Scilex Holding Company to Present Poster on ELYXYB® (celecoxib oral solution) at the 66th Annual Scientific Meeting of the American Headache Society (AHS) to be Held in San Diego, CA on June 13-16, 2024

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- Up to 60% of patients with migraine do not sufficiently respond to triptans.
- Efficacy of celecoxib oral solution in participants with insufficient response to triptans for the acute treatment of migraine: pooled results from a post-hoc analysis of two Phase 3 randomized clinical trials.
- In patients who had an insufficient response to triptans, significantly more patients in the ELYXYB®-treated arm achieved 2-hour pain freedom (the gold standard for efficacy endpoint in migraine) than placebo (33.3% vs. 14.3%, p=0.0036). The likelihood of achieving pain freedom was 200% greater with ELYXYB® than with placebo (OR=3.0).

PALO ALTO, Calif., June 13, 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 it will be presenting a poster on ELYXYB® (celecoxib oral solution) at the 66th Annual Scientific Meeting of the American Headache Society (AHS) to be held in San Diego, CA on June 13-16, 2024.

Presenting Author: Richard B. Lipton, M.D., Director of the Montefiore Headache Center and Edwin S. Lowe Professor and Vice Chair of Neurology, Professor of Epidemiology and Population Health and Professor of Psychiatry and Behavioral Sciences at the Albert Einstein College of Medicine. Poster Session 1 on June 13, 2024 at 6:00PM PT to 7:30PM PT.

The poster presentation will describe the efficacy of celecoxib oral solution in participants with insufficient response to triptans for the acute treatment of migraine: pooled results from a post hoc analysis of two Phase 3 randomized clinical trials. Key highlights of the ELYXYB® (celecoxib oral solution) presentation:

- Efficacy of celecoxib oral solution in participants with insufficient response to triptans for the acute treatment of migraine: pooled results from a post-hoc analysis of two Phase 3 randomized clinical trials.
- In a post-hoc analysis of two Phase 3 randomized clinical trials, the efficacy of ELYXYB® was compared with placebo in patients who were previously treated with triptans.
- In patients who had an insufficient response to triptans, significantly more patients in the ELYXYB®-treated arm achieved 2-hour pain freedom (the gold standard for efficacy endpoint in migraine) than placebo (33.3% vs. 14.3%, p=0.0036). The likelihood of achieving pain freedom was 200% greater with ELYXYB® than with placebo (OR=3.0).

“Up to 60% of patients with migraine do not sufficiently respond to triptans. The magnitude of ELYXYB’s treatment effect in these patients differentiates it from other acute treatments and makes ELYXYB a potentially valuable treatment option in migraine,” said Richard B. Lipton, M.D., Director of the Montefiore Headache Center and Edwin S. Lowe Professor and Vice Chair of Neurology, Professor of Epidemiology and Population Health and Professor of Psychiatry and Behavioral Sciences at the Albert Einstein College of Medicine.

To download the poster presentation, please click here

For more information on Scilex Holding Company, refer to www.scilexholding.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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info@scilexholding.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, which was launched on June 10, 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 and which 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 chronic neck pain and for which Scilex has recently completed a Phase 2 trial in 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 efficacy and treatment potential of ELYXYB compared to other acute treatment alternatives.

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, 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.

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.

Gloperba® is the subject of an exclusive, transferable license to Scilex Holding Company to use the registered trademark.

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All other trademarks are the property of their respective owners.

Source: Scilex Holding Company