# Richter and DM Bio agreement on technology transfer and license-in of biosimilar Trastuzumab

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Gedeon Richter Plc. ("Richter") today announces that it has signed a technology transfer and license-in agreement with DM Bio ("DM Bio") in respect of the development and commercialization of DM Bio's biosimilar monoclonal antibody, Trastuzumab.

According to the agreement, Richter receives exclusive distribution rights for Europe, the CIS region and Latin American countries and it also obtains the pilot technology for further development.

Under the terms of the agreement Richter shall make an upfront payment upon signature of the contract and further milestone payments shall be made depending on the progress of the technology transfer and clinical programme of the product. In addition, further sales related royalties will become payable to DM Bio subsequent to the launch of the product.

"The development of biosimilar products has been considered as an important strategic initiative for Richter in becoming a specialty pharma company, therefore we made significant efforts to establish our presence in the field of biotechnology. This agreement is considered to be a significant step towards finding strategic partners for the development and distribution of biosimilar products", stated 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 HER2-Positive Breast Cancer and Trastuzumab:**

Worldwide, nearly 2 million women are diagnosed with breast cancer each year, making it the second most common cancer in the world. HER2-positive breast cancer is an aggressive form of breast cancer that tests positive for the human epidermal growth factor receptor 2 (HER2), which promotes cancer cell growth. Approximately 20% to 30% of primary breast cancers are HER2-positive. Trastuzumab is indicated for the treatment of certain HER2-positive early stage and metastatic breast cancer as well as HER2-positive metastatic gastric cancer.

#### **About DM Bio**

DM Bio is a joint venture company formed by Dong-A Socio Holdings of Korea and Meiji Seika Pharma of Japan, and is in charge of constructing and operating production facilities for bio-pharmaceuticals that are jointly developed by the two companies. DM Bio was officially launched as a bio-pharmaceutical company in April 2015, and began production in May. It received manufacturing business approval from the Korean Ministry of Food and Drug Safety (MFDS) in September 2015.

### **About Gedeon 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 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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