



Press Release

STADA and Richter signed a license and distribution agreement for biosimilar Pegfilgrastim

Bad Vilbel and Budapest, August 6, 2015 – STADA Arzneimittel AG (“STADA”) and Gedeon Richter Plc. (“Richter”) today announced that the two companies have signed a license and distribution agreement to commercialize Richter’s biosimilar Pegfilgrastim in Europe. According to the agreement STADA receives non exclusive distribution rights for the area of geographical Europe (excluding Russia), while Richter retains its rights to distribute and market biosimilar Pegfilgrastim worldwide.

Under the terms of the agreement in addition to a payment on the event of signing the contract, STADA is obliged to make further payments each depending on the progress of the project. With the start of marketing, STADA will report the resulting sales and make license related further payments to Richter.

“We succeeded once again in continuing our strategy of selective in-licensing with a competent partner. With the agreement, we ensure that we will be able to offer a low-cost and high-quality alternative to the original product immediately following the expiration of the patent in 2017. This way, we also further expand our position in the promising and attractive-margin biosimilar market and strengthen our portfolio with an additional biosimilar in a low cost and low risk manner”, said Hartmut Retzlaff, Chairman of the Executive Board of STADA Arzneimittel AG, on the advantages of the cooperation.

“Development of biosimilar products has been considered as a paramount strategic objective for Richter in becoming a specialty pharma company. A hopefully successful completion of the Pegfilgrastim development project is deemed to be a first step on the way of becoming an acknowledged participant on the high-end market of biological products. The current agreement brings a worthwhile addition to our strategy”, added Erik Bogsch, Managing Director of Gedeon Richter Plc.

Executive Board: Hartmut Retzlaff (Chairman) / Helmut Kraft / Dr. Matthias Wiedenfels
Chairman of the Supervisory Board: Dr. Martin Abend



About biosimilars

A biosimilar medicine is a biological medicine, contains mostly protein as active ingredient, that is developed to be highly similar to an existing biological medicine (the 'reference medicine'). The biosimilar medicines do not have any meaningful differences from the reference medicine in terms of quality, safety or efficacy.

About Pegfilgrastim

Pegfilgrastim is a pegylated recombinant, human granulocyte-colony stimulating factor and is used in adult patients for treatment of neutropenia. This illness often accompanies cytotoxic chemotherapies and depicts a decrease in certain white blood cells. The active ingredient is a further development (a so-called second generation Filgrastim) of Filgrastim, which STADA has been selling as a biosimilar since 2014.

About STADA Arzneimittel AG

STADA Arzneimittel AG is a publicly-listed company with headquarters in Bad Vilbel, Germany. STADA consistently focuses on a multi-pillar strategy of generics and branded products (OTC) with an increasingly international market orientation. The Group is the only independent generics producer in Germany. Worldwide, STADA is represented by around 50 sales companies in more than 30 countries. Branded products such as Grippostad and Ladival are among the top sellers in their product category in Germany. In financial year 2014, STADA achieved Group sales of Euro 2,062.2 million, adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of Euro 431.9 million and adjusted net income of Euro 186.2 million. As of December 31, 2014, STADA employed 10,363 people worldwide.

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. Richter's consolidated sales were approximately Euro 1.1 billion (US\$ 1.5 billion), while its market capitalization amounted to Euro 2.1 billion (US\$ 2.5 billion) in 2014. The product portfolio of Richter covers almost all 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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