Pharmacovigilance Risk Assessment Committee (PRAC) has initiated a review of Esmya

Budapest, Hungary – 04 December 2017 – The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has started a review of drug induced liver injury potentially related to Esmya (ulipristal acetate). The review started due to four reports of serious liver injury, occurred since 2012; the date of the EU marketing authorization, three of which ended in liver transplantation, in patients treated with the medicine.

Following the PRAC meeting held on 30 November 2017, the European Comission (EC) initiated a referral procedure within the EU and requested the Agency to assess the above mentioned concern.

Richter is determined to work with PRAC and provide the necessary information to allow them to complete a fair assessment in a timely manner.

Richter takes patient safety seriously. We are confident about the safety of Esmya based on all available data collected from clinical studies and committed to providing this unique treatment option to women suffering from uterine fibroids.

About Esmya

To date approximately 670,000 patients have been treated with Esmya, based on the post-marketing database in Europe. In completed clinical trials, over 7,100 subjects have been exposed to ulipristal acetate and 1,972 subjects received repeated doses of ulipristal acetate. No signs of liver toxicity were identified during the development program of UPA.

Richter, has provided PRAC with a thorough analysis for all cases of liver toxicity in women receiving Esmya, and based on the analysis, the causal relationship to Esmya could not be established due to the confounding factors such as the use of other medications, viral infection and potential underlying conditions of the liver in some of these patients.

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 3.7 billion (US$ 3.9 billion) by the end of 2016, Richter's consolidated sales were approximately EUR 1.3 billion (US$ 1.4 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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