Sangamo Therapeutics Receives U.S. FDA Fast Track Designation for ST-503 for the Treatment of Small Fiber Neuropathy

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RICHMOND, Calif., Dec. 02, 2025 (GLOBE NEWSWIRE) -- Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicine company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to ST-503, an investigational epigenetic regulator for the treatment of intractable pain due to small fiber neuropathy (SFN), a type of chronic neuropathic pain.

Fast Track Designation aims to facilitate the development and expedite the review of new therapeutics that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Companies granted this designation are given the opportunity for more frequent interactions with the FDA. These clinical programs may also be eligible to apply for Accelerated Approval and Priority Review if relevant criteria are met.

"We are very pleased to receive FDA Fast Track Designation for ST-503. SFN is a debilitating chronic pain disorder, with limited effective treatment options currently available," said Nathalie Dubois-Stringfellow, Ph.D., Sangamo's Chief Development Officer. "This designation underscores the high unmet patient need in SFN and the urgency to develop safe and effective nonopioid treatment alternatives. We are preparing to dose the first patient in our Phase 1/2 study and look forward to sharing data once available."

ST-503 is currently being evaluated in the Phase 1/2 STAND study, where patient recruitment and enrollment are in progress. In September 2025, Sangamo presented updated nonclinical data highlighting the pharmacology and safety of ST-503 in chronic neuropathic pain at the 9th International Congress on Neuropathic Pain. The data demonstrated the durability, potency and selectivity of ST-503 in nonhuman primates, alongside a favorable safety profile, supporting its development for the treatment of chronic neuropathic pain. A copy of the presentation is available in the Presentations section of the Sangamo website. Sangamo expects to dose the first Phase 1/2 STAND study patient in the coming months.

About the STAND Study
Sangamo is preparing for the Phase 1/2 STAND study, a multicenter, double-blind, randomized, sham-controlled dose escalation study to assess the safety, tolerability and preliminary efficacy of a one-time dose of ST-503, administered intrathecally to patients with SFN. The STAND study is enrolling adult patients with a confirmed diagnosis of SFN who have pain that has been refractory to first line medical therapies for at least 6 months.

About Small Fiber Neuropathy
Small Fiber Neuropathy (SFN) is a condition that damages small nerve fibers, leading to burning, prickling, stabbing or "lightning-like" intractable pain, numbness, as well as autonomic issues like heart rate changes, digestion problems and orthostatic intolerance. SFN can be caused by a broad array of pathologies impacting the central or peripheral nervous systems, such as surgical trauma, spinal cord injury, nerve compression, neurological and infectious diseases, or metabolic and hereditary syndromes. SFN has an estimated prevalence of 53 people out of every 100,000 in the U.S., and more broadly, peripheral neuropathies are estimated to affect nearly 40 million Americans. Antidepressants, anticonvulsants, opioids and topical therapies are potential treatment options, although no long-lasting or curative therapies are currently available for SFN patients, leading to a high unmet medical need for this patient population.

About Sangamo Therapeutics

Sangamo Therapeutics is a genomic medicine company dedicated to translating ground-breaking science into medicines that transform the lives of patients and families afflicted with serious neurological diseases who do not have adequate or any treatment options. Sangamo believes that its zinc finger epigenetic regulators are ideally suited to potentially address devastating neurological disorders and that its capsid discovery platform can expand delivery beyond currently available intrathecal delivery capsids, including in the central nervous system. Sangamo's pipeline also includes multiple partnered programs and programs with opportunities for partnership and investment. To learn more, visit www.sangamo.com and connect with us on LinkedIn and X.

Forward-Looking Statements

This press release contains forward-looking statements regarding Sangamo's current expectations. These forward-looking statements include, without limitation, statements relating to the ability of the Fast Track designation to facilitate the development and expedite the review of ST-503, the ability of ST-503 to meet relevant criteria in order to be eligible to apply for Accelerated Approval and Priority Review, the therapeutic potential of ST-503, including its potential to improve the lives of patients and to have a favorable effect on small fiber neuropathy, Sangamo's expectation for, and timelines related to, dosing patients in the Phase 1/2 STAND study and other statements that are not historical fact. These statements are not guarantees of future performance and are subject to risks and uncertainties that are difficult to predict. Sangamo's actual results may differ materially and adversely from those expressed. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to: reliance on results of early clinical trials, such as the Phase 1/2 STAND study, which results are not necessarily predictive of future clinical trial results; the research and development process, including the enrollment, operation and results of clinical trials and the presentation of clinical data; the unpredictable regulatory approval process for product candidates across multiple regulatory authorities; the manufacturing of products and product candidates; the commercialization of approved products; the potential for technological developments that obviate technologies used by Sangamo; Sangamo's need for substantial additional funding to execute its operating plan and to continue to operate as a going concern; the effects of macroeconomic factors or financial challenges on the global business environment, healthcare systems and Sangamo's business and operations; Sangamo's reliance on collaborators and the potential inability to secure additional collaborations; and Sangamo's ability to achieve expected future financial performance.

All forward-looking statements about Sangamo's future plans and expectations, including Sangamo's development plans for its product candidates, are subject to Sangamo's ability to secure adequate additional funding. There can be no assurance that Sangamo and its current or potential future

partners will be able to develop commercially viable products. Actual results may differ materially from those projected in these forward-looking statements due to the risks and uncertainties described above and other risks and uncertainties that exist in the operations and business environments of Sangamo and its collaborators. These risks and uncertainties are described more fully in Sangamo's Securities and Exchange Commission, or SEC, filings and reports, including in Sangamo's Annual Report on Form 10-K for the year ended December 31, 2024, as supplemented by its Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, each filed with the SEC, and future filings and reports that Sangamo makes from time to time with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Sangamo undertakes no duty to update such information except as required under applicable law.

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