European CHMP Issues Positive Opinion for repeated intermittent use of Esmya® 5 mg in the long term management of Uterine Fibroids

Budapest, Hungary – 27 April 2015 – 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 on the company's application to extend the indication of Esmya® 5 mg tablets (ulipristal acetate) to the long term repeated intermittent treatment of moderate to severe symptoms of uterine fibroids.

The CHMP positive opinion will be forwarded to the European Commission, which is expected to amend the EU marketing authorisation for Esmya® 5 mg applicable to all countries of European Union, within two months from the opinion.

Esmya® 5 mg tablets initial community Marketing Authorization was for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The extension of indication to include the repeated intermittent treatment will give, should it be approved, the opportunity to many women suffering from this condition to be relieved from the symptoms of fibroids.

The submission of this extension of indication for Esmya® 5 mg was based on the results of the PEARL IV study, which evaluated and confirmed the efficacy and safety of the long term repeated intermittent treatment with ulipristal acetate 5 and 10 mg in subjects with uterine fibroids and heavy uterine bleeding.

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, anaemia, pain, frequent urination or incontinence, and infertility.

About Esmya®

Esmya® 5 mg containing ulipristal acetate, a new chemical entity, is a first-in-class, orally active, selective progesterone receptor modulator which reversibly blocks the progesterone receptors in target tissues. The repeated intermittent 3-month treatment courses of once-a-day oral therapy is effective to stop uterine bleeding, correct anaemia, shrink fibroid volume and improve quality of life. Esmya® has been developed by PregLem, the wholly owned subsidiary of Richter.

About Gedeon Richter Plc.

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. Richter's consolidated sales were approximately EUR 1.1 billion (USD$ 1.5 billion), while its market capitalization amounted to EUR 2.1 billion (USD$ 2.5 billion) in 2014. The product portfolio of Richter covers almost all 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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