Press release

STADA: EMA started the evaluation of resubmitted marketing authorisation application for biosimilar pegfilgrastim

Bad Vilbel, March 2, 2018 – STADA Arzneimittel AG ("STADA") was informed today by Gedeon Richter Plc. ("Richter") that the European Medicines Agency (EMA) has accepted the regulatory resubmission of its proposed biosimilar to Amgen's Neulasta (pegfilgrastim).

The resubmission follows the successful completion of an additional clinical study, which provided data demonstrating biosimilarity of both the pharmacokinetics and pharmacodynamics of the proposed biosimilar and Neulasta. The biosimilar pegfilgrastim is currently under review by the EMA for the same indications as the reference product.

In December 2016 Richter withdrew its Marketing Authorization Application (MAA) from the EMA for biosimilar pegfilgrastim, following a CHMP (Committee for Medicinal Products for Human Use) meeting, according to which it has been indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment.

According to the license and distribution agreement signed by STADA and Richter in 2015, upon approval, biosimilar pegfilgrastim is expected to be launched under both STADA and Richter labels in the European Economic Area.

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 pegfilgrastim

Pegfilgrastim, a pegylated recombinant, human granulocyte-colony stimulating factor is used in cancer patients to help with some of the side effects of their treatment. Chemotherapy that is cytotoxic also kills white blood cells, which can lead to neutropenia and the development of infections. Pegfilgrastim is used to reduce the duration of neutropenia and the occurrence of febrile neutropenia.

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. Worldwide, STADA is represented in more than 30 countries with more than 50 subsidiaries. Branded products such as Grippostad and Ladival are among the highest selling in their product categories in Germany. In financial year 2016, STADA achieved adjusted Group sales of Euro 2,167.2 million, adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of Euro 398 million and adjusted net income of Euro 177.3 million. As of December 31, 2016, STADA employed 10,900 people worldwide.

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