

Richter Announces Withdrawal of its Marketing Authorisation Application for Efglatin (biosimilar pegfilgrastim)

Budapest, 01 February 2019 – Gedeon Richter Plc. (“Richter”) announced today that it has withdrawn its Application for a Marketing Authorisation (MAA) from the European Medicines Agency (EMA) for Efglatin, its biosimilar pegfilgrastim.

This withdrawal occurred subsequent to a MAA resubmission, which was based on completion of an additional clinical study.

The decision to withdraw the MAA was taken because Richter could not address the CHMP concerns within the given timeframe.

The Company reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

About biosimilars

A biosimilar is a biological medicine similar to another biological medicine (the ‘reference medicine’) that is already authorised in the EU. 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 neutropenia (low levels of neutrophils, a type of white blood cell), which is a common side effect of cancer treatment and can leave patients vulnerable to infections. It is given specifically to reduce the duration of neutropenia and prevent febrile neutropenia (neutropenia accompanied by fever).

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 (USD 4.9 billion) by the end of 2017, Richter's consolidated sales were approximately EUR 1.4 billion (USD 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.

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