Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Provides Business Update and Reports Second Quarter 2020 Financial Results

- *Completed treatment phase of pivotal EMERGE™ Phase 3 efficacy trial of STS101 as planned and remain on track to report top-line results in late September or early October 2020*

- *Initiated patient enrollment in ASCEND™ Phase 3 open-label safety trial of STS101*

- *Cash, cash equivalents and marketable securities of $93.7 million as of June 30, expected to provide cash runway through end of 2021 and planned STS101 NDA filing in Q4 2021*

South San Francisco, CA, August 11, 2020 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company, today summarized recent business progress and reported financial results for the second quarter ended June 30, 2020.

"As evidenced by the completion of the treatment phase of our Phase 3 EMERGE efficacy trial and the recent initiation of patient enrollment in our Phase 3 open-label ASCEND safety trial, we continue to execute our STS101 development program according to plan," commented John Kollins, Satsuma's President and Chief Executive Officer. "We expect to announce EMERGE trial topline results in the near future, and we anticipate the results, if successful, will position STS101 to become an important and differentiated acute treatment option for people with migraine."

Recent Highlights

STS101

EMERGE Phase 3 efficacy trial

As reported in early June, Satsuma completed enrollment in the EMERGE efficacy trial with more than the planned 1,140 migraine patients randomized to one of two STS101 dosage strengths or placebo. Following randomization, patients had 56 days in which to treat a single qualifying migraine attack of at least moderate pain severity with study medication. As of July 30, all patients had completed the treatment phase of the trial. The Company is on track to report topline data in late September or early October of this year.

ASCEND Phase 3 open-label long-term safety trial

Last week, Satsuma initiated patient enrollment in the ASCEND open-label safety trial in which patients will treat their migraines on an as-needed basis with STS101 for up to 12 months. The

trial is expected to enroll up to 300 migraine patients, with at least 150 treating a minimum of two attacks per month with STS101 over a six-month period and at least 50 over a 12-month period.

Virtual Scientific Meeting Presentations

In May, Satsuma announced that two scientific presentations were selected for the 2020 American Academy of Neurology Science Highlights Virtual Platform:

- *Water-insoluble Mucoadhesive Formulation Enables Consistent and Rapid Intranasal Absorption of Drugs, including Granisetron, Zolmitriptan and Dihydroergotamine*
- *PK Comparison of STS101, an Intranasal Dry Powder Formulation of Dihydroergotamine, with Other Intranasal, Injectable and Oral Inhaled DHE Formulations*

In June, Satsuma virtually presented two posters at the 2020 American Headache Society Annual Scientific Meeting:

- *Safety of Dihydroergotamine for the Acute Treatment of Migraine: Reality vs. Perception*
- *The Efficacy of Dihydroergotamine versus Emerging Acute Migraine Medications*

Copies of these poster presentations are available for download in the publications section of Satsuma's website: www.satsumarx.com/publications.

Addition to the Board of Directors

In July, Satsuma appointed biopharmaceutical industry veteran Thomas M. Soloway to its Board of Directors. Mr. Soloway currently serves as Executive Vice President and Chief Operating Officer of Audentes Therapeutics Inc., an Astellas genetic medicines company committed to developing and commercializing innovative gene therapy products for patients living with rare, life-threatening diseases.

Expansion of Intellectual Property Portfolio

Satsuma continues to expand its intellectual property portfolio, with notices of claims allowance recently received from the United States Patent and Trademark Office (USPTO) for two pending patent applications licensed or owned by Satsuma. The Company anticipates the pending applications will issue around the end of this year and, when issued, will have estimated expiration dates in 2037 and 2039 (not taking into account any adjustments or extensions of term). When the pending patents issue, they will bring the total number of issued U.S. patents owned or licensed by Satsuma to ten, reflecting the highly innovative and differentiated nature of the proprietary dry-powder nasal delivery and formulation technologies incorporated in STS101.

Financial Results for Second Quarter 2020

Net loss for the second quarter 2020 was $11.3 million, or $0.65 per share of common stock,

compared to a net loss of $6.3 million, or $5.48 per share of common stock, for the same period in 2019. As of June 30, 2020, the Company had $93.7 million of cash, cash equivalents and marketable securities. The Company believes it has sufficient financial resources to fund operations through the end of 2021.

Research and development expenses were $8.8 million for the second quarter 2020, compared to $5.5 million for the same period of 2019. Second quarter expenses increased by $3.3 million, primarily due to additional expenses for the EMERGE clinical trial activities, development and production of clinical trial materials, as well as increases in salaries and employee-related expenses.

General and administrative expenses were $2.7 million for the second quarter 2020, compared to $1.0 million for the same period of 2019. Second quarter expenses increased by $1.7 million, primarily due to an increase of $0.9 million of director and officer liability insurance, professional fees for legal, consulting, accounting, tax and other services and an increase of $0.8 million of payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, due to increase in headcount.

About the STS101 Clinical Program

EMERGE Phase 3 efficacy trial

Designed to evaluate the efficacy, safety, and tolerability of STS101 (DHE nasal powder) as an acute treatment for migraine, the EMERGE trial is a multi-center, randomized, double-blind, placebo-controlled, parallel group trial in more than 1,140 migraine patients that is being conducted at 121 sites located across 32 U.S. states. EMERGE is designed in accordance with U.S. FDA recommendations outlined in its 2018 guidance document, *Migraine: Developing Drugs for Acute Treatment*. Based on dialogue with the FDA, the Company believes that EMERGE, if successful, will fulfill the regulatory requirement for demonstration of STS101 efficacy.

After establishing eligibility during a 28-day screening period, EMERGE trial participants were randomized (1:1:1) to receive one of three treatments: STS101 3.9 mg, STS101 5.2 mg, or placebo and instructed to treat their next migraine attack of at least moderate pain severity with the allocated blinded study medication. Following randomization, trial participants have up to 56 days in which to treat a qualifying migraine attack; following treatment of a qualifying attack, trial participants return to their trial sites for a final follow-up visit.

The two co-primary endpoints of the EMERGE trial, both of which are assessed two hours following administration of study medication, are (1) freedom from pain, and (2) freedom from most-bothersome-symptom (MBS) from among photophobia, phonophobia, or nausea. Responder analyses will be conducted on these co-primary endpoints. The trial is powered at greater than 99% on the freedom-from-pain endpoint and at greater than 95% for the freedom-from-MBS endpoint.

In addition, EMERGE is designed to prospectively evaluate the efficacy of STS101 on a number of secondary endpoints and in patient subgroups that could significantly enhance the

differentiated clinical profile of STS101.

ASCEND Phase 3 open-label long-term safety trial

The ASCEND trial, the second of two Phase 3 trials that Satsuma plans to complete in support of STS101 registration, initiated patient enrollment in August 2020. The primary objective of the ASCEND trial is to evaluate the long-term safety of STS101 as an as-needed acute treatment for migraine. The trial is expected to enroll up to 300 patients, with at least 150 patients treating a minimum of two attacks per month with STS101 over a six-month period and at least 50 patients over a 12-month period.

The Company anticipates that data from the EMERGE trial, if successful, in conjunction with results from the ASCEND open-label safety trial, 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 clinical and regulatory development plans; the Company's expectations with regard to the availability of data to be derived from its ongoing Phase 3 clinical trials; the timing and likelihood of regulatory filings and approvals for STS101; the Company's expected cash needs and sufficiency of cash on hand. 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 June 30, 2020, to be 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; 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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Satsuma Pharmaceuticals, Inc.

SATSUMA PHARMACEUTICALS, INC.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 8,829	$ 5,455	$ 18,477	$ 7,605
General and administrative	2,671	967	5,194	1,531
Total operating expenses	$ 11,500	$ 6,422	$ 23,671	$ 9,136
Loss from operations	(11,500)	(6,422)	(23,671)	(9,136)
Interest income	325	250	827	271
Interest expense	(94)	(122)	(198)	(244)
Other income, net	—	3	—	3
Net loss	$ (11,269)	$ (6,291)	$ (23,042)	$ (9,106)
Unrealized gain on marketable securities	250	—	218	—
Comprehensive loss	$ (11,019)	$ (6,291)	$ (22,824)	$ (9,106)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.65)	$ (5.48)	$ (1.33)	$ (8.05)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	17,394,466	1,148,984	17,388,741	1,131,147

SATSUMA PHARMACEUTICALS, INC.
BALANCE SHEET DATA
(in thousands)
(unaudited)

	June 30, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 93,701	$ 117,900
Working capital	94,073	106,773
Total assets	102,615	126,276
Debt	3,988	4,930
Accumulated deficit	(66,043)	(43,001)
Total stockholders' equity	93,934	115,335