Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Announces First Patient Dosed in EMERGE™, a Phase 3 Efficacy Trial of STS101 for the Acute Treatment of Migraine

SAN FRANCISCO, Aug. 22, 2019 /PRNewswire/ -- Satsuma Pharmaceuticals, Inc. ("Satsuma" or "the Company"), a clinical-stage biopharmaceutical company, today announced dosing of the first patient in its Phase 3 EMERGE efficacy trial of STS101 (dihydroergotamine (DHE) nasal powder) for the acute treatment of migraine.

Satsuma's President and Chief Executive Officer, John Kollins, commented, "We are pleased to have recently dosed the first patient in our Phase 3 EMERGE efficacy trial, which we believe is the largest-ever clinical trial undertaken with any DHE product. This milestone brings us a step closer to achieving our goal of making STS101, a compact, simple-to-use, self-administered, and non-injectable DHE dosage form, available as a differentiated treatment option for people with migraine."

The Phase 3 EMERGE efficacy trial of STS101 is a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in approximately 1,140 migraine patients that is being conducted in the United States. The EMERGE study was designed in accordance with FDA recommendations outlined in the FDA Guidance *Migraine: Developing Drugs for Acute Treatment*, February 2018. After establishing full eligibility, EMERGE trial participants are randomized (1:1:1) to receive one of three treatments: STS101 DHE 3.9 mg, STS101 DHE 5.2 mg or matching placebo and instructed to treat their next migraine attack of at least moderate pain severity with the allocated blinded study medication. The two co-primary endpoints of the EMERGE trial to be assessed at two hours after STS101 administration are freedom from pain and freedom from most bothersome symptom (from among photophobia, phonophobia or nausea). The trial is statistically designed for greater than 99% power for the freedom from pain endpoint and greater than 95% power for the freedom from most bothersome symptom endpoint. In addition, the EMERGE trial design incorporates a number of secondary endpoints and prospective evaluations of the clinical performance of STS101 in a number of patient subgroups that could differentiate the clinical profile of STS101.

Satsuma expects to report top-line data from the EMERGE trial in the second half of 2020.

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 could, if approved, potentially 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, recently 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.

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