Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals and SNBL Resubmits the New Drug Application for STS101 (Dihydroergotamine Nasal Powder) for the Acute Treatment of Migraine With or Without Aura

DURHAM, N.C., Oct. 30, 2024 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc., a late-stage biopharmaceutical company, and its corporate parent, Shin Nippon Biomedical Laboratories, Ltd. (TSE:2395), today announced the resubmission of the new drug application (NDA) for the investigational product STS101 (dihydroergotamine nasal powder) for the acute treatment of migraine with or without aura.

The U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) inJanuary 2024 for the original NDA submitted in March 2023. After a Type A meeting to discuss the contents of the CRL, Satsuma and SNBL believe the NDA resubmission addresses all findings in the CRL.

In the prior CRL, the FDA noted no concerns related with the clinical trial results, including the safety of STS101, and did not request additional clinical trials. However, the Agency provided additional comments primarily related to formulation (Chemistry, Manufacturing, and Control - CMC).

"The resubmission of the STS101 NDA resubmission is a critical step in our mission to bring this unique and new therapy to patients experiencing migraine who often have inadequate treatment options," said Ryoichi Nagata, President and CEO of Satsuma, M.D., Ph.D., FFPM.

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 visitwww.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

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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.

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