Scilex Holding Company Announces Filing of a New Drug Submission (NDS) to Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for the Approval of ELYXYB® for Acute Treatment of Migraine With or Without Aura in Canada

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- 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 is estimated to be $2.3 billion in 2025.[2]
- According to market data from 2018, it was found that migraine was more severe than other types of headaches and it impacted more than 2.7 million Canadians with the Canadian migraine therapeutics market estimated to reach approximately $400 million by 2025.[2]
- There is strong evidence for the use of non-steroidal anti-inflammatory drugs (NSAIDs) as a first-line treatment for migraine. ELYXYB® (celecoxib oral solution) is in the same class of agents, is fast acting, and has the potential to have the lowest gastrointestinal (GI) side effects of all NSAIDs.[3]
- The anticipated timeline for approval in Canada is approximately 12 months depending on review cycles and information requests by Health Canada.

PALO ALTO, Calif., Dec. 26, 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 that it has filed a New Drug Submission (NDS) to Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for the approval of ELYXYB® for acute treatment of migraine with or without aura in Canada.

Clinicians in a recent market research study expressed their desire for fast and safe alternatives for two large pools of acute migraine patients – those who have an insufficient response to triptan therapy, and those who have contraindications to triptan use. ELYXYB®'s product profile mapped with a high degree of certainty to these stated unmet needs. In clinical studies, patients treated with ELYXYB® demonstrated pain relief in as little as 15 minutes, and significant pain relief compared to placebo within 45 minutes in approximately 50% of patients.[4,5]

"We are very excited about the potential of ELYXYB® since launching the product in the U.S. in April 2023. This is a highly complementary commercial asset that allows us to provide physicians with another tool in their pain management armamentarium to treat migraines earlier in the patient journey. We believe the filing of the NDS in Canada furthers our commitment to continue working towards redefining the role of opioids as a last resort rescue medication worldwide," said Jaisim Shah, Chief Executive Officer and President of Scilex.

For more information on ELYXYB®, including Full Prescribing Information, please visit ELYXYB.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 FDAScilex 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 estimates for the migraine therapeutic market and the patient population for migraine in Canada, , the timing of Health Canada's review process and whether it approves the NDS for ELYXYB®, ELYXYB®'s potential to further expand Scilex's non-opioid portfolio and its potential to address high unmet needs in treating acute migraine, 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 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.

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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: Mordor Intelligence - MIGRAINE THERAPEUTICS MARKET (2020-2025)
3) Source: Acute Migraine Headache: Treatment Strategies. https://www.aafp.org/pubs/afp/issues/2018/0215/p243.html
4) Data on file. Scilex Holding Company
5) Lipton RB, et al. J Pain Res 2021; 14:549-560.

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.

Source: Scilex Holding Company