Scilex Holding Company Announces that It Will Be Filing Today of a Supplemental New Drug Application with the FDA for ELYXYB® in Acute Pain Indication

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- ELYXYB®, a rapid onset and ready-to-use formulation of Celecoxib, delivers a first line non-opioid therapeutic alternative to habit-forming opioids and acetaminophen, the leading cause of acute liver failure in the U.S.(1)
- DelveInsight estimates there were approximately 100 million cases of acute pain in the United States and that the total acute pain market in the U.S. was approximately $3 billion in 2021.(2)
- Approximately 40 million Americans with acute pain are prescribed an opioid to manage their discomfort each year.(3)
- ELYXYB® is the first and only ready to use oral solution designed to deliver fast and long-lasting migraine relief with the proven safety of COX-2 selectivity that is FDA-approved for the acute treatment of migraine, with or without aura, in adults.(4)
- Acute pain has been defined as "the physiologic response and experience to noxious stimuli that can become pathologic, is normally sudden in onset, time limited, and motivates behaviors to avoid actual or potential tissue injuries."(1) Acute pain usually lasts for less than seven days but often extends up to 30 days; for some conditions, acute pain episodes may recur periodically. In some patients, acute pain persists to become chronic.(5)

PALO ALTO, Calif., Jan. 21, 2025 (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 and, following the formation of its proposed joint venture with IPMC Company, in neurodegenerative and cardiometabolic disease, today announced that it will be filing today of a Supplemental New Drug Application (SNDA) with the FDA for ELYXYB® in acute pain indication.

The analgesic efficacy and safety of ELYXYB®, a new oral liquid formulation of celecoxib with more rapid absorption than the capsule, were evaluated in the treatment of acute pain in adult patients after dental surgery. In this randomized, double-blind, placebo-controlled, dose-ranging study, 120 otherwise healthy adults who underwent the extraction of bilateral impacted mandibular third molar teeth and experienced moderate to severe pain post-surgery were randomly assigned to receive one dose of either placebo or ELYXYB®: 62.5, 125, or 250 mg. All 3 doses of ELYXYB® were significantly superior to placebo in SPID6 (summed pain intensity difference over 6 hours). In addition, ELYXYB® was generally superior to placebo in other endpoints, including reduction of pain intensity, speed and magnitude of pain relief, treatment satisfaction, and rescue medication use (oxycodone / acetaminophen). ELYXYB® was similar to placebo in the incidence of adverse events with no apparent dose-related effects.(6)

“It is very exciting to see the advancement of new effective therapeutic options for acute pain. Opioid-sparing medications are a priority in both non-operative and post-operative pain control. Reducing reliance on opioids with a new rapidly absorbed liquid formulation of celecoxib is very much welcomed. The rapid onset of action and convenience of dosing will significantly improve our armamentarium to provide the best patient care,” said Aakash A. Shah, M.D., physician for NBA team Miami Heat and President of the Medical Staff at Mid-America Surgery Institute.

ELYXYB® is formulated using the self-microemulsifying drug delivery system (SMEDDS), which is a clear, thermodynamically stable, oil-in-water emulsion of lipid, solubilized drug, and two surfactants, which spontaneously forms droplets < 100 nm in diameter. These components help deliver pre-solubilized drugs to the gastrointestinal tract, while protecting them from degradation in gastric acid or first-pass hepatic metabolism. The American Headache Society recently updated their consensus statement for the acute treatment of migraine and included a selective cyclo-oxygenase-2 selective inhibitor formulated in SMEDDS, celecoxib oral solution. (4) This SMEDDS formulation showed pronounced improvement in bioavailability compared with celecoxib capsules, allowing for a low dose of celecoxib in the oral solution to provide safe and effective acute migraine treatment.(7)

“We are well positioned to broaden the ELYXYB ® label with an additional acute pain indication and further solidify the potential role of ELYXYB® as a cornerstone in opioid-sparing acute pain management regimens that support accelerated recovery and eventually freedom from pain”, said Dmitri Lissin, M.D., Chief Medical Officer of Scilex.

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

For more information on Semnur Pharmaceuticals, Inc., refer to www.semnurpharma.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 and, following the formation of its proposed joint venture with IPMC Company, in neurodegenerative and cardiometabolic disease. 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 is 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.

Scilex Holding Company is headquartered in Palo Alto, California.

About Semnur Pharmaceuticals, Inc.

Semnur Pharmaceuticals, Inc. ("Semnur") is a clinical late-stage specialty pharmaceutical company focused on the development and commercialization of novel non-opioid pain therapies. Semnur's product candidate, SP-102 (SEMDEXA™), is the first non-opioid novel gel formulation administered epidurally in development for patients with moderate to severe chronic radicular pain/sciatica.

Semnur Pharmaceuticals, Inc. 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 Elyxyb's potential as an acute pain therapy, whether the FDA approves the sNDA for ELYXYB, ELYXYB's potential to further expand Scilex's non-opioid portfolio and its potential to address high unmet needs in treating acute pain, the potential market size and the size of the patient population for acute pain in the U.S., Gloperba being the first and only liquid oral version of the anti-gout medicine, Scilex's plans to commercialize Gloperba and the potential for the amended license agreement to accelerate Scilex's commercialization plans, Scilex's proposed joint venture with IPMC Company and the potential development and commercialization of treatments for obesity, neurodegenerative, cardiometabolic disease.

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: Scilex's ability to commercialize GLOPERBA outside of the US, Scilex's ability to consummate a joint venture or any other transaction with IPMC Company and develop and commercialize treatments for obesity, neurodegenerative, cardiometabolic disease; 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 with the SEC, 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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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 a registered trademark owned by Scilex Holding Company.

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