



Richter announces that PregLem, its wholly owned subsidiary, receives positive EMA/CHMP opinion for Esmya[®] for the pre-operative treatment of uterine fibroids (myomas)

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Budapest, Hungary - 16 December 2011 – **Gedeon Richter Plc. (“Richter”)** announces that the **Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA)** has adopted a positive opinion for **Esmya[®] 5mg tablet as pre-operative treatment of moderate to severe symptoms of uterine fibroids**. Subject to approval by the European Commission, PregLem, the wholly owned subsidiary of Richter, is expected to receive in early 2012, a marketing authorization for **Esmya[®]** valid for all European Union Member States.

- **Esmya[®]** (ulipristal acetate) is a first-in-class[®], orally active, selective progesterone receptor modulator which reversibly blocks the progesterone receptors in target tissues.
- **Esmya[®]** successfully completed two Phase III clinical trials in Europe in June 2010 and was filed in late 2010 for European registration for the treatment of uterine fibroids, a benign tumour that affects millions of women worldwide.

The CHMP opinion is based on the assessment of extensive pre-clinical data, quality data, and clinical data involving 498 subjects treated with **Esmya[®]**, which include data from the two Phase III pivotal clinical studies, PEARL I and PEARL II.

“Richter is dedicated to bring to market innovative, patient-friendly treatment like **Esmya[®]** that will improve and simplify the treatment of patients with fibroids”, said Erik Bogsch, Managing Director of Gedeon Richter Plc. “We are encouraged by this positive opinion from the CHMP and we shall do our best to make **Esmya[®]** available to physicians and patients in Europe during 2012.”

“**Esmya[®]** is the first new treatment to be launched for that condition in more than 20 years. The positive CHMP opinion confirms **Esmya[®]** therapeutic potential and is an important milestone towards making **Esmya[®]** available for addressing the unmet medical needs of women with uterine fibroids”, said Dr. Ernest Loumaye, Chief Executive Officer of PregLem.

About uterine fibroids

Uterine fibroids are the most common benign, solid tumours of the female genital tract, affecting between 20 and 25 percent of women of reproductive age. It is estimated that about 300,000 surgical procedures are performed annually in the EU for uterine fibroids, including approximately 230,000 hysterectomies. The condition is characterized by excessive uterine bleeding, anemia, pain, frequent urination or incontinence, and infertility. GnRH agonists are the only approved pre-operative treatment for uterine fibroids but their use has been relatively limited due to side effects resulting from the suppression of estrogen to castration levels (hot flashes, depression, mood swings, loss of libido, vaginitis and loss of bone mineral density).



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About Esmya®

Esmya® containing ulipristal acetate, a new chemical entity licensed from HRA Pharma, is a first-in-class, orally active, selective progesterone receptor modulator which reversibly blocks the progesterone receptors in target tissues. The 12 weeks once-a-day oral therapy (vs. injectable GnRH agonist) is effective to stop uterine bleeding, correct anemia and shrink fibroid volume while preparing for surgery. Thus, it improves quality of life and has no castration side effects compared to GnRH agonists. There are no data available on treatment with duration longer than 3 months.

About the study

PEARL I, double-blind, placebo controlled, multi-center clinical, demonstrated superior efficacy of Esmya® versus placebo in reduction of excessive uterine bleeding, correction of anemia and reduction of fibroid size.

PEARL II, double-blind, double-dummy, multi-center study comparing Esmya® versus the injectable GnRH agonist (Leuprorelin), demonstrated non-inferior efficacy of Esmya® in reduction of excessive bleeding and fibroid size and superior safety and tolerance of Esmya® regarding castration-related symptoms and their consequences. Esmya® most common side effects were headaches and hot flashes.

About Richter

Gedeon Richter Plc. (www.richter.hu) headquartered in Budapest/Hungary, is a major pharmaceutical company in Hungary and one of the largest in Central Eastern Europe, with an expanding direct presence in Western Europe in the field of gynaecology. Richter's consolidated sales was approximately EUR 1 billion (USD 1.3 billion) while its market capitalization amounted to EUR 2.9 billion (USD 3.8 billion) in 2010. The product portfolio of the Company covers almost all important therapeutic areas, including gynaecology, central nervous system and cardiovascular. The Company has the largest R&D unit in Central Eastern Europe. Original research activity focuses on CNS disorders with main clinical targets being schizophrenia, anxiety, chronic pain and depression. With its widely acknowledged steroid chemistry expertise Richter is also a significant player in the female healthcare field worldwide.

PregLem Holding SA (www.preglem.com), the wholly owned subsidiary of Richter, is a Swiss speciality biopharmaceutical company, based in Geneva, dedicated to the development and commercialization of a new class of drugs for women's reproductive health conditions. PregLem has an experienced senior management team, with a proven track record in developing, registering and commercializing reproductive health products.



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