



## Investor News

### **For use outside the US only**

U.S. approval for a new oral contraceptive:

#### **Bayer receives approval for Beyaz<sup>®</sup> in the U.S.**

- First and only contraceptive to raise folate levels, reducing the risk of neural tube defects
- First and only FDA-approved birth control pill with four indications

**Leverkusen, September 27, 2010** – Bayer Schering Pharma AG, Germany, has received approval from the U.S. Food and Drug Administration (FDA) for its new Beyaz<sup>®</sup>. It is the first and only oral contraceptive (OC) approved to raise folate levels in women who choose an OC for birth control. In these women, Beyaz raises folate levels for the purpose of reducing the risk of a neural tube defect (NTD) in a pregnancy conceived while taking Beyaz or shortly after discontinuing it. It combines the hormone ingredients in the birth control pill YAZ<sup>®</sup> with Metafolin<sup>®\*</sup>, a stable form of the naturally occurring folate predominantly found in food. Folates belong to the group of B vitamins.

“By combining one of the world’s leading birth control pills with folate, Bayer is once again at the forefront of medical innovation in reproductive health. Beyaz offers women an oral contraceptive that now also improves a woman’s folate status,” said Phil Smits, Head of the Business Unit Women's Healthcare at Bayer Schering Pharma. “Beyaz represents Bayer’s ongoing commitment to advancing the OC market paradigm by providing women with non-contraceptive health benefits beyond just birth control.”

Folate is an essential nutrient that many women of childbearing age lack. It is well established that folates play an important role during the first weeks of pregnancy. The Centers for Disease Control and Prevention, the U.S. Preventive Services Task Force, the March of Dimes and other leading health authorities recommend that all women of childbearing age supplement their diet with at least 400 mcg of folic acid daily. A well-established body of evidence supports folate supplementation as a means to reduce the incidence of neural tube defects – or birth defects of the brain and spinal cord. Folate

supplementation is particularly important at least one month before and three months after conception.

Combining an oral contraceptive with folate is important, because women who discontinue OCs or do not take them correctly may become pregnant before seeking preconception counseling from their healthcare provider until after they become pregnant. Therefore combining an oral contraceptive with folate is a significant medical advance.

Beyaz is the first and only birth control approved by the FDA for four indications:

- Prevention of pregnancy (99% effective when taken as directed)
- Treatment of symptoms of premenstrual dysphoric disorder (PMDD) for women who choose an oral contraceptive for birth control
- Treatment of moderate acne for women at least 14 years of age, who choose an oral contraceptive for birth control, and have started having menstrual periods
- To raise folate levels in women who choose an oral contraceptive for birth control, for the purpose of potentially reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product

Beyaz is taken in a 24/4 day regimen consisting of 24 days of 3 mg drospirenone / 20 mcg ethinyl estradiol with Metafolin<sup>®</sup> (levomefolate calcium 451 mcg) followed by four days of Metafolin<sup>®</sup> only. Beyaz is expected to be available in the U.S. in October by prescription only.

### **About Beyaz's Clinical Development Program**

The FDA approval of Beyaz to raise folate levels is based on a pivotal 24-week clinical trial involving 379 healthy women aged 18-40 years, which found that Beyaz treatment increased folate levels from baseline. This multicenter, randomized, double-blind, parallel group study conducted in the U.S. population with folate fortified food evaluated the effect of Beyaz on red blood cell (RBC) folate and plasma folate levels compared to YAZ during 24 weeks of treatment. At week 24, the mean changes from baseline were significantly higher ( $p < 0.0001$ ) for women who took Beyaz as compared to women who took YAZ, for RBC folate ( $420 \pm 347$  nmol/L vs.  $34.3 \pm 171$  nmol/L, respectively) and plasma folate ( $15.8 \pm 20.4$  nmol/L vs.  $-2.2 \pm 14.6$  nmol/L, respectively) levels.

The addition of folate to an OC was further evaluated in a separate European study, which looked at YASMIN® (3 mg drospirenone/30 mcg ethinyl estradiol) in combination with either 451 mcg of Metafolin or 400 mcg of folic acid for 24 weeks, followed by 20 weeks of treatment with YASMIN only (no folate intake). This study found that the Metafolin treatment produced maximum mean increases in plasma folate ( $33.5 \pm 14.5$  nmol/L) and in RBC folate ( $782 \pm 260$  nmol/L) levels at 24 weeks. Upon discontinuation of folate intake, the average RBC and plasma folate levels gradually decreased to starting levels (or baseline) over 20 weeks.

Women who stop taking Beyaz should be advised about maintaining folate supplementation.

The other three indications for Beyaz are supported by five clinical trials involving YAZ, including a one-year contraceptive efficacy study, two 3-cycle studies in women with premenstrual dysphoric disorder (PMDD), and two 6-cycle studies in women with moderate acne.

## References

\* Levomefolate calcium (Metafolin®) is licensed and supplied by Merck & Cie, Switzerland. Metafolin® is a registered trademark of Merck KGaA, Germany.

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<http://www.cdc.gov/ncbddd/folicacid/recommendations.html>

<http://www.uspreventiveservicestaskforce.org/uspstf/uspnsrnfol.htm>

[http://www.marchofdimes.com/hbhb\\_syndication/173\\_769.asp](http://www.marchofdimes.com/hbhb_syndication/173_769.asp)

<http://www.uspreventiveservicestaskforce.org/uspstf09/folicacid/folicacidrs.htm#rationale>

<http://www.ahrq.gov/clinic/uspstf09/folicacid/folicacidrs.htm>

## About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, 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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. Bayer HealthCare's aim is to discover, manufacture and market products that will improve human and animal health worldwide. Find more information at [www.bayerhealthcare.com](http://www.bayerhealthcare.com).

### **About Bayer Schering Pharma**

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at [www.bayerscheringpharma.de](http://www.bayerscheringpharma.de).

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