PRESS RELEASE

October 31, 2024

SNBL's Subsidiary Satsuma Pharmaceuticals Resubmits New Drug Application for STS101 for Acute Treatment of Migraine With or Without Aura

TOKYO and KAGOSHIMA, Japan, October 31, 2024 – Shin Nippon Biomedical Laboratories, Ltd. (TSE Prime: 2395, Representative Chairman, President & CEO: Ryoichi Nagata, M.D., Ph.D.; hereinafter "SNBL") is pleased to announce 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, resubmitted the new drug application (NDA) for the investigational product STS101 (dihydroergotamine nasal powder) for the acute treatment of migraine with or without aura on October 30, 2024, US Eastern time.

The U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) in January 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 impact of this matter has already been incorporated into SNBL's consolidated financial forecasts for the fiscal year ending March 31, 2025.

"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."

Inquiries
Shin Nippon Biomedical Laboratories, Ltd.
IR & Corporate Communications
Email: ir@snbl.com

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