Scilex Holding Company Announces that ZTlido® Achieves a Major Milestone - Over One Million Patients Treated Since its Launch - and Two Additional Milestones Met

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PALO ALTO, Calif., Feb. 26, 2024 (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, today announced ZTlido® has reached three major milestones since it launched in October 2018.

The following three milestones are a testament to the perceived confidence that patients and health care providers have in ZTlido®:

- Over one million patients are estimated to have been treated with ZTlido® since its launch according to Symphony Health prescription data.
- ZTlido® is now the number one prescribed non-opioid branded pain medication by pain specialists in the United States, based on Symphony Health prescription data gathered from January 2023 to November 2023.
- Patients report 89% satisfaction with ZTlido®, in a 2023 patient survey conducted by Scilex (n=100, rating as "completely" or "mostly" satisfied with ZTlido ® treatment).

ZTlido has been strategically designed to address poor adhesion, a leading complaint associated with other currently marketed topical lidocaine products. In clinical studies, the technology behind ZTlido manufacturing provided significantly improved adhesion over Lidoderm® (a branded, prescription 5% lidocaine patch product) and other generic lidocaine patches at 12 hours after application. In a head-to-head study of 44 subjects, ZTlido demonstrated statistically significant adhesion at all-time points compared to other lidocaine patches.[1]

"We are pleased to learn that an estimated over 1 million patients in the U.S. have been treated with ZTlido® emphasizing one of the key paradigm shifts in patient care of increasing use of opioid sparing regimens. We strive to continue to support the market's ongoing migration away from opioid agents in 2024 and lead the way in providing increasing non-opioid pain relief therapeutics with our upcoming third opioid sparing product launch, Gloperba®", said Jaisim Shah, Chief Executive Officer and President of Scilex.

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.

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, expected to launch in 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; (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; 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 and a Phase 2 clinical trial is expected to commence in 2024.

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 estimates for patient figures treated with ZTlido®, reports that ZTlido® is the number one prescribed non-opioid branded pain medication and statements regarding patient satisfaction reports, the market's migration away from opioid agents and the potential to provide increased non-opioid pain relieve with the launch of Gloperba, Scilex's plans to launch Gloperba in 2024 and plans to initiate a Phase 2 trial in 2024 for SP-104.

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, 2022 and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, 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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Reference

1) A Scilex-sponsored head-to-head comparative adhesion study (SCI-LIDO-ADH-003)

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 registered trademark by Scilex Holding Company.

All other trademarks are the property of their respective owners.

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