

Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals and SNBL Receive FDA Acceptance of NDA Resubmission of STS101 for the Acute Treatment of Migraine With or Without Aura

DURHAM, N.C., Nov. 26, 2024 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc., a late-stage biopharmaceutical company, and its corporate parent, Shin Nippon Biomedical Laboratories, Ltd. (TSE:2395), are pleased to announce that the U.S. Food and Drug Administration (FDA) has accepted for review a resubmission to original new drug application (NDA) for the investigational product STS101 (dihydroergotamine nasal powder) for the acute treatment of migraine with or without aura as a complete response to their January 2024 action letter.

The Prescription Drug User Fee Act (PDUFA) date is set as April 30, 2025.

Almost 40 million people in the United States suffer from migraine, especially among working women in their 20s to 40s. The U.S. market for acute migraine medications is estimated to be over USD 1.0 Billion.

Closing Statements

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 in Japan 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 through 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://snbl.com>. 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

*Satsuma
Pharmaceuticals and
SNBL Receive FDA
Acceptance of
Resubmission of
STS101 for the Acute
Treatment of Migraine*

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://snbl.com/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.

<https://investors.satsumarx.com/2024-11-26-Satsuma-Pharmaceuticals-and-SNBL-Receive-FDA-Acceptance-of-NDA-Resubmission-of-STS101-for-the-Acute-Treatment-of-Migraine-With-or-Without-Aura>