

Richter launched Terrosa[®], its biosimilar teriparatide across Europe

Budapest, Hungary – 20 August 2019 – Gedeon Richter Plc. (“Richter”) today announced that it has launched its biosimilar teriparatide, Terrosa[®] in Europe. The product is approved in adults for the same indications as Eli Lilly’s Forsteo[®], i.e. used for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture and treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non vertebral fractures but not hip fractures has been demonstrated.

Biosimilar teriparatide has been developed by Richter-Helm BioTec GmbH & Co. KG. The product has been launched under the label Terrosa[®] by Richter via its affiliates in Europe immediately following the patent expiry of the reference product in August 2019.

The European Commission (EC) approved Terrosa[®] in January 2017, following the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP), which concluded that the data derived from the comprehensive physico-chemical and biological characterisation, in vivo non-clinical studies and the clinical trial, constituting the development programme of Terrosa[®] had demonstrated biosimilarity with Forsteo[®]. The EC approval of Terrosa[®] applies to all 28 European Union (EU) member states and European Economic Area (EEA) member states.

“We are excited about the introduction of Terrosa[®], our first own-developed biosimilar product in Europe, as it reflects our commitment to scientific programmes linked to complex medications such as biologicals. Biosimilars will increase choice and access for patients in the European countries, while providing potential cost savings to healthcare systems. We look forward to bringing more high quality and affordable biosimilar products to the market”, said Gábor Orbán, Chief Executive Officer of Richter.

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-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 Central 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 in 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, 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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