

Satsuma Pharmaceuticals Announces Positive Pharmacokinetic, Tolerability and Safety Results From Phase 1 Trial of STS101 at Multiple Dose Strengths

- *All three dose strengths of STS101, administered with improved 2nd-generation nasal delivery device were well-tolerated and achieved target pharmacokinetic profile -*
- *Initiating SUMMIT Phase 3 efficacy trial to evaluate STS101 5.2 mg in the acute treatment of migraine attacks -*

South San Francisco, CA, June 16, 2021 – [Satsuma Pharmaceuticals, Inc.](https://investors.satsumarx.com) (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 pharmacokinetic, tolerability and safety results from a Phase 1 trial of STS101. The Phase 1 data showed that all three dose strengths (5.2 mg and two higher dose strengths) administered with Satsuma’s improved second-generation nasal delivery device were well-tolerated and achieved the target pharmacokinetic profile. Based on results from this Phase 1 trial and other data, including preliminary results to date from the ongoing Phase 3 ASCEND long-term, open-label safety trial of STS101 5.2 mg, Satsuma is initiating its SUMMIT Phase 3 efficacy trial with the 5.2 mg dosage strength of STS101. As previously communicated, top-line results from the SUMMIT trial are expected in the second half of 2022.

“The totality of data generated in our STS101 development program, including these new Phase 1 data and improved delivered dose results, strongly support evaluating the 5.2 mg dosage strength of STS101 in the upcoming SUMMIT Phase 3 efficacy trial,” stated John Kollins, Satsuma’s President and Chief Executive Officer. “With the second-generation STS101 device and improved instructions-for-use, we expect subjects in SUMMIT will consistently self-administer the full DHE dose with less variability than in the previous EMERGE Phase 3 trial. We believe these improvements, in combination with the adjustments to the conduct of the trial, should result in STS101 demonstrating robust anti-migraine activity in the SUMMIT trial that could support product approval with differentiated labeling.”

Satsuma has provided further detail on the STS101 development program, including STS101 Phase 1 trial results, preliminary results from the ongoing ASCEND trial, and further details on the design of the SUMMIT trial, in its latest corporate presentation available for download from its website: <https://investors.satsumarx.com/events>

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 2nd-generation 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 plasma levels over time with low dose to dose variability. STS101 also now incorporates an improved 2nd-generation nasal delivery device designed to provide more consistent nasal dosing, irrespective of user administration technique. Although 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, disadvantages of current DHE liquid nasal spray and injectable products, including invasive and burdensome administration processes and/or sub-optimal clinical performance, have limited the widespread use of DHE. Featuring a compact and convenient 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.

About the SUMMIT Phase 3 Trial

The STS101 SUMMIT Phase 3 efficacy trial is a multi-center, single-treatment, randomized, double-blind, placebo-controlled, parallel group study to be conducted in the United States which seeks to enroll approximately 1,400 migraine patients. The SUMMIT study is designed in accordance with FDA recommendations outlined in the FDA Guidance *Migraine: Developing Drugs for Acute Treatment*, February 2018. After establishing full eligibility, SUMMIT trial participants will be randomized (1:1) to receive either STS101 DHE 5.2 mg or matching placebo and instructed to treat their next migraine attack of at least moderate pain severity with the allocated blinded study medication. Consistent with the previous EMERGE Phase 3 trial, the two co-primary endpoints of the SUMMIT trial are freedom from pain and freedom from most bothersome symptom (from among photophobia, phonophobia or nausea), both of which are assessed at two hours after administration of study medication.

Satsuma is headquartered in South San Francisco, California with offices in both South San Francisco and Durham, 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 initiation and data readouts for ongoing and planned clinical trials, and the potential for STS101 to be an important and differentiated acute treatment option for migraine. 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, 2021, 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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