Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces Completion of Enrollment in SUMMIT Pivotal Phase 3 Efficacy Trial of STS101 for the Acute Treatment of Migraine

- More than 1,400 subjects randomized -
- Satsuma expects to announce topline SUMMIT trial results in Q4 2022 -

South San Francisco, CA, August 2, 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 completion of subject enrollment in the Company's ongoing STS101 SUMMIT pivotal Phase 3 efficacy trial, with more than 1,400 subjects randomized. Satsuma expects to announce topline results from the SUMMIT trial in the fourth quarter of 2022.

"We are pleased to report completion of subject enrollment in the STS101 SUMMIT Phase 3 efficacy trial, the largest-ever randomized and controlled trial of a DHE product," stated John Kollins, Satsuma's President and Chief Executive Officer. "This marks an important milestone in our STS101 development program. We look forward to reporting SUMMIT trial topline results in the fourth quarter of 2022, and, in the interim, to reporting further STS101 development program progress and clinical data, including topline results from our ongoing STS101 ASCEND Phase 3, open-label, long-term safety trial."

STS101 SUMMIT Pivotal Phase 3 Efficacy Trial

The STS101 SUMMIT pivotal Phase 3 efficacy trial is a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in more than 1,400 subjects with migraine that is being conducted in the United States. The trial is designed in accordance with recommendations contained in the U.S. Food and Drug Administration's (FDA) current guidance document for industry (*Migraine Developing Drugs for Acute Treatment, February 2018*) and the International Headache Society's (IHS) published guidelines for controlled trials of acute treatment of migraine attacks in adults.[1] The SUMMIT trial, the largest-ever randomized and controlled trial of a DHE product, provides a basis for STS101 to become the first and only DHE product to demonstrate efficacy in a randomized and controlled trial on co-primary endpoints (freedom from pain and freedom from most bothersome symptom at two hours post-treatment) currently recommended by the FDA and IHS. Based on Satsuma's communications with the FDA, including a Type B, clinical pre-NDA videoconference meeting held in May 2022, the Company believes the SUMMIT trial, if successful, will support inclusion of differentiating efficacy claims in the STS101 prescribing information, presuming STS101 is approved for marketing.

After establishing full eligibility, SUMMIT trial participants are randomized (1:1) to receive either STS101 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. Following randomization, participants have 56 days in which to treat the qualifying migraine attack.

The co-primary endpoints of the SUMMIT trial, to be assessed at two hours after STS101 administration, are freedom from pain and freedom from most bothersome symptom (from among photophobia, phonophobia or nausea). The trial is designed for greater than 99% statistical power for the freedom from pain endpoint and greater than 95% statistical power for

the freedom from most bothersome symptom endpoint. In addition, the SUMMIT trial incorporates a number of secondary endpoints and prospective evaluations of the clinical performance of STS101 that could differentiate the clinical profile of STS101.

Satsuma expects to report topline results from the SUMMIT trial in the fourth quarter of 2022.

For further information regarding the STS101 SUMMIT Phase 3 efficacy trial, see www.ClinicalTrials.gov, identifier NCT04940390: A Randomized, Double-Blind, Placebo-Controlled Study to Assess STS101 in the Acute Treatment of Migraine (SUMMIT).

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

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 2nd-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 March 31, 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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