Scilex Pharmaceuticals Inc, a Wholly Owned Subsidiary of Scilex Holding Company, Announces Successful End of Phase II Meeting with FDA Leading to an Agreed Path Forward to NDA Upon Completion of Phase III Trials for Blockbuster Product Candidate, SP-103 (Lidocaine Topical System) 5.4%, a Next-Generation, Triple-Strength Formulation of ZTlido, for the Treatment of Chronic Neck Pain Associated with Muscle Spasms

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- Successful end of Phase II meeting with FDA leading to an agreed path forward to NDA upon completion of Phase III trials for blockbuster product candidate, SP-103, for the treatment of chronic neck pain associated with muscle spasms.
- SP-103 (lidocaine topical system) 5.4%, ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of chronic neck pain. It is estimated that the U.S. low back and neck pain market will reach $134.5 billion.[6] Based on the independent market research conducted by Syneos Health Consulting ("Syneos"), with the substantial intent in utilization for SP-103 with peak sales potential projected to reach $1.2 billion annually in the 6th year post launch.
- As previously announced that Scilex Holding Company's Board of Directors has authorized management to explore ways to maximize the value of Scilex Holding Company and its wholly owned subsidiary, Scilex Pharmaceuticals Inc., including by way of conducting a spinoff or public listing of securities of Scilex Pharmaceuticals Inc.

PALO ALTO, Calif., Oct. 30, 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 it had a successful end of Phase II meeting with the FDA leading to an agreed path forward to NDA upon completion of Phase III trials for blockbuster product candidate, SP-103 (lidocaine topical system) 5.4%, a next-generation, triple-strength formulation of ZTlido, for the treatment of chronic neck pain associated with muscle spasms.

Based on the independent market research conducted by Syneos Health Consulting ("Syneos"), with the substantial intent in utilization for SP-103 with peak sales potential projected to reach $1.2 billion annually in the 6th year post launch.

"We are very pleased with the end of Phase II meeting and received a clear path forward to NDA for our blockbuster product candidate, SP-103. SP-103 has the potential to meet our core goal of developing leading pain management therapies to significantly improve the lives of patients for the treatment of chronic neck pain associated with muscle spasms who are seeking new effective treatments. We are looking forward to conducting Phase 3 trials and believe that Scilex is the only company with technology allowing much higher lidocaine concentration than any other topical lidocaine system treatments. Higher concentration of a drug per covered area of skin is important for achieving therapeutic response", said Dmitri Lissin, M.D., Chief Medical Officer of Scilex.

- Scilex Pharmaceuticals, Inc. has three FDA-approved commercial products on the market and 3X version follow-on product, SP-103, is the next generation of ZTlido®:
  - ZTlido® (lidocaine topical system) 1.8%, a prescription lidocaine topical product for the relief of neuropathic pain associated with postherpetic neuralgia, which is a form of post-shingles nerve pain with an average of 50% growth in gross sales for the past two years. ZTlido® is expected to be distributed outside of the U.S. in 2025 with exclusive territory distributors in the Middle East and North/South Africa countries with a $105 million minimum 5 year purchase commitment.
  - ELYXYB® is a 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.[1] The U.S. oral

migraine drug market size was estimated to be $1.8 billion in 2022.[2]

- ELYXYB® filed a New Drug Submission (NDS) to Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for the approval of for acute treatment of migraine with or without aura in Canada. It is estimated to have impacted more than 2.7 million Canadians with the Canadian migraine therapeutics market estimated to reach approximately $400 million by 2025.[3]

- Gloperba®, the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults. Gout is a painful arthritic disorder affecting an estimated 9.2 million people in the United States[4]. The gout treatment market is projected to reach $2.0 billion in the U.S. by 2028 with a well-defined area of unmet need.[5]

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

For more information on Scilex Holding Company Sustainability Report, refer to www.scilexholding.com/investors/sustainability.

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. 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.

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, 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 development of SP103, the Company's outlook, goals and expectations for 2024 and 2025, and the Company's development and commercialization plans.

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; general economic, political and business conditions; 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 SEC, including Scilex's Annual Reports 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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4) https://jamanetwork.com/journals/jama/fullarticle/2787544#:~:text=How%20Common%20Is%20Gout%3F,%25%20of%20the%20adult%20population
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6) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8725362/#:~:text=Neck%20pain%20is%20a%20multifactorial,100%2C000%2C%20respectively%20%5B5%5D

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 Scilex Holding Company to use the registered trademark.

ELYXYB® is a registered trademark owned by Scilex Holding Company.

All other trademarks are the property of their respective owners.

Source: Scilex Holding Company