Press Release

STADA receives “positive opinion” from the EMA for teriparatide biosimilar

Bad Vilbel, November 14, 2016 – As expected and within the scope of the current EU-wide approval procedure, STADA Arzneimittel AG (“STADA”) on November 11 received a so-called “positive opinion” for the biosimilar teriparatide from the responsible EU approval authority, EMA. In line with the application, this “positive opinion” covers osteoporosis in men and post-menopausal women with a high fracture risk as well as the treatment of osteoporosis in men and women with a high fracture risk associated with systematic long-term glucocorticoid therapy. An EU-wide approval of teriparatide from the EU Commission is expected in January 2017.

STADA and Richter-Helm BioTec GmbH Co. KG (“Richter-Helm”) signed a licensing and sales agreement for the marketing of the teriparatide biosimilar in Europe in October 2014. STADA received semi-exclusive sales rights for the European Union and nine non-EU countries, while Richter has the right to sell and market teriparatide in geographical Europe and the CIS.

“Teriparatide will be a key part of our portfilio in the future. The positive opinion from the EMA is a clear indication that we have relied on the right cooperation partners for our biosimilar strategy. Despite all of the uncertainties that could have delayed the approval of this innovative medication, we are moving forward as planned with the expansion of our biosimilar business”, says Dr. Matthias Wiedenfels, Chairman of the Executive Board at STADA Arzneimittel AG, summarizing the advantages of the cooperation.

Under the terms of the agreement, in addition to a payment at the signing of the contract, STADA will also make further payments, each depending on the progress of the project. With the EU-wide launch of marketing planned to coincide with the expiration of the patent at the beginning of 2019, STADA will report the resulting sales and make further license payments to Richter-Helm.

About biosimilars

A biosimilar is a pharmaceutical product produced through bio-technology with a protein as active ingredient developed with the aim of being comparable to an existing biological pharmaceutical product (the “reference pharmaceutical product”). There are no significant differences in quality, safety and effectiveness between biosimilars and reference pharmaceutical products.

About teriparatide

Teriparatide is a fragment of the human parathormone for hypodermic injection which is produced recombinant. Teriparatide is used for the treatment of post-menopausal women with manifest osteoporosis and a high fracture risk, of men with osteoporosis and a high fracture risk, as well as for glucocorticoid-induced osteoporosis of adults with an elevated fracture risk.

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. STADA is represented in more than 30 countries with approximately 50 sales companies worldwide. Branded products such as Grippostad and Ladival are among the highest selling in their product category in Germany. In financial year 2015, STADA achieved Group sales of Euro 2,115.1 million, adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of Euro 389.4 million and adjusted net income of Euro 165.8 million. As of December 31, 2015, STADA employed 10,532 people worldwide.

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