Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces U.S. FDA Approval for Atzumi™ (Dihydroergotamine) Nasal Powder for the Acute Treatment of Migraine

- *Atzumi™ (dihydroergotamine(DHE)) nasal powder is the first and only DHE nasal powder for the acute treatment of migraine with or without aura in adults in an easy-to-use, easy-to-carry device.*
- *Atzumi is the first and only product utilizing the SMART (Simple MucoAdhesive Release Technology) platform which combines a proprietary advanced powder and device technology to simplify delivery of DHE.*
- *In clinical studies, Atzumi administration provided rapid and sustained DHE concentrations with low variability.*

DURHAM, N.C., April 30, 2025 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc., a late-stage biopharmaceutical company dedicated to bringing novel treatments to people who suffer from migraine and other debilitating conditions, and its corporate parent, Shin Nippon Biomedical Laboratories, Ltd. (TSE:2395), today announced that the U.S. Food and Drug Administration (FDA) has approved a 505(b)(2) New Drug Application (NDA) for Atzumi™(dihydroergotamine (DHE)) nasal powder for the acute treatment of migraine with or without aura in adults. Atzumi was previously known as STS101.

Migraine is a neurological disorder that is thought to be the result of temporary changes in the chemicals, nerves and blood vessels in the brain, with symptoms that are often incapacitating. According to the American Migraine Foundation, approximately 40 million Americans live with migraine. It is the second leading cause of disability worldwide in terms of time lost to disability and most common cause of disability among young women.

"The approval of Atzumi is a milestone to celebrate, providing a new option for the acute treatment of migraine combining long-proven benefits of DHE with a patient-friendly and easy-to-use delivery system developed based on SNBL's novel intranasal drug delivery platform technology," said Dr. Ryoichi Nagata, President and CEO of Satsuma. "We believe that Atzumi will contribute to improving the quality of life of patients struggling for relief from these highly disabling problems."

"DHE plays a unique clinical role in the acute treatment of migraine, providing patients long lasting effects and the unique ability to provide benefit even when taken late in a migraine attack. The convenience of Atzumi, the only DHE nasal powder, will offer patients ease of use combined with the important known DHE clinical advantages", said Dr. Stewart J. Tepper, M.D., Vice President of the New England Institute for Neurology and Headache in Stamford, Connecticut.

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 an easy-to-use and easy-to-carry treatment option.

The FDA approval for Atzumi is based on two clinical studies (Phase 1 PK trial and ASCEND Phase 3 open-label, long-term safety trial), which demonstrated fast absorption, rapid achievement of high DHE plasma concentrations, and sustained DHE plasma levels over time as well as safety and tolerability in subjects with migraine.

About Dihydroergotamine (DHE)

Since its approval in 1946, DHE has long been recommended in published migraine treatment guidelines as a first-line acute treatment option for migraine and has significant advantages versus other anti-migraine treatments for many patients. However, disadvantages of current DHE liquid nasal spray and injectable products, including invasive and burdensome administration and/or sub-optimal clinical performance, have limited the widespread use of DHE.

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 (eg, 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 us 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/.

Cautionary Note on 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 Satsuma's future business, future position and results of operations, including estimates, forecasts, targets and plans for Satsuma. 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 uncertainty of commercial success for new and existing products; claims or concerns regarding the safety or efficacy of product candidates; 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; fluctuations in interest and currency exchange rates; the impact of health crises such as the coronavirus pandemic on Satsuma and its clients and suppliers, including foreign governments in countries in which Satsuma 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 Satsuma'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://en.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.

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