PRESS RELEASE

January 18, 2024

FDA Issues Complete Response Letter for Satsuma's STS101

TOKYO and KAGOSHIMA, Japan, January 18, 2024 – Shin Nippon Biomedical Laboratories, Ltd. (TSE Prime: 2395, Chairman and President: Ryoichi Nagata, M.D., Ph.D., "SNBL") announced today that 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, received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) in response to the Satsuma's New Drug Application (NDA) for STS101 (dihydroergotamine nasal powder). STS101 is an investigational product for the acute treatment of migraine with or without aura in adults.

The FDA indicated in the CRL that it has completed its review of the NDA and determined that it cannot be approved in its present form. The principal reasons described in the CRL relate to chemistry, manufacturing, and controls (CMC) considerations. Satsuma intends to provide potential timing for a resubmission following consultation with the FDA. The CRL did not indicate any concerns about the clinical data package in the NDA, and the FDA did not request any new clinical trials to support the approval of STS101.

"We remain committed to working expeditiously with the FDA to complete the review for STS101 as soon as possible," said Dr. Ryoichi Nagata, President and Chief Executive Officer of Satsuma.

About STS101

STS101 is a proprietary drug device investigational 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's review for STS101 was 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. For more information about STS101, please visit, www.satsumarx.com.

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. SNBL also operates the Medipolis business, making use of a large tract of land and forests it owns in Ibusuki City in Kagoshima, Japan, to promote the local economy and environmental conservation thorough its power generation and hospitality businesses, and other sustainability initiatives. For further information, please visit www.snbl.co.jp.

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://www.snbl.co.jp/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.

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