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Investor News

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Bayer Updates U.S. Labels for Drospirenone-containing Combined Oral Contraceptives

Leverkusen, Germany, April 11, 2012 – The U.S. Food and Drug Administration (FDA) and Bayer HealthCare Pharmaceuticals have agreed to update the labels for its drospirenone-containing combined oral contraceptives (COCs) in the United States.

The updated labels in the U.S. include additional information from recently published studies evaluating the risk of venous thromboembolism (blood clots) in women taking drospirenone-containing COCs. Specifically, the new U.S. labels state that COCs containing drospirenone may be associated with a higher risk of venous thromboembolism (VTE) than COCs containing levonorgestrel or some other progestins. Epidemiologic studies that compared the risk of VTE reported that the risk ranged from no increase to a three-fold increase. The U.S. labels state that before initiating use of drospirenone-containing COCs in a new COC user or a woman who is switching from a contraceptive that does not contain drospirenone, consider the risks and benefits of a drospirenone containing COC in light of her risk of a VTE.

Women should talk to their healthcare professional about their risk for blood clots before deciding which birth control method to use. Known risk factors for VTE include smoking, obesity, and family history of VTE, in addition to other factors that contraindicate use of COCs. The risk of VTE is highest during the first year of COC use. The greatest risk of VTE is present after initially starting a COC or restarting (following a 4 week or greater pill-free interval) the same or a different COC.

The revised U.S. labels update information that there is a risk of VTE among all COCs, but that the risk of VTE associated with pregnancy is even greater than the risk associated with any COC use, including drospirenone-containing COCs.

Bayer has consistently updated the FDA and other regulatory authorities around the world as new data have become available regarding drospirenone-containing COCs, and has worked with the agencies to make label updates as appropriate.

In 2011 Bayer HealthCare Pharmaceuticals updated labels for drospirenone containing products in various countries, e.g. Europe, Canada and Australia.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), 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, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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