Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces Updated STS101 Development Plan

-New STS101 Phase 3 efficacy trial planned to begin mid-2021 with topline results expected second half of 2022-

-Proceeds from $80 million private placement and existing cash expected to fund operations into second half of 2023-

-Conference call this morning at 8:00 AM ET; dial in details are listed below-

South San Francisco, CA, March 1, 2021 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA) a clinical-stage biopharmaceutical company, today announced an update to the development plan for STS101 (dihydroergotamine (DHE) nasal powder), an investigational acute treatment for migraine. The updated STS101 development plan includes a new Phase 3 efficacy trial, which the Company anticipates initiating in mid-2021, with topline results expected in the second half of 2022. The new Phase 3 trial takes into account findings from the EMERGE pivotal study in which STS101 showed numerical differences in favor of STS101 5.2 mg and 3.9 mg versus placebo but did not achieve statistical significance versus placebo on the co-primary endpoints of freedom from pain and most bothersome symptom at two hours post-administration. In addition, the Company plans to explore dose strengths greater than 5.2 mg by conducting a Phase 1 trial in the second quarter of 2021 to evaluate the pharmacokinetics, safety, and tolerability of STS101 5.2 mg and two higher dose strengths. The Company plans to select the STS101 dose strength to utilize in its next Phase 3 efficacy trial based on the results of this Phase 1 trial.

Satsuma also announced today that it has entered into a securities purchase agreement with existing and new investors for an $80 million private placement financing. The Company believes that net proceeds from the private placement financing, together with its existing cash, cash equivalents and short-term investments of $68.2 million as of December 31, 2020, will be sufficient to fund company operations into the second half of 2023.

The Company is holding a conference call this morning to discuss its updated STS101 development plan, as well as preliminary results to date from the ongoing open-label ASCEND long-term safety trial of STS101 5.2 mg, and a synopsis of key EMERGE trial findings.

“We continue to have strong conviction that STS101 has the potential to be an important and differentiated acute treatment option that can address the unmet needs of many people with migraine. After conducting a comprehensive, multi-functional review of our STS101 program, including EMERGE trial findings and preliminary results to date from our ongoing ASCEND open-label, long-term safety trial, we believe there is a compelling rationale for continuing development of STS101 and undertaking a second Phase 3 efficacy trial,” said John Kollins, President & Chief Executive Officer of Satsuma. “We are pleased to have strong support for our updated STS101 development plan from our expert clinical advisors and leading specialist healthcare investors.”

EMERGE Phase 3 efficacy trial results

On September 10, 2020, the Company announced topline results from the EMERGE Phase 3 efficacy trial of STS101. As detailed in the table below, 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 dose strength.

EMERGE Co-primary Endpoints[1]:	**3.9 mg**	**5.2 mg**	**Placebo**
Patients	n=354	n=353	n=358

Freedom from Pain at 2 hours			
N	69/354	68/353	53/358
% responders	**19.5%**	**19.3%**	**14.8%**
Difference vs Placebo	4.7%	4.5%	---
p-value	0.10	0.11	---
Freedom from Most Bothersome Symptom at 2 hours			
N	133/340	139/343	119/353
% responders	**39.1%**	**40.5%**	**33.7%**
Difference vs Placebo	5.4%	6.8%	---
p-value	0.14	0.06	---

Both dose strengths of STS101 did, however, demonstrate significant effects (nominal p-value < 0.05) on both freedom from pain and most bothersome symptom endpoints by three hours post-dose and later time points. Consistent with the safety and tolerability results to date observed in other STS101 clinical trials, including the ongoing ASCEND open-label, long-term safety trial, both STS101 dose strengths were well-tolerated in the EMERGE trial, with low adverse event rates and no drug-related serious adverse events reported.

Based on its analyses, the Company believes it has identified, and is taking steps to address in the new Phase 3 efficacy trial, the key reasons that STS101 did not achieve statistical significance versus placebo on the co-primary endpoints in the EMERGE trial.

ASCEND Phase 3 open-label, long-term safety trial preliminary results to date

As of February 23, 2021, the Company has enrolled more than 275 subjects in its ongoing ASCEND open-label, long-term safety trial who have treated a total of more than 2,200 migraine attacks with STS101 5.2 mg. STS101 5.2 mg has been been well-tolerated to date in the ASCEND trial, with low adverse event rates and no drug-related serious adverse events reported. In addition, the Company believes that, based on the preliminary results from the ASCEND open-label, long-term safety trial, STS101 5.2 mg demonstrates anti-migraine activity at the two-hour time point.

Anticipated STS101 development milestones

Second Quarter 2021 – Complete Phase 1 safety and pharmacokinetic study with STS101 5.2 mg and two higher dose strengths
Mid-2021 – Initiate second STS101 Phase 3 efficacy trial
Second Half 2022 – Read out topline results from second Phase 3 efficacy trial
Fourth Quarter 2022 – File STS101 NDA

Conference Call and Webcast Details
The Company's management team will host a conference call and webcast this morning, Monday, March 1, at 8:00am ET / 5:00am PT.

The call is accessible via the below teleconference numbers and the Conference ID#:**13716986#**
USA/Canada: +1 (877) 705-6003
International Dial-In Number: +1 (201) 493-6725

The webcast can be followed live online via the linkhttp://public.viavid.com/index.php?id=143740

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic product candidate for the acute treatment of migraine. Its product candidate, STS101, is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate, or DHE, which is designed to be quickly and easily self-administered with a proprietary pre-filled, single-use, nasal delivery device. DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine and have significant advantages over other therapeutics for many patients. However, broad use has been limited by invasive and burdensome administration and/or sub-optimal clinical performance of available

injectable and liquid nasal spray products. STS101 is specifically designed to deliver the clinical advantages of DHE while overcoming these shortcomings.

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 trial, the potential for STS-101 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 September 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. 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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[1] Per the EMERGE trial Statistical Analysis Plan, subjects who did not report efficacy data for the 2-hour post-treatment time point were imputed to be non-responders, irrespective of response status as of the last time point prior to 2 hours when efficacy data was reported.
