Scilex Holding Company announces the commercial launch of ELYXYBTM (celecoxib oral solution) in the U.S., strengthening its leadership position in non-opioid pain management

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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 $1.8 billion in 2022.[2]
- There is strong evidence for the use of NSAIDs as a first-line treatment for migraine. Celecoxib is in the same class of agents, is fast acting, and has the potential to have the lowest GI side effects of all NSAIDs.[3]
- Strong re-launch commercialization efforts including multiple manuscripts, five posters at American Headache Society (AHS), and more than six thousand interactions with potential customers have laid the groundwork for what Scilex believes will be the successful re-introduction of ELYXYB™
- The New Drug Application (NDA) for ELYXYB™ has been transferred to Scilex. Scilex is planning to launch the product in the second quarter of 2023 through its wholly owned subsidiary, Scilex Pharmaceuticals Inc.
- Scilex is well-positioned to market and distribute ELYXYB™ which is highly complementary to Scilex's existing commercial offerings.
    - Scilex is negotiating a distribution agreement with a major third-party logistic provider for warehousing and distribution of ELYXYB™.
    - Scilex has a very experienced commercial and managed care team that has successfully launched and grown market access for ZTlidoÒ (lidocaine topical system) for over 200 million covered lives in the U.S.
    - The combined commercial pain portfolio of ZTlidoÒ, GloperbaÒ and ELYXYB™ offers end-to-end non-opioid solutions along the pain pathway.

PALO ALTO, CA – February 27, 2023 /Newswire/ — Scilex Holding Company (Nasdaq: SCLX, "Scilex"), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (OTC: SRNEQ), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain, announced the commercial launch of ELYXYB™ (celecoxib oral solution) in the U.S. Starting today, ELYXYB™ is available in pharmacies to customers and supplied through their normal wholesaler and distributor channels. ELYXYB™ was approved by the U.S. Food and Drug Administration (FDA) on May 6, 2020, for the treatment of acute migraine with or without aura in adults.

Strong re-launch commercialization efforts including multiple manuscripts, five posters at American Headache Society (AHS), and more than six thousand interactions with potential customers have laid the groundwork for what Scilex believes will be the successful re-introduction of ELYXYB™ into the outpatient marketplace.

"This is an important day for Scilex as the launch of ELYXYB expands our pain management industry leadership and marks a major milestone in our strategy to build a robust offering of novel, non-opioid treatments to improve patient care along the acute and chronic pain pathway," said Jaisim Shah, Chief Executive Officer and President of Scilex. "ELYXYB is a highly complementary commercial asset that allows us to provide physicians with another tool in their pain management armamentarium to tackle migraines earlier in the patient journey as we continue to redefine the role of opioids as a last resort rescue medication. Importantly, ELYXYB will diversify our revenue stream, enhance our topline, and we believe it will provide meaningful synergies that we expect to drive substantial near- and long-term accretion to our cash flows and earnings."

The Scilex sales force, consists of approximately 65 pain specialists who cover more than 80 percent of the physicians Scilex is targeting for ELYXYB™. Since we acquired ELYXYB™, our team has been executing a training and market access strategy, working closely with key customers to initiate the review process to obtain access for ELYXYB™.

"We intend to build off the FDA-approved acute migraine indication through a targeted clinical and regulatory expansion plan encompasses clinical development, partnerships with key clinical leaders and robust publication and medical education plans," said Dmitri Lissin M.D., Chief Medical Officer

of Scilex Holding Company.

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 has applied for breakthrough therapy designation and expects to seek priority review for SEMDEXA™ for the treatment of sciatica. Scilex 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 in October 2018, in-licensed a commercial product in June 2022, and is 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 postherpetic 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 is planning to commercialize Gloperba® in 2023 and is well-positioned to market and distribute the product. 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, triple-strength formulation of ZTlido®, for the treatment of low back pain, with FDA Fast Track status; 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 expected to initiate Phase 2 trials this year. For further information regarding the SP-102 Phase 3 efficacy trial, see NCT identifier NCT03372161 – Corticosteroid Lumbar Epidural Analgesia for Radiculopathy – Full Text View – ClinicalTrials.gov.

Scilex Holding Company is headquartered in Palo Alto, California. For further information please visit www.scilexholding.com.

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 their 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 Scilex's potential plans and timing to launch ELYXYB ™, the status of Scilex's negotiations of a distribution agreement with a major third-party logistics provider, ELYXYB™s potential to further expand Scilex's non-opioid portfolio and increase Scilex's revenue, cash flow and earnings, the potential market size for U.S. oral migraine drugs and for pain management therapeutics,Scilex's long-term objectives and commercialization plans, including the re-launch plans for ELYXYB ™, 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 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 that Scilex may not achieve the results expected from the commercialization of ELYXYB™; general economic, political and business conditions; risks related to the ongoing COVID-19 pandemic; 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 results of the Phase 2 trial for SP-103 or Phase 1 trials for 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 SEC. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release except as may be required by law.

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Reference

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https://www.neurologylive.com/view/celecoxib-oral-solution-gets-goahead-for-acute-migraine
2. Source: Evaluate Pharma data February 16, 2023
3. Source: Acute Migraine Headache: Treatment Strategies. https://www.aafp.org/pubs/afp/issues/2018/0215/p243.html

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