

Satsuma Pharmaceuticals Announces Enrollment of First Patient in the ASCEND™ Phase 3 open-label, safety trial of STS101

ASCEND results expected to support STS101 NDA filing in Q4 2021

South San Francisco, CA, August 6, 2020 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company, today announced the initiation of patient enrollment in the ASCEND trial, a multi-center, open-label, 12-month study to evaluate the safety and tolerability of STS101 (dihydroergotamine (DHE) nasal powder) as an acute treatment for migraine.

“We are pleased to have enrolled the first patient in our Phase 3 open-label, safety trial of STS101,” commented John Kollins, Satsuma’s President and Chief Executive Officer. “We anticipate that the results of the ASCEND trial will support the long term safety and tolerability of STS101 as an acute treatment for migraine when patients administer the product candidate on an as-needed basis. The ASCEND trial is complementary to our STS101 EMERGE Phase 3 pivotal trial, which has completed the patient treatment phase and for which we expect to report topline results in late September or early October 2020.”

The STS101 ASCEND open-label, safety trial will enroll subjects between 18 and 65 years of age who have a history of migraine and will be conducted at geographically diverse sites located throughout the United States. The primary objective of the trial is to evaluate the long-term safety of STS101 as an as-needed acute treatment for migraine. Secondary outcome measures include efficacy evaluations, for example proportion of subjects free from pain and most bothersome symptom (from among photophobia, phonophobia and nausea) at multiple time points up to 48 hours following administration of STS101. The trial is expected to enroll up to 300 subjects, with at least 150 subjects treating a minimum of two migraine attacks per month with STS101 over a six-month period and at least 50 participants over a 12-month period. The Company anticipates that data from the ASCEND trial, in conjunction with results from the STS101 EMERGE Phase 3 pivotal trial, if successful, will support a New Drug Application filing in the fourth quarter of 2021.

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

For further information regarding the STS101 Phase 3 EMERGE efficacy trial, see www.ClinicalTrials.gov, identifier NCT03901482: [A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate STS101 in the Acute Treatment of Migraine](#) (EMERGE).

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic product for the acute treatment of migraine, STS101. STS101 is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate (DHE), which can be quickly and easily self-administered with a proprietary pre-filled, single-use, nasal delivery device. In developing STS101, Satsuma has applied proprietary nasal drug delivery, dry-powder formulation, and engineered drug particle technologies to create a compact, simple-to-use, non-injectable DHE product that can be rapidly self-administered in a matter of seconds. The Company believes STS101 would, if approved, be an attractive migraine treatment option for many patients and may enable a larger number of people with migraine to realize the long-recognized therapeutic benefits of DHE therapy. STS101 has undergone extensive pre-clinical development, completed a Phase 1 clinical trial, and is currently in Phase 3 development.

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 Company’s expectations with regard to the initiation and availability of data to be derived from its ongoing and planned Phase 3 clinical trials; and the timing and likelihood of regulatory filings and approvals for STS101. 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, 2020, 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; the risk that the COVID-19 worldwide pandemic may negatively impact the Company’s business, operations, clinical trials or ability to raise capital; the unpredictability of the regulatory process; regulatory developments in the United States and foreign countries; and the Company’s ability

to raise additional 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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