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Investor News

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Bayer starts Phase III study program with Vilaprisan in the treatment of symptomatic uterine fibroids

Leverkusen, Germany, July 3, 2017 – Bayer announced today that the first patient was enrolled in a Phase III clinical study program ASTEROID which will investigate vilaprisan in women suffering from uterine fibroids. Vilaprisan, discovered at Bayer, is a novel oral, selective progesterone receptor modulator (SPRM) which may allow for effective long-term treatment of uterine fibroids.

Uterine fibroids are the most common benign gynaecological tumors of women of reproductive age. They are frequently characterised by heavy menstrual bleeding, pain and bulk symptoms. Uterine fibroids are a leading cause of hysterectomy (removal of the uterus) and their impact on a woman's life can be significant. Approximately 5–10% of women of reproductive age have symptoms of uterine fibroids and require treatment.

"Based on the promising results we have seen with vilaprisan in the Phase II clinical study program, we are very excited about the start of the Phase III trials that aims for a new symptom control for symptomatic uterine fibroids in a long-term treatment option. While this condition impacts women in their everyday life, current medical treatment options are not satisfactory," said Dr Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. "It is our ambitious goal that our research efforts in this field result in a medical therapy that controls symptoms and thereby significantly improves the quality of life for women with uterine fibroids."

The planned ASTEROID Phase III clinical study program will include several studies to investigate the efficacy and safety of vilaprisan 2mg in patients with symptomatic uterine fibroids. The program aims at enrolling more than 3600 patients at about 900 centres in about 40 countries and it is anticipated that it will take 3 years to complete the progam. Efficacy measures to be assessed within the trial program will include the effect on heavy

menstrual bleeding (amenorrhea rate, controlled bleeding), reduction in fibroid size and improvement in quality of life.

The design and dosing of the Phase III clinical study program was based on results from the ASTEROID Phase II clinical study program (ASTEROID 1+2) investigating vilaprisan in patients with symptomatic uterine fibroids. ASTEROID 1 was a Phase IIb study that investigated the efficacy and safety of four different doses of vilaprisan compared to placebo in patients with symptomatic uterine fibroids; results were presented at the 72nd American Society of Reproductive Medicine (ASRM) 2016 Scientific Congress & Expo in Salt Lake City, UT, USA. ASTEROID 2 was a Phase IIb study that assessed the efficacy and safety of vilaprisan in patients with symptomatic uterine fibroids compared to placebo and ulipristal acetate (Esmya®). First results of ASTEROID 2 will be presented at an upcoming scientific congress.

About Vilaprisan

Vilaprisan is a novel oral, highly potent and selective progesterone receptor modulator (SPRM), which is currently in clinical development for the treatment of symptomatic uterine fibroids as well as endometriosis. Modulation of the progesterone receptor (PR) balances out the cycle-dependent, naturally occurring hormonal fluctuations at the PR and inhibits activation of the receptor via progesterone. As a result, menstrual bleeding is discontinued leading to therapeutic amenorrhea (non-bleeding), a condition which can be reversed with treatment cessation. Progesterone receptor modulation may allow long-term treatment of uterine fibroids and endometriosis.

About Uterine Fibroids

Uterine fibroids (also known as leiomyomas or myomas) are the most common benign gynaecological tumors of women of reproductive age. Approximately 5–10% of women of reproductive age have symptoms of uterine fibroids and require treatment. Fibroids consist of muscle cells and other tissues that grow in and around the wall of the uterus, or womb. They are frequently characterised by heavy menstrual bleeding, pain and bulk symptoms, and are a leading cause of hysterectomy (removal of the uterus). The symptoms can range from mild to severe and have the potential to impact a woman's day-to-day life. A substantial proportion of women with symptomatic uterine fibroids experience heavy menstrual bleeding (HMB), and/or prolonged menstruation, which can lead to anemia, pelvic pressure and pain, as well as bladder, and reproductive dysfunction. Uterine fibroids are among the leading causes of hospitalisation for gynaecological disorders, and are a primary indication for hysterectomy.

About Gynecology at Bayer

Bayer is committed to delivering *Science For A Better Life* by advancing a portfolio of innovative treatments. Women's health including family planning and menopause management has been in the center of Bayer's gynecology franchise for many years. Today, our research efforts focus on finding new treatment options for gynecological diseases with a high medical need such as uterine fibroids and endometriosis, which affect a large number of women in our society. The gynecology pipeline at Bayer includes several investigational compounds in various stages of preclinical and clinical development. Together, these projects reflect the company's approach to research, which prioritizes targets and pathways with the potential to alter the way that gynecological diseases are treated.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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