Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces Topline Results from EMERGE Phase 3 Trial of STS101 for the Acute Treatment of Migraine

- Topline data did not show statistically significant differences between either dosage strength of STS101 and placebo on co-primary endpoints of freedom from pain and most bothersome symptom at two hours post-administration

- STS101 was well-tolerated in this trial with low adverse event rates and no serious adverse events reported

- Further analyses of the EMERGE trial data are ongoing, and Satsuma expects to provide a more detailed update on its business plans after these analyses are completed

South San Francisco, CA, September 10, 2020 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company, today announced topline results from its Phase 3 EMERGE efficacy trial of STS101 (dihydroergotamine (DHE) nasal) powder as an acute treatment for migraine.

Although topline data showed numerical differences in favor of STS101 3.9 mg and 5.2 mg versus placebo on the pre-specified co-primary endpoints of freedom from pain and freedom from most bothersome symptom (from among photophobia, phonophobia and nausea) at two hours post-administration, these differences did not achieve statistical significance for either dosage strength. Both dosage strengths of STS101 did, however, demonstrate significant effects on both freedom from pain and most bothersome symptom by three hours post-dose and later time points.

Both STS101 dosage strengths were well-tolerated in the EMERGE trial, with low adverse event rates and no serious adverse events reported.

John Kollins, President and Chief Executive Officer of Satsuma commented, “We are surprised and disappointed that STS101 did not achieve statistical significance on the co-primary endpoints in our EMERGE trial. On behalf of everyone at Satsuma, I’d like to thank the many people with migraine who participated in EMERGE as well as the staff at the trial sites for their dedication and diligence in completing the trial, despite the challenges posed by the ongoing COVID-19 pandemic.”

Further analysis of EMERGE trial data is ongoing, and Satsuma expects to provide a more detailed update on its business plans after these analyses are completed. As of June 30, 2020, the Company had cash, cash equivalents and marketable securities of $93.7 million.

About the EMERGE trial

The Phase 3 EMERGE efficacy trial of STS101 is a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in over 1,140 migraine patients conducted in the United States. The EMERGE study was designed in accordance with FDA recommendations outlined in the FDA Guidance *Migraine: Developing Drugs for Acute Treatment*, February 2018. After establishing full eligibility, EMERGE trial participants were randomized (1:1:1) to receive one of three treatments: STS101 DHE 3.9 mg, 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. The two co-primary endpoints of the EMERGE trial were freedom from pain and freedom from most bothersome symptom (from among photophobia, phonophobia or nausea), both of which were assessed at two hours after administration of study medication. The trial was statistically designed for greater than 99% power for the freedom from pain endpoint and greater than 95% power for the freedom from most bothersome symptom endpoint. In addition, the EMERGE trial design incorporated a number of secondary endpoints and prospective evaluations of the clinical performance of STS101 in a number of patient subgroups.

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.

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. These forward-looking statements include, but are not limited to, statements about the Company’s expectations regarding STS101 and its future business plans. 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 June 30, 2020, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time. 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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