

# Scilex, a Sorrento Company, Highlights Safety Data From Phase 1 Trial of SP-104, a Proprietary Low Dose Naltrexone for Fibromyalgia

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- SP-104 is a novel, proprietary, fixed dose, delayed burst release of low dose naltrexone hydrochloride, 4.5 mg, for treatment of fibromyalgia (FM).
- There is a clear medical need for new, safe and effective treatments with the potential to improve care for the estimated 10 million FM patients in the U.S. and more than 200 million worldwide
- Phase 1 clinical trial data showed that SP-104 treated healthy volunteers and had lower rates
  of adverse events, as compared with immediate release naltrexone -treated volunteers.

PALO ALTO and SAN DIEGO, CA. May 11, 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 today that safety data from Scilex's Phase 1 clinical trial demonstrated that SP-104 was better tolerated than immediate release naltrexone hydrochloride 4.5 mg at the same dose in healthy volunteers. A second Phase 1 pharmacokinetic trial has completed enrollment and results will be available soon.

SP-104 is a novel, proprietary, fixed dose, delayed burst release of low dose naltrexone, for the treatment of FM and has an end goal of reducing side effects associated with formulations of immediate release naltrexone and FM disease burden. SP-104 has key clinical data supporting its use in the treatment of FM. Prior investigational trials support the use and development of SP-104, delayed burst release naltrexone hydrochloride 4.5 mg, for FM. Currently there are no low-dose formulations (i.e., less than 5 mg) available. Physicians currently use the commercially available high-dose tablets (naltrexone hydrochloride 50 mg) and have compounding pharmacies aliquot lower doses for patients. Pharmacy-compounding is inherently inaccurate and does not involve analyses to confirm that the aliquoted product has the target level of drug, and there is no assurance as to content uniformity within a batch as well as other quality attributes critical for pharmaceutical product performance. This can lead to errors in dosing and challenges with titration. The commercial products and pharmacy-compounded products also allow for the immediate release of the drug in the stomach, which can lead to compliance challenges due to severe side effects. Common side effects for naltrexone include hyperalgesia, dysphoria, insomnia and anxiety. All these issues culminate into patient compliance issues and result in the eventual abandonment of an otherwise viable therapy to treat this debilitating disease. SP-104 uses delayed burst release technology that bypasses the stomach and releases the drug in the gut (upper intestine). When taking SP-104 at night before bed, peak drug levels are achieved at night during sleep, allowing the patient to avoid conscious perception of hyperalgesia and other side effects. The combination of the delayed-release and administration at night may also maximize efficacy as most endorphin/enkephalin release is during sleep, which maximizes the product's potential to elicit compensatory response.

Scilex is committed to develop SP-104 for FM. Phase 1 studies are to characterize the pharmacokinetic and safety profile of SP-104, and Scilex intends to initiate a Phase 2 study in the second half of 2022. If successful, we believe SP-104 can become a pivotal treatment for management of FM, which represents a large commercial opportunity with high unmet needs. "There is a clear medical need for new, safe and effective treatments with the potential to improve care for the estimated 10 million FM patients in the U.S. and more than 200 million worldwide," commented Dmitri Lissin, M.D., Chief Medical Officer of Scilex. "Our Phase 1 clinical trial data demonstrated that healthy volunteers treated with SP-104 had lower rates of adverse events, as compared with immediate release naltrexone -treated volunteers. This is an especially encouraging result when viewed in the background of the large number of current FM patients and high provider dissatisfaction with the few existing approved FM treatments".

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 VCKAs 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<sup>TM</sup>, 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<sup>TM</sup>, 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 <a href="https://www.scilexholding.com">www.scilexholding.com</a>.

#### 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, COVI-AMG™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™ ε 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<sup>TM</sup>), 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<sup>TM</sup>, 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 <a href="https://www.sec.gov">www.sec.gov</a>.

## Participants in the Solicitation

VCKA and its directors and executive officers may be deemed participants in the solicitation of proxies from VCKAs 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-104 for treatment of FM in patients, the ability of SP-104 to address limitations of currently used commercially available high-dose tablets in treating FM, Scilex's expected timeline to complete this Phase 1 study, plans for a second Phase 1 pharmacokinetic trial and plans for subsequent phase 2 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 (SEMDEXATM), 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, 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; VCKAs 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 Nasdag 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 or Phase 1 trial 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; 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 VCKAs shareholders is not obtained; the risk of failure to realize the anticipated benefits of the proposed transaction; the amount of redemption requests made by VCKAs shareholders and other risks and uncertainties indicated from time to time and other risks set forth in Sorrento's and VCKAs 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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