Pharmacovigilance Risk Assessment Committee (PRAC) starts review of Esmya®

Budapest, Hungary – 13 March 2020 – Gedeon Richter Plc. announces today that subsequent to its meeting held on 09-12 March 2020 the Pharmacovigilance Risk Assessment Committee (PRAC) of European Medicines Agency (EMA) has started a review procedure following a recent case of liver injury which led to liver transplantation in a patient taking Esmya® and published the following:

"PRAC recommends suspension of ulipristal acetate for uterine fibroids during ongoing review of liver injury risk

The PRAC has recommended, as a precautionary measure, that women should stop taking 5-mg ulipristal acetate (Esmya and generic medicines) for uterine fibroids while a safety review started this month is ongoing. No new patients should start treatment with these medicines.
The start of the review follows a recent case of liver injury, which led to liver transplantation in a patient taking the medicine.
A 2018 PRAC review concluded that there is a risk of rare but serious liver injury with ulipristal acetate medicines for uterine fibroids, and measures were implemented to minimise the risk. However, as the new case of serious liver injury occurred despite adherence to these measures, the Committee has started a new review.
Cases of serious liver injury have been reported, including five that led to transplantation, out of over 900,000 patients who have been treated with ulipristal acetate for fibroids since its authorisation in 2012."

Further information and updated recommendations will be provided once the review is concluded.

About Esmya®

Esmya®5mg tablets containing ulipristal acetate is a first-in-class, orally active, selective progesterone receptor modulator characterised by a tissue specific mixed progesterone antagonist/agonist effect. It reversibly blocks the progesterone receptors in target tissues. As previously published in the New England Journal of Medicine, the short term treatment with Esmya® 5mg proved to be effective to stop uterine bleeding, correct anaemia and shrink fibroid volume. It improves quality of life and has no castration side effects unlike GnRH agonists. Data published confirmed the efficacy and safety of repeated intermittent use of Esmya® 5mg in long term management of uterine fibroids allowing women to avoid surgical intervention.

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 capitalization of EUR 3.6 billion (USD 4.1 billion) by the end of 2019, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.7 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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