

Richter announces approval in Japan of its licensed-out biosimilar teriparatide

Budapest, Hungary – 20 September 2019 – Gedeon Richter Plc. (“Richter”) today announced that its license partner Mochida Pharmaceutical Co., Ltd. (“Mochida”) received marketing authorization from the Japanese Ministry of Health, Labour and Welfare (MHLW) for biosimilar teriparatide developed by Richter-Helm BioTec GmbH & Co. KG.

The product is a biosimilar to teriparatide which Mochida has developed for Japan based on a comprehensive license and collaboration agreement signed in 2010 with Richter.

The European Commission (EC) approved Richter’s biosimilar teriparatide, Terrosa® in January 2017, and the product was launched in Europe in late August 2019 following the patent expiry of the reference product.

About biosimilars

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines.

About teriparatide

Teriparatide is biosimilar 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, but it can occur in both men and women as a side effect of glucocorticoid treatment.

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, in China and in Latin America. Having reached a market capitalisation of EUR 3.2 billion (USD 3.6 billion) by the end of 2018, 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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