



Scilex Holding Company, a majority-owned subsidiary of Sorrento Therapeutics, Inc., Announces Final Results for SP-102 (SEMDEXA™) Efficacy and Safety from its Pivotal Phase 3 Clinical Trial Program for Sciatica Pain Management Supporting the Potential for First to Market Opportunity

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- SP-102 (SEMDEXA™), with 401 patients enrolled in the C.L.E.A.R. trial (Corticosteroid Lumbosacral Epidural Analgesia in Radiculopathy) experienced a rapid onset of pain relief, measured by Numeric Pain Rating Scale of average daily pain in the affected leg, with highly statistically significant improvement against placebo over the first 4 weeks, following a single transforaminal injection, LS Mean (SEM) difference -1.08 (0.17), with a p-value < 0.001.
- SP-102 (SEMDEXA™) showed continued reduction of pain beyond one month, and the median time to open-label repeat injection was 99 days (95% CI: 78, 129 days) according to a Kaplan-Meier estimation. By contrast, off-label injectable steroids typically provide pain relief for periods ranging from less than a week and up to one month, and then a repeat injection may be required.
- The key secondary endpoint of Oswestry Disability Index, the gold standard for measuring degree of disability and estimating quality of life, showed a 28% improvement at 4 weeks on SP-102 (SEMDEXA™) compared to baseline (minimal clinically meaningful improvement 8%-12%)¹³. The LS Mean (SEM) difference as compared to placebo was -6.28 (1.49), with a p-value < 0.001.
- Safety analysis demonstrated a very clean safety profile with no identified safety risks. There were no serious adverse events related to the drug or injection procedure, and no adverse events of special interest reported, such as hematoma and infection at the injection site, or paraplegia. These events are associated with the off-label use of non-approved injectable steroid preparations. The C.L.E.A.R trial also established the safety of repeat injections, as patients who experienced moderate-to-severe radicular pain between 4 and 23 weeks were allowed to receive open-label additional SP-102 (SEMDEXA™) injection. The safety analysis was comparable between treatment groups through 4, 12 and 24 weeks of study period.

PALO ALTO, CA., March 18, 2022 (GLOBE NEWSWIRE) – Scilex Holding Company (“Scilex”), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”), today announced highly significant positive final results from its SP-102 (SEMDEXA™) Phase 3 Pivotal Trial C.L.E.A.R. Program. SP-102 (SEMDEXA™) has received Fast Track status from the FDA.

The C.L.E.A.R. Trial (Corticosteroid Lumbosacral Epidural Analgesia for Radiculopathy) was designed to investigate safety and analgesic effects of a single and repeat transforaminal injections of SP-102 (SEMDEXA™) compared to placebo (saline injection). The trial enrolled 401 low back pain subjects with unilateral intervertebral disc herniation in lumbar spine resulting in radicular pain symptoms of moderate to severe leg pain. It is the largest known randomized well-controlled trial in sciatica using epidural steroid injections. The primary endpoint of change in average daily pain in the affected leg over 4 weeks following the initial injection demonstrated LS Mean (SEM) group difference of -1.08 (0.17) compared to placebo with a p-value <0.001. SP-102 (SEMDEXA™) is the first non-opioid novel injectable corticosteroid gel formulation product in development for the treatment of lumbar radicular pain, and it contains no preservatives, surfactants, solvents, or particulates.

The key secondary endpoint of Oswestry Disability Index, the gold standard for measuring degree of disability and estimating quality of life, showed a 28% improvement at 4 weeks on SEMDEXA™ compared to baseline (minimal clinically meaningful improvement 8%-12%)¹³. The LS (Least Square) Mean (Standard Error of Means) difference as compared to placebo was -6.28 (1.49), with a p-value < 0.001.

SP-102 (SEMDEXA™) demonstrated pain relief that continued through 12 weeks. Other pain measurements, such as worst daily and current pain in the affected leg and average daily pain in lower back, demonstrated statistically significant results compared to placebo. Most of the other secondary endpoints in hierarchical arrangement for sequential testing procedure also demonstrated statistically significant results, and included Global

Impression of Change, Brief Pain Inventory, PainDETECT, and cumulative use rescue medications (acetaminophen).

Safety analysis demonstrated a very clean safety profile with no identified safety risks. There were no serious adverse events related to the drug or injection procedure, and no adverse events of special interest reported, such as hematoma and infection at the injection site, or paraplegia. These events are associated with the off-label use of non-approved steroid preparations. The C.L.E.A.R trial had also established safety of repeat injections, as patients who experienced moderate-to-severe radicular pain between 4 and 23 weeks were allowed to receive open-label additional SP-102 (SEMDEXA™) injection. The safety analysis was comparable between treatment groups through 4, 12 and 24 weeks of study period.

"We are very pleased with the positive outcome and these trial results are very remarkable. They will impact greatly the pain management community and will enable us to proceed with our plans for registering SP-102 (SEMDEXA™) with the FDA for the treatment of subacute lumbosacral radicular pain. We believe SP-102 (SEMDEXA™) has the potential to be a transformative treatment option for sciatica, an area that has not seen any significant advancement in therapies that patients and physicians have been seeking for decades. We plan to present the results from the Phase 3 C.L.E.A.R trial at upcoming scientific conferences and submit for publication in a peer-reviewed journal," said Dmitri Lissin, MD, Chief Medical Officer of Scilex.

Scilex intends to use the results from this pivotal Phase 3 trial to discuss with the FDA in 2022 licensure application requirements and Breakthrough Designation Status for the high unmet need sciatica indication for which no treatments have been approved in the U.S. Scilex has extensive clinical and pre-clinical data (including multiple Phase 2 clinical trials) with the novel viscous gel formulation of SP-102 (SEMDEXA™), which was designed to provide extended local effect and non-opioid pain relief for sciatica patients. Scilex expects to present the robust data collected over the course of the company's multi-year clinical development program to the FDA as part of a New Drug Application (NDA).

More than 60% of U.S. opioid prescriptions are for the treatment of chronic low back pain (CLBP)¹ despite the fact that opioids are associated with serious and potentially life-threatening side effects and have not demonstrated efficacy in the treatment of CLBP.^{2,3,4} In 2018, more than 67,000 drug overdose deaths occurred in the United States⁵ of which almost 47,000 (70%) were opioid related. Over 70% of the 70,630 deaths in 2019 involved an opioid.⁶ Provisional data release by the Centers for Disease Control and Prevention showed drug overdose deaths rose by nearly 29% over a 12-month period ending in April 2021, to an estimated 100,306.⁷

"We are delighted with these highly significant positive clinical results for the pivotal SP-102 (SEMDEXA™) Phase 3 trial and this may provide encouraging news for the many millions of people worldwide who are confronting painful radicular pain (sciatica). We believe that SP-102 (SEMDEXA™) could be the first FDA-approved epidural steroid gel injection product for patients suffering from this common, very painful condition. I really appreciate the work of the Scilex team and their passion for addressing America's opioid crisis and in continuing our mission to improve our ability to help millions of patients dealing with acute and chronic pain issues, in exciting new ways. These final data results mark an exciting and important milestone in our journey to become the premier non-opioid pain management company," said Jaisim Shah, President and Chief Executive Officer of Scilex.

SP-102 (SEMDEXA™) is the first non-opioid novel injectable corticosteroid gel formulation product in development for the treatment of lumbar radicular pain, and it contains no preservatives, surfactants, solvents, or particulates. If approved by the FDA, the SP-102 (SEMDEXA™) formulation will be available in a pre-filled syringe formulation and will be administered as an epidural injection for the treatment of sciatica. Based on preclinical and clinical studies, SP-102 (SEMDEXA™) extends the residency time at the site of injection and does not show the safety concerns that led the FDA to warn against using other injectable steroid formulations by the epidural route of administration.

While off-label used steroids provide pain relief for periods ranging from less than a week and up to one month, after which a repeat injection may be required, SP-102 (SEMDEXA™) showed continued reduction of pain beyond one month, and the median time to open-label repeat injection was 99 days (95% CI: 78, 129 days) according to Kaplan-Meier estimation

By 2022, the overall estimated number of epidural steroid injection (ESI) procedures in the U.S. is expected to be 12.1 million across all Medicare and private coverage patients, with lumbar radiculopathy/sciatica procedures comprising approximately 88% of all ESIs administered, according to a proprietary study by Syneos Health Consulting. 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 novel, non-particulate ESI formulation that demonstrates safety and effectiveness in controlled clinical trial evaluations.¹²

In the U.S., more than 30 million people suffer from low back and radicular pain. This population is expected to grow as the overall population ages.^{8,9} Many patients experience moderate to severe pain with intolerance of and/or inadequate response to current analgesic therapies such as opioids and nonsteroidal anti-inflammatory drugs (NSAIDs).^{10,11} There is a great need for highly effective analgesic medications to provide patient relief without the toxicity and tolerability challenges of NSAIDs and opioids.⁹

Scilex Holding Company and Vickers Vantage Corp. I (Nasdaq: VCKA) ("VCKA"), a special purpose acquisition company sponsored by Vickers Venture Fund VI Pte Ltd and Vickers Venture Fund VI (Plan) Pte Ltd, have entered into a definitive business combination agreement ("BCA"). Upon closing of the transaction, the combined company (the "Combined Company") will be renamed Scilex Holding Company, and its common stock is expected to be listed on Nasdaq under the ticker symbol "SCLX". The boards of directors of each of VCKA, Scilex and Sorrento have unanimously approved the proposed transaction. The closing of the transaction, which is expected to occur by the third quarter of 2022, is subject to the approval of VCKA's shareholders and the satisfaction or waiver of certain other customary closing conditions.

A corporate presentation describing Scilex's development plans can be found at www.scilexholding.com.

[Download Presentation](#)

About Scilex Holding Company

Scilex Holding Company, a majority-owned subsidiary of Sorrento Therapeutics, Inc., is dedicated to the development and commercialization of non-opioid pain management products for 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. 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 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'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%, or SP-103, a Phase 2, next-generation, triple-strength formulation of ZTlido®, for the treatment of low back pain; and SP-104, 4.5 mg Delayed Burst Release Low Dose Naltrexone

Hydrochloride (DBR-LDN) Capsule, for the treatment of chronic pain, fibromyalgia in multiple Phase 1 programs to be initiated 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 immunology platforms, including key assets such as 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 Abivertinib, COVI-AMG™, COVISHIELD™, COVI-MSCTM and COVIDROPS™; and diagnostic test solutions, including COVITRACK™ and COVISTIX™.

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a 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 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 post-herpetic 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. SEMDEXA announced highly statistically significant positive top-line results from its Phase III Pivotal Trial C.L.E.A.R Program for its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica). ZTlido® was approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.com.

About Vickers Vantage Corp. I

Vickers Vantage Corp. I is a blank check company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities.

Important Information and Where to Find It

This press release references a proposed transaction between Scilex and VCKA. This press release does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the transaction described herein, VCKA intends to file relevant materials with the SEC, including a registration statement on Form S-4, which will include a document that serves as a prospectus and proxy statement of VCKA, referred to as proxy statement/prospectus. After the registration statement is declared effective by the SEC, the proxy statement/prospectus will be sent to all VCKA shareholders as of a record date for the meeting of VCKA shareholders to be established for voting on the proposed business combination. VCKA will also file other documents regarding the proposed transaction with the SEC. This press release does not contain all of the information that will be contained in the proxy statement/prospectus or other documents filed or to be filed with the SEC. Before making any voting decision, investors and security holders of VCKA are urged to read the registration statement, the proxy statement/prospectus and all other relevant documents filed or that will be filed with the SEC in connection with the proposed transaction as they become available because they will contain important information about the proposed transaction. **Investors and security holders of VCKA are urged to read these materials (including any amendments or supplements thereto) and any other relevant documents in connection with the transaction that VCKA files with the SEC when, and if, they become available because they will contain important information about VCKA, Scilex and the proposed transaction.** Investors and security holders will be able to obtain free copies of the registration statement, the proxy statement/prospectus and all other relevant documents filed or that will be filed with the SEC by VCKA through the website maintained by the SEC at www.sec.gov.

Participants in the Solicitation

VCKA and its directors and executive officers may be deemed participants in the solicitation of proxies from VCKA's shareholders in connection with the transaction. A list of the names of such directors and executive officers and information regarding their interests in the proposed business combination will be contained in the proxy statement/prospectus when available. You may obtain free copies of these documents as described in the preceding paragraph.

Scilex and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of VCKA in connection with the proposed transaction. Information about Scilex's directors and executive officers and information regarding their interests in the proposed transaction will be included in the proxy statement/prospectus for the proposed transaction.

Non-Solicitation

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of VCKA, the Combined Company or Scilex, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

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 VCKA, Sorrento Therapeutics, Inc. and its subsidiaries, including but not limited to Scilex, 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 proposed business combination between Scilex and VCKA, including the timing of such business combination, the potential listing of the Combined Company's common stock on Nasdaq or other major securities exchange and the anticipated stock ticker symbol for such shares, the expectation that VCKA will file a registration statement on Form S-4 with the SEC, which would include a proxy statement/prospectus, the estimated or anticipated future results and benefits of the Combined Company following the proposed business combination, including the likelihood and ability of the parties to successfully consummate the proposed business combination, future opportunities for the Combined Company, the timing of the completion of the proposed business combination, Scilex's and the Combined Company's proposed business strategies, the expected cash resources of the Combined Company and the expected uses

thereof; Scilex's expectation that SP-102 (SEMDEXA™) would be the first FDA-approved non-opioid epidural injection for sciatica; Scilex's intent to use the results from the pivotal Phase 3 trial to discuss with the FDA a licensure application and Breakthrough Designation Status for sciatica and to support a New Drug Application, as well as the timing of a proposed NDA filing for SP-102; Scilex's and the Combined Company'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 SP-102 (SEMDEXA™), 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, including the potential for Scilex's product candidates to be best-in-class or first-in-class therapies. 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: the inability of the parties to consummate the proposed business combination transaction for any reason or the occurrence of any event, change or other circumstances that could give rise to the termination of the BCA, including any failure to meet applicable closing conditions; changes in the structure, timing and completion of the proposed transaction between VCKA and Scilex; VCKA's ability to continue its listing on the Nasdaq Capital Market until closing of the proposed transaction; the Combined Company's ability to list its securities on Nasdaq or other major securities exchange after closing of the proposed transaction; the ability of the parties to achieve the benefits of the proposed transaction, including future financial and operating results of the Combined Company; the ability of the parties to realize the expected synergies from the proposed transaction; risks related to the outcome of any legal proceedings that may be instituted against the parties following the announcement of the proposed business combination; 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 prior results of the clinical trials of SP-102 (SEMDEXA™) may not be replicated; regulatory and intellectual property risks; the risk that any requisite regulatory approvals to complete the transaction are not obtained, are delayed or are subject to unanticipated conditions that could adversely affect the Combined Company or the expected benefits of the proposed transaction or that the approval of VCKA's shareholders is not obtained; the risk of failure to realize the anticipated benefits of the proposed transaction; the amount of redemption requests made by VCKA's shareholders and other risks and uncertainties indicated from time to time and other risks set forth in Sorrento's and VCKA's filings with the Securities and Exchange Commission. 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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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.

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