Press release

STADA: FDA approves biologics facility to supply key medicine to patients in US

- Norbitec biotech facility in Uetersen, Germany, a company controlled by STADA, passes inspection by the US Food and Drug Administration (FDA)
- FDA certification enables STADA to extend long-standing agreement to cover epoetin biologic medicine supplies to patients in the US
- STADA CEO Peter Goldschmidt: "This FDA accreditation serves as a further proof point of STADA's rapid progress as a leader in Specialty medicines and of the Group's commitment to ensuring patients around the world have sustainable access to high-quality medicines."

Bad Vilbel – 1 June 2023 – Following a six-day inspection of the Norbitec biologics facility in Uetersen, Germany, the US Food and Drug Administration (FDA) has approved the STADA-controlled entity as a manufacturing and storage site for epoetin alfa-epbx drug substance, an important biologic therapy for anemia that has annual US sales in excess of US$300 million.

Through the FDA certification, STADA will be able help ensure continued US patient access to one of the top-selling biosimilars in the US.

"This FDA accreditation serves as a further proof point of STADA's rapid progress as a leader in Specialty medicines and of the Group's commitment to ensuring patients around the world have sustainable access to high-quality medicines," stated STADA CEO Peter Goldschmidt. "We look forward to safeguarding epoetin supplies in the US."

The US supply deal extends a long-standing partnership whereby the Norbitec facility supplies epoetin drug substance for Europe.A joint venture between STADA's Bioceuticals Arzeimittel AG subsidiary and Nordmark Pharma GmbH, Norbitec is located on Nordmark's campus in Uetersen, near Hamburg. It serves as a center of excellence for supplying STADA's own commercial operation in Europe, where the Group was a pioneer in the biosimilars sector as one of the first companies in Europe to gain approval for, and make available to patients, an epoetin biosimilar medicine. The company has more than 15 years of experience in supplying biosimilars to patients in Europe.

"The positive outcome of the FDA inspection is the result of STADA's strong commitment to quality and our mission of expanding access to critical medicines," commented STADA's Chief Technical Officer, Miguel Pagan. "This was a truly collaborative effort among the Norbitec team, STADA global functions, and of course valued partners, including Nordmark. We look forward to continuing to build strong capabilities in our European manufacturing network to support our growing Specialty business."

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2022, STADA achieved group sales of EUR 3,797.2 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 884.7 million. As of 31 December 2022, STADA employed 13,183 people worldwide.

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