Scilex, a Sorrento Company, Announces Pivotal Phase 3 SP-102 (SEMDEXA™) Data Presentation At The American Society Of Interventional Pain (ASIPP) 2022 Annual Meeting

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Results from a Pivotal Phase 3, DB, R, Placebo-controlled, Multicenter Trial of SP-102, a Novel Dexamethasone Injectable Formulation, for the Treatment of Patients with Lumbosacral Radiculopathy (Sciatica)

- 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 study met its primary endpoint with a highly statistically significant reduction in average daily leg pain in patients receiving SEMDEXA™ compared to placebo ($p<0.001$).
- Data demonstrated the utility of SEMDEXA™ in rapidly reducing sciatica pain with an extended effect for up to 99 days following a single epidural injection of SP-102 (SEMDEXA™).
- Safety analysis demonstrated a clean safety profile with no identified safety risks. There were no serious adverse events related to the drug or injection procedure. No adverse events of special interest such as hematoma and infection at the injection site, or paraplegia were reported. 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 20 weeks were allowed to receive open-label additional SP-102 (SEMDEXA™) injection.
- 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%).[1] The LS Mean (SEM) difference as compared to placebo was -6.28 (1.49), with a p-value < 0.001.
- “It has been a while since new drugs have been developed for interventional pain procedures. We are anxiously awaiting a new injectable formulation of viscous gel dexamethasone with extended local effect and its FDA approval for the treatment of radicular pain based on the results of this large randomized multicenter placebo-controlled trial. If approved by the FDA, it will be the first corticosteroid ever approved for epidural injections addressing safety issues with steroid medications that have been used off-label in the past few decades. This could be an important addition to treatment options for these patients, a game-changer”, said Prof. Dr. Nebojsa Nick Knezevic, M.D., Ph.D.

PALO ALTO, CA. May 5, 2022 /Newswire/ — Scilex Holding Company (“Scilex”), a Sorrento Company (nearly 100% or over 99.9% majority-owned subsidiary of Sorrento Therapeutics, Inc.) (Nasdaq: SRNE, “Sorrento”) and a commercial biopharmaceutical company focused on developing and commercializing non-opioid therapies for patients with acute and chronic pain, announced pivotal Phase 3 SEMDEXA™ data presentation at the American Society of Interventional Pain 2022 annual meeting. The pivotal Phase 3 SP-102 (SEMDEXA™) trial has a highly positive results evaluating SEMDEXA™ in sciatica patients following an epidural injection was presented at the Innovation summit session of the 2022 American Society of Interventional Pain (ASIPP) Annual Scientific Meeting in Las Vegas, Nevada. Results from this multicenter, randomized, double-blind, placebo-controlled study demonstrated that patients experienced rapid onset of pain reduction in sciatica pain and the effect lasted for up to 99 days following a single injection of SEMDEXA™ at the end of the procedure. This is the first time this trial study data has been presented at a major North American medical meeting.

The podium presentation described the Phase 3 trial, known as the C.L.E.A.R. trial program, randomized 401 lumbosacral radicular pain/sciatica patients at 40 sites across 25 states in the U.S., which is the largest double-blind randomized controlled epidural steroid injection clinical trial in sciatica.

Presenting Author: Prof. Dr. Nebojsa Nick Knezevic, M.D., Ph.D., Professor of Anesthesiology and Surgery, College of Medicine, University of Illinois at Chicago, President of the Illinois Society of Interventional Pain Physicians, Director-at-Large of the North American Society of Neuromodulation,

Vice-Chair for Research and Education, Advocate Illinois Masonic Medical Center, Department of Anesthesiology and Pain Management.

The presentation at the Innovation Summit session, ASIPP on May 5, 2022, described the outcome of the C.L.E.A.R. trial. Key findings from this study include:

- The study met its primary endpoint with a highly statistically significant reduction in average daily leg pain in patients receiving SEMDEXA™ compared to placebo ($p<0.001$).
- A total of 401 sciatica patients were enrolled at 40 clinical sites in US.
- The median time (days) to repeat injection in Placebo group was 57 and 99 days in the SEMDEXA™ group, according to Kaplan-Meier estimation ($p<0.001$)
- Safety analysis demonstrated a 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. 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 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%)

"These Phase 3 data demonstrate that the median time to repeat injection for patients treated with SEMDEXA™ was significantly longer than those treated with placebo," said Dmitri Lissin, SVP and CMO of Scilex Holding. "We believe these data coupled with Phase 2 results from our repeat-dose trial and earlier PK/PD trial in sciatica patients will help support product registration with the FDA and utility of SEMDEXA™ in a pain clinic setting. This is the first time that these pivotal Phase 3 data are being presented at a North American medical meeting and we believe this is another important milestone as we execute on our clinical and pre-commercial strategies."

There is about 60% use of opioid pain medications for chronic back pain[2] which is directly linked to many new persistent opioid users every year and up to many new cases of Opioid Use Disorder annually, making low back pain opioid use an important contributor to the opioid epidemic in the United States.

"With more than 30 million low back pain and sciatica patients every year in the US[3,4], there is enormous need for an approved treatment and a desperate need for effective non-opioid alternatives," said Annu Navani, Secretary ASIPP and Medical Director, Comprehensive Spine & Sports Center and Adjunct Clinical Associate Professor, Stanford University School of Medicine. "Epidural steroid injections have been used more than half a century for low back and leg pain, and there has always been a need for safer, longer lasting and more efficacious formulations."

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, entered into a definitive business combination agreement ("BCA") on March 17, 2022. Upon the 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.

About Scilex Holding Company

Scilex Holding Company, a Sorrento Company (nearly 100% or over 99.9% 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. Highly positive 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 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%, a Phase 2, 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 expected 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 immuno-oncology 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, COVISHIELD™ and 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 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 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

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 for Investors and Stockholders

This press release relates to 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. **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 efficacy and safety profile of SP-103 for treatment of LBP in patients, the ability of SP-103 to address limitations of prescription lidocaine patches in treating acute LBP, Scilex's expected timeline to complete this Phase 2 study and plans for subsequent phase 3 trial(s),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 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™) or SP-103, 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 results of the Phase 2 trial for SP-103 may not be successful; risks that the prior results of the clinical trials of SP-102 (SEMDEXA™) or SP-103 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 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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References

1. Yoshina et al., 2019 and Ostelo, de Vet. Clinically important outcomes in low back pain. Best Practice & Research Clinical Rheumatology. Volume 19, Issue 4, August 2005, Pages 593-607.
2. Deyo & Weinstein 2001

3. Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 76 & 80
4. Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 40