GEDEON RICHTER

European Commission decision adopts CHMP opinion on restricting the use of Esmya®

Budapest, Hungary – 15 January 2021 – Gedeon Richter Plc. ("Richter") announces that the European Commission (EC) implemented a decision concerning the marketing authorisations of ulipristal acetate 5 mg (Esmya®) as a result of cases of serious liver injury. This decision follows the opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on 13 November 2020 and is applicable for all Member States in the European Economic Area.

Esmya® can now only be used to treat uterine fibroids in premenopausal women for whom surgical procedures (including uterine fibroid embolisation) are not appropriate or have not worked. Esmya® must not be used for controlling symptoms of uterine fibroids while awaiting surgical treatment.

Information on the risk of liver failure (requiring liver transplantation in some cases) will be added to the summary of product characteristics and the package leaflets for ulipristal acetate 5 mg medicines as well as in educational material for doctors and cards for patients.

EMA's safety committee (PRAC) review of serious liver injury with ulipristal acetate 5 mg had found that it was not possible to identify either patients most at risk of liver injury or measures that could reduce the risk. The PRAC had therefore advised that these medicines should not be marketed in the EU.

The CHMP endorsed the PRAC's assessment of the risk of liver injury. However, it considered that the benefits of ulipristal acetate 5 mg in controlling fibroids may outweigh this risk in women who have no other treatment options. As a result, the CHMP recommended that the medicine remains available to treat premenopausal women who could not have surgery (or for whom surgery had not worked).

For details of the decision please visit:

https://www.ema.europa.eu/en/medicines/human/referrals/ulipristal-acetate-5mg-medicinal-products

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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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