Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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U.S. FDA approves Natazia™ as the first combined oral contraceptive to treat heavy menstrual bleeding (HMB)

Leverkusen, Germany, March 15, 2012 – The U.S. Food and Drug Administration (FDA) has approved a new indication for Natazia™ (estradiol valerate and dienogest) tablets for the treatment of heavy menstrual bleeding (HMB) that is not caused by any diagnosed conditions of the uterus (womb), in women who choose to use a combined oral contraceptive for contraception. With this approval, Natazia is the first and only combined oral contraceptive indicated for the treatment of heavy menstrual bleeding in the U.S..

“Heavy menstrual bleeding is a medical condition in which bleeding is excessive enough to interfere with a woman’s lifestyle and daily activities,” said Dr. Flemming Ornskov, Head of Strategic Marketing General Medicine at Bayer HealthCare Pharmaceuticals. “As the first combined oral contraceptive treatment for heavy menstrual bleeding, Natazia represents a non-invasive treatment approach for this medical condition in addition to our intrauterine system Mirena®. Both products underline Bayer’s ongoing commitment to advancing women’s health by providing them with multiple treatment options.”

Natazia was approved in the U.S. in May 2010 for the prevention of pregnancy. It is the first combined oral contraceptive that contains an estrogen called estradiol valerate in combination with a progestogen called dienogest. Estradiol valerate is converted to estradiol which is the same estrogen produced in a woman’s body. In Europe the product has been marketed since May 2009 as a combined oral contraceptive under the tradename Qlaira®. The indication to treat heavy menstrual bleeding in women without organic pathology who desire oral contraception was first approved in Europe in 2010.

About Natazia™

Natazia is taken once a day. The dosing regimen consists of 28 pills with varying doses of estradiol valerate and estradiol valerate in combination with dienogest: 22 days of estradiol valerate/dienogest, four days of estradiol valerate and two hormone free pills.

About Natazia's HMB Clinical Program

The approval of Natazia for this HMB indication was based on two identically-designed, multicenter, double-blind, randomized, placebo controlled trials – one in North America and one in Europe and Australia. The studies included a total of 421 women, who were 18 years of age or older, with a diagnosis of dysfunctional uterine bleeding characterized as heavy, prolonged and/or frequent bleeding without organic pathology.

Subjects were treated for seven 28-day cycles with either Natazia or placebo. The proportion of the intent-to-treat subjects with complete symptom relief (based on 8 strictly defined criteria for success during the 90-day efficacy assessment phase) was 29.2 percent in the Natazia group compared to 2.9 percent in the placebo group in the first study and 29.5 percent in the Natazia group compared to 1.2 percent in the placebo group in the second study. Patients with HMB (defined as menstrual blood loss of 80 mL or more in at least 2 bleeding episodes during a 90-day run in phase) who were treated with Natazia achieved a statistically significant reduction in menstrual blood loss compared with patients in the placebo group ($p<0.0001$ for both studies).

Most common adverse reactions (greater than or equal to two percent) in Natazia clinical trials included headache, including migraine, breast pain/discomfort/tenderness, menstrual disorders, nausea or vomiting, acne, mood changes, and increased weight.

About heavy menstrual bleeding

According to NICE[1] Guidelines, HMB should be defined for clinical purposes, as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms. The new indication for Natazia is approved in the absence of organic pathology or medical illness (e.g. endometrial polyps or uterine fibroids).

References

[1] N*ational Institute for Health and Clinical Excellence. Heavy Menstrual Bleeding. Costing Report. Implementing NICE guidance in England. London; 2007.*

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition 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. Find more information at www.bayerhealthcare.com.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)
Ute Menke (+49-214-30-33021)

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