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

- First oral therapy to demonstrate efficacy and safety for uterine fibroids in two U.S. pivotal studies –
- VENUS II study reinforces efficacy, safety seen in VENUS I study, meeting all co-primary and secondary endpoints--
- New Drug Application to be filed with U.S. FDA in 2017 --

DUBLIN, Ireland and BUDAPEST, Hungary – 17 January 2017 -- Allergan Plc (NYSE: AGN) and Gedeon Richter Plc. today announced positive results from Venus II, the second of two pivotal phase III clinical trials evaluating the efficacy and safety of ulipristal acetate in women with abnormal bleeding due to uterine fibroids. A new drug application filing for ulipristal acetate is planned for the second half of 2017.

"We are pleased with the favourable results of Venus II supporting the efficacy and safety profile of ulipristal acetate as shown in our Venus I trial," said David Nicholson, Chief Research and Development Officer, Allergan. "Allergan is committed to identifying, developing and bringing to market therapies that address unmet need and provide significant value to the healthcare system, including a potential new treatment for symptomatic uterine fibroids. We are confident that the results of our phase III trials for ulipristal acetate may potentially offer the first and only oral treatment option for women suffering from uterine fibroids in the U.S."

The study included 432 U.S. patients with 162 and 157 patients randomized to ulipristal acetate 5 and 10 mg respectively, and 113 to placebo. The average age of patients enrolled was 41 years and 67% of enrolled patients were Black/African Americans. 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 on treatment during Treatment Course One (12-week duration). Significantly more patients in the 10 mg group (54.8%) and the 5 mg group (42.0%) achieved absence of bleeding compared to placebo (0%).

The secondary efficacy endpoints were the percentage of patients with absence of uterine bleeding from Day 11 to end of the first treatment course; the percentage of patients with absence of uterine bleeding after the second treatment course; time to absence of uterine bleeding on treatment during treatment course two; and the change from baseline in the UFS-QOL revised Activities subscale at the end of the first treatment course.

More patients in the 10 mg group (55.4%) and the 5 mg group (34.6%) achieved absence of bleeding within 10 days after treatment initiation in Treatment Course One compared to placebo (0.0%). Significantly more patients in the 10 mg group (57.3%) and the 5 mg group (40.5%) achieved absence of bleeding compared to placebo (8.0%) in Treatment Course Two. The improvement from baseline in the UFS-QOL revised activities subscale was

significantly greater in the 10 mg group (56.7%) and the 5 mg group (48.3%) compared to placebo (13.0%).

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

“It is indeed very encouraging that we have another successful phase III study conducted in patients with uterine fibroid symptoms, which shows that ulipristal acetate could bring promising treatment for women suffering from this condition,” added Dr István Greiner, Research Director of Gedeon Richter Plc. “We remain committed to the development of female healthcare products aiming towards the improvement of the quality of life of women in all age groups.”

The most common adverse events (≥ 5%) on ulipristal acetate treatment were hot flush, headache, fatigue, and nausea in the combined period of Treatment Course One and first off-treatment interval. The most common adverse event (≥ 5%) on ulipristal acetate treatment was headache in the combined period of Treatment Course Two and second off-treatment interval.

About Venus II

This study was a multi-center, randomized, double-blind, placebo-controlled clinical trial in premenopausal women in North America 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 to ulipristal acetate 5 mg, 10 mg or placebo for two separate 12-week treatment courses followed by a 12-week treatment-free follow-up period.

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 has been evaluated in two phase III US studies of more than 589 adult women of reproductive age. Ulipristal acetate is protected by a patent that expires in 2029.

The Venus I and II trials build upon data collected from prior efficacy and safety studies of ulipristal acetate for fibroids conducted Ex-US. In Europe, ulipristal acetate is marketed under the trade name Esmya® by Gedeon Richter. In Canada, ulipristal acetate is available under the trade name Fibristal™. Esmya® and Fibristal™ are currently approved for the pre-

operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

To date, more than 310,000 women have been treated with ulipristal acetate for fibroids in over 65 countries worldwide.

About Uterine Fibroids

Uterine fibroids, also known as myomas, are the most common benign growths[6,7,12] that affect up to 80 percent of women in the United States by the age of 50[7,10,12] and are more prevalent in African-American women.[1,2,3,7,8] Fibroids are made of muscle cells and other tissues that grow in and around the wall of the uterus, or womb.[12] Uterine fibroids are a significant cause of morbidity[6,7]. It is estimated that up to 50 percent of women with fibroids will experience symptoms.[9] Women report serious symptoms such as heavy menstrual bleeding, painful menses, pelvic pain, urinary symptoms, bowel dysfunction, pressure within the abdomen and on adjacent pelvic organs, and impact on fertility.[7,9,12] In fact, women reported severe to very severe symptoms related to menstrual pain/cramps, heavy or prolonged bleeding, and abdominal pain/cramping.[7,12] Moreover, heavy uterine bleeding can be associated with iron deficiency anemia, pain, social embarrassment, interference with daily and social activities as well as lost productivity in the work place.[7,11,12]

The current mainstay of management is mainly surgical.[10] In fact, uterine fibroids are responsible for over 350,000 hospitalizations and are the leading cause of hysterectomies[5,6,7,10,12], accounting for approximately one-third of all hysterectomies annually in the US.[10] The economic burden of uterine fibroids is also large[10], costing the economy over $ 34 billion each year.[13]

About Allergan

Allergan Plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 15,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what it is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live healthier lives every day.

For more information, visit Allergan's website at www.Allergan.com.

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 Annual Report on Form 10-K for the year ended 31 December 2015 and Quarterly Report on Form 10-Q for the quarter ended 30 September 2016 (certain of 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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