Scilex Holding Company Announces Complete Enrollment of a Phase 2 Study to Evaluate the Safety and Efficacy of SP-103 (lidocaine topical system) 5.4%, Triple Strength Formulation of ZTlido®, for the Treatment of Acute Low Back Pain

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- Scilex Holding Company, 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 complete enrollment of its SP-103 Phase 2 study to evaluate the safety and efficacy in subjects with acute low back pain. Top-line data from the Phase 2 study is expected in Q3-2023.
- The Phase 2, randomized, double-blind, placebo-controlled, parallel group, multicenter study will evaluate the safety and efficacy of SP-103 (lidocaine topical system) 5.4% in subjects with moderate to severe acute lower back pain (LBP). The trial is to enroll approximately 80 patients at 10 sites across the U.S. with acute LBP.
- 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., May 04, 2023 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex”), 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 complete enrollment in a Phase 2, randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate the safety and efficacy of SP-103 (lidocaine topical system) 5.4% triple strength formulation for ZTlido®, in subjects with acute LBP.

"We are very pleased to have achieved this important milestone and would like to commend the experienced investigators and advisors of the SP-103 trial 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 with acute low back pain who are seeking new effective treatments,” said Jaisim Shah, Chief Executive Officer and President of Scilex.

“We are looking forward to analyzing the data and making further decisions regarding the potential Phase 3 program plans. We believe that Scilex is the only company with the technology allowing much higher lidocaine concentration than any other topical lidocaine treatments. Higher concentration of a drug per covered area of skin is important for achieving therapeutic response. We are very excited about the potential of SP-103,” said Dmitri Lissin, M.D., Chief Medical Officer of Scilex.

Scilex is developing SP-103 to be a triple-strength, non-aqueous lidocaine topical system for the treatment of acute LBP. Acute LBP can range in intensity from a dull, constant ache to a sudden, sharp sensation that leaves the person incapacitated. It is estimated that approximately 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.

More than 60% of U.S. opioid prescriptions are for the treatment of chronic low back pain (CLBP)[2] despite the fact that opioids are associated with serious and potentially life-threatening side effects and have not demonstrated efficacy in the treatment of CLBP.[3,4,5] Provisional data from CDC’s National Center for Health Statistics indicate there were an estimated 107,622 drug overdose deaths in the United States during 2021, an increase of nearly 15% from the 93,655 deaths estimated in 2020.[6] The new data show overdose deaths involving opioids increased from an estimated 70,029 in 2020 to 80,816 in 2021.[6]

There are currently no approved non-NSAID (non-steroidal anti-inflammatory drugs) pharmaceutical treatments specifically indicated for the treatment of acute LBP. The market we intend to address with SP-103, if approved, includes etiologies that are currently treated with non-procedural or non-surgical interventions, and where available treatments provide inadequate pain relief or result in unacceptable adverse effects. These treatments may include NSAIDs, antidepressants and opioids, as well as off-label lidocaine patches.

The safe and effective treatment of acute LBP represents a high unmet need and creates a large market opportunity. LBP is one of the most costly benign conditions in industrialized countries. Experts have estimated that approximately 80% of Americans will experience LBP during their lifetime. The annual prevalence of LBP is 15% to 45% with a point prevalence of approximately 30% in the United States. Sixty percent of those who suffer from acute LBP recover in six weeks and up to 80-90% recover within 12 weeks[7]. However, the recovery of the remaining patients with LBP is less certain. LBP accounts for 19% of all workers' compensation claims in the United States. Americans spent at least $135 billion in 2016 on treating low back and neck pain, which was the highest expenditure among 154 conditions.[8]

SP-103 builds on the learnings from ZTlido because both products share the same adhesive drug delivery formulation and manufacturing technology. If approved, we believe that SP-103 could become the leading lidocaine topical product for acute LBP indications. All current uses of topical lidocaine products for acute LBP are off label. SP-103 has three times the drug load of ZTlido (108 mg versus 36 mg) in the same adhesive system to potentially deliver threefold the level of the drug within a targeted area, still with the convenience of a single topical system. Additionally, SP-103 is designed to deliver a localized dose of lidocaine that is three times greater than any lidocaine topical product that we are aware of either on the market or in development. If approved, we believe SP-103 may be able to address the limitations of prescription lidocaine patches in treating acute LBP by delivering a higher dose of lidocaine to the application site. As part of the lifecycle management, Scilex will also target localized musculoskeletal pain, acute and chronic pain conditions, and post operation pain management to focus on developing and commercializing non-opioid therapies for patients with acute and chronic pain. Scilex expects to get top line data in the third quarter of 2023. The outcome of the Phase 2 study should enable planning of a subsequent Pivotal Phase 3 trial.

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 intends to submit a request to the FDA for a type D meeting for purposes of pre-NDA discussion with 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 in-licensed its third FDA-approved product Elyxyb™ in February 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 is planning to commercialize Gloperba® and Elyxyb™ in 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 treatment of LBP in patients, the ability of SP-103 to address limitations of prescription lidocaine patches in treating acute LBP and the potential for it to become a leading agent for the treatment of LBP, Scilex's expected timeline to receive top-line data from this Phase 2 study and plans for subsequent Phase 3 trial(s), Scilex's long-term objectives and commercialization plans, future opportunities for Scilex, Scilex's future business strategies, 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 SEC. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release except as may be required by law.

Contacts:

Investors and Media
Scilex Holding Company
960 San Antonio Road
Palo Alto, CA 94303
Office: (650) 516-4310

Email: investorrelations@scilexholding.com

Website: www.scilexholding.com

SEMDEXA™ (SP-102) is a trademark owned by Semnur Pharmaceuticals, Inc., a wholly-owned subsidiary of Scilex Holding Company. A proprietary name review by the FDA is planned.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc., a wholly-owned subsidiary of Scilex Holding Company.

Gloperba® is the subject of an exclusive, transferable license to use the registered trademark by Scilex Holding Company.

ELYXYB™ is the subject of an exclusive, transferable license to use the trademark by Scilex Holding Company.

All other trademarks are the property of their respective owners.

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Source: Scilex Holding Company