Bayer



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Investor News

Visanne® - new long-term treatment for endometriosis submitted for registration in Europe

Leverkusen, January 7, 2009 – Bayer Schering Pharma AG, Germany, has submitted Visanne® for the treatment of endometriosis for registration to all Member States of the European Community. The Netherlands will serve as the Reference Member State for the Decentralized Procedure to receive European-wide Marketing Authorization. Visanne contains 2 mg of Dienogest and is administered orally once a day. In contrast to other drugs used for the treatment of this chronic gynecological disease, Visanne is an endometriosis-specific therapy for the long-term treatment of endometriosis. The current standard-therapy with GnRH analogue is only suitable for short-term treatment due to severe side-effects.

“We focus on gynecological markets with significant growth potential where we aim for global leadership. With the submission of Visanne we have reached another important strategic milestone in the development of innovative gynecological products geared towards improving women’s health”, said Phil Smits, M.D., Head of Bayer Schering Pharma´s business unit Women’s Healthcare. “As endometriosis is a long-lasting gynecological condition that causes dramatic and recurrent pain, turning a woman’s life upside down, there is a need for an effective and well tolerated treatment that can be used over a long period of time. Visanne adresses this need with an endometriosis-specific therapy that has the same efficacy as the current therapeutic standard but with significantly less side effects, thus allowing for long-term treatment”, said Smits.

The standard therapy GnRH analogue is only effective for the short-term relief of symptoms associated with endometriosis as safety concerns like decreased bone mineral density and hot flushes limit its long-term use. Further, both medical and surgical treatments are associated with high relapse rates which commonly result in the use of different combinations of the available treatment options and even repeat surgical procedures. Therefore, there is a need for new treatment options.

Visanne’s efficacy and tolerability in treatment of endometrosis have been proven in several clinical studies. To date, more than 700 women have been treated with Visanne for up to 15 months. First data of the study results were presented at the annual meeting of the American Society for Reproductive Medicine (ASRM) in November 2008. Further data are planned for publication.

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.

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.

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