Richter announces withdrawal of its marketing authorisation application for biosimilar pegfilgrastim

Budapest, **19 December 2016** – Gedeon Richter Plc. ("Richter") today announced that it has withdrawn its Marketing Authorization Application (MAA) from the European Medicines Agency (EMA) for its biosimilar pegfilgrastim.

The MAA filing was based on comparative quality, non-clinical and clinical data from the Company's completed biosimilar development programme. During the November 2016 Committee for Medicinal Products for Human Use (CHMP) meeting, the CHMP indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment.

The Company's management is committed to continue the clinical development and regulatory process of its biosimilar pegfilgrastim in order to eliminate the remaining uncertainties identified by CHMP during the review process.

About biosimilars

A biosimilar medicine is a biological medicine, that is developed to be highly similar to an already authorized biological medicine (the 'reference medicine'). The biosimilar medicines do not have any significant differences from the reference medicine in terms of quality, safety or efficacy.

About pegfilgrastim

Pegfilgrastim, a pegylated recombinant, human granulocyte-colony stimulating factor is used in cancer patients to help with some of the side effects of their treatment. Chemotherapy that is cytotoxic also kills white blood cells, which can lead to neutropenia and the development of infections. Pegfilgrastim is used to reduce the duration of neutropenia and the occurrence of febrile neutropenia.

About Gedeon 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. Having reached a market capitalisation of EUR 3.3 billion (US$ 3.6 billion) by the end of 2015, Richter's consolidated sales were approximately EUR 1.2 billion (US$ 1.3 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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