Scilex Holding Company Announces the Completion of its SP-103 (lidocaine topical system) 5.4%, Triple Strength Formulation of ZTlido®, Phase 2 trial which achieved its objectives to Evaluate the Safety and Efficacy of SP-103 in Subjects with Moderate to Severe Acute Lower Back Pain (LBP)

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- Scilex Holding Company announced completion of its SP-103 Phase 2 study to evaluate the safety and efficacy in subjects with acute LBP.
- The Phase 2, randomized, double-blind, placebo-controlled, parallel group, multicenter study evaluated the safety and efficacy of SP-103 (lidocaine topical system 5.4%) in subjects with moderate to severe acute LBP. The trial enrolled 75 patients at 10 sites across the U.S.
- SP-103 received Fast Track status from the FDA in September 2022.
- SP-103 is a pharmacologically validated drug candidate and has the potential as a leading agent for the treatment of LBP without the limitations of current therapies, including the addictive potential of opioids.
- An estimated 65 million adults in the U.S., or 25% of adults in the U.S., suffer from acute LBP[1] with a total potential global market opportunity of approximately $10.0 billion by 2026 (Brand Essence Research 2020).

PALO ALTO, Calif., Sept. 14, 2023 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or “Company”), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (OTC: SRNEQ), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain, announced the completion of its SP-103 Phase 2, randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate the safety and efficacy in subjects with acute LBP. Objectives of the trial were to assess safety and tolerability of SP-103 and to provide treatment effect estimates in patient population that can be used to power future studies. The trial enrolled 75 subjects, 38 received SP-103, and 37 received placebo. Topical systems were applied to the area of most tenderness in the lower back in 12-hours ON/ 12-hours OFF regimen.

Preliminary analysis demonstrated the following results:

- No Serious Adverse Events (SAEs) or deaths observed.
- No Treatment Emergent Adverse Events (TEAEs) leading to early withdrawal.
- None of the subjects in the active group and 3 (8.1%) subjects in placebo group had AEs of special interest (signs of lidocaine systemic toxicity).
- Incidence of dermal AEs or application site reactions was low overall.
- SP-103 was safe and well-tolerated.
- Increase in lidocaine load in topical system by three times, compared with approved ZTLido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment.
- A meaningful reduction of pain over the first week, using SPID-7 analysis, -1.5 (95% CI: -0.2 to 3.2) was observed in sub-population of patients with higher severity of muscle spasms.
- Overall, the trial achieved its objectives.

Scilex continues to analyze the data to gather a full understanding of the analgesic signal, population to be selected for subsequent trial, and specific indication to be pursued for product registration. The Company is very encouraged to see reduction of pain as compared to placebo in patients whose LBP is driven predominantly by muscle spasms. Scilex is also very pleased with the safety outcome of the trial, confirming our expectations and performance of SP-103 previously demonstrated in phase 1 trials.

Further, the Company recently completed an Investigator-Initiated Research study at Johns Hopkins University using ZTLido in subjects with chronic non-radicular neck pain. It was a randomized, crossover, placebo-controlled trial, which enrolled 76 patients. Preliminary results show reduction of average daily pain over one month treatment period. The Company will explore selection of chronic non-radicular neck pain as a population for subsequent trials and potential indication for SP-103, as higher drug penetrance through skin to the muscle may provide greater clinical benefit.

“We are very pleased to have achieved this important milestone and would like to commend the experienced investigators and advisors for their persistence and diligence in enrolling these patients. SP-103 has the potential to meet our core goal of developing leading pain management therapies to significantly improve the lives of patients who are seeking new effective treatments,” said Dmitri Lissin, MD, Chief Medical Officer, Scilex Holding.

About Scilex Holding Company

Scilex Holding Company is an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain. Scilex is uncompromising in its focus to become the global pain management leader committed to social, environmental, economic, and ethical principles to responsibly develop pharmaceutical products to maximize quality of life. Results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. Scilex participated in the type C meeting for purposes of pre-NDA discussion with the FDA and is pending official minutes in writing from the FDA. Scilex targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with moderate to severe pain. Scilex launched its first commercial product ZTlido® in October 2018, in-licensed a commercial product Gloperba® in June 2022, and launched its third FDA-approved product Elyxyb™ in April 2023. It is also developing its late-stage pipeline, which includes a pivotal Phase 3 candidate, and one Phase 2 and one Phase 1 candidate. Its commercial product, ZTlido® (lidocaine topical system) 1.8%, or ZTlido®, is a prescription lidocaine topical product approved by the U.S. Food and Drug Administration for the relief of pain associated with post-herpetic neuralgia, which is a form of post-shingles nerve pain. Scilex in-licensed the exclusive right to commercialize Gloperba® (colchicine USP) oral solution, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. Scilex in-licensed the exclusive rights to commercialize Elyxyb™ (celecoxib oral solution) in the U.S. and Canada, the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults. Scilex launched Elyxyb™ in April 2023, and is planning to commercialize Gloperba® in the fourth quarter of 2023, and is well-positioned to market and distribute those products. Scilex’s three product candidates are SP-102 (injectable dexamethasone sodium phosphate viscous gel product containing 10 mg dexamethasone), or SEMDEXA™, a Phase 3, novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, with FDA Fast Track status; SP-103 (lidocaine topical system) 5.4%, a Phase 2 study, triple-strength formulation of ZTlido®, for the treatment of acute low back pain, with FDA Fast Track status; and SP-104, 4.5 mg Delayed Burst Release Low Dose Naltrexone Hydrochloride (DBR-LDN) Capsule, for the treatment of chronic pain, fibromyalgia that has completed multiple Phase 1 trial programs and is expected to initiate Phase 2 trials in 2023. For further information regarding the SP-102 Phase 3 efficacy trial, see NCT identifier NCT03372161 – Corticosteroid Lumbar Epidural Analgesia for Radiculopathy – Full Text View – ClinicalTrials.gov.

Scilex Holding Company is headquartered in Palo Alto, California.

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting concerning the matters discussed in this press release contain forward-looking statements related to Scilex and its subsidiaries under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the efficacy and safety profile of SP-103 for the treatment of LBP in patients, the potential for it to become a leading agent for the treatment of LBP, Scilex’s excepted timeline to receive top-line data from this Phase 2 study and plans for subsequent Phase 3 trial(s), Scilex’s belief that it is well positioned to continue its growth over the next several years, Scilex’s long-term objectives and commercialization plans, Scilex’s potential to attract new capital, future opportunities for Scilex, Scilex’s future business strategies, the expected cash resources of Scilex and the expected uses thereof; Scilex’s current and prospective product candidates, planned clinical trials and preclinical activities and potential product approvals, as well as the potential for market acceptance of any approved products and the related market opportunity; statements regarding ZTlido®, Gloperba®, ELYXYB™, SP-102 (SEMDEXA™), SP-103 or SP-104, if approved by the FDA; Scilex’s development and commercialization plans; and Scilex’s products, technologies and prospects.

Risks and uncertainties that could cause Scilex’s actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: risks associated with the unpredictability of trading markets and whether a market will be established for Scilex’s common stock; general economic, political and business conditions; risks related to the ongoing COVID-19 pandemic; the risk that the potential product candidates that Scilex develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; risks relating to uncertainty regarding the regulatory pathway for Scilex’s product candidates; the risk that Scilex will be unable to successfully market or gain market acceptance of its product candidates; the risk that Scilex’s product candidates may not be beneficial to patients or successfully commercialized; the risk that Scilex has overestimated the size of the target patient population, their willingness to try new therapies and the willingness of physicians to prescribe these therapies; risks that the results of the Phase 2 trial for SP-103 or Phase 1 trials for SP-104 may not be successful; risks that the prior results of the clinical trials of SP-102 (SEMDEXA™), SP-103 or SP-104 may not be replicated; regulatory and intellectual property risks; and other risks and uncertainties indicated from time to time and other risks set forth in Scilex’s filings with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Scilex undertakes no obligation to update any forward-looking statement in this press release except as may be required by law.

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References

1. Chronic Back Pain; Georgetown Health Policy Institute (https://hpi.georgetown.edu/backpain/)

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