



Scilex Holding Company announces successful FDA audit of enhanced ZTlido® manufacturing facility in Japan

November 30, 2023 2:00 PM EST

- **Enhanced 250kg manufacturing facility assures increased capacity to meet rapidly growing ZTlido® demand.**
- **Two new patents previously announced covering ZTlido® in the U.S. ensures proprietary protection through January 2031**

PALO ALTO, Calif., Nov. 30, 2023 (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 the successful completion of a Good Manufacturing Practices (GMP) inspection by the U.S. Food and Drug Administration (FDA) of the enhanced manufacturing facility of Oishi Koseido Co., Ltd. (Oishi) for ZTlido® located in Tosu, Saga, Japan. This successful audit allows Scilex to continue commercializing ZTlido® product manufactured at 250kg scale at Oishi's facility. This facility is also the manufacturing site for SP-103 (lidocaine topical system, at triple strength formulation of ZTlido®) that recently completed trials in acute back pain and neck pain.

"This successful FDA GMP inspection highlights the GMP and quality assurance of our partner Oishi's manufacturing facility in Japan, which is essential as we scale the commercial production of ZTlido®," said Jaisim Shah, Chief Executive Officer and President of Scilex. "The successful FDA inspection for this enhanced manufacturing site marks an important milestone for Scilex that will enable us to increase our capacity to meet the growing demand for ZTlido®."

As previously announced, in November 2023, the United States Patent and Trademark Office (USPTO) issued U.S. Patents No. 11,793,766 and No. 11,786,455 related to ZTlido®. The patent No. 11,793,766 titled "Non-aqueous Patch for the Relief of Pain," covers a method of relieving pain through the application of a lidocaine-containing patch. The patent No. 11,786,455 titled "Non-aqueous Patch," covers a non-aqueous lidocaine patch with certain specifications, as well as a method of relieving pain through the application of a non-aqueous lidocaine-containing patch.

These patents further strengthen the Company's intellectual property portfolio and coverage for its lead commercial product, ZTlido® (lidocaine topical system) 1.8%. Scilex submitted this patent for listing in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) in November 2023.

For more information on ZTlido including Full Prescribing Information, refer to www.ztlido.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 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 reached agreement on a path forward to file an NDA for SP-102 (SEMDEXA™) in Lumbosacral Radicular Pain (Sciatica) 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 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® by 2024, 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 chronic neck pain, with FDA Fast Track status. We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute low back pain associated with muscle spasms. SP-103 was safe and well-tolerated. Increase of 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. We will continue to analyze the SP-103 Phase 2 trial data along with a recently completed investigator study of ZTlido in patients with chronic neck pain which also has showed promising top-line efficacy and safety results. Scilex is planning to initiate Phase 2/3 trial in chronic neck pain in 2024; 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 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 potential impact of the successful FDA audit on Scilex's commercialization plans for ZTlido[®], Scilex's plans to initiate a Phase 2/3 trial in chronic neck pain in 2024 and plans to initiate Phase 2 trials in 2024 for SP-104, 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 that Scilex may not achieve the results expected from the commercialization of ZTlido[®]; 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 for SP-102, SP-103 or 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.

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.

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