PRESS RELEASE

November 26, 2024

SNBL's Subsidiary, Satsuma Pharmaceuticals Receives FDA Acceptance of NDA Resubmission of STS101 for the Acute Treatment of Migraine With or Without Aura

TOKYO and KAGOSHIMA, Japan, November 26, 2024 – Shin Nippon Biomedical Laboratories, Ltd. (TSE Prime: 2395, Representative Chairman, President & CEO: Ryoichi Nagata, M.D., Ph.D.; hereinafter "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, are pleased to announce that the U.S. Food and Drug Administration (FDA) has accepted for review a resubmission to original new drug application (NDA) for the investigational product STS101 (dihydroergotamine nasal powder) for the acute treatment of migraine with or without aura as a complete response to their January 2024 action letter.

The Prescription Drug User Fee Act (PDUFA) date is set as April 30, 2025.

Almost 40 million people in the United States suffer from migraine, especially among working women in their 20s to 40s. The U.S. market for acute migraine medications is estimated to over USD 1.0 Billion.

The impact of this matter has already been incorporated into SNBL's consolidated financial forecasts for the fiscal year ending March 31, 2025.

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