



Scilex Holding Company, a Sorrento Company, Announces That the FDA Has Granted Fast Track Designation for SP-103 (Lidocaine Topical System) 5.4%, Next Generation Triple Strength Formulation Of ZTlido®, For The Treatment Of Acute Low Back Pain (LBP)

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- SP-103 receives Fast Track Designation, which makes it eligible for some or all of the following:
 - More frequent meetings or written communication with the FDA to discuss the SP-103 development plan and ensure collection of appropriate data needed to support drug approval
 - Eligibility for Accelerated Approval or Priority Review, if relevant criteria are met
 - Rolling Review, which means that Scilex can submit completed sections of its New Drug Application (NDA) for review by the FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.
- Despite an overall lack of evidence to support their efficacy, opioids continue to be prescribed to treat acute LBP when patients seek medical evaluation.
- According to the CDC in 2020, LBP was the most common type of pain reported by patients, with 25% of U.S. adults reporting LBP in the prior 3 months¹
- LBP is estimated to have a total potential global market opportunity of approximately \$10.0 billion by 2026 ².

PALO ALTO, CA. August 30, 2022 /Newswire/ — Scilex Holding Company (“Scilex”), a commercial biopharmaceutical company focused on developing and commercializing non-opioid therapies for patients with acute and chronic pain, today announced that FDA has granted fast track designation for its investigational drug and device product candidate, SP-103. Scilex is a nearly 100% (or over 99.9%) majority-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”). Scilex is developing SP-103 to be a non-opioid triple-strength, non-aqueous lidocaine topical system for the treatment of acute LBP. If approved, SP-103 could become the first FDA-approved lidocaine topical product for the treatment of acute LBP. Acute LBP can range in intensity from a dull, constant ache to a sudden, sharp sensation that leaves the person incapacitated. According to the CDC in 2020, LBP was the most common type of pain reported by patients, with 25% of U.S. adults reporting LBP in the prior 3 months¹. LBP is estimated to have a total potential global market opportunity of approximately \$10.0 billion by 2026.²

“We are pleased that the FDA has granted Fast Track Designation for SP-103”, said Dr. Dmitri Lissin, Chief Medical Officer of Scilex. “The FDA’s decision to place SP-103 in a category that may enable expedited development and review is an important milestone for Scilex.”

There are currently no approved pharmaceutical treatments specifically indicated for the treatment of acute LBP. The market Scilex intends to address with SP-103, if approved, includes etiologies that are currently treated with non-procedural or non-surgical interventions, and where available treatments provide inadequate pain relief or result in unacceptable adverse effects. These treatments may include NSAIDs, antidepressants and opioids, as well as off-label use of lidocaine patches.

“We are very pleased that the FDA has granted Fast Track designation for the non-opioid SP-103 program, the next generation triple strength formulation of ZTlido®,” said Jaisim Shah, President and Chief Executive Officer of Scilex. There are currently very limited approved treatment options for acute low back pain, a serious condition the prevalence of which continues to rise, leaving this affected group with very limited safe and effective treatment options to date. Receiving this designation underscores the potential of the ZTlido® platform and the need for a new therapy like SP-103 that may improve outcomes for those with this serious debilitating condition.”

The safe and effective treatment of acute LBP represents high unmet needs and creates a large market opportunity. LBP is one of the costliest musculoskeletal conditions in industrialized countries. Experts have estimated that approximately 80% of Americans will experience LBP during their lifetime. The annual prevalence of LBP is 15% to 45% with a point prevalence of approximately 30% in the United States. Sixty percent of those who suffer from acute LBP recover in six weeks and up to 80-90% recover within 12 weeks. However, the recovery of the remaining patients with LBP is less certain. LBP accounts for 19% of all workers’ compensation claims in the United States. ³ Americans spent at least \$135 billion in 2016 on treating low back and neck pain, which was the highest expenditure among 154 conditions studied by the Department of the Institute for Health Metrics and Evaluation at the University of Washington.⁴

Scilex’s triple-strength SP-103 is an investigational, non-aqueous lidocaine topical system undergoing clinical development in acute LBP conditions. SP-103 builds on the learnings from Scilex’s FDA-approved product, ZTlido® (topical lidocaine system) 1.8%, because both products share the same adhesive drug delivery formulation and manufacturing technology. Scilex believes that, if approved, SP-103 could become the first FDA-approved lidocaine topical product for acute LBP indications. All current uses of topical lidocaine products for acute LBP are off-label. SP-103 has three times the drug load of ZTlido® (108 mg versus 36 mg) in the same adhesive system to potentially deliver a three-fold level of the drug within a targeted area, but retaining the convenience of a single topical system. Additionally, SP-103 is designed to deliver a localized dose of lidocaine that is three times

greater than any lidocaine topical product that Scilex is aware of either on the market or in development. Scilex believes that, if approved, SP-103 may be able to address the limitations of prescription lidocaine patches in treating acute LBP by delivering a higher dose of lidocaine to the application site. As part of the lifecycle management, Scilex will also target localized musculoskeletal pain, acute and chronic pain conditions, and post-operation pain management, to focus on developing and commercializing non-opioid therapies for patients with acute and chronic pain. Scilex expects to complete its current Phase 2 trial of SP-103, randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate the safety and efficacy in subjects with acute lower back pain (LBP) in 10 U.S. sites, in Q1-2023. The outcome should enable planning of subsequent Phase 3 trial(s). ClinicalTrials.gov link: [Safety and Efficacy of SP-103 in Subjects With Moderate to Severe Acute Lower Back Pain – Full Text View – ClinicalTrials.gov](#)

Under Section 561A(f)(2) of the United States Federal Food, Drug, and Cosmetic Act, Scilex is required to make our expanded access policy for SP-103 (lidocaine topical system) 5.4% publicly available by September 10, 2022 (within 15 days of the signature date of the FDA Fast Track letter).

Scilex Holding Company and Vickers Vantage Corp. I (Nasdaq: VCKA) (“Vickers”), 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”) 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 and warrants to purchase common stock are expected to be listed on Nasdaq under the ticker symbol “SCLX” and “SCLXW”, respectively. The boards of directors of each of Vickers, Scilex and Sorrento have unanimously approved the proposed transaction. The closing of the transaction, which is expected to occur in the third quarter or early fourth quarter of 2022, is subject to the approval of Vickers’s and Scilex’s shareholders and the satisfaction or waiver of certain other customary closing conditions.

About Scilex Holding Company

Scilex Holding Company, a nearly 100% (or over 99.9%) majority-owned subsidiary of Sorrento Therapeutics, Inc., is an innovative revenue-generating company focused on acquiring, developing 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. Results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXATM, 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, 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® beginning in the first half of 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 SEMDEXATM, 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 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.

About Sorrento Therapeutics

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 next-generation tyrosine kinase inhibitors (“TKIs”), fully human antibodies (“G-MABTM library”), immuno-cellular therapies (“DAR-TTM”), antibody-drug conjugates (“ADCs”), and oncolytic virus (“SeprehvecTM”). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including STI-1558, COVISHIELDTM and COVIDROPSTM; and diagnostic test solutions, including COVIMARKTM.

Sorrento’s commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance (TRPV1 agonist) non-opioid pain management small molecule, resiniferatoxin (“RTX”), and SP- 102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXATM), 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 SEMDEXATM, 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 Vickers. 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, Vickers has filed a Registration Statement on Form S-4 (the “Registration Statement”), which includes a document that serves as a prospectus and proxy statement of Vickers, referred to as the proxy statement/prospectus. After the Registration Statement is declared effective by the SEC, the proxy statement/prospectus will be sent to all Vickers shareholders as of a record date for the meeting of Vickers shareholders to be established for voting on the proposed business combination. Vickers 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 Vickers are urged to read these materials (including any amendments or supplements thereto) and any other relevant documents in connection with the transaction that Vickers files with the SEC when, and if, they become available because they will contain important information about Vickers, 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 Vickers through the website maintained by the SEC at www.sec.gov.

Participants in the Solicitation

Vickers and its directors and executive officers may be deemed participants in the solicitation of proxies from Vickers'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 Vickers 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 Vickers, 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 Vickers, Sorrento 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 any potential benefits of the Fast Track Designation for SP-103, the total potential global market opportunity for LBP, the ability of SP-103 to address limitations of prescription lidocaine patches in treating acute LBP, Scilex's expected timeline to complete the Phase 2 trial for SP-103, the proposed business combination between Scilex and combination, the potential listing of the Combined Company's common stock and warrants to purchase such shares and warrants to purchase common stock, the expectation that including the timing of such business common stock on Nasdaq or other major securities exchange and the anticipated stock ticker symbol for Registration Statement on Form S-4, 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 or SP-104, if approved by the FDA; Scilex's amendments to the (SEMDEXATM), SP-103 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: 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 Vickers and Scilex; Vickers'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 mic; 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 (SEMDEXATM), 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 Vickers'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 Vickers's shareholders and other risks and uncertainties indicated from time to time and other risks set forth in Sorrento's and Vickers's filings with the SEC, including in the Registration Statement. 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: jshah@scilexpharma.com

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

Investors and Media Contact:

Contact:
Brian Cooley

Email: mediarelations@sorrentotherapeutics.com

Website: www.sorrentotherapeutics.com

For Vickers Vantage Corp. I

Jeffrey Chi
Chief Executive Officer
85 Broad Street, 16th Floor
New York, NY 10004
Phone: (646) 974-8301
Email: jeff.chi@vickersventure.com

Website: www.vickersvantage.com

Investors and Media Contact:

Nicolette Ten, Senior Account Executive, SPRG

Email: nicolette.ten@sprg.com.sg

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SEMDEXATM (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.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc., a wholly owned subsidiary of Scilex Holding Company.

Gloperba® is an exclusive, transferable license to use the trademark by Scilex Holding Company. All other trademarks are the property of their respective owners.

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References

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