Richter received positive opinion from CHMP for marketing authorisation application for biosimilar teriparatide

Budapest, 14 November 2016 – Gedeon Richter Plc. ("Richter") today announced that it received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending that marketing authorization be granted for its biosimilar teriparatide, Terrosa. Upon approval, Terrosa is expected to be used in the same indications as its reference product, Elli Lilly's Forsteo, i.e. for the treatment of osteoporosis in men and in post-menopausal women with a high fracture risk.

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

The CHMP´s positive opinion was based on data collected from analytical, pre-clinical and clinical studies related to the development program of the biosimilar teriparatide which demonstrated biosimilarity to Elli Lilly's Forsteo (teriparatide).

"The positive CHMP opinion for our first biosimilar, teriparatide marks an important milestone for our biosimilars business. Richter is building upon its expertise in developing and manufacturing biologics by bringing forward these important therapies. Biosimilars will increase choice and access for patients in the EU, while providing potential cost savings to healthcare systems", said Erik Bogsch, Managing Director of Gedeon Richter Plc.

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 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. 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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