



Phase-III data presented at the World Congress of Gynecology & Obstetrics (FIGO):

Bayer's novel oral contraceptive Qlaira[®] significantly reduces heavy menstrual bleeding

Results also confirm significant improvement in blood iron levels

Leverkusen, October 5, 2009 – Qlaira[®], the novel oral contraceptive containing estradiol valerate/dienogest significantly reduced menstrual blood loss (MBL) in a clinical study with women suffering from heavy and/or prolonged menstrual bleeding without organic pathology. The results of this international trial were presented today by Ian Fraser, M.D.¹, the principal investigator, at the World Congress of the International Federation of Gynecology and Obstetrics (FIGO). Qlaira[®] also improved iron metabolism parameters in these women. Abnormal uterine bleeding is a very common symptom among women of reproductive age.

“The excellent data from our Phase III study with Qlaira[®] clearly underscore that our new oral contraceptive could offer a new treatment option for many women who suffer from this common disorder”, said Phil Smits, M.D., Head of Women’s Healthcare at Bayer Schering Pharma.

In a double-blinded, randomized, placebo-controlled trial with 231 women in Europe and Australia Qlaira[®] was compared to a placebo. Study participants were confirmed to have heavy and/or prolonged menstrual bleeding over a 90-day run-in period before they were randomized into the Qlaira[®] or placebo treatment group. During the 90-day-treatment period, MBL was reduced by 458 ml in the Qlaira[®] group and by 93 ml in the placebo group.

A significant improvement in iron metabolism parameters was only observed in the Qlaira[®] group; the adjusted mean difference in haemoglobin and ferritin concentrations

with Qlaira[®] vs. placebo was +0.6g/dL (95%CI 0.3–1.0; p<0.0001) and +8.2ng/mL (95%CI 3.5–12.9; p=0.002), respectively.

Data from a second Phase III study with the same study design, conducted in parallel in the USA and Canada, will be presented at the 65th Annual Meeting of the American Society for Reproductive Medicine (ASRM) in Atlanta on October 17-21, 2009.

Bayer submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for this new estradiol-based oral contraceptive (estradiol valerate/dienogest) in July 2009. It is seeking approval for two indications: oral contraception and the treatment of heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception. Bayer is planning to seek approval for the indication heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception in Europe in 2010. This new oral contraceptive has been available in several European countries since May 2009 under the tradename Qlaira[®] for the indication oral contraception.

About the Phase III-study

The 231 study participants of the multicenter-study in Europe and Australia were aged >18 years. The participating women underwent a 90-day run-in phase to confirm the diagnosis of prolonged bleeding (two bleeding episodes, each lasting more than eight days), frequent bleeding (more than five episodes with more than 20 bleeding days overall), or heavy bleeding (more than two episodes each with a blood loss volume of more than 80 ml). Mean MBL during this run-in-period was 639 – 645 ml in total. Normal blood loss per monthly cycle is approximately 80 ml.

Following the run-in-phase the study participants were randomized to Qlaira[®] (n=149) or the placebo (n=82) for treatment over 196 days (7 treatment cycles). Data from the last 90 days of treatment and the 90-day run-in period was compared. Women who received Qlaira[®] as a study medication lost on average (adjusted mean difference) 373 ml less blood over the 90-day-treatment period than women on the placebo (95%CI -490, -255; p<0.0001). The items were assessed by using objective quantification methods.

About Qlaira®

This 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 has a unique dosing regimen which has been designed to deliver hormones at the right levels at the right time during the cycle.

About heavy and/or prolonged menstrual bleeding

Heavy and/or prolonged menstrual bleeding is defined as abnormal uterine bleeding in the absence of organic pathology or medical illness (e.g. fibroid, endometriosis).

Prevalence studies indicate that abnormal uterine bleeding is a very common symptom suffered by women of reproductive age. In the US, menstrual disorders affect nearly 2.5 million women annually and are the most prevalent gynecological condition².

Studies assessing the prevalence of heavy bleeding (blood loss of 80 ml or more per menstrual period) using the objective measurement of blood loss report a worldwide prevalence range of between 9% and 14%³. Objective measurement only captures one of the symptoms suffered by women with abnormal uterine bleedings (AUB), whereas subjective or self-reported measurement considers the overall impact on quality of life and is therefore likely to result in higher prevalence rates⁴.

References:

1. *A novel oral contraceptive comprising estradiol valerate/dienogest for the treatment of heavy and/or prolonged menstrual bleeding without organic cause: a double-blind, randomized, placebo-controlled trial (Fraser, I.S., Zeun S, Machlitt A, Mellinger U, oral presentation at FIGO; Oct 05, 2009.)*
2. *Kjerulff KH, Erickson BA, Langenberg PW. Chronic gynecological conditions reported by US women: findings from the National Health Interview Survey, 1984 - 1992. Am J Public Health 1996 Feb;86(2):195-9.*
3. *Original citations: Cole SK, Billewicz WZ, Thomson AM. Sources of variation in menstrual blood loss. J Obstet Gynaecol Br Commonw 1971 Oct;78(10):933-9., Janssen CA, Scholten PC, Heintz AP. Reconsidering menorrhagia in gynecological practice. Is a 30-year-old definition still valid? Eur J Obstet Gynecol Reprod Biol 1998 May;78(1):69-72., Hallberg L, Hogdahl AM, Nilsson L, Rybo G. Menstrual blood loss - a population study. Variation at different ages and attempts to define normality. Acta Obstet Gynecol Scand 1966;45(3):320-51.*
4. *Fraser IS, Langham S and Uhl-Hochgraeber K. The health-related quality of life and economic burden of abnormal uterine bleeding: A critical review; Expert Reviews in Obstetrics and Gynecology 2009, in press*

About Bayer HealthCare

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