Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals and SNBL Announce Publication of Impression of Use and Satisfaction with STS101 (Dihydroergotamine Nasal Powder (Atzumi™)) in Headache

Results show that participant impression through 12 months of treatment indicate STS101 is perceived as favorable across multiple attributes.

Exploratory Efficacy Endpoints showed that STS101 provided rapid freedom from pain, from most bothersome symptoms at 2 hours and sustained treatment benefits over 48 hours after dosing.

DURHAM, N.C., Nov. 5, 2025 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc., a late-stage biopharmaceutical company and its corporate parent, Shin Nippon Biomedical Laboratories, Ltd. (TSE:2395) are dedicated to bringing novel treatments to people who suffer from migraine and other debilitating conditions. 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 this important impression and use data from our pivotal Phase 3 ASCEND study, which further reinforce the potential for STS101 to be a unique, well-tolerated treatment that 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."

In this study, most participants considered STS101 easy to use and indicated they would be likely to use the product if it were available because it worked faster and more consistently, enabling them to return to normal more rapidly in comparison to their usual migraine medications.

"I am pleased that the data supported the clinical benefit of STS101 in the acute treatment of migraine with a reliable and easy to use delivery system. This is exciting and important information for people living with migraine who have experienced difficulties with existing therapies and the practitioners who treat them who are in need of new options," said Jessica Ailani, M.D., Neurologist and UCNS certified headache specialist, Washington, DC. "There remains a need for novel non-oral treatment options for subjects with migraine who are often unable to achieve rapid relief with orally administered medications."

The publication can be found here, http://doi.org/10.1111/head.15086.

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.

About Atzumi™

Atzumi™ is a proprietary drug device product incorporating both Satsuma's advanced nasal powder formulation of dihydroergotamine (DHE) administered via its unique nasal delivery device. The product is designed to provide patients with an easy-to-use and easy-to-carry treatment option.

IMPORTANT SAFETY INFORMATION

WARNING: PERIPHERAL ISCHEMIA FOLLOWING COADMINISTRATION WITH STRONG CYP3A4 INHIBITORS

Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with strong CYP3A4 inhibitors. Because CYP3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of Atzumi™ with strong CYP3A4 inhibitors is contraindicated.

Indication

Atzumi™ is an ergotamine derivative indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

Atzumi™ is not indicated for the preventive treatment of migraine or for the management of hemiplegic migraine or migraine with brainstem aura.

Contraindications

Atzumi™ is not recommended in patients with:
Concomitant use of strong CYP3A4 inhibitors
Ischemic heart disease or coronary artery vasospasm
Uncontrolled hypertension, peripheral arterial diseases, sepsis, following vascular surgery, or severe hepatic or renal impairment
Hypersensitivity to ergot alkaloids
Concomitant use of other 5-HT_1 agonists or ergotamine-containing or ergot-type medication within 24 hours
Concomitant use of peripheral and central vasoconstrictors

Warnings and Precautions

Atzumi™ may cause:
Cardiac events: Cardiac events in patients with risk factors of coronary artery diseases: Consider administration of the first dose of Atzumi™ under medical supervision (including the use of an electrocardiogram)
Cerebrovascular events: Cerebrovascular events (e.g., cerebral hemorrhage, subarachnoid hemorrhage, and stroke) have been reported, particularly with dihydroergotamine mesylate injection
Vasospasm/elevated blood pressure: Dihydroergotamine may cause vasospasm or elevation in blood pressure
Medication overuse headache: Detoxification may be necessary
Preterm labor: Advise pregnant women of the risk
Fibrotic complications: Rare cases have been reported following prolonged daily use of dihydroergotamine mesylate. Administration of Atzumi™ should not exceed the dosing guidelines or be used for chronic daily administration
Local irritation: Local irritation has been reported following administration of Atzumi™
Most Common Adverse Reactions
Most common adverse reactions (incidence >1%) were rhinitis, nausea, altered sense of taste, application site reaction, dizziness, vomiting, somnolence, pharyngitis, and diarrhea.

Use in Special Populations

Pregnancy: Available data from published literature indicate an increased risk of preterm delivery with Atzumi™ use during pregnancy.

Lactation: Patients should not breastfeed during treatment with Atzumi™ and for 3 days after the last dose.

Please see the Atzumi™ Full Prescribing Information, including Boxed Warning and Medication Guide.

The risk information provided here is not comprehensive. The FDA-approved product labeling can be found at www.satsumarx.com. You can also call 1-888-273-2480 for additional information.

About Satsuma Pharmaceuticals

Satsuma Pharmaceuticals Inc., a wholly-owned subsidiary of Shin Nippon Biomedical Laboratories, Ltd. (SNBL), is a late-stage biopharmaceutical company headquartered in Research Triangle Park, North Carolina. Since its inception in 2016, Satsuma has focused on combining great science, cutting-edge technology and proven drug therapies to create improved therapeutic products that address the significant unmet needs of patients. Satsuma's team has extensive experience successfully developing, manufacturing and commercializing pharmaceutical products within both large and small companies, and we have particular expertise in the area of drug-device combination products delivered via inhalation. For further information, please visit www.satsumarx.com.

About SNBL

Shin Nippon Biomedical Laboratories, Ltd. ("SNBL") (TSE:2395) is a listed nonclinical contract research organization (CRO) that was founded in Kagoshima, Japan, in 1957. Based on its corporate philosophy of "Committed to the environment, life, and people", and with a proven track record of accomplishment as the oldest and most established Japanese nonclinical CRO, SNBL is proud to offer 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 engages in drug discovery, with the focus on business development and out-licensing of its proprietary intranasal drug delivery technologies and intranasal devices. For further information, please visit https://en.snbl.com/.

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

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