Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces Positive Results from the Ongoing STS101 ASCEND Phase 3 Open-label, Long-term Safety Trial

- STS101 demonstrated a favorable safety and tolerability profile, consistent with clinical experience to date
- Over 8,000 migraine attacks treated with more than 10,000 doses of STS101; of which, over 5,500 migraine attacks treated with more than 6,900 doses of STS101Mk2, the investigational product incorporating the improved, second-generation nasal delivery device for which Satsuma intends to seek marketing approval
- Subject exposures over time with STS101Mk2 exceed FDA requirement to support planned NDA submission in Q1 2023, and potential approval
- Subjects using STS101Mk2 exclusively to treat their migraine attacks achieved freedom from pain by 2 hours post-treatment in 34.2% of treated attacks and freedom from most-bothersome-symptom (MBS) by 2 hours post-treatment in 53.4% of treated attacks
- In exploratory post-hoc analyses, STS101Mk2 demonstrated improved clinical performance versus STS101Mk1 (the investigational product incorporating a first-generation nasal delivery device)

South San Francisco, CA, September 20, 2022 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company developing STS101 (dihydroergotamine (DHE) nasal powder), a novel investigational therapeutic product candidate for the acute treatment of migraine, today announced positive safety, tolerability and efficacy results from its recent analysis of the Company's ongoing STS101 ASCEND Phase 3 open-label, long-term safety trial.

The primary objective of the ASCEND trial is to assess the safety and tolerability of STS101 in the acute treatment of migraine attacks over 6 and 12 months. Satsuma expects the results from this analysis, in addition to Phase 1 trial data and results from its ongoing SUMMIT Phase 3 efficacy trial, which the Company expects to announce in the fourth quarter of 2022, to support submission of a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) planned for the first quarter of 2023. Satsuma intends to seek marketing approval for and, if approved, commercialize $STS101_{Mk2}$, which incorporates the improved, second-generation nasal delivery device.

A secondary objective of the ASCEND open-label trial is to assess the efficacy of STS101 in the acute treatment of migraine attacks over time. In addition, exploratory post-hoc analyses were performed to assess the clinical performance of $STS101_{Mk2}$ versus $STS101_{Mk1}$.

"The results reported today from this open-label, long-term safety trial in which subjects administered STS101 to treat their migraine attacks for as long as 18 months in a real-world setting, confirm the favorable safety and tolerability profile of STS101 observed to date in more than 1,600 clinical trial participants and provide important safety information for our planned NDA submission," stated John Kollins, Satsuma's President and Chief Executive Officer. "Additionally, the efficacy signals observed with $STS101_{Mk2}$, including the robust reported rates for freedom-from-pain and freedom-from-MBS by 2 hours post-treatment, are consistent with its demonstrated improved drug delivery performance as compared to $STS101_{Mk1}$, which incorporated a first-generation nasal delivery device."

"New and effective evidence-based treatments for migraine are urgently needed, especially for the many people with migraine for whom other treatment options, including triptans and gepants, are slow to work, provide insufficient relief or are not well-tolerated," stated Alan M. Rapoport, M.D., Professor of Neurology at UCLA and former President of the International Headache Society. "DHE has long been recommended as a first-line option for the acute treatment of migraine, but the currently-available injectable and liquid nasal spray dosage forms have significant drawbacks that result in limited prescribing, utilization and acceptance among patients. The totality of data generated to date with STS101 point to its potential to transform the paradigm for the acute treatment of migraine attacks. If the outcome of the ongoing SUMMIT Phase 3 efficacy trial is positive and leads to FDA approval, I anticipate many health care practitioners will incorporate STS101 into their treatment plans for their migraine patients."

STS101 demonstrated a favorable safety and tolerability profile, consistent with Phase 1 and Phase 3 clinical experience to date

Among 344 subjects who self-administered at least one dose of $STS101_{Mk2}$, and in total more than 6,900 doses, to treat their migraine attacks on an as-needed basis for up to approximately 18 months (as of June 30, 2022), safety and tolerability results were as follows:

- No clinically relevant nasal safety or tolerability findings, clinically relevant systemic safety findings, or unexpected

treatment-related serious adverse events were reported
- Treatment-related, treatment-emergent adverse events (TEAEs) reported among 5% or more of subjects or in 5% or more of attacks treated with $STS101_{Mk2}$ were as follows:
    - nasal discomfort, which occurred in 11% of subjects and 6.1% of treated attacks; and
    - dysgeusia, which occurred in 7.6% of subjects and in 2.8% of treated attacks
- TEAEs were typically mild (82.7%) and transient
- Nausea or vomiting attributed to treatment with $STS101_{Mk2}$ occurred infrequently: 1.7% of subjects reported nausea in 0.2% of total treated attacks, and 1.2% of subjects reported vomiting in 0.1% of total treated attacks
- A low proportion of subjects (4.1%) cited an adverse event as the reason for discontinuing participation in the trial

Subject exposures over time $STS101_{Mk2}$ exceed FDA requirement to support NDA filing and potential marketing approval

The number of subjects (n=166) who treated an average of at least two migraine attacks per month for at least six months with $STS101_{Mk2}$ exceeded the 150-subject exposure-over-time requirement communicated to the Company by the FDA as necessary to support the planned NDA filing and potential marketing approval.

Among 172 trial participants who treated 1,932 migraine attacks exclusively with $STS101_{Mk2}$:

- Freedom from pain by 2 hours post-treatment (2hPF response) was achieved in 34.2% of all treated attacks
- Freedom from most-bothersome-symptom by 2 hours post-treatment (2hMBS response) was achieved in 53.4% of all treated attacks
- In more than 81% of treated attacks, subjects did not report utilizing an allowed second dose of $STS101_{Mk2}$ within 48 hours of administering the first dose
- In more than 94% of treated attacks, subjects did not report utilizing any rescue medications within 48 hours of administering $STS101_{Mk2}$
- A high proportion of treated attacks were characterized by baseline symptoms predictive of inadequate response to treatment, such as severe pain (47% of attacks), photophobia (97% of attacks), phonophobia (94% of attacks) and nausea (65% of attacks)[2]

Exploratory post-hoc analyses of $STS101_{Mk2}$ versus $STS101_{MK1}$ clinical performance

Among subjects who treated their first migraine attack following trial enrollment with $STS101_{Mk2}$, the 2hPF and 2hMBS response rates for the first treated attack were respectively 7.8% and 6.9% greater, in absolute percentage points, than the corresponding 2hPF and 2hMBS response rates reported by subjects who treated their first migraine attack in the trial with $STS101_{Mk1}$.

The Company believes the higher first-treated-attack 2hPF and 2hMBS response rates achieved in the ASCEND trial with $STS101_{Mk2}$ may reflect its demonstrated improved drug delivery performance versus $STS101_{Mk1}$. $STS101_{Mk2}$ is being evaluated for efficacy and safety in the ongoing SUMMIT Phase 3, placebo-controlled trial.

STS101 ASCEND Phase 3 Long-term Safety Trial

The STS101 ASCEND Phase 3 long-term safety trial is a multi-center, open-label trial in subjects with migraine that is being conducted in the United States. The primary objective of the ASCEND trial is to assess the safety and tolerability of STS101 in the acute treatment of migraine attacks over 6 and 12 months. A secondary objective the trial is to assess the efficacy of STS101 in the acute treatment of migraine attacks over time. The trial is designed (i) to meet the subject exposure-over-time requirements communicated by the FDA to Satsuma, and (ii) in accordance with recommendations contained in the FDA's current guidance document for industry (*Migraine Developing Drugs for Acute Treatment, February 2018*).

Initiated in August 2020, the ASCEND trial enrolled more than 480 subjects, 466 of whom self-administered at least one dose of either $STS101_{Mk1}$ or $STS101_{Mk2}$ study medication. The Company completed a transition of study medication from $STS101_{Mk1}$ to $STS101_{Mk2}$ in the first half of 2021. As of June 30, 2022, study participants had treated more than 8,000 migraine attacks with more than 10,000 doses of STS101, and approximately 100 subjects remained active in the trial. Approximately 19% of subjects who enrolled in the trial were discontinued by the Company due to having an insufficient number of migraine attacks to contribute toward attainment of the exposure-over-time objectives for the trial.

STS101 is administered intermittently in the ASCEND trial to reflect the episodic nature of migraine and mimic the way in which patients often experience and treat migraine attacks. After establishing full eligibility, ASCEND trial participants are instructed to treat their migraine attacks with a single dose of STS101, and may do so for as long as approximately 18 months. Trial participants have the option of taking a second dose of STS101 or rescue medication to treat a nonresponding migraine or migraine recurrence, subject to a maximum of twelve doses of STS101 per month.

Programming of the electronic diary device utilized by ASCEND subjects may result in early efficacy data entry by trial participants. As in the previously-reported EMERGE Phase 3 efficacy trial, ASCEND subjects self-reported efficacy results using an electronic diary device that was programmed with an alarm to prompt study subjects to enter their efficacy results into the device prior to the nominal post-treatment timepoints.

For further information regarding the STS101 ASCEND Phase 3 long-term safety trial, see www.ClinicalTrials.gov, identifier NCT04406649: A Study to Evaluate STS101 in the Acute Treatment of Migraine (ASCEND).

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 early efficacy, and sustained DHE plasma levels over time with low dose-to-dose variability. STS101 also now incorporates an improved second-generation nasal delivery device designed to provide more consistent nasal dosing, irrespective of user administration technique. 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 South San Francisco, California with operations in both California and 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, the potential results of the ASCEND and SUMMIT trials, the timing of data readouts for ongoing clinical trials, the anticipated timing for a potential STS101 NDA submission, the potential for STS101 to be an important and differentiated acute treatment option, and the expected cash runway of the Company. 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 June 30, 2022, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the Company's ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of STS101; the results of preclinical and clinical studies may not be predictive of future results; and the risk that the COVID-19 worldwide pandemic may negatively impact the Company's business, operations, clinical trials or ability to raise capital. 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.

This press release discusses STS101, a product candidate that is in clinical development, and which has not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of STS101 for the therapeutic use for which STS101 is being studied.

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[1] In this communication, we refer to "STS101$_{Mk2}$" as the investigational product incorporating the improved, second-generation nasal delivery device and to "STS101$_{Mk1}$" as the investigational product incorporating a previous first-generation nasal delivery device.

[2] Christoph-Diener et al, NEUROLOGY 2004;63:520-524

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https://investors.satsumarx.com/2022-09-20-Satsuma-Pharmaceuticals-Announces-Positive-Results-from-the-Ongoing-STS101-ASCEND-Phase-3-Open-label,-Long-term-Safety-Trial