

Richter acquires all Bemfola® rights in respect of US

Budapest, Hungary – 10 July, 2018 – Gedeon Richter Plc (“Richter”) today announced that it concluded a sale and purchase agreement with Fertility Biotech AG (“Fertility Biotech”), a Swiss corporation, in connection with the transfer of intellectual property rights, relevant studies, related data and documents of r-hFSH containing product, BEMFOLA® / AFOLIA, for the use in the United States.

On 30 June 2016 Richter acquired Finox Holding, a privately held Swiss biotech company focused on development and commercialisation of innovative and cost effective products addressing female fertility, obtaining global rights for BEMFOLA® except for the US. At that time the product was already commercialised in the European Union, in Israel, in the Middle East and in Australia. US rights were transferred to Fertility Biotech, a company whose main shareholder is Dr h.c. Willy Michel, the Founder, and previous Chairman of the Board and previous majority shareholder of Finox Holding.

The parties valued the transaction at CHF 5 million.

About r-hFSH

The products used to stimulate follicular growth are highly complex biologicals and development and registration is time consuming and expensive - and for this reason there are relatively few competitors and new entrants into the market. The market is highly concentrated into few IVF (In Vitro Fertilisation) centres per country, which allows for small and specialised sales forces with a comparatively low cost base compared to other therapeutic areas.

About BEMFOLA®

BEMFOLA® is produced using recombinant DNA technology. Both BEMFOLA® and the reference product GONAL-f® are formulations of the naturally occurring hormone FSH, which plays a key role in human reproduction.

BEMFOLA® was granted marketing authorisation in EU in May 2014 and is currently registered in 40 countries. The European MA for BEMFOLA® was supported by data from a large Phase III study, in which BEMFOLA® therapy was found to be similar to the reference product – GONAL-f®, based on the numbers of oocytes retrieved after completing FSH therapy. In this Phase III study, similar efficacy and safety profiles were observed between the two study arms and similar numbers of live babies were born to patients who became pregnant following completion of therapy.

BEMFOLA® is available in 5 single use monodose presentations available in the following dosage forms: 75, 150, 225, 300 and 450 IU.

BEMFOLA® is supplied in a single-use, unique, state-of-the-art delivery system which results in a simple, once-a-day disposable device, allowing the patient to self-inject.

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, in China and in Latin America. Having reached a market capitalisation of EUR 4.1 billion (USD 4.9 billion) by the end of 2017, 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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