

European Commission decision adopted CHMP opinion on the Esmya[®] referral

Budapest, Hungary – 30 July, 2018 – Gedeon Richter Plc. (“Richter”) announces that the **European Commission (EC) implemented a decision concerning the marketing authorisations of Esmya[®] 5 mg.** This decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on 1 June 2018 and is applicable for all Member States in the European Economic Area.

A question has been referred to the European Medicines Agency in December 2017, which lead to a review procedure on drug induced liver injury potentially related to Esmya[®]. The European Commission specifies the amended conditions of the marketing authorizations.

For details of the decision please visit

http://ec.europa.eu/health/documents/community-register/2018/20180726141599/dec_141599_en.pdf

About uterine fibroids

Uterine fibroids are the most common benign, solid tumours of the female genital tract, affecting between 20% and 25% of women of reproductive age. The condition is characterized by excessive uterine bleeding, anaemia, pain, frequent urination or incontinence, and infertility. Uterine fibroids are commonly treated surgically. Symptomatic uterine fibroids are the leading reason for hysterectomy. It is estimated that about 300,000 surgical procedures are performed annually in the EU for uterine fibroids, including approximately 230,000 hysterectomies. Available treatments were limited to short-term pre-operative use and comprise of either ulipristal acetate (Esmya) or gonadotropin releasing hormone (GnRH) agonists. Surgery may not be a suitable option for all patients, e.g. for medical or personal reasons or if the woman would rather wait that the symptoms of uterine fibroids decrease as result of menopause. Thus, there was a medical need for a long-term medical treatment of fibroids.

About 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, in China and in Latin America. Having reached a market capitalisation of EUR 4.1 billion (USD 4.9 billion) by the end of 2017, Richter's consolidated sales were approximately EUR 1.4 billion (USD 1.6 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, 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 Women's healthcare field worldwide. Richter is also active in biosimilar product development.

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