

## PRESS RELEASE



May 1, 2025

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

**TOKYO and KAGOSHIMA, Japan, May 1, 2025 – Shin Nippon Biomedical Laboratories, Ltd.** (TSE Prime: 2395, Chairman and President: Ryoichi Nagata, M.D., Ph.D., “SNBL”) and its wholly-owned US subsidiary, Satsuma Pharmaceuticals, Inc., a late-stage biopharmaceutical company dedicated to bringing novel treatments to people who suffer from migraine and other debilitating conditions, 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, previously known as STS101, is the first FDA-approved intranasal drug developed based on SNBL's unique intranasal drug delivery platform technology.

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 impact of this matter on SNBL's consolidated business performance is under review, and we will promptly make an announcement, should any matter arise that needs to be disclosed.

"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."

#### **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 and 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).

#### **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](http://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

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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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