

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

Budapest, 8 December 2015 – Gedeon Richter Plc. ("Richter") today announced that the European Medicines Agency (EMA) has accepted Richter's regulatory submission for its proposed biosimilar to Amgen's Neulasta (pegfilgrastim).

The biosimilar pegfilgrastim has been developed by Richter. According to the license and distribution agreement signed by Richter and STADA earlier this year, biosimilar pegfilgrastim is expected to be launched under both Richter and STADA labels in geographical Europe (excluding Russia) following the patent expiry of the original product.

Richter is seeking approval for the same indications as the reference product. Pegfilgrastim is a prescription medicine administered to reduce the chance of infections related to a low white blood cell count in patients with cancer who receive chemotherapy.

About biosimilars

A biosimilar medicine is a biological medicine, contains mostly protein as active ingredient, 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. Richter's consolidated sales were approximately Euro 1.1 billion (US\$ 1.5 billion), while its market capitalization amounted to Euro 2.1 billion (US\$ 2.5 billion) in 2014. The product portfolio of Richter covers almost all important therapeutic areas, including gynaecology, 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 female healthcare field worldwide. Richter is also active in biosimilar product development.

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