# Scilex Holding Company, a Subsidiary of Sorrento Therapeutics, Announces Continuous Sales Growth in ZTlido® and Expects to Complete Enrollment on its SP-102 (SEMDEXA™) Phase 3 Pivotal Trial Program in 2020

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PALO ALTO, Calif., Oct. 07, 2020 (GLOBE NEWSWIRE) — Scilex Holding Company ("Scilex"), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento"), today announced continuous sales growth in ZTlido ® from quarter to quarter in 2020. Scilex expects third quarter 2020 ZTlido® net sales to grow 26% to approximately $7.2MM, compared to $5.7MM in Q2-2020. The preliminary third quarter 2020 net sales information presented in this press release is based on Scilex's current expectations and may be adjusted as a result of, among other things, completion of customary quarterly review procedures.

Scilex's SP-102 (SEMDEXA™) is currently being evaluated in a pivotal Phase 3 clinical trial in the U.S. to evaluate patients with lumbosacral radicular pain/sciatica. The trial is expected to complete enrollment in the fourth quarter of 2020 and top-line data is expected in the second quarter of 2021. Scilex intends to use the results from this pivotal Phase 3 trial to discuss with U.S. health authorities the basis for licensure application to the U.S. Food and Drug Administration (FDA) for this high unmet need indication where no treatments have been approved and which is responsible for millions of people suffering in the U.S. alone. Scilex has extensive clinical and pre-clinical data (including multiple Phase 2 clinical trials) with the novel viscous formulation of SP-102, which was designed to provide extended local effect for sciatica patients. The robust data collected over the course of the company's multi-year clinical development program will be presented to the U.S. FDA as part of a new drug application.

The CLEAR ("Corticosteroid Lumbar Epidural Analgesia for Radiculopathy") clinical study is a randomized, double-blind, placebo-controlled Phase 3 trial that is expected to enroll 400 patients with lumbosacral radicular pain at 40+ sites across the U.S. The primary endpoint of the study is mean change in the Numeric Pain Rating Scale (NPRS) for leg pain with SP-102 epidural injection compared to intramuscular injection of placebo over four weeks. The secondary endpoints include other measures of pain at 4 and 12 weeks as well as time to repeat injection of SP-102, safety and function. The study includes an open-label extension to build the safety database of patients treated with SP-102. "We are anxiously awaiting a new injectable formulation of dexamethasone and registration for treatment of radicular pain based on results of a large, randomized placebo-controlled multi-center trial. If approved by the FDA, SP-102 would be the first corticosteroid for epidural injections addressing safety issues with steroid medications, currently used off-label, and an important addition to armamentarium of interventional pain physicians," said Dr. Steve Cohen, Chief of Pain Medicine and Professor of Anesthesiology & Critical Care Medicine, Neurology and Physical Medicine & Rehabilitation, Johns Hopkins School of Medicine, and Professor of Anesthesiology and Physical Medicine & Rehabilitation, Walter Reed National Military Medical Center, Uniformed Services University of the Health Sciences.

SP-102 is a novel, non-opioid injectable viscous gel formulation in development for the treatment of lumbosacral radicular pain, containing no neurotoxic preservatives, surfactants, solvents or particulates. The SP-102 formulation is administered by epidural injection. Based on preclinical and clinical studies conducted to date, it extends the residency time at the site of injection and has not demonstrated the safety concerns that led the FDA to issue a class warning on the currently off-label use of injectable corticosteroids to include information about the risk of serious neurologic events with epidural steroid injections (ESIs).

"Lumbosacral radicular pain, otherwise known as sciatica, is commonly treated by off-label epidural steroid injections. There are an estimated ten to eleven million epidural steroid injections administered per year in the U.S. alone and there are no approved steroids for epidural injections.[2] The clinical results for the pivotal Phase 3 trial for SP-102 will be a seminal milestone for Scilex and may provide encouraging news for the many millions of people who are confronting debilitating radicular pain/sciatica. We believe that SP-102 could be the first FDA-approved epidural steroid product for patients suffering from this common, painful condition," said Jaisim Shah, President and Chief Executive Officer of Scilex.

In 2019, the overall estimated number of ESI procedures in the U.S. was 11.6 million across all Medicare and private coverage patients, with lumbar radiculopathy / sciatica procedures comprising approximately 88% of all ESIs administered. Despite widespread utilization of ESIs, concerns persist in the market about particulate steroids and potential side effect and safety concerns (e.g., stroke) from current off-label use. As a result, a significant unmet medical need exists within the market for a potent, non-particulate ESI formulation that demonstrated safety and effectiveness in controlled clinical trial evaluations.[1]

In the U.S., more than 30 million people live with low back and radicular pain, with this population expected to grow as the population ages.[4,5] Many patients experience moderate to severe pain with intolerance and/or inadequate response to current analgesic therapies such as opioids and nonsteroidal anti-inflammatory drugs (NSAIDs).[6,7] There is a great need for highly effective analgesic medications to provide patient relief without the toxicity and tolerability challenges of NSAIDs and opioids.[5] Opioid prescriptions account for about 40 percent of the chronic pain market and carry a well-known risk of abuse and misuse, underscoring the need for alternative pain therapies without the medical and societal challenges.[5,8]

Chronic pain affects 100 million, or almost one- in-three, Americans[9], with nearly 33 million patients suffering from lower back pain in the U.S.[10], and costs the United States approximately $560 to $635 billion annually., Government agencies, physicians, patients, and payers are looking for alternatives to opioids to reduce the risk of dependency or addiction, and serious side effects (such as respiratory depression and constipation), while still offering potent solutions for people living with chronic pain.

**About Sorrento Therapeutics, Inc.**

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers 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 fully human antibodies ("G-MAB™ library"), clinical stage immuno-cellular therapies ("CAR-T", "DAR-T"), antibody-drug conjugates ("ADCs"), and clinical stage oncolytic virus ("Seprehvir ®", "Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIDTRAP™, ACE-MAB™, COVI-MAB™, COVI-GUARD™, COVI-SHIELD™, COVI-AMG™ and T-VIVA-19™; and diagnosti solutions, including COVI-TRACK™, COVI-STIX™ and COVI-TRACE™

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, resiniferatoxin ("RTX"), and ZTlido ® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX has completed a phase 1B trial for intractable pain associated with cancer and a phase 1B trial in osteoarthritis patients. ZTlido® was approved by the FDA on February 28, 2018. SP-102 is undergoing a Phase 3 pivotal trial for the treatment of lumbosacral radicular pain/sciatica.

For more information visit www.sorrentotherapeutics.com

**About Scilex Holding Company.**

Scilex Holding Company, a majority-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE), is a commercial-stage, non-opioid pain management company focused on the development and commercialization of topical and injectable therapies. Scilex targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with moderate to severe chronic pain. Scilex launched its first commercial product in October 2018 and is developing its late-stage pipeline, which includes a pivotal Phase 3 candidate and a Phase 2 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's two product candidates are SP-102 (10 mg, dexamethasone sodium phosphate viscous gel), or SEMDEXA™, a Phase 3, novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and SP-103 (lidocaine topical system) 5.4%, or SP-103, a Phase 2, next-generation, triple-strength formulation of ZTlido, for the treatment of chronic low back pain.

**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 Sorrento Therapeutics, Inc. and its subsidiaries, including but not limited to Scilex Holding Company, Scilex Pharmaceuticals, Inc. and Semnur Pharmaceuticals, Inc. 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 expected timing for completing enrollment for the Phase 3 trial for SP-102; expected third quarter 2020 ZTlido® net sales; the expected timing for receipt of top-line data for the Phase 3 trial for SP-102; discussions with the FDA and health authorities regarding any new drug application for SP-102; clinical trial endpoints; expectations that SP-102 may be the first FDA-approved epidural steroid product for the treatment of sciatica; the outcome of the data from a clinical trial for SP-102; Scilex Holding's prospects; future clinical trials and the results thereof and market and patient population trends. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to risks related to the completion of the customary quarterly financial statement review procedures; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risks that prior test, study and trial results may not be replicated in future studies and trials; risks that SP-102 may not meet all endpoints of the clinical study and that the data may not support an NDA submission; risks of difficulties or delays in obtaining regulatory approvals and risks related to the global impact of COVID-19. 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.

**Media and Investor Relations**

Contact: Alexis Nahama, SVP Corporate Development
Telephone: 1.858.203.4120
Email: mediarelations@sorrentotherapeutics.com
Website: www.sorrentotherapeutics.com

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ZTlido® is a trademark owned by Scilex Pharmaceuticals Inc.

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