Allergan and Richter Announce Positive Phase III Results for Ulipristal Acetate 5 and 10 mg in the Treatment of Uterine Fibroids

Phase III study met all co-primary and secondary endpoints and achieved statistically significant results

DUBLIN, Ireland and BUDAPEST, Hungary – 9 May 2016, -- Allergan Plc (NYSE: AGN) and Gedeon Richter Plc. today announced positive results from Venus I, one of two pivotal Phase III clinical trials evaluating the efficacy and safety of ulipristal acetate in women with uterine fibroids.

The study included 157 patients, with 101 patients randomized to ulipristal acetate 5 and 10mg and 56 to placebo. The study met all the co-primary and secondary endpoints with both ulipristal treatment arms achieving statistically significant results over placebo ($p<0.0001$). The co-primary efficacy endpoints were percentage of patients with absence of uterine bleeding and time to absence of uterine bleeding. Significantly more patients in the 10 mg group (58.3%; $p<0.0001$) and the 5 mg group (47.2%; $p<0.0001$) achieved absence of bleeding compared to placebo (1.8%).

"We are pleased with the positive efficacy and safety results demonstrated in this clinical trial. Uterine Fibroids are the leading cause of hysterectomies in the US. Ulipristal acetate has the potential to offer the first and only non-invasive long-term treatment option for women suffering from uterine fibroids in the US." said David Nicholson EVP and President of Global R&D, Allergan.

The secondary efficacy endpoints were the percentage of patients with absence of uterine bleeding from Day 11 to end of treatment and the change from baseline in the UFS-QOL revised Activities subscale at the end of treatment. Significantly more patients in the 10 mg group (58.3%; $p<0.0001$) and the 5 mg group (43.4%; $p<0.0001$) achieved absence of bleeding from Day 11 to the end of treatment compared to placebo (0%). The improvement from baseline in the UFS-QOL revised Activities subscale was significantly greater in the 10 mg group (59.0; $p<0.0001$) and the 5 mg group (52.1; $p<0.0001$) compared to placebo (21.2).

The UFS-QOL is a disease-specific symptom and health-related quality of life questionnaire. This questionnaire is an established instrument to assess disease impact on patient's well-being in women with uterine fibroids.

"We are delighted with this significant step forward for ulipristal acetate as it confirms and underlines that it could provide medical therapy to many women suffering from this condition.", said Dr. István Greiner, Research Director of Gedeon Richter Plc. "We remain committed to the development of women healthcare products which improve quality of life for the female population in all age groups."

There were no treatment-related serious adverse events. No patients discontinued ulipristal acetate treatment due to adverse events. The most common adverse events (≥ 5%) on ulipristal acetate treatment were hypertension (N=6), blood creatine phosphokinase increased (N=5), hot flush (N=5) and acne (N=3).

Venus I is the first clinical trial to report topline results. The second of two clinical trials—Venus II—is anticipated to be completed this year with topline results expected in the first half of 2017. A new drug application for the treatment of uterine fibroids is planned to be submitted in 2017.

About Venus I Clinical Trial

This study was a multi-center, randomized, double-blind, placebo-controlled clinical trial in premenopausal women between 18 and 50 years old with cyclic (22 to 35 days) abnormal uterine bleeding in ≥4 of the last 6 menstrual cycles, menstrual blood loss ≥80 mL as measured by the alkaline hematin method over the first 8 days of menses, ≥1 discrete uterine fibroid of any size and location observable by transvaginal ultrasound, follicle-stimulating hormone ≤20 mIU/mL, and uterine volume ≤20 weeks by exam. Eligible patients were randomized 1:1:1 to ulipristal acetate 5 mg, 10 mg or placebo for one 12-week treatment course followed by a 12-week treatment-free follow-up period. African-American women represented 69% of patients enrolled. The average BMI was 31.7.

The Venus I trial is the first completed pivotal study of ulipristal acetate for uterine fibroids in the US population. It is designed to meet FDA requirements for approval.

About Ulipristal Acetate

Ulipristal acetate, an investigational drug for the medical treatment of uterine fibroids, is a selective progesterone receptor modulator (SPRM), which acts directly on the progesterone receptors in 3 target tissues: the endometrium (uterine lining), uterine fibroids, and the pituitary gland. Ulipristal acetate exerts a direct effect on the endometrium (suppressing uterine bleeding) and direct action on fibroid size by decreasing the formation of new fibroid cells and promoting fibroid cell death. The safety and efficacy of ulipristal acetate is being evaluated in two phase 3 US studies of more than 550 adult women of reproductive age. Ulipristal acetate is protected by a patent that expires in 2029.

The Venus I builds upon data collected from prior efficacy and safety studies of ulipristal acetate for fibroids conducted in Europe, where ulipristal acetate is marketed under the trade name Esmya® by Richter, and is currently approved for the pre-operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

In Canada, ulipristal acetate, available under the trade name Fibristal™, received Health Canada approval in June 2013 for the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age, who are eligible for surgery. To date, more than 300,000 women have been treated with ulipristal acetate for fibroids in over 50 countries.

About Uterine Fibroids

Uterine fibroids, also known as myomas, are the most common benign tumors that affect up to 80 percent of women in the United States by the age of 50. Studies show that the incidence of uterine fibroids is more prevalent among African-American women. Fibroids are the leading cause of hysterectomies in the US and cost the economy over $34 billion each year.

Fibroids are made of muscle cells and other tissues that grow in and around the wall of the uterus, or womb. Symptoms of uterine fibroids can range from mild to severe and have the potential to impact a woman's day-to-day functioning. Symptoms often include, but are not limited to, abnormal uterine bleeding including long, heavy, and/or irregular menstrual cycles, passing clots; bulk symptoms including pelvic pain, pelvic pressure, and abdominal distortion; infertility and recurrent pregnancy loss. The cause of fibroids is unknown.

About Allergan

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a unique, global pharmaceutical company and a leader in a new industry model — Growth Pharma. Allergan is focused on developing, manufacturing, and commercializing innovative branded pharmaceuticals, high-quality generic and over-the-counter medicines, and biologic products for patients around the world.

Allergan markets a portfolio of best-in-class products that provide valuable treatments for the central nervous system, eye care, medical aesthetics, gastroenterology, women's health, urology, cardiovascular and anti-infective therapeutic categories, and operates the world's third-largest global generics business, providing patients around the globe with increased access to affordable, high-quality medicines. Allergan is an industry leader in research and development, with one of the broadest development pipelines in the pharmaceutical industry and a leading position in the submission of generic product applications globally.

Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Quarterly Report on Form 10-Q for the quarter ended (such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

About Gedeon Richter

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe. Having reached a market capitalisation of EUR 3.3 billion (US$ 3.6 billion) by the end of 2015, Richter's consolidated sales were approximately EUR 1.2 billion (US$ 1.3 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including gynaecology, central nervous system, and cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the female healthcare field worldwide. Richter is also active in biosimilar product development.

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