Scilex Holding Company Presented Post-Hoc Analysis of the C.L.E.A.R. Trial on Clinical Meaningfulness of Safety and Efficacy of SP-102 for the Treatment of Lumbosacral Radicular Pain (LRP) at the 27th Annual Meeting of American Society of Interventional Pain Physicians (ASIPP), May 15-17, 2025 in Orlando, FL

May 16, 2025 1:00 PM EDT

PALO ALTO, Calif., May 16, 2025 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or “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 and neurodegenerative and cardiometabolic disease, today presented the presentation of post-hoc analysis of the C.L.E.A.R. trial (Corticosteroid Lumbar Epidural Analgesia in Radiculopathy) interpreting clinical meaningfulness of safety and efficacy of SP-102 (SEMDEXA™) for the treatment of lumbosacral radicular pain (LRP) at the 27th Annual Meeting of American Society of Interventional Pain Physicians (ASIPP), May 15-17, 2025 in Orlando, FL.

Poster Content: Interpreting Clinical Meaningfulness of SP-102 for the Treatment of Lumbosacral

Radicular Pain (LRP): A Post-hoc Analysis of the CLEAR-1 Trial and A Systematic Review of Literature. **Click here to download the poster.**

Authors: Miller AM, Knezevic NN, Nalamachu S, Meske D, Ambrose C, Vought K, Chan EK, and Lissin D.

The poster is on display throughout the meeting from Thursday, May 15 through Saturday, May 17, 2025, allowing all attendees to view it. It is also available via the conference app and will be published in the Pain Physician journal.

Interpretation of the clinical meaningfulness of results requires consideration of primary and secondary endpoints assessed with-in subject based on consensus benchmarks, and the between group differences in the context of the overall risk-benefit and in comparison, to other approved products for similar indications. The results of the CLEAR Trial show clear clinically meaningful separation between SP-102 and placebo in multiple with-in subject endpoints (NPRS Responder Analyses, ODI and BPI Pain Interference). This result is enhanced when solely considering a population that was confirmed to receive study drug by an independent expert (i.e., the mITT population). This trend is also observed in the magnitude of group mean differences, particularly when the standard effect size of SP-102 is compared to other marketed and approved analgesics for chronic low back pain (CLBP), as well as other TSIs. The formulation of SP-102 was intentionally created to offer a safer alternative to current off-label use of products that contain warnings of the potential dangerous and life-threatening adverse events. Collectively, the benefit-risk profile presented supports SP-102 being a safe and efficacious product that has the potential to offer much-needed therapy for the treatment of LRP.

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

For more information on Semnur Pharmaceuticals, Inc., refer to www.semnurpharma.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.

For more information on Gloperba®, including Full Prescribing Information, refer to www.gloperba.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 and neurodegenerative and cardiometabolic disease. 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 is 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.

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 was 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 acute pain and for which Scilex has recently completed a Phase 2 trial in acute low back pain. SP-103 has been 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.

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 presentation of post-hoc analysis of the C.L.E.A.R. trial (Corticosteroid Lumbar Epidural Analgesia in Radiculopathy) interpreting clinical meaningfulness of safety and efficacy of SP-102 (SEMDEXA™) for the treatment of lumbosacral radicular pain (LRP).

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: Scilex's ability to remain in compliance with the Nasdaq continued listing requirements and to maintain the listing of the Company's securities thereon; Scilex's ability to develop and commercialize treatments for obesity, neurodegenerative, and cardiometabolic disease; 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, 2024 and subsequent Quarterly Reports on Form 10-Q that the Company has filed or may file with the SEC, 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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