Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals and SNBL Announce Publication of STS101 (Dihydroergotamine Nasal Powder) Pivotal Phase 3 ASCEND Study in CNS Drugs

Study shows the repeated long-term, as-needed use of STS101 for the acute treatment of a migraine attack demonstrated a favorable safety profile and was well tolerated.

Exploratory Efficacy Endpoints showed that STS101 provided rapid freedom from pain (37% of attacks), and rapid freedom from most bothersome symptoms (54% of attacks) at 2 hours and sustained treatment benefits over 48 hours after dosing.

DURHAM, N.C., Oct. 8, 2024 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc., a late-stage biopharmaceutical company currently seeking regulatory approval from the U.S. Food and Drug Administration for STS101 (dihydroergotamine (DHE) nasal powder), a novel investigational therapeutic product candidate for the acute treatment of migraine, and its corporate parent, Shin Nippon Biomedical Laboratories, Ltd. (TSE:2395), today announced publication the STS101 ASCEND Phase 3 long-term, open-label safety trial in CNS Drugs. STS101 is the only product to combine Satsuma's proprietary SMART™ (Simple MucoAdhesive Release Technology) with an easy-to-use, easy-to carry nasal delivery device.

"We are proud to announce the publication of our pivotal safety data, which further reinforce the potential for STS101 to be a unique, well-tolerated treatment that, subject to approval by the FDA, has the potential to deliver rapid and enduring symptom relief for patients with acute migraine," said Ryoichi Nagata, President and CEO of Satsuma, M.D., Ph.D., FFPM. "We were particularly pleased to see that a vast majority of patients reported that STS101 was easy to use over the entire duration of the study."

The publication, can be found here, https://link.springer.com/article/10.1007/s40263-024-01118-8

"I am pleased that the data demonstrates that STS101 was safe, well tolerated, and easy for patients to use over the long term. This is exciting and important information for people living with migraine who have experienced inadequate relief with existing therapies and the practitioners who treat them who are in need of new options," said Stewart Tepper, MD, Vice President of the New England Institute for Neurology and Headache in Stamford, Connecticut. "Even with the introduction of new treatment options in the past few years, there is a critical need for novel non-oral treatment options for patients who are often unable to achieve rapid relief with oral routes of administration."

About the ASCEND Study

ASCEND Study was a pivotal Phase 3 open-label study that evaluated the safety, tolerability, exploratory efficacy, and patient acceptability of STS101. The trial was conducted at 54 sites in the United States and enrolled 482 patients who had a documented diagnosis of migraine with or without aura, with 4 to 12 migraine attacks per month in each of the 3 months prior to the study. In the trial, 446 patients received at least one dose of STS101 and used 10,137 doses of STS101 for up to 18 months.

In the study, STS101 was well tolerated over up to 18-months of as-needed use, with STS101-related treatment-emergent AEs were reported in 14.3 percent of migraine attacks treated with STS101 device planned for commercialization. Furthermore, there was a low rate of adverse event related discontinuation (7% percent). No new safety signals were observed in this study following STS101 treatment.

The study also assessed patient-reported exploratory efficacy. Pain freedom, the most bothersome symptom freedom, and pain relief at 2 hours post-STS101 were self-reported in an eDiary, with two-thirds of patients reporting pain relief at two hours following STS101 administration.

Exploratory endpoints included a patient global impression questionnaire (PGI) assessing the patient's impression of STS101 usability and effectiveness. Most patients reported a positive overall impression of STS101, STS101 was easy to use, and they would use the STS101 if available.

About Satsuma and STS101

Satsuma Pharmaceuticals, a wholly-owned subsidiary of Shin Nippon Biomedical Laboratories, Ltd. (SNBL), is a late-stage biopharmaceutical company that is currently seeking regulatory approval from the U.S. Food and Drug Administration for STS101, a novel, investigational therapeutic product for the acute treatment of migraine. STS101 is a unique and proprietary nasal powder formulation of the well-established anti-migraine drug, dihydroergotamine mesylate (DHE), administered via Satsuma's proprietary nasal delivery device. STS101 is designed to provide patients the combination of quick and convenient

self-administration. Satsuma's nasal powder DHE formulation has demonstrated fast absorption, rapid achievement of high DHE plasma concentrations, sustained DHE plasma levels over time and low dose-to-dose variability.

Satsuma is headquartered in Research Triangle Park, North Carolina. For further information, please visit www.satsumarx.com.

About SNBL

Shin Nippon Biomedical Laboratories, Ltd. ("SNBL") (TSE:2395) is a listed contract research organization (CRO) that was founded in Kagoshima, Japan, in 1957. SNBL's corporate mission has been to support drug development and the improvement of medical technology to free mankind from suffering. Based on its corporate mission, and with a proven record of accomplishment as the oldest and established CRO in Japan, SNBL is proud to be the only company inJapan that can provide a comprehensive portfolio of services and solutions for drug discovery and development for pharmaceutical companies, biotech ventures, universities, and research institutions both in Japan and overseas. The SNBL's Translational Research Business has engaged in drug discovery, with the focus on business development and out-licensing of its proprietary intranasal drug delivery technologies and intranasal devices. SNBL also operates the Medipolis Business, making use of 900 acres of land, mostly forests it owns in Ibusuki-City in Kagoshima prefecture, to promote the local economy and environmental conservation at the same time thorough its geothermal power generation and hospitality businesses including Proton Center for cancer patients. The aim of the Medipolis Business is to contribute to people's well-being, improved quality of life, and happiness. For further information, visit https://www.snbl.co.jp. Inquiries: SHIN NIPPON BIOMEDICAL LABORATORIES, LTD. IR & Corporate Communications (ir@snbl.com)

Cautionary Note on Forward-Looking Statements

Forward-Looking Statements This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding SNBL's future business, future position and results of operations, including estimates, forecasts, targets and plans for SNBL. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding SNBL's business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of product candidates; the impact of health crises such as the coronavirus pandemic on SNBL and its clients and suppliers, including foreign governments in countries in which SNBL operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to SNBL's operations and the timing of any such divestment(s); and other factors identified in SNBL's most recent securities report ("Yuka Shoken Houkokusho") and SNBL's other reports filed with the Financial Services Agency, available on SNBL's website at: https://www.snbl.co.jp/ir/library/ or at https://disclosure.edinet-fsa.go.jp/. SNBL does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or related stock exchange rule. Past performance is not an indicator of future results and the results or statements of SNBL in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of SNBL's future results.

Medical information

This press release contains information about product candidates that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

Inquiries:
Satsuma Pharmaceuticals, Inc.
E-mail: info@satsumarx.com
Website: www.satsumarx.com

SOURCE Satsuma Pharmaceuticals, Inc.
