Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces FDA Acceptance of 505(b)(2) NDA for STS101, a Novel and Investigational Dihydroergotamine (DHE) Nasal Powder Product for the Acute Treatment of Migraine

January 2024 PDUFA date expected

If approved, STS101 would become the only DHE product evaluated in a randomized, placebo-controlled trial (the SUMMIT trial) against modern outcome measures recommended by both the U.S. Food and Drug Administration (FDA) and International Headache Society

Unlike current DHE products, STS101 is designed to be easy-to-carry, quick and easy to self-administer within seconds without need for involved administration procedures and to rapidly achieve high drug plasma levels believed necessary for robust efficacy and to be below those levels associated with adverse events such as nausea and vomiting

As announced on April 13, 2023 Satsuma entered into a definitive agreement to be acquired by Shin Nippon Biomedical Laboratories, Ltd. (SNBL; TSE: 2395), and on May 5, 2023 SNBL commenced a tender offer for Satsuma, which will expire at 12:00 A.M. (Eastern time) at the end of June 5, 2023 unless extended or earlier terminated

South San Francisco, CA, May 18, 2023 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a development-stage biopharmaceutical company today announced that its 505(b)(2) new drug application (NDA) for STS101, a novel and investigational therapeutic product candidate for the acute treatment of migraine, has been accepted for review by the FDA.

Satsuma's President and Chief Executive Officer, John Kollins, stated, "We are proud to announce the FDA acceptance for review of our STS101 NDA, as it represents an important milestone for our company and an important step toward achieving our goal of making STS101 available as an easy-to-use, effective, and safe and well-tolerated DHE treatment that can address the significant unmet clinical needs of many people with migraine."

Satsuma's STS101 NDA is supported primarily by clinical trials results from the Phase 1 comparative pharmacokinetic and safety trial of STS101 completed in June 2021 and the STS101 ASCEND Phase 3 long-term, open-label safety trial in which 446 subjects treated more than 9,000 migraine attacks with more than 10,500 doses of STS101 for up to 18 months.

Although not required for approval based on Satsuma's communications with the FDA, results from the 1,600-subject STS101 SUMMIT Phase 3 double-blind, placebo-controlled efficacy trial are also included in the NDA. Satsuma announced topline SUMMIT trial results in November 2022 and subsequently announced further results in December 2022. Although STS101 demonstrated numerical, but not statistical significance on SUMMIT trial primary outcome measures (% of subjects free from pain and % of subjects free from most-bothersome-symptom[1] at two hours post-dose), STS101 did demonstrate robust and sustained effects ($p<0.001$) on those endpoints at all post-dose timepoints after two hours (3, 4, 6, 12, 24 and 48 hours). STS101 also demonstrated robust and sustained antimigraine effects across numerous secondary endpoints considered relevant and recommended for assessment in efficacy trials by the FDA in its current industry guidance document and/or the

International Headache Society's guidelines for controlled trials of acute treatment of migraine attacks[2,3].

Pending acquisition of Satsuma by SNBL

On April 16, 2023, Satsuma Pharmaceuticals announced that it had entered into a definitive agreement to be acquired by Shin Nippon Biomedical Laboratories, Ltd. (TSE: 2395, "SNBL") for $0.91 in cash per share at the closing of the transaction plus one non-tradeable contingent value right ("CVR") of up to $5.77 per share. CVR holders will be entitled to receive payments related to proceeds received by SNBL in a future transaction involving STS101, including a potential sale, license, or other grant of rights ("Monetization Event"). The CVR is based on cumulative proceeds received by SNBL from the Monetization Event after making certain deductions. On May 5, 2023 SNBL commenced a tender offer for Satsuma, which will expire at 12:00 A.M. (Eastern time) at the end of June 5th unless extended or earlier terminated.

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic product, STS101, for the acute treatment of migraine. STS101 is a unique and proprietary nasal powder formulation of the well-established anti-migraine drug, dihydroergotamine mesylate (DHE), administered via Satsuma's proprietary nasal delivery device. STS101 is designed to provide significant benefits versus existing acute treatments for migraine, including the combination of quick and convenient self-administration and other clinical advantages, that current DHE liquid nasal spray products and injectable dosage forms lack. Satsuma's dry powder DHE formulation has demonstrated fast absorption, rapid achievement of high DHE plasma concentrations which Satsuma believes is necessary for robust efficacy, and sustained DHE plasma levels over time with low dose-to-dose variability. 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. Featuring an easy-to-carry and easy-to-use dosage form, STS101 is designed to overcome these shortcomings and provide patients an improved therapeutic solution for acutely treating migraines that consistently delivers robust clinical performance.

Satsuma is headquartered in Research Triangle Park, North Carolina. For further information, please visit www.satsumarx.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements concerning the business, operations and financial performance and condition of Satsuma Pharmaceuticals, Inc. (the "Company"), as well as the Company's plans, objectives and expectations for its business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about the Company's expectations regarding the potential safety and efficacy of STS101, whether STS101 will be approved, the ability to complete the transactions contemplated by the merger agreement, including the parties' ability to satisfy the conditions to the consummation of the offer contemplated thereby and the other conditions set forth in the merger agreement, the expected PDUFA date, and expectations regarding the potential applicability of STS101 to treat migraines. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The Company's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time. In addition to the risks described above and in the Company's other filings with the SEC, other unknown or unpredictable factors could also affect the Company's results. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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[1] From among photophobia, phonophobia or nausea as indicated by subjects immediately prior to treatment with study medication.

[2] FDA Guidance, *Migraine: Developing Drugs for Acute Treatment*, February 2018

[3] Diener et al., *Guidelines of the International Headache Society for controlled trials of acute treatment of migraine attacks in adults: Fourth Edition, Cephalalgia, 2019*

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