Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces Publication of STS101 Phase 1 Clinical Trial Results in HEADACHE: The Journal of Head and Face Pain

South San Francisco, CA, January 28, 2020 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company, today announced that Phase 1 trial results detailing pharmacokinetics (PK), tolerability, and safety with its lead product candidate, STS101 (DHE (or dihydroergotamine) nasal powder for the acute treatment of migraine), have been published online in the official peer-reviewed journal of the American Headache Society, *Headache, The Journal of Head and Face Pain*.

The publication reports results from a Phase 1, open-label, 2-part, active-controlled, 3-period crossover study sponsored by Satsuma and designed to investigate and compare the safety and PK of STS101, DHE liquid nasal spray (Migranal®), and intramuscular (IM) DHE injection in healthy subjects.

Study authors concluded that STS101 showed a favorable tolerability profile and resulted in DHE plasma concentrations comparable to IM DHE and exceeding Migranal. Based on data from this study and the results from other clinical studies with DHE (including injected, liquid nasal spray, and orally inhaled DHE dosage forms), the authors posited that STS101 is anticipated to demonstrate rapid pain relief, improvement in functionality, and excellent 2-hour and sustained pain freedom rates. STS101 is currently being evaluated as an acute treatment for migraine in an ongoing Phase 3 efficacy trial (the EMERGE™ trial), for which Satsuma expects to report top-line data in the second half of this year.

Key findings described in the American Headache Society, *Headache, The Journal of Head and Face Pain* publication included the following:

- STS101 showed rapid absorption, achieving within 10 minutes the mean DHE plasma concentration threshold (1 ng/ml) that Satsuma estimates to be minimally necessary for efficacy based on prior clinical studies.
- Drug exposure was substantially greater than Migranal, comparable to IM DHE, and exceeded exposures previously reported for an orally inhaled DHE product candidate (MAP0004) by approximately 30 minutes post-dose and at all subsequent time points. MAP0004 previously demonstrated rapid onset of clinical efficacy and robust anti-migraine efficacy in a large, double-blind, placebo-controlled Phase 3 trial.
- STS101 PK variability was lower than Migranal, suggesting STS101 may have more predictable, reliable, and robust clinical performance.
- With STS101, maximum DHE plasma concentrations were sufficiently low so as to avoid nausea or vomiting, which are common side-effects with intravenous DHE.
- STS101 demonstrated a favorable tolerability profile and all treatment-related adverse events were mild, transient, and related to the nasal route of administration or known effects of DHE.

The paper titled, A Phase 1, Randomized, Open-Label, Safety, Tolerability, and Comparative Bioavailability Study of Intranasal Dihydroergotamine Powder (STS101), Intramuscular Dihydroergotamine Mesylate, and Intranasal DHE Mesylate Spray in Healthy Adult Subjects, can be accessed at the following link: https://headachejournal.onlinelibrary.wiley.com/doi/epdf/10.1111/head.13737

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, including the comparability to other DHE products; the Company’s clinical and regulatory development plans; the Company’s expectations with regard to the data to be derived from its planned Phase 3 clinical trials and the timing of reporting top-line results therefrom; the likelihood of regulatory filings and approvals for STS101; and the Company’s commercialization plans and expectations. 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, 2019, 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 Company’s ability to select suitable dosing regimens; the results of preclinical and clinical studies may not be predictive of future results; the unpredictability of the regulatory process; regulatory developments in the United States and foreign countries; the costs of clinical trials may exceed expectations; 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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