



Investor News

CHMP's Pharmacovigilance Working Party completes review:

Bayer will update Yasmin[®] label in the EU

Positive benefit/risk profile of Yasmin[®] confirmed

Leverkusen, March 26, 2010 – Bayer Schering Pharma will update its label for Yasmin[®] (drospirenone / ethinylestradiol) in the European Union to include results of four epidemiological studies.

Bayer sponsored two large observational post authorization safety studies (EURAS and Ingenix) on combined oral contraceptive (COC) use for European and US (Food and Drug Administration) Health Authorities. These prospective cohort studies conducted by independent investigators found that the risk for venous thromboembolism (VTE) in Yasmin users is comparable to the risk found for women who use levonorgestrel-containing COCs. Bayer Schering Pharma will update the European Summary of Product Characteristics for Yasmin with these results.

At the request of the Pharmacovigilance Working Party (PhVWP) of the Committee for Medicinal Products for Human Use (CHMP) two recently published retrospective studies (Lidegaard et al., van Hylckama Vlieg et al.) will also be included in the update. These two studies found the VTE risk in Yasmin users to be between the risk associated with levonorgestrel-containing COCs and desogestrel/gestodene-containing COCs. The results of one of these two studies were not statistically significant. Leading epidemiologists as well as Bayer Schering Pharma, have identified several methodological issues in these recently published studies that need to be clarified before a final conclusion on Yasmin's VTE risk can be made. Bayer Schering Pharma is working with the PhVWP on a reanalysis of some of these data.

"Yasmin's positive benefit/risk profile remains unchanged. Our wealth of post-marketing safety data includes more than 42 million women years of drospirenone use, as well as

two epidemiological studies involving more than 120,000 oral contraceptive users. We are convinced that Yasmin is a good choice for women seeking convenient and reliable contraception if they use the product as directed. Bayer will continue to provide information which will support health care providers and their patients in taking informed decisions about appropriate treatment choices,” said Kemal Malik, MD, Chief Medical Officer at Bayer Schering Pharma.

Since the introduction of Yasmin in the year 2000, Bayer has updated the post-marketing section of the prescribing information to communicate a range of adverse events reported with post-marketing use of the drug, including the types of the risk of VTE events. Both the current and the new EU labels for all COCs – including those containing drospirenone, desogestrel and gestodene – state that VTE is rare among users of all COCs, regardless of which progestin they contain and that the risk for VTE in women who take low-dose COCs is lower than the risk associated with pregnancy and following childbirth.

References:

Publication of EURAS data: Dinger, Jürgen et al.: The safety of a drospirenone-containing oral contraceptive: final results from the European Active Surveillance study on Oral Contraceptives based on 142,475 women-years of observation. In: Contraception, 75, 2007, 344– 354.

Publication of INGENIX data: Seeger, John et al.: Risk of Thromboembolism in Women Taking Ethinylestradiol/Drospirenone and Other Oral Contraceptives. In: Obstetrics & Gynecology, Vol. 110, No. 3, September 2007, 587 – 893.

Lidegaard publication: Lidegaard O, Lokkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. BMJ. 2009;339:b2890.

Van Hylckama Vlieg publication: Van Hylckama Vlieg A, Helmerhorst FM, Vandenbroucke JP, Doggen CJ, Rosendaal FR. The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study. BMJ. 2009;339:b2921.

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