Scilex Holding Company Provides Responses to Product Composition Questions Related to its ELYXYB® Patent in Canada for a New Drug Submission Under Review by Health Canada 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]
- 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. Scilex filed the NDS with Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences in December 2023

PALO ALTO, Calif., March 18, 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 that it has responded to questions on the product composition in the ELYXYB patent from Health Canada's Office of Patented Medicines and Liaison (OPML) during review 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.

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]

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

For more information on ELYXYB®, including Full Prescribing Information, refer to www.elyxyb.com.

For more information on ZTlido® including Full Prescribing Information, refer to www.ztlido.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, expected to launch in the first half of 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 has 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 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 and a Phase 2 clinical trial is expected to commence 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 expectation to launch Gloperba® in the first half of 2024 and plans to initiate a Phase 2 clinical trial in 2024 for SP-104.

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, 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: 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.

Source: Scilex Holding Company