Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Provides STS101 Development Program and Corporate Update

- Further analysis of results from recently-completed SUMMIT Phase 3 efficacy trial of STS101 for the acute treatment of migraine shows differentiating robust and sustained antimigraine effects on clinically important secondary endpoints

- Qualitative and quantitative primary market research conducted post-SUMMIT trial readout and incorporating updated STS101 profile consistent with SUMMIT trial results indicates headache specialists continue to have strong interest in STS101, with high prescribers of migraine therapeutics anticipating prescribing it to approximately 30% of their migraine patients

- Based on communications with FDA in multiple Type C meetings and May 2022 Type B clinical pre-NDA meeting, and discussions with legal-regulatory consultants, Satsuma believes the results of its STS101 clinical trial program support planned NDA filing in Q1 2023 and potential approval

- Based on input from expert legal-regulatory and statistical consultants, Satsuma believes there is a compelling rationale, with regulatory precedents, for including a portion of the SUMMIT trial efficacy results in the STS101 prescribing information, despite STS101 not achieving statistical significance ($p<0.05$) versus placebo on study co-primary endpoints at the primary timepoint of two hours post-treatment

- Commercial manufacturing capability established to support NDA filing, potential approval and subsequent product launch

- Satsuma is working to secure a commercialization partner for STS101

South San Francisco, CA, December 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 provided an update on its STS101 development program and corporate update.

SUMMIT Phase 3 efficacy trial recap

Recapping results from the STS101 SUMMIT Phase 3 efficacy trial, the largest-ever clinical trial conducted with any DHE product:

- High proportions of subjects' treated migraine attacks had symptoms predictive of poor response to treatment.
- STS101 demonstrated numerical but not statistically significant differences versus placebo on the study co-primary endpoints (% of subjects free from pain and % of subjects free from most-bothersome-symptom (MBS)[1] at two hours post-dose.)
- STS101 demonstrated robust and sustained effects ($p<0.001$) on the key study endpoints, freedom from pain and freedom from MBS, at all post-dose timepoints after 2 hours (3, 4, 6, 12, 24 and 48 hours).
- As detailed below, STS101 demonstrated robust and sustained antimigraine effects across numerous secondary endpoints considered clinically relevant and recommended for assessment in efficacy trials by the U.S. Food and Drug Administration (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]

Endpoint	Time (post-dose)	p-value (nominal)*
Pain relief	All timepoints 2 – 48h	<0.002
Sustained freedom from pain	2 – 24h	0.0470
No use of rescue medication	within 24h and 48h	<0.0001
Freedom from photophobia	all timepoints 3 – 48h	≤0.01
Freedom from phonophobia	all timepoints 3 – 48h	≤0.02
Freedom from nausea	all timepoints 3 – 48h	≤0.01
Time to pain freedom	-na-	<0.0001
Time to MBS freedom	-na-	<0.0001
Total Migraine Freedom**	all timepoints 3 – 48h	≤0.014
Return to normal function	all timepoints 4*** – 48h	≤0.001
* For endpoints evaluated at multiple timepoints, listed p-values are the highest of any timepoint in range		

** Total Migraine Freedom defined as freedom from pain, photophobia, phonophobia and nausea

*** Return to normal function assessed at only at 1, 2, 4, 24 and 48h timepoints

- In addition, STS101 demonstrated efficacy in subjects who experienced common and difficult-to-treat migraine attack types, including migraine with allodynia and menstrually-associated migraine.
- Consistent with clinical trial experience to date in subjects who have administered more than 10,000 doses of STS101 to treat their migraine attacks, STS101 demonstrated a favorable safety and tolerability profile in SUMMIT. The only treatment-emergent adverse event reported by more than 5% of SUMMIT subjects who self-administered STS101 was nasal discomfort, reported by 8.3% and 1.5% of subjects who self-administered STS101 and placebo, respectively. No treatment-related serious adverse events or cardiovascular events occurred.

STS101 demonstrates differentiated profile with primary market research conducted post-SUMMIT trial readout indicating potential for broad use

The Company believes STS101 has the potential to address the unmet needs of many of the ~40 million people with migraine in the U.S. given its differentiated profile characterized by (i) demonstration of robust and sustained single-dose antimigraine effects in a large, randomized, placebo-controlled clinical trial; (ii) elegant simplicity and ease-of-use; and (iii) favorable safety and tolerability. Qualitative and quantitative primary market research with headache specialists and prescribers of migraine therapeutics undertaken by Satsuma following announcement of SUMMIT trial results, and which utilized an updated STS101 product profile incorporating SUMMIT trial results, indicate physicians view STS101 as having broad potential therapeutic utility across a variety of migraine patient- and attack types. Interviewed and surveyed physicians expressed strong interest in prescribing STS101 for a broad range of migraine patient and migraine attack types, with surveyed physicians indicating intent to prescribe STS101 for approximately 30% of their patients with migraine[4]. The results of this primary market research are consistent with previous market research conducted by Satsuma indicating that physicians' strong interest in and intent to prescribe STS101 was minimally dependent on the magnitude of effect size demonstrated by STS101 against co-primary endpoints at two hours post-dosing in a Phase 3 efficacy trial, and rather was driven by the unique overall profile and attributes of STS101.

Clear near-term path to regulatory approval with compelling rationale for inclusion of SUMMIT trial efficacy results in STS101 prescribing information

Based on its communications with FDA in multiple Type C meetings and the May 2022 Type B clinical pre-NDA meeting, Satsuma believes the results of its STS101 clinical trial program, and in particular results from the Phase 1 comparative PK study completed in 2021 and the on-going ASCEND long-term, open-label safety trial, support a planned NDA filing in Q1 2023 and potential approval. In addition, based on input from expert legal-regulatory and statistical consultants, Satsuma believes there is a compelling rationale, with regulatory precedents, for including a portion of the SUMMIT trial efficacy results in the STS101 prescribing information, despite STS101 not achieving statistical significance ($p<0.05$) versus placebo on study co-primary endpoints at the primary timepoint of two hours post-treatment.

"Further analysis of SUMMIT trial results, input from our legal-regulatory and statistical consultants, and results of recent qualitative and quantitative physician market research, all confirm our view that STS101 has a highly differentiated profile that positions it as the first and only DHE product suitable for broad use by, and with the potential to address the unmet needs of many of, the estimated forty million people in the United States who experience migraine," stated John Kollins, Satsuma's President and Chief Executive Officer. "The totality of high-quality evidence from our SUMMIT trial, as well as from our other STS101 clinical trials, clearly indicate STS101 has robust and sustained antimigraine effects, including for subjects and attacks characterized by the presence of symptoms that predict poor response to treatment. We believe the results of our STS101 clinical program will support our planned STS101 NDA filing in Q1 2023 and subsequent approval, with compelling arguments for inclusion of efficacy results from the SUMMIT trial in the STS101 prescribing information."

Consistent with prior guidance, Satsuma remains on track to submit the STS101 NDA in the first quarter of 2023. In parallel, the Company is working to secure a commercialization partner for STS101.

Updated Investor Presentation

Concurrent with today's update, Satsuma has made available an updated investor presentation, which can be found in the Events and Presentations section of the company's Investors website, here.

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 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 September 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.

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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*

[4] Survey of ~100 physicians who are high prescribers of migraine therapeutics, approximately half of whom were neurologists and half primary care physicians.
