Scilex Holding Company Announces that its Board of Directors has Authorized Management to Explore Ways to Maximize the Value of its Wholly Owned Subsidiary, Scilex Pharmaceuticals Inc., including by way of conducting a spinoff or public listing of securities of Scilex Pharmaceuticals Inc. Scilex Pharmaceuticals Commercial Products Include Three Non-Opioid Approved Products and Pipeline of Phase 3 Ready SP-103 With Greater Than a $1.0 Billion Revenue Potential

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- Scilex Holding Company seeks to maximize the value of its stockholders, including by way of conducting a spinoff or public listing of securities of Scilex Pharmaceuticals ("Scilex Pharma") in markets and on securities exchanges in or outside of the U.S., including Hong Kong.
- Scilex Holding Company management believes the potential value of Scilex Pharma may exceed the current valuation of its parent company, Scilex Holding Company, and that a potential spinoff or public listing of Scilex Pharma would serve to unlock the potential value of Scilex Pharma and its parent, Scilex Holding Company. Also a potential strategic transaction and/or dividend of Scilex Pharma common stock to Scilex Holding Company stockholders.

- Scilex Pharma has three FDA-approved commercial products in the market and 3X version follow-on product, SP-103, for 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, estimated to exceed $180 million gross sales in 2024.

    - 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.
        - The anticipated timeline for approval in Canada is expected to be Q1-2025.

        - According to market data from 2018, it was found that migraine was more severe than other types of headaches and 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]

- SP-103 (lidocaine topical system) 5.4%, ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of acute 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.

PALO ALTO, Calif., Oct. 16, 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 that its board of directors has authorized management to explore ways to maximize the value of its wholly owned subsidiary, Scilex Pharma, including by way of conducting a spinoff or public listing of securities of Scilex Pharma in markets and on securities exchanges outside of the U.S., including Hong Kong, and/or a potential strategic transaction or dividend of Scilex Pharma common stock to Scilex stockholders.

Scilex Pharma launched its first commercial product in October 2018, ZTlido (lidocaine topical system) 1.8% ("ZTlido"), a prescription lidocaine topical system that is designed with novel technology to address the limitations of current prescription lidocaine therapies by providing significantly improved adhesion and continuous pain relief throughout the 12-hour administration period. In 2023, ZTlido® was recognized as the most prescribed non-opioid branded pain treatment by pain specialists, according to Prescription Data from Symphony Health and ZTlido® profile being viewed as a leading prescription lidocaine patch by pain specialists. Based on the independent market research conducted by Syneos Health Consulting ("Syneos"), with the new campaign, health care providers (HCPs) report increased awareness and substantial intent to utilize for ZTlido® with peak sales potential projected to reach over $500 million in the next 6 years in the U.S. In June 2022, Scilex Pharma in-licensed the exclusive right to commercialize GLOPERBA (colchicine USP) oral solution ("GLOPERBA"), a U.S. Food and Drug Administration ("FDA")-approved prophylactic treatment for painful gout flares in adults, in the United States of America ("U.S." or the "United States"). In February 2023, Scilex Pharma acquired the rights related to ELYXYB (celecoxib oral solution) ("ELYXYB") and the commercialization thereof in the U.S. and Canada. 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. Scilex Pharma launched ELYXYB in the U.S. in April 2023 and commercialized GLOPERBA in the U.S. in June 2024.

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, 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 the potential terms, structure and timing of any value maximizing transaction involving Scilex Pharma, including any potential spin-off or public listing of Scilex Pharma securities, the expectation that such listing or other transaction will maximize stockholder value, Scilex management's estimates for the equity value of Scilex Pharma and any potential proceeds from an initial public offering, Scilex's estimates for peak potential sales for ZTlido in the next six years in the U.S. , 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 and whether a market will be established for Scilex's or Scilex Pharma's common stock; risks related to the ability to engage in any value maximizing transaction involving Scilex Pharma, including the failure to satisfy any regulatory or stock exchange listing requirements for the listing of Scilex Pharma's securities; 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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Reference

1) Source: Celecoxib Oral Solution Approved for Acute Migraine March 2020. https://www.neurologylive.com/view/celecoxib-oral-solution-gets-goahead-for-acute-migraine
2) Source: Evaluate Pharma data February 16, 2023
3) Source: Mordor Intelligence - MIGRAINE THERAPEUTICS MARKET (2020-2025)
4) https://jamanetwork.com/journals/jama/fullarticle/2787544#:~:text=How%20Common%20Is%20Gout%3F,%25%20of%20the%20adult%20population
5) Evaluate Pharma data
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