



Investor News

US approval for the indication pregnancy prevention:

Bayer receives approval for its new oral contraceptive in the U.S.

- The first and only contraceptive to bring estradiol valerate together with dienogest in a new dosing regimen
 - Product will be marketed as Natazia® in the U.S.
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Leverkusen, May 7, 2010 – Bayer Schering Pharma AG, Germany, has received approval from The U.S. entity of Food and Drug Administration (FDA) for its new Natazia® (estradiol valerate/ dienogest) pill for the prevention of pregnancy. This new product with an estradiol valerate/ dienogest combination is the first in a new class of oral contraceptives to deliver estradiol. Natazia is expected to be available in the U.S. this summer. Outside the US the product is marketed as Qlaira® since May 2009.

“We are very pleased that now also women in the U.S. have the option to choose our new oral contraceptive Natazia as an effective option for the prevention of pregnancy.,” said Phil Smits, MD, Head of Bayer Schering Pharma’s business unit Women’s Healthcare. “We are also working with the FDA on an indication for menstrual bleeding disorders to offer women a tailored therapy for this debilitating condition”, Smits said.

Natazia delivers varying doses of estradiol valerate, and the combination of estradiol valerate and dienogest on different days of the cycle. One Natazia pill is taken daily for 28 days, including 22 days of estradiol valerate/dienogest, four days of estradiol valerate alone and two hormone free pills.

About Natazia’s Clinical Program

The FDA approval of Natazia for the prevention of pregnancy is based on a New Drug Application (NDA) that included efficacy and safety data from a clinical study program comprising three multi-center trials involving a total of 2,266 healthy women aged 18-50 years. Two of the trials investigating primarily the contraceptive efficacy were non-

comparative, open labeled, single arm studies with a treatment duration of up to 28 cycles. The other trial was a double-blind, randomized comparative study, which compared Natazia to a 20 mcg ethinyl estradiol/levonorgestrel preparation over a treatment duration of seven cycles mainly with regard to bleeding pattern and cycle control.

Contraceptive reliability of Natazia was evaluated in two large studies and shown as effective as other marketed birth control pills.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, 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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. Bayer HealthCare's aim is to discover, manufacture and market products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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