

News Release – for medical media only

Oral contraceptive Qlaira[®] (estradiol valerate/dienogest) significantly reduces heavy menstrual bleeding

Newbury, Berkshire, 09 October, 2009 – Bayer Schering Pharma's Qlaira, the unique oral contraceptive containing estradiol valerate/dienogest, significantly reduced menstrual blood loss (MBL) in a new clinical study with women suffering from heavy and/or prolonged menstrual bleeding without organic pathology.

The results of this international trial were presented recently by Ian Fraser, M.D.,¹ the principal investigator, at the World Congress of the International Federation of Gynaecology and Obstetrics (FIGO October 2009). Qlaira also improved iron metabolism parameters in these women. Heavy bleeding is a common symptom among women of reproductive age.

“Menstrual disorders are too often left under-treated. Heavy bleeding has an adverse effect on many women in the UK. These data from this important phase III study with estradiol valerate/dienogest could pave the way for Qlaira to be the first and only oral contraceptive to be indicated for this common disorder. This will bring relief to the daily lives of the many women who suffer from it,” commented Dr Diana Mansour, Head of Contraception and Sexual Health Specialist in Newcastle-Upon-Tyne.

In this double-blind, randomised, placebo-controlled trial involving 231 women from 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 randomised into either the Qlaira or placebo treatment group. During the 90-day-treatment period, menstrual blood loss was significantly reduced by 458 ml in the Qlaira group and by 93 ml in the placebo group ($p = 0.001$).²

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.

About Qlaira

Qlaira, with an estradiol valerate/dienogest combination, is the first in a new class of oral contraceptives to deliver estradiol, the oestrogen identical to the one produced by the female body. It has a unique dosing regimen which has been designed to deliver stable levels of hormones and provide good cycle control with an estradiol-based pill.

Bayer Schering Pharma was granted a UK oral contraception indication in December 2008 and Qlaira was launched in May 2009. It is planning to seek a license for the indication heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception in the UK and Europe.

About heavy and/or prolonged menstrual bleeding

Prevalence studies indicate that heavy bleeding is a common symptom suffered by women of reproductive age. In England alone, NICE estimate that as many as 884,000 women suffer from heavy menstrual bleeding.³

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%.⁴

About the Phase III-study

The 231 study participants of the multicentre-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 randomised 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.

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References

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