



News Release

Bayer submits first-in-class estradiol-based oral contraceptive for approval in the U.S.

FDA approval requested for oral contraception and treatment of heavy and/or prolonged menstrual bleeding

Berlin, July 8, 2009 – Bayer has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for a new estradiol-based oral contraceptive (estradiol valerate/dienogest). It seeks approval for the indications oral contraception and treatment of heavy and/or prolonged menstrual bleeding. The new product with an estradiol valerate/dienogest combination is the first in a new class of oral contraceptives to deliver estradiol, the estrogen identical to the one produced by the female body. It is marketed in Europe under the tradename Qlaira®.

“We are pleased to be able to submit the NDA for this new estradiol-based oral contraceptive in the U.S. only a few weeks after Qlaira’s launch in Europe,” said Phil Smits, M.D., Head of Women’s Healthcare at Bayer Schering Pharma. “We see a high interest in this new oral contraceptive by women and gynecologists. The NDA underscores the culmination of years of research and development that confirms our goal of developing innovative products that deliver benefits beyond reliable contraception.”

Over the past 50 years, many new progestins have been developed for use in oral contraceptives, but the estrogen component remained the same – ethinylestradiol. The new oral contraceptive contains the combination of estradiol valerate - which is immediately metabolized to estradiol, equivalent to the estrogen as produced by a woman’s ovaries - with the progestin dienogest in a unique dosing regimen. This dosing regimen has been designed to deliver hormones at the right levels at the right time during the cycle. If approved by the FDA, the introduction of this new product will offer women a new choice in oral contraception.

An approval for the additional indication - treatment of heavy and/or prolonged menstrual bleeding in the absence of organic pathology in women who desire oral contraception - would represent another important milestone. No other oral contraceptive has yet been approved for treating this condition.

The new oral contraceptive has been available under the tradename Qlaira since May 2009, in several European countries, for the indication oral contraception. Additional European countries will launch Qlaira in autumn 2009 . Bayer is planning to submit the indication heavy and/or prolonged menstrual bleeding in Europe in 2010.

About Bayer

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About Bayer Schering Pharma

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Contact:

Dr. Friederike Lorenzen, Phone: +49 30 468 15805

E-mail: friederike.lorenzen@bayerhealthcare.com

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