U.S. Food and Drug Administration issues Complete Response Letter for Ulipristal Acetate New Drug Application

Budapest, Hungary – 22 August 2018 – Gedeon Richter Plc. hereby informs its shareholders that Allergan Plc. made the following statements in respect of the FDA response to their New Drug Application for ulipristal acetate:

"DUBLIN, IRELAND – AUGUST 21, 2018 – Allergan plc (NYSE: AGN) today announced it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) in response to the New Drug Application (NDA) for ulipristal acetate (UPA) for the treatment of abnormal uterine bleeding in women with uterine fibroids.

The letter from the FDA indicates it is not able to approve the ulipristal acetate NDA in its current form and is requesting additional information. The agency cited safety concerns regarding ESMYA post-marketing reports outside the United States. Allergan plans to meet with the FDA to discuss their comments and next steps.

"Allergan continues to believe in the need for novel treatment options for women who are looking for a non-surgical treatment for uterine fibroids," said David Nicholson, Chief Research and Development Officer, Allergan. "We intend to meet with the FDA to discuss the Complete Response Letter and determine the potential next steps for our ulipristal acetate NDA."

The New Drug Application for ulipristal acetate included the results of a robust clinical trial program which included two U.S. Phase 3 clinical trials and all Phase 3 EU registration studies as well as real-world data in more than 700,000 women with uterine fibroids across 80 countries worldwide."

For additional sections of the announcement, namely
- About ulipristal acetate
- About Allergan plc. and
- Forward-Looking Statement,

please visit Allergan's website at www.Allergan.com.