

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

Budapest, 4 January 2016 – Gedeon Richter Plc. ("Richter") today announced that the European Medicines Agency (EMA) has accepted Richter's regulatory submission for the proposed biosimilar to Eli Lilly's Forteo (teriparatide).

The biosimilar teriparatide has been developed by Richter-Helm BioTec GmbH & Co. KG. According to the relevant license agreements, biosimilar teriparatide is expected to be launched under both Richter and STADA labels in geographical Europe following the patent expiry of the original product.

Richter is seeking approval for the same indications as the reference product. Teriparatide is prescription only medicine used for the treatment of osteoporosis, leading to frequent bone fractures.

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 teriparatide

Teriparatide is identical to the biologically active fragment of the human parathyroid hormone, it replaces the natural hormone and stimulates bone formation. Teriparatide is used for the treatment of osteoporosis as it reduces the risk of bone fracture in various patient groups. Osteoporosis is more common in women after the menopause, and it can also occur in both men and women as a side effect of glucocorticoid treatment.

About Richter-Helm BioTec GmbH & Co. KG

Richter-Helm-BioTec GmbH&Co.KG based in Hamburg develops biosimilar pharmaceuticals for worldwide markets. Richter-Helm-BioTec GmbH&Co.KG is the biotechnology joint venture of Gedeon Richter Plc., located in Budapest, a leading pharmaceutical firm in Eastern Europe with branches in more than 100 countries, and Hamburg-based HELM AG, one of the largest independent chemical and pharmaceutical marketing enterprises in the world present more than 30 countries.

About 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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