Satsuma Pharmaceuticals, Inc.

PRESS RELEASE

Satsuma Pharmaceuticals Announces First Subject Randomized in SUMMIT™, a Phase 3 Efficacy Trial of STS101 for the Acute Treatment of Migraine

South San Francisco, CA, July 28, 2021 – 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 announced randomization of the first subject in its SUMMIT Phase 3 efficacy trial of STS101 for the acute treatment of migraine.

Satsuma's President and Chief Executive Officer, John Kollins, commented, "We are pleased to have initiated the SUMMIT trial and begun randomizing subjects in accordance with our previously communicated timeline objectives. We believe the likelihood of success for SUMMIT is high given the utilization of the second-generation STS101 nasal delivery device and improved subject training in combination with the trial design and conduct adjustments we've made based on our analyses of results from the previous EMERGE Phase 3 trial. We believe SUMMIT will provide the basis for STS101, with subsequent FDA approval, to become the first and only DHE product to have established efficacy on the current standard and FDA-accepted endpoints for acute treatment of migraine in a randomized, placebo-controlled trial."

The SUMMIT Phase 3 efficacy trial of STS101 is a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in approximately 1,400 subjects with migraine that is being conducted in the United States. The SUMMIT study was designed in accordance with FDA recommendations outlined in the FDA Guidance Migraine: Developing Drugs for Acute Treatment, February 2018. The study design and conduct take into account learnings from the Company's previously-completed EMERGE Phase 3 efficacy trial. After establishing full eligibility, SUMMIT trial participants are randomized (1:1) to receive either STS101 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 co-primary endpoints of the SUMMIT 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 designed for greater than 99% statistical power for the freedom from pain endpoint and greater than 95% statistical power for the freedom from most bothersome symptom endpoint. In addition, the SUMMIT trial incorporates a number of secondary endpoints and prospective evaluations of the clinical performance of STS101 that could differentiate the clinical profile of STS101.

Consistent with its previous communications, Satsuma expects to report top-line data from the SUMMIT trial in the second half of 2022.

For further information regarding the STS101 SUMMIT Phase 3 efficacy trial, see www.ClinicalTrials.gov, identifier NCT04940390: A Randomized, Double-Blind, Placebo-Controlled Study to Assess STS101 in the Acute Treatment of Migraine (SUMMIT).

Satsuma Pharmaceuticals, Inc.

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 2nd-generation 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 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.

INVESTOR AND CORPORATE CONTACTS:

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

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