Scilex Holding Company Announces Publication in PAIN Journal Regarding Phase 3 Results of the Pivotal Registration Trial of SP-102 (SEMDEXA™) in Lumbosacral Radicular Pain (Sciatica)

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- The Phase 3 study results are being published in PAIN® Journal, which is the leading journal devoted to pain medicine and research. PAIN is the official journal of the International Association for the Study of Pain, and features original research on the nature, mechanisms and treatment of pain.
- This Phase 3 study met primary and important key secondary endpoints, with SP-102 (SEMDEXA™) treatment, decreasing pain intensity for over a month in sciatica patients and resulting in statistically significant and clinically meaningful improvement in the disability index score while maintaining safety comparable to placebo.
- This Phase 3 topline data result was presented at the American Society of Interventional Pain (ASIPP) conference in Las Vegas in May 2022 in an oral presentation by Dr. Nebojsa Nick Knezevic, M.D., Ph.D., Professor of Anesthesiology and Surgery, College of Medicine, University of Illinois at Chicago, President of the Illinois Society of Interventional Pain Physicians, Director-at-Large of the North American Society of Neuromodulation, Vice-Chair for Research and Education, Advocate Illinois Masonic Medical Center, Department of Anesthesiology and Pain Management.
- This Phase 3 study represents a potential significant improvement in treatment of adult patients with lumbosacral radicular pain (sciatica), who struggle with the clinical consequences of no currently FDA approved therapies, suboptimal formulations of corticosteroids used off-label and/or excess pain and disability.
- SP-102 (SEMDEXA™) was granted Fast Track status from the FDA in 2017.

PALO ALTO, Calif., June 14, 2024 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or the “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, today announced the publication of results of the pivotal registration trial of SP-102 (SEMDEXA™) in PAIN, the official journal of the International Association for the Study of Pain, which features original research on the nature, mechanisms and treatment of pain.

SP-102 (SEMDEXA™) is a novel injectable corticosteroid gel formulation product in development for the treatment of lumbosacral radicular pain, which contains no preservatives, surfactants, solvents, or particulates.

The C.L.E.A.R. Trial (Corticosteroid Lumbosacral Epidural Analgesia for Radiculopathy) was designed to investigate safety and analgesic effects of a single and repeat transforaminal injections of SP-102 (SEMDEXA™) compared to placebo (saline injection). The trial enrolled 401 low back pain subjects with unilateral intervertebral lumbar disc herniation, resulting in radicular pain symptoms of moderate to severe leg pain. It is the largest known randomized well-controlled trial in sciatica using epidural steroid injections.

The trial met its primary and important key secondary endpoints with statistical significance, demonstrating clinically meaningful reduction of pain, improvement in disability and functional outcomes.

Safety analysis demonstrated a clean safety profile with no identified safety risks. There were no serious adverse events related to the drug or injection procedure, and no adverse events of special interest reported, such as hematoma and infection at the injection site, or paraplegia. By contrast, these events are associated with the off-label use of non-approved steroid preparations. The C.L.E.A.R trial also established safety of repeat injections, as patients who experienced moderate-to-severe radicular pain between 4 and 23 weeks following initial injection were allowed to receive an open-label additional SP-102 (SEMDEXA™) injection. The safety analysis was comparable between treatment groups through 4, 12 and 24 weeks of the study period.

“I am very glad to be involved in the C.L.E.A.R. trial, having first-hand experience with SP-102 (SEMDEXA™), pain management medication with extended local effect. Currently, we have to use steroid formulations developed for other uses, which are unapproved for epidural administration. If SP-102 (SEMDEXA™) is approved by the FDA, it would be the first corticosteroid ever approved for epidural injections, addressing safety issues with current formulations. This could be an important addition to treatment options for patients with lumbosacral radicular pain,” said Alan Miller, M.D., Principal Investigator from Coastal Clinical Research Specialists, Jacksonville, Florida, primary author of the publication.

A copy of the publication can be downloaded here.

For more information on Scilex Holding Company, refer to www.scilexholding.com

For more information on ZTlido® including Full Prescribing Information, refer to www.ztlido.com.

For more information on ELYXYB®, including Full Prescribing Information, refer to www.elyxyb.com.

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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 targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with acute and chronic pain and are dedicated to advancing and improving patient outcomes. Scilex's commercial products include: (i) ZTlido® (lidocaine topical system) 1.8%, a prescription lidocaine topical product approved by the U.S. Food and Drug Administration (the "FDA") for the relief of neuropathic pain associated with postherpetic neuralgia, which is a form of post-shingles nerve pain; (ii) ELYXYB®, a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults; and (iii) Gloperba®, the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults and will be launched on June 10, 2024.

In addition, Scilex has three product candidates: (i) SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) ("SEMDEXA™" or "SP-102"), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, for which Scilex has completed a Phase 3 study and has granted Fast Track status from the FDA in 2017; (ii) SP-103 (lidocaine topical system) 5.4%, ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of chronic neck pain and for which Scilex has recently completed a Phase 2 trial in low back pain. SP-103 has granted Fast Track status from the FDA in low back pain; and (iii) SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) ("SP-104"), a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia, for which Phase 1 trials were completed in the second quarter of 2022.

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 Scilex's expectation that SP-102's Phase 3 study represents a potential paradigm shift in treatment for adult patients with lumbar radicular pain (sciatica) over many years, statements regarding SP-102 (SEMDEXA™), if approved by the FDA, including that SP-102 (SEMDEXA™) would be the first FDA-approved corticosteroid for epidural injections addressing safety issues with steroid medications that have been used off-label in the past few decades, Scilex's expectation that SP-102 (SEMDEXA™) would be an important addition to treatment options for patients with lumbosacral radicular pain, Scilex's development and commercialization plans, and the expected launch of Gloperba®.

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 COVID-19 (and other similar disruptions); 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 outcome of the trials and studies for SP-102, SP-103 or SP-104 may not be successful or reflect positive outcomes; risks that the prior results of the clinical and investigator-initiated 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 described in Scilex's most recent periodic reports filed with the Securities and Exchange Commission, including Scilex's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q that the Company has filed or may file, including the risk factors set forth in those filings. 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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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.

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