Scilex Holding Company, a majority-owned subsidiary of Sorrento Therapeutics, Inc., acquires rights to FDA-Approved ELYXYBTM in the U.S. and Canada for the acute treatment of migraine

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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 acute migraine drug market size is expected to reach US$9.26 billion by 2030.[3]
- There is strong evidence for use of NSAIDs as first-line treatment for migraine, and celecoxib is in same class of agents, fast acting and has the potential to have the lowest GI side effects of all NSAIDs.[2]
- ELYXYB™ has the potential to further expand Scilex's non-opioid portfolio in broader acute pain indications and its acquisition establishes a growth platform for Scilex and fits within Scilex's existing commercial team.
- The pain management therapeutics market size is estimated to reach US$ 101.27 billion by 2029 and growing at a CAGR of 4.3% from 2022 to 2030.[4]
- ELYXYB™ is protected by six Orange Book-listed method-of-use patents that expire in 2036.
- Scilex is well-positioned to market and distribute ELYXYB™:
  - Scilex has a direct distribution network to national and regional wholesalers and pharmacies throughout the U.S.
  - Scilex has a very experienced commercial and managed care team that has successfully launched and grown market access for ZTlido (lidocaine topical system) for over 200 million covered lives in the U.S.

PALO ALTO, February 12, 2023 /Newswire/ — Scilex Holding Company (Nasdaq: SCLX, "Scilex"), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento"), 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 that it has acquired rights to 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.

"I am delighted that liquid celecoxib will remain on the market. It is a very important medication we use to treat migraine, with fast onset and favorable safety and tolerability profile." Said Dr. Peter McAllister, Medical Director of the New England Institute for Neurology and Headache and Chief Medical Officer of the New England Institute for Clinical Research and Ki Clinical Research, Associate Professor of Neurology at the Yale University School of Medicine, New Haven, Connecticut, and Clinical Professor of Neurology and Anatomy at the Frank H. Netter School of Medicine at Quinnipiac University, Hamden, Connecticut.

"The acquisition of ELYXYB reaffirms Scilex's commitment to offer innovative, non-opioid pain management products and to develop meaningfully differentiated programs that address significant unmet needs leading to better health outcomes for the millions of acute and chronic pain patients," commented Henry Ji, Ph.D., Executive Chairperson of Scilex and Chairman and Chief Executive Officer of Sorrento.

"We are very pleased to announce the addition of ELYXYB ™ to our current portfolio of two FDA-approved commercial non-opioid pain products. We expect this third product will accelerate our strong commitment to offer novel formulations that are opioid sparing and non-addictive for millions of acute and chronic pain patients and will be a great fit within our top-notch commercial team," said Jaisim Shah, President and Chief Executive Officer of Scilex.

ELYXYB™ is an oral solution of celecoxib, formulated using a self-micro emulsifying drug delivery system that improves solubility and bioavailability of the drug leading to better absorption[5]. In pivotal studies, ELYXYB™ demonstrated a rapid onset of action which is critically important to patients suffering from acute migraine attacks. The results from pivotal studies with ELYXYB™ have established the efficacy of celecoxib in the treatment of migraine with very few adverse events. This allows for the administration of a lower dose of drug to achieve therapeutic effect relative to a conventional oral solid dosage form. For adult patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. ELYXYB™s unit-dose of oral solution makes it convenient for patients to take it immediately upon emergence of acute migraine attacks.

About Scilex Holding Company

Scilex Holding Company, a majority-owned by Sorrento Therapeutics, Inc., 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, with operations in both Palo Alto and San Diego, California. For further information please visit www.scilexholding.com.

About Sorrento Therapeutics, Inc.

Sorrento is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease and COVID-19. Sorrento's multimodal, multipronged approach to fighting cancer is made possible by its extensive immuno-oncology platforms, including key assets such as next-generation tyrosine kinase inhibitors ("TKIs"), fully human antibodies ("G-MAB™ library"), immuno-cellular therapies ("DAR-T™"), antibody-drug conjugates ("ADCs"), and oncolytic virus ("Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including STI-1558, COVISHIELD™ and COVIDROPS™, COVI-MSC™; and diagnostic test solutions, including COVIMARK™.

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a TRPV1 agonist, non-opioid pain management small molecule, resiniferatoxin ("RTX"), and SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXA™), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and to commercialize ZTlido® (lidocaine topical system) 1.8% for the treatment of postherpetic neuralgia (PHN). RTX has been cleared for a Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. Positive final 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. ZTlido® was approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.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, Sorrento 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 ELYXYB™'s potential to further expand Scilex's non-opioid portfolio, the potential market size for migraine drugs and for pain management therapeutics,Scilex's long-term objectives and commercialization plans, Scilex's potential to attract new capital and avoid the effects of negative debt leverage, 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 Sorrento's products, technologies and prospects and Scilex's products, technologies and prospects.

Risks and uncertainties that could cause Sorrento's and Scilex's actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: 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 Sorrento's and 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.

Contacts:

For Scilex Holding Company

Jaisim Shah
Chief Executive Officer
Scilex Holding Company
960 San Antonio Road
Palo Alto, CA 94303
Office: (650) 516-4310

Email: investorrelations@scilexholding.com

Website: www.sorrentotherapeutics.com and www.scilexholding.com

Investors and Media Contact:

Contact: Stephen Ma

Email: investorrelations@scilexholding.com

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