Press release

STADA's US partner Supernus submits NDA for apomorphine infusion pump

- STADA's US commercial partner Supernus files New Drug Application (NDA) with US Food and Drug Administration for an apomorphine infusion pump (SPN-830).
- The NDA filing for SPN-830 for continuous treatment of ON-OFF episodes in adults with Parkinson's disease is based on data from an extensive development program completed by STADA's Britannia Pharmaceuticals and its US partners.
- STADA CEO Peter Goldschmidt: "This filing is further evidence of how STADA is working around the world to develop added-value medicines and to expand its offering of speciality pharmaceuticals in addition to standard generics and consumer healthcare products."

Bad Vilbel, 15 September 2020 – STADA Arzneimittel's US commercial partner Supernus Pharmaceuticals, Inc. has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for its apomorphine infusion pump (SPN-830) for the continuous treatment of ON-OFF episodes in adults with Parkinson's disease (PD) whose motor control is unsatisfactory with oral levodopa and at least one other non-invasive PD therapy.

Supernus earlier this year acquired US licenses from STADA's Britannia Pharmaceuticals neurology and central nervous system center of excellence for the marketed APOKYN® (apomorphine) pen as well as for an apomorphine pump product candidate.

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Britannia's managing director, Robert Wood, added: "Submission of this NDA for an apomorphine infusion pump is an important step in the partnership between Supernus and STADA's Britannia with the goal of offering US patients, caregivers and health professionals a broader range of treatments for Parkinson's disease."

"We believe the continuous treatment of "OFF" episodes may offer PD patients an important alternative over currently available acute treatments," said Jack Khattar, President and CEO of Supernus. "Current alternatives to acute treatment often require continuous infusion of levodopa through a gastric tube or surgical intervention such as deep brain stimulation. SPN-830, if approved by the FDA, would offer patients a less invasive and a convenient option in the form of a continuous subcutaneous infusion of apomorphine."

The NDA for SPN-830 is based on data from an extensive development program completed by Britannia and US WorldMeds (USWM, LLC). The program includes the TOLEDO study, a pivotal Phase III study (conducted in Europe, ref. Katzenschlager et al, Lancet Neurology 2018; 17: 749–59) and a supportive safety and efficacy study (conducted in the US).

TOLEDO was a Phase III, multi-center, double-blind, placebo-controlled study that investigated the efficacy and safety of apomorphine subcutaneous infusion in PD subjects whose motor fluctuations were not adequately controlled on optimized treatment. The US study is an open-label study which investigated the safety and effectiveness of SPN-830. The study eligibility criteria, apomorphine administration and dosing, study schedule, and efficacy and safety measures in both studies were similar.

Both studies included PD subjects with average daily OFF time ≥3 hours. The primary efficacy endpoint in both studies was the change from baseline to Week-12 in mean daily OFF time over 24 hours recorded by the subject in a motor symptom diary. In TOLEDO, the reduction in mean daily OFF time with SPN-830 in comparison with placebo was statistically significant (SPN-830: 2.47 hours, n=53; placebo: 0.58 hours, n= 53; p=0.0025). In the US study, mean daily OFF time decreased from baseline to Week-12 by 3.0 hours (n=94, p<0.0001). Treatment-related adverse events (AEs) were predominantly mild or moderate in severity. Infusion site AEs, nausea and dyskinesia were the most frequently reported AEs related to study treatment.

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a two-pillar strategy consisting of generics, including specialty pharmaceuticals and non-prescription consumer health products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2019, STADA achieved adjusted Group sales of EUR 2,608.6 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 625.5 million. As of December 31, 2019, STADA employed 11,100 people worldwide.

About Britannia Pharmaceuticals Limited

Britannia is a UK-based speciality pharmaceutical company operating in over 30 countries and is part of the STADA Arzneimittel AG group. Britannia was acquired by STADA in 2007, and has since become a global speciality pharmaceutical centre of excellence. Britannia continues to develop pioneering treatments and innovate drug delivery methods for Parkinson's and other central nervous system disorders and leads the way in innovative technology and patient support.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy; Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy; APOKYN® (apomorphine hydrochloride injection) for the acute treatment of hypomobility in advanced Parkinson's disease (PD); MYOBLOC® (rimabotulinumtoxinB) for the treatment of cervical dystonia and treatment of chronic sialorrhea in adults; and XADAGO® (safinamide) as an adjunctive treatment to levodopa/carbidopa in PD patients with hypomobility. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-812 for the treatment of ADHD; SPN-830 for hypomobility in PD; SPN-820 for treatment-resistant depression; and SPN-817 for the treatment of epilepsy.

See full Prescribing Information for our products here: Trokendi XR, Oxtellar XR, APOKYN, MYOBLOC, and XADAGO.

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