Satsuma Pharmaceuticals, Inc.

PRESS RELEASE

Satsuma Pharmaceuticals Reports 2021 Full Year and Fourth Quarter Financial Results and Business Highlights

- STS101 SUMMIT Phase 3 efficacy trial enrollment ongoing; key trial on track to read out topline results in Q4 2022 -

- $95.8 million in cash, cash equivalents and marketable securities as of December 31, 2021, provides runway into second half of 2023 -

March 15, 2022

South San Francisco, CA, March 15, 2022 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company developing STS101 (dihydroergotamine (DHE) nasal powder), a novel investigational therapeutic product candidate for the acute treatment of migraine, today reported financial results for the fourth quarter and full year ended December 31, 2021 and summarized its business highlights.

"The coming twelve months promise to be eventful and marked by important milestones for Satsuma, including the reporting of results from our SUMMIT Phase 3 efficacy trial, the potential filing of an NDA for STS101 and the initiation of our commercial launch preparations," stated John Kollins, President and Chief Executive Officer of Satsuma. "We look forward to advancing STS101 as an innovative and important new therapy for the acute treatment of migraine, and to sharing data on STS101 and DHE at upcoming medical meetings."

Full Year and Recent Business Highlights

Initiated the STS101 SUMMIT Phase 3 efficacy trial, a double-blind, randomized, placebo-controlled trial expected to enroll approximately 1,400 subjects – June 2021

- The SUMMIT trial is designed to provide the basis for (i) STS101 to become the first and only DHE product to have established efficacy in a randomized and controlled trial on co-primary endpoints (freedom from pain and freedom from most bothersome symptom at two hours post-treatment) currently recommended by the FDA in its guidance document and by the International Headache Society in its current controlled trials guidelines; and (ii) the STS101 prescribing information to include differentiating efficacy claims in the event STS101 is approved for marketing[1,2].
- Satsuma plans to report topline results from the SUMMIT trial in Q4 2022. The Company believes the SUMMIT trial, if successful, will support a planned New Drug Application (NDA) filing in Q1 2023.

[1] FDA Guidance, *Migraine: Developing Drugs for Acute Treatment*, February 2018
[2] Diener et al., *Guidelines of the International Headache Society for controlled trials of acute treatment of migraine attacks in adults: Fourth Edition*, Cephalalgia, 2019

Satsuma Pharmaceuticals, Inc.

Completed Phase 1 trial confirming pharmacokinetic, tolerability & safety profile of STS101 5.2 mg dose strength and informing dose selection for SUMMIT Phase 3 efficacy trial – June 2021

- The Company announced pharmacokinetic, tolerability and safety results from a Phase 1 trial of STS101 5.2 mg and two higher dose strengths.
- All three dose strengths of STS101, which incorporated the improved second-generation nasal delivery device, were well-tolerated and achieved pharmacokinetic profiles featuring rapid and sustained target plasma concentrations with low pharmacokinetic variability.
- Based on these Phase 1 trial results and other data, including preliminary results from the ongoing ASCEND Phase 3 long-term, open-label safety trial of STS101 5.2 mg, Satsuma selected the 5.2 mg dose strength of STS101 to evaluate in the ongoing SUMMIT Phase 3 efficacy trial.

Completed Subject Enrollment in ASCEND Phase 3 open-label, long-term safety trial

In August 2020, Satsuma announced initiation of subject enrollment in the ASCEND trial, a multi-center, open-label, 12-month trial to evaluate the safety and tolerability of STS101 5.2 mg for the acute treatment of migraine. As of March 11, 2022, more than 480 subjects were enrolled in ASCEND and treated more than 6,000 migraine attacks. The Company plans to report interim results from the ASCEND trial at the American Academy of Neurology 2022 Annual Meeting (April 2-7) and to report top-line results in the second half of 2022.

- STS101 5.2 mg continues to demonstrate a favorable safety and tolerability profile, with low rates of adverse events reported.
- Although no differences in the safety or tolerability profiles of the first- and second-generation STS101 nasal delivery devices utilized by ASCEND subjects have been observed to date, the company in the second half of 2021 increased the ASCEND enrollment by approximately 180 subjects to ensure target subject exposure requirements previously communicated to it by the FDA are achieved with STS101 investigational product incorporating the second-generation delivery device.

Upcoming Events and Key Milestones in 2022

- Report top-line results from SUMMIT Phase 3 efficacy trial in Q4 2022
- Report top-line results from ASCEND Phase 3 open-label safety trial in 2H 2022
- Present further data on STS101, DHE, and the proprietary dry-powder nasal drug delivery technologies incorporated in STS101 at 2022 medical meetings, including American Academy of Neurology 2022 Annual Meeting (April 2-7) and the American Headache Society's 64th Annual Scientific Meeting (June 9-12)

Financial results for the fourth quarter and full year 2021

Net losses for the fourth quarter and full year 2021 were $15.6 million and $51.2 million, respectively, or $0.49 and $1.75 per common share, respectively. This compared to net losses

of $12.5 million and $47.6 million, respectively, or $0.72 and $2.73 per common share, respectively for the same periods in 2020.

Research and development expenses were $11.9 million and $37.6 million for the fourth quarter and full year 2021, respectively, compared to $9.0 million and $36.3 million for the same periods of 2020, respectively. Fourth quarter expenses increased by $2.8 million, primarily due to increases for the ASCEND and SUMMIT studies and higher payroll and personnel expenses, partially offset by decreases in clinical expenses related to the EMERGE study as it was concluding and lower product development expenses.

General and administrative expenses were $3.7 million and $13.5 million for the fourth quarter and full year 2021, respectively, compared to $3.4 million and $12.1 million for the same periods of 2020, respectively. Fourth quarter expenses increased by $0.3 million, primarily due to pre-commercialization activities and higher payroll and personnel expenses, partially offset by lower legal expenses and other administrative costs.

Cash runway into second half 2023

As of December 31, 2021, Satsuma had $95.8 million in combined cash, cash equivalents and marketable securities, which it believes is sufficient to fund operations into the second half of 2023 and through projected completion of the STS101 Phase 3 clinical development programs and potential filing of an NDA for STS101 in Q1 2023.

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic product, STS101, for the acute treatment of migraine. STS101 is a unique and proprietary nasal powder formulation of the well-established anti-migraine drug, dihydroergotamine mesylate (DHE), administered via Satsuma's proprietary nasal delivery device. STS101 is designed to provide significant benefits versus existing acute treatments for migraine, including the combination of quick and convenient self-administration and other clinical advantages, that current DHE liquid nasal spray products and injectable dosage forms lack. Satsuma's dry powder DHE formulation has demonstrated fast absorption, rapid achievement of high DHE plasma concentrations which Satsuma believes is necessary for early efficacy, and sustained plasma levels over time with low dose to dose variability. STS101 also now incorporates an improved 2nd-generation nasal delivery device designed to provide more consistent nasal dosing, irrespective of user administration technique. Although DHE has long been recommended in published migraine treatment guidelines as a first-line acute treatment option for migraine and has significant advantages versus other anti-migraine treatments for many patients, disadvantages of current DHE liquid nasal spray and injectable products, including invasive and burdensome administration processes and/or sub-optimal clinical performance, have limited the widespread use of DHE. Featuring a compact and convenient dosage form, STS101 is designed to overcome these shortcomings and provide patients an improved therapeutic solution for acutely treating migraines that consistently delivers robust clinical performance.

Satsuma Pharmaceuticals, Inc.

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 and SUMMIT trials, the timing of data readouts for ongoing clinical trials, the anticipated timing for a potential NDA filing of STS-101, 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-K for the year ended December 31, 2021, 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; 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.

INVESTOR AND CORPORATE CONTACTS:

Satsuma Pharmaceuticals, Inc.

Corey Davis, PhD
LifeSci Advisors, LLC
cdavis@lifesciadvisors.com

Tom O'Neil, Chief Financial Officer
Satsuma Pharmaceuticals, Inc.
tom@satsumarx.com

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SATSUMA PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 11,866	$ 9,043	$ 37,635	$ 36,270
General and administrative	3,694	3,444	13,531	12,058
Total operating expenses	$ 15,560	$ 12,487	$ 51,166	$ 48,328
Loss from operations	(15,560)	(12,487)	(51,166)	(48,328)
Interest income	33	79	157	1,115
Interest expense	(24)	(70)	(163)	(350)
Net loss	$ (15,551)	$ (12,478)	$ (51,172)	$ (47,563)
Unrealized (loss) gain on marketable securities	(30)	(56)	(71)	12
Comprehensive loss	$ (15,581)	$ (12,534)	$ (51,243)	$ (47,551)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (0.72)	$ (1.75)	$ (2.73)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,532,401	17,429,756	29,174,386	17,405,688

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

	December 31, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 95,770	$ 68,236
Working capital	91,356	65,740
Total assets	109,832	81,033
Debt	1,080	3,032
Accumulated deficit	(141,736)	(90,564)
Total stockholders' equity	101,340	71,936

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