Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Business Highlights

- Announced updated STS101 development plan featuring a new Phase 3 efficacy trial scheduled to begin enrollment mid-2021 with topline results expected in second half of 2022

- Closed $80 million private placement of common stock financing with new and existing investors

- Cash runway into second half of 2023 and through readout of Phase 3 clinical trials and potential NDA filing by end of 2022

South San Francisco, CA, March 25, 2021 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company developing STS101, a novel therapeutic product candidate for the acute treatment of migraine, today reported financial results for the quarter and full year ended December 31, 2020 and summarized recent business highlights.

“Having significantly strengthened our balance sheet with the recent completion of a private placement financing, we are well-positioned to execute against our updated STS101 development plan,” stated John Kollins, Satsuma’s President and Chief Executive Officer. “Our team remains steadfast in its commitment to developing STS101 as an important and differentiated acute treatment option for people living with migraines and to initiating a new Phase 3 efficacy trial this summer.”

Recent Business Highlights

$80 Million Private Placement of Common Stock Financing

- In March 2021, Satsuma closed an $80 million private placement of common stock financing led by Commodore Capital and New Enterprise Associates, L.P. with participation from new and existing investors including RA Capital Management, Vivo Capital, Samlyn Capital, Surveyor Capital (a Citadel company), Aspire Capital Fund, funds managed by Ghost Tree Capital Group, LP, Point72 Asset Management and Logos Capital as well as Satsuma co-founder, Shin Nippon Biomedical Laboratories.

- The Company believes the proceeds from this financing, combined with cash, cash equivalents, and marketable securities of $68.2 million at the end of 2020, are sufficient to fund its operations into the second half of 2023 and through key clinical and regulatory milestones, including completion of the STS101 Phase 3 clinical development program in the second half of 2022 and potential filing of a New Drug Application by the end of 2022.

STS101 development plan update

- In March 2021, Satsuma announced an updated STS101 development plan which includes a new Phase 3 efficacy trial that the Company anticipates initiating in mid-2021, with topline results expected in the second half of 2022. The new Phase 3 trial will take into account our findings from analyses of the EMERGE Phase 3 pivotal trial results.
- In addition, the Company plans to explore dose strengths greater than 5.2 mg, the higher of the two STS101 dose strength evaluated in the EMERGE trial, by conducting a Phase 1 trial to evaluate the pharmacokinetics, safety, and tolerability of STS101 5.2 mg and two higher dose strengths. The Company anticipates completing this Phase 1 trial in the second quarter of 2021 and plans to select the STS101 dose strength to utilize in its next Phase 3 efficacy trial based on its results.

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

In August 2020, Satsuma announced the initiation of patient enrollment in the ASCEND trial, a multi-center, open-label, 12-month study to evaluate the safety and tolerability of STS101 as an acute treatment for migraine.

- In conjunction with its March 2021 STS101 development plan update, the Company reported preliminary results to date from the ASCEND trial. As of February 23, 2021, the Company had enrolled more than 275 subjects in the ASCEND trial who had treated a total of more than 2,200 migraine attacks with STS101 5.2 mg. To date, STS101 5.2 mg has been generally well-tolerated in the ASCEND trial, with low adverse event rates and no treatment-related serious adverse events reported.

Upcoming 2021 & 2022 milestones

- Complete Phase 1 safety and pharmacokinetic study with STS101 5.2 mg and two higher dose strengths in the second quarter of 2021
- Initiate new STS101 Phase 3 efficacy trial in mid-2021
- Report top-line results from new Phase 3 efficacy trial in second half of 2022
- Complete ASCEND Phase 3 open-label safety trial in second half of 2022
- Present further data on STS101, DHE, and the proprietary dry-powder nasal drug delivery technologies incorporated in STS101 at medical meetings in 2021 and 2022
- File STS101 NDA by the end of 2022

Expansion of Intellectual Property Portfolio

Satsuma continues to expand its intellectual property portfolio, with the U.S. Patent and Trademark Office issuing two U.S. patents relating to STS101 in the fall of 2020. These two new patents, one owned and one exclusively licensed by Satsuma, have estimated 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 owns or 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 dry-powder nasal delivery and formulation technologies incorporated in STS101.

Financial results for the fourth quarter and full year 2020

Net losses for the fourth quarter and full year 2020 were $12.5 million and $47.6 million, respectively, or $0.72 and $2.73 per common share, respectively. This compared to net losses of $10.8 million and $28.2 million, respectively, or $0.62 and $4.80 per common share, respectively for the same periods in 2019. As of December 31, 2020, the Company had $68.2 million of cash, cash equivalents and marketable securities. Including the recent financing, the Company believes it has sufficient financial resources to fund operations into the second half of 2023.

Research and development expenses were $9.0 million and $36.3 million for the fourth quarter and full year 2020, respectively, compared to $9.2 million and $24.2 million for the same periods of 2019, respectively. Fourth quarter expenses decreased by $0.1 million, primarily due to a decrease in the clinical expenses as the EMERGE study was concluding offset by increases for the ASCEND study and higher payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses.

General and administrative expenses were $3.4 million and $12.1 million for the fourth quarter and full year 2020, respectively, compared to $2.1 million and $4.7 million for the same periods of 2019, respectively. Fourth quarter expenses increased by $1.3 million, primarily due to higher stock-based compensation expense, D&O insurance, legal expenses and other administrative costs.

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 in Phase 3 development and 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 Company's clinical and regulatory development plans; the Company's expectations with regard to the initiation and availability of data to be derived from its ongoing and planned clinical trials; the timing and likelihood of regulatory filings and approvals for STS101; and 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 Annual Report on Form 10-K for the year ended December 31, 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; 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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