

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

- Analysis of results from EMERGE™ Phase 3 efficacy trial of STS101 ongoing; expect to communicate next steps by early 2021
- Cash, cash equivalents and marketable securities of \$82.1 million as of September 30,
 2020; based on current operating plans, expected to provide runway through end of 2021

South San Francisco, CA, November 10, 2020 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company focused on developing STS101 (a dihydroergotamine (DHE) nasal powder) for the acute treatment of migraine, today reported financial results for the third quarter ended September 30, 2020 and provided a clinical development and corporate update.

"As reported in early September, the EMERGE Phase 3 efficacy trial of STS101 as an acute treatment for migraine did not achieve statistical significance on the pre-specified co-primary endpoints (freedom from pain and most bothersome symptom) at the two-hour post-administration time point," commented John Kollins, Satsuma's President and Chief Executive Officer. "However, we remain encouraged that STS101 demonstrated numerical superiority on these endpoints at two hours following administration, with statistical significance achieved at three hours and all later time points."

Mr. Kollins continued, "Given the STS101 efficacy signal observed in the EMERGE trial, as well as the favorable STS101 safety and tolerability profile observed to date, we are methodically analyzing EMERGE trial data in order to understand the reasons for the trial outcome and to inform our decisions regarding potential plans to advance development of STS101. We anticipate providing an update on our business plans by early 2021 after completing our analyses."

Recent Highlights

STS101

Analysis of results from EMERGE™ Phase 3 efficacy trial ongoing

In early September, Satsuma reported topline data from the EMERGE Phase 3 efficacy trial of STS101. 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. Both dose strengths of STS101 did, however, demonstrate significant effects on both freedom from pain and most bothersome symptom by three hours post-dose and all later time points. Consistent with the results to date observed in other STS101 clinical trials, both



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

The EMERGE study was designed in accordance with FDA recommendations outlined in the FDA Guidance Document, *Migraine: Developing Drugs for Acute Treatment*, February 2018.

ASCEND™ Phase 3 open-label long-term safety trial

In August, Satsuma initiated patient enrollment in the ASCEND open-label safety and tolerability 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.

Expansion of Intellectual Property Portfolio

Satsuma continues to expand its intellectual property portfolio, with the U.S. Patent and Trademark Office recently issuing two U.S. patents relating to STS101, one owned and one exclusively licensed by Satsuma, with expiration dates in 2039 and 2037, respectively, not including any potential adjustments or extensions of term. The issuance of these patents brings the total number of issued U.S. patents exclusively licensed or owned by Satsuma to ten, and in total, Satsuma currently has exclusive license rights under more than sixty U.S. and foreign patents and pending applications. The Company believes that the breadth of its intellectual property portfolio reflects the highly innovative and differentiated nature of the proprietary drypowder nasal delivery and formulation technologies incorporated in STS101.

Financial Results for Third Quarter 2020

Net loss for the third quarter 2020 was \$12.0 million, or \$0.69 per share of common stock, compared to a net loss of \$8.3 million, or \$2.26 per share of common stock, for the same period in 2019. As of September 30, 2020, the Company had \$82.1 million of cash, cash equivalents and marketable securities. Based on current operating plans, 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 third quarter 2020, compared to \$7.4 million for the same period of 2019. Third quarter expenses increased by \$1.5 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 partially offset by a decrease in travel expenses of \$0.2 million, as a result of reduced travel due to COVID-19.

General and administrative expenses were \$3.4 million for the third quarter 2020, compared to \$1.0 million for the same period of 2019. Third quarter expenses increased by \$2.4 million, primarily due to an increase of \$1.1 million of director and officer liability insurance, professional fees for legal, consulting, accounting, tax and other services, an increase of \$0.5 million of payroll



and personnel expenses, including salaries, benefits and stock-based compensation expenses, due to increase in headcount and an increase of \$0.8 million in pre-commercialization expenses.

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 forwardlooking 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 potential continued development of STS101: the Company's expectations regarding the completion of its analysis of the EMERGE trial data and announcement of its updated business plans by early 2021; 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 ASCEND trial; the Company's expected cash needs and sufficiency of cash on hand to fund its operations until the end of 2021. 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 guarter ended September 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 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. Condensed Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts)

(unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,			
	2020		2019		2020		2019
\$	8,750	\$	7,441	\$	27,227	\$	15,046
	3,420		1,029		8,614		2,560
\$	12,170	\$	8,470	\$	35,841	\$	17,606
	(12,170))	(8,470)		(35,841)		(17,606)
	209		331		1,036		602
	(82))	(121)		(280)		(365)
	_						3
\$	(12,043)	\$	(8,260)	\$	(35,085)	\$	(17,366)
·	(150)	,	12		68		12
\$	(12,193)	\$	(8,248)	\$	(35,017)	\$	(17,354)
\$	(0.69)	\$	(2.26)	\$	(2.02)	\$	(8.74)
1	7,415,146	,	3,658,504		17,397,607		1,986,190
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SATSUMA PHARMACEUTICALS, INC. BALANCE SHEET DATA

(in thousands) (unaudited)

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	September 30, 2020	December 31, 2019		
Balance Sheet Data:				
Cash, cash equivalents and marketable securities	\$ 82,096	\$ 117,900		
Working capital	82,357	106,773		
Total assets	92,216	126,276		
Debt	3,511	4,930		
Accumulated deficit	(78,086)	(43,001)		
Total stockholders' equity	82,988	115,335		