



First estradiol-based oral contraceptive Qlaira[®] cleared for market launch in Europe

A new oral contraceptive providing the same estrogen produced by the female body

Leverkusen, October 16, 2008 – Bayer Schering Pharma AG has successfully completed the decentralized drug approval procedure in Europe for its new oral contraceptive Qlaira[®] (dienogest/estradiol valerate). Qlaira[®] is an oral contraceptive whose estrogen component is based on estradiol, the same estrogen that is produced by the female body. For the first time, the use of estradiol in oral contraceptives is made possible with Qlaira[®] through the combination of estradiol with the progestin dienogest in a unique dosing regimen. With Qlaira[®], Bayer Schering Pharma offers women a new choice of estrogen and establishes a new class of oral contraceptives.

“We are very proud that once again, only months after the approval for our low-dose oral contraceptive YAZ[®] in May 2008, we reached another milestone with the successful closure of the decentralized procedure for Qlaira[®] in Europe”, said Phil Smits, M.D., Head of Women’s Healthcare at Bayer Schering Pharma. “Qlaira[®] is the first oral contraceptive providing a body-identical estrogen. With Qlaira[®]’s approval, Bayer Schering Pharma begins a new chapter in the history of oral contraception.”

Over the past 50 years, many new progestins have been developed for use in oral contraceptives, but the estrogen component remained the same. With the advent of Qlaira[®] a new choice of estrogen is introduced. Up to now, efforts to use estradiol in oral contraception have failed to achieve a satisfactory level of bleeding control. The combination of estradiol and dienogest in a unique dosing regimen ensures good cycle control and reliable contraception. Clinical studies have shown that the new combination’s bleeding control is as good as that of oral contraceptives containing 20 µg of ethinyl estradiol.

Bayer Schering Pharma is also developing Qlaira® for the treatment of excessive, prolonged, and frequent menstrual bleeding (dysfunctional uterine bleeding, DUB). Approval of Qlaira® for this additional indication would represent another important milestone; no other contraceptive has yet been approved for treating this disease.

About Bayer

The Bayer Group is a global enterprise with core competencies in the fields of health care, 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, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture 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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