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Investor News

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Bayer's drospirenone-containing combination oral contraceptives:

FDA Advisory Committees affirm positive benefit-risk profile and recommend an update of US labels to reflect information from available studies

Leverkusen, December 9, 2011 – Bayer HealthCare today announced that at a joint meeting of the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA), the majority of Advisory Committee members voted (15 to 11) that the benefits of drospirenone-containing combination oral contraceptives (COCs) for prevention of pregnancy outweigh the potential risks. The Committee members also voted (21 to 5) that the current US-labels for Bayer's drospirenone-containing combination oral contraceptives do not adequately reflect the benefit-risk profile for these products and should be revised to include additional information from available studies assessing the risk for venous thromboembolism.

Recommendations from the Committees will be considered by the FDA in making its final decision.

"We thank the Committee members for their efforts and participation in the discussion on the benefit-risk profile for drospirenone-containing combination oral contraceptives," said Pamela A. Cyrus, M.D., Vice President and Head of U.S. Medical Affairs, Bayer HealthCare Pharmaceuticals.

Bayer has consistently worked with 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. Bayer will continue to do so.

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 16.9 billion (2010), 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 and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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