EMA started the evaluation of Richter's resubmitted marketing authorisation application for biosimilar pegfilgrastim

Budapest, **02 March 2018** – Gedeon Richter Plc. ("Richter") today announced that the European Medicines Agency (EMA) has accepted Richter's regulatory resubmission for its proposed biosimilar to Amgen's Neulasta® (pegfilgrastim).

This resubmission follows the successful completion of an additional clinical study, which provided data demonstrating biosimilarity of both the pharmacokinetics and pharmacodynamics of the proposed biosimilar and Neulasta®. The biosimilar pegfilgrastim of Richter is currently under review by the EMA for the same indications as the reference product.

In December 2016 Richter withdrew its Marketing Authorization Application (MAA) from the EMA for its biosimilar pegfilgrastim, following a CHMP (Committee for Medicinal Products for Human Use) meeting, according to which it has been indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment.

The biosimilar pegfilgrastim has been developed by Richter. According to the license and distribution agreement signed by Richter and STADA in 2015, upon approval, biosimilar pegfilgrastim is expected to be launched under both Richter and STADA labels in the European Economic Area.

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, in China and in Latin America. Having reached a market capitalisation of EUR 4.1 billion (US$ 4.9 billion) by the end of 2017, Richter's consolidated sales were approximately EUR 1.4 billion (US$ 1.6 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.

For more information:

Investors:
Katalin Ördög: +36 1 431 5680
Media:
Zsuzsa Beke: +36 1 431 4888