



Press Release

STADA expands biosimilar range and in-licenses filgrastim product from Apotex Inc. European approval opens the door for Grastofil

Bad Vilbel, October 28, 2013 – STADA Arzneimittel AG has strengthened its activities in the biosimilars area and in-licensed a filgrastim product from the largest Canadian owned pharmaceutical company Apotex Inc. The biosimilar, marketed under the name Grastofil, received approval from the European Commission for the treatment of Neutropenia in adults. The condition results in an abnormally low number of neutrophil granulocytes, a type of white blood cell that is essential for a functional immune system. STADA shall assume sales of the biosimilar for nearly all EU countries. Sales are planned to commence in 2014.

“With Grastofil, we are consequently following our strategy of selectively in-licensing biosimilars from high-profile partners,” says Dr. Michael Mack, Vice President of Biotechnology at STADA. “The agreement with Apotex puts us in the position to expand our portfolio with a high-quality biosimilar at very favorable conditions. STADA brings its excellent international sales structures and comprehensive experience in the European market to the cooperation, which both partners will benefit from.”

Grastofil will be available in pre-filled syringes with two different active ingredient concentrations for intravenous or subcutaneous injection. “The effectiveness, tolerability and quality of Grastofil are comparable to the original product within the approved area of application,” explains Mack. “This was proven in comprehensive, comparative studies with the original product and has now been confirmed with the approval of the European Commission. With Grastofil, we will be able to offer an inexpensive alternative therapy in the future that doctors, patients and even the public health care system will benefit from.”



Neutropenia can arise as a result of cytotoxic chemotherapy, for example. Grastofil promotes the generation of neutrophil granulocytes and their release from the bone marrow and, therefore, can be used to support chemotherapy for malignant diseases in order to reduce the risk of neutropenia-induced infection as well as to support the antibiotic treatment of this type of infection. The approval also comprises the application to mobilize peripheral blood stem cells.

About biosimilars

A biosimilar is a drug with a protein produced by biotechnological process as an active pharmaceutical ingredient and developed in comparison to an original product which is already on the market, and that is so similar to this original product that the biosimilar has proven therapeutic equivalence.

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 traditionally has a strong presence in Europe and is the only independent generics producer in Germany. Worldwide, STADA is one of the five leading companies in the generics industry and is represented in more than 30 countries with approximately 50 subsidiaries. STADA GmbH, STADApHarm, ALIUD PHARMA, cell pharm and Hemopharm are German sales companies of the STADA Group. Branded products such as Mobilat, Grippostad and Ladival are among the highest selling in their product category in Germany. In financial year 2012, STADA achieved Group sales of Euro 1,837.5 million, adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of Euro 367.5 million and adjusted net income of Euro 147.9 million. As of December 31, 2012, STADA employed 7,761 people worldwide.

About Apotex Inc.

Apotex Inc. is the largest Canadian-owned pharmaceutical company and employs over 7,500 people in research, development, manufacturing and distribution facilities worldwide. Apotex produces more than 300 generic pharmaceuticals in a range dosages and formats which, in Canada, are used to fill over 85 million prescriptions a year - the largest amount of any pharmaceutical company in the country. Apotex plans to invest CAD 2 billion in research and development over the next ten years. The company currently has more than 600 products in the development pipeline.



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