

Richter and Hikma sign exclusive commercialisation and license agreement for denosumab in the US, a proposed biosimilar referencing Prolia® and Xgeva®

Budapest, Hungary – London, UK – 9 December 2021 – Gedeon Richter Plc. (“Richter”) and Hikma Pharmaceuticals PLC (“Hikma”) today announced that they have entered into an exclusive license agreement to commercialise Richter’s denosumab, comprising two biosimilar products referencing Prolia® and Xgeva® (“Products”), in the United States (“US”). The Products are used for the treatment of osteoporosis and fractures due to bone metastasis respectively and are currently in global Phase 1 and Phase 3 clinical studies.

According to the agreement, Richter is responsible for the development of the Products (to conduct both Phase 1 and Phase 3 global clinical studies) and will supply finished commercial Products for the US market. Hikma is responsible for registering the Products with the US Food and Drug Administration and will have exclusive rights to commercialise them in the US.

Under the financial arrangements of the licensing agreement, Richter is eligible for an upfront payment upon signature as well as certain milestone payments linked to reaching defined development stages totalling a double-digit million USD figure.

“We are looking forward to collaborating with Hikma on this important biosimilar project targeting the US market,” said Gábor Orbán, Chief Executive Officer of Richter. “Extending our partnership with a highly respected company having a strong US presence further increases our confidence in the viability of our specialty pharma strategy.”

“Biosimilars are a growing area of interest for Hikma and we are delighted to add two new products to our portfolio, building on our position as one of the leading suppliers of sterile injectable medicines in the US,” said Siggí Olafsson, Chief Executive Officer of Hikma. “This key collaboration is highly complementary and strengthens our US oncology and auto-immune offerings. Gedeon Richter brings strong technical capabilities for biological products which, combined with our well-established commercial presence in the US market makes for a partnership with exciting potential.”

This agreement, which builds on Richter and Hikma’s existing partnership in MENA, will help equip doctors and patients in the US with more treatment options.

About denosumab

Denosumab is marketed under two brands – it is a biosimilar to the reference products Prolia® (60 mg/ml solution for injection in PFS) and Xgeva® (120 mg/1,7 ml solution for injection in vial), a human monoclonal antibody for the treatment of osteoporosis and fractures due to bone metastasis. Denosumab is a RANKL inhibitor which works by preventing the development of osteoclasts, which are cells that break down bone. It is used for patients with osteoporosis at high risk for fractures, bone loss due to certain medications, and in cancer patients with bone metastases or giant cell tumours of the bone.

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/stable Fitch)
Hikma helps put better health within reach every day for millions of people around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

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 capitalization of EUR 3.8 billion (USD 4.7 billion) by the end of 2020, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.8 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.