diagnostic Imaging, General Medicine, Hematology/Neurology, and Oncology. 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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(1) van Eijkeren MA, Christiaens GC, Sixma JJ, Haspels AA. Menorrhagia: A review. *Obstet Gynecol Surv* 1989; 44:421.

(2) Mayo Clinic: <http://www.mayoclinic.com/health/menorrhagia/DS00394/DSECTION=symptoms>

(3) Bayer: data on file.

SOURCE Bayer HealthCare Pharmaceuticals

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