Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Provides Corporate Update and Prepares to Advance Lead Product Candidate, STS101, Into Phase 3 Efficacy Trial for Acute Migraine

- STS101 for the acute treatment of migraine demonstrates highly differentiated pharmacokinetic (PK) profile in Phase 1 clinical trial

- Satsuma successfully completes FDA meeting, establishing key elements of the STS101 Phase 3 development program to support NDA

- Phase 3 clinical efficacy trial start planned for third quarter 2019

- Tom O'Neil joins Satsuma as Chief Financial Officer

SOUTH SAN FRANCISCO, Calif., Feb. 20, 2019 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc. ("Satsuma" or "the Company"), a clinical-stage biopharmaceutical company, today provided a corporate update, including recent progress with its development of STS101 for the acute treatment of migraine.

STS101 is a novel and proprietary investigational drug-device combination product specifically designed to enable intranasal administration of the anti-migraine drug, dihydroergotamine (DHE), with a PK profile optimized to provide consistent and robust clinical efficacy.

In a recently completed Phase 1 clinical trial, STS101 demonstrated a highly differentiated PK profile. The STS101 PK profile was characterized by rapid absorption, with clinically-relevant drug concentrations observed within ten minutes, sustained high drug exposure levels over time comparable to those achieved by intramuscular DHE injection, and low inter-subject variability. STS101 was well tolerated by clinical trial subjects, with all reported adverse events deemed mild and not clinically relevant. Importantly, no subjects administered STS101 experienced nausea or vomiting, which are common side effects of DHE when administered by injection. Satsuma plans to present results of the STS101 Phase 1 clinical trial at an upcoming medical meeting.

Detlef Albrecht, M.D., Chief Medical Officer of Satsuma, commented, "We are excited to report that the intranasal administration of STS101 in our Phase 1 clinical trial achieved a PK profile that is favorable in comparison with other non-injectable DHE formulations, including liquid nasal spray and pulmonary-route orally inhaled products. The STS101 PK profile is well-suited to the treatment of acute migraine and predicts rapid and robust therapeutic effects that may be sustained for 24-48 hours following administration. Completing the STS101 Phase 1 clinical trial brings us one step closer to achieving our goal: making the long-recognized and differentiated therapeutic benefits of DHE broadly available to migraine sufferers in a compact, simple-to-use, self-administered, and non-injectable product."

Satsuma also announced the successful completion of a meeting with the U.S. Food and Drug Administration (FDA). In consultation with the FDA, the Company has established key elements of the Phase 3 development program to support a New Drug Application (NDA) for STS101 for the acute treatment of migraine.

Satsuma plans to initiate a randomized, double-blind, placebo-controlled Phase 3 clinical trial in the third quarter of 2019 to evaluate the efficacy and safety of STS101 as an acute treatment for migraine.

In addition to providing an update on STS101 development, Satsuma also announced that Tom O'Neil has joined the Company as its Chief Financial Officer. He joined the Company from Protagonist Therapeutics, where he served as Chief Financial Officer since early 2016.

John Kollins, President and Chief Executive Officer of Satsuma, commented, "Tom brings to Satsuma a wealth of relevant finance and operations experience within the biopharmaceutical industry, including leading successful initial public offering and private equity transaction initiatives, and we will benefit from his knowledge and

experience as we continue to build the Company."

About Satsuma Pharmaceuticals
Satsuma Pharmaceuticals is a biopharmaceutical company focused on developing STS101 as an important and differentiated therapeutic option for the acute treatment of migraine. STS101 is a novel and proprietary investigational drug-device combination product specifically designed to enable intranasal administration of the anti-migraine drug, dihydroergotamine (DHE), with a pharmacokinetic profile optimized to provide consistent and robust clinical efficacy. 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, self-administered, and non-injectable DHE product. The Company believes STS101 will be an attractive migraine treatment option for many patients and may enable a larger number of migraine sufferers to realize the long-recognized therapeutic benefits of DHE therapy. STS101 has undergone extensive pre-clinical optimization and recently completed a Phase 1 clinical trial. Satsuma plans to initiate a randomized, double-blind, placebo-controlled Phase 3 clinical trial in the third quarter of 2019 to evaluate the efficacy and safety of STS101 as an acute treatment for migraine.

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.

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