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Investor News

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European Commission gives green light to Bayer HealthCare's Flexyess®

Flexyess is the first combined oral contraceptive with a flexible extended dosing regimen offering women "personal period planning"

Leverkusen, October 9, 2012 – The European Commission has issued its go ahead for the approval of Bayer HealthCare's new low-dose combined oral contraceptive Flexyess. Based on the European Commission's positive decision, the Health Authorities of the EU Member States will grant national approvals in the coming weeks.

Flexyess (3 mg drospirenone/0.02 mg ethinylestradiol) will be the first low-dose combined oral contraceptive approved in the EU member states for a flexible extended regimen, offering women the option of 'personal period planning', meaning they can choose both the number and timing of their periods according to their needs (within the limits permitted by the approved dosing regimen). The new dosing regimen involves a daily intake for a minimum period of 24 days and up to a maximum period of 120 days. During day 25 to 120, women can schedule a 4-day tablet-free interval individually which triggers the period. This offers the option of flexibly reducing the number of periods to three per year.

"Once Flexyess is launched, women will have the convenience and flexibility to influence the timing of their periods according to their individual needs", said Dr. Flemming Ornskov, Chief Marketing Officer at Bayer HealthCare's Pharmaceuticals division.

Flexyess comes with Clyk™, an innovative digital tablet dispenser that is designed to support women with the new regimen and remind them when to take their pill. The tablet dispenser is expected to improve the adherence to tablet intake because it not only reminds women when to take their pill, but also advises them what to do if they have missed a pill and warns them if additional contraception is needed due to missed pills.

Flexyess provides reliable contraception when taken as directed. It has proven to be effective in preventing pregnancy in clinical studies involving over 2,500 women aged 18-45 years. During the clinical development program, Flexyess was shown to have an overall safety profile that is comparable to the known safety profiles of other estrogen/progestin containing combined oral contraceptives.

First launches of the product in the EU are expected in the second half of 2013. The name of the combined oral contraceptive can vary from country to country.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture 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. More information at www.healthcare.bayer.com.

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