



News Release

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Bayer's drospirenone-containing combination oral contraceptives:

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

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**Wayne, NJ, December 8, 2011** – Bayer HealthCare Pharmaceuticals, Inc. 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) in the prevention of pregnancy outweigh the potential risks. The Committee members also voted (21 to 5) that the current labels for Bayer's drospirenone-containing combination oral contraceptives do not adequately reflect the risk benefit profile for these products and should be revised to include additional information from available studies.

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 Pharmaceuticals Inc.**

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare Pharmaceuticals provides products for Diagnostic Imaging, General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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**Forward-Looking Statement:**

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