

## Investor News

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### **Visanne<sup>®</sup> cleared for market launch in Europe as new treatment option for endometriosis**

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**Leverkusen, December 7, 2009** – Bayer Schering Pharma AG, Germany, has successfully completed the decentralized part of drug approval procedure in Europe for a new treatment of endometriosis called Visanne<sup>®</sup>. Visanne is a once-daily oral tablet containing dienogest 2 mg that has been developed specifically for the treatment of endometriosis. A dedicated clinical study programme has proven that Visanne relieves endometriosis pain with high efficacy, reduces endometriosis lesions and demonstrates a favourable safety and tolerability profile. Market launch of the product is planned from the second quarter 2010 onwards.

“With Visanne, we will be able to offer women a new treatment option which can reduce the substantial burden of endometriosis,” said Phil Smits, MD, Head of Bayer Schering Pharma’s Business Unit Women’s Healthcare. “Surgical treatment of endometriosis is associated with high relapse rates and many currently available medical therapy options have side effects which do not allow for long-term use. Patients often need to use different combinations of the available treatment options and even undergo repeat surgical procedures. There is therefore a high medical need for new treatment options.”

The current standard therapy (regarding efficacy), GnRH analogue, can only be used for the short-term relief of symptoms associated with endometriosis, as safety concerns such as decreased bone mineral density and side effects such as hot flushes limit its long-term use. Visanne has been shown to be as effective as GnRH analogue and to be superior to placebo in reducing pain related to endometriosis. Pain relief is sustained over time (shown in a clinical study lasting 15 months) and includes dysmenorrhea-like pain, premenstrual pain, diffuse pelvic pain and dyspareunia.

### **About Endometriosis**

Endometriosis is a chronic gynecological disease defined by presence of endometrium-like tissue outside the uterus, which induces a chronic, inflammatory reaction. The endometrium is a layer of mucous tissue, which lines the uterus cavity and undergoes hormone-dependent changes during the menstrual cycle. Endometriosis is a common disease among women of reproductive age. The prevalence is estimated to be around 5-10% in women of childbearing age. Lower abdominal and pelvic pain, cramping menstrual pains (dysmenorrhea), painful sexual intercourse (dyspareunia) and infertility are well recognized symptoms of endometriosis.

### **About Bayer**

The Bayer Group is a global enterprise with core competencies in the fields of health care, 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, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture 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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