

# Sorrento Therapeutics Announces the Merger of Scilex and Semnur to Create a Global Leader in Non-Opioid Pain Management

March 22, 2019

Semnur's SP102, addressing multi-billion dollar unmet market needs, in Pivotal Phase 3 Trial with Fast Track Status from the FDA

With non-opioid ZTlido, RTX, and SP102 commercial and near-commercial product lines, Sorrento and its subsidiaries are addressing \$63 billion market in pain management (1)

SAN DIEGO, March 22, 2019 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE) announced today that its majority owned subsidiary Scilex Pharmaceuticals Inc. (Scilex) has closed a transaction to merge with Mountain View, California, based Semnur Pharmaceuticals, Inc. (Semnur) to form a new company, Scilex Holding Company (Scilex Holding). Sorrento's equity stake in Scilex (77%) has been converted into a 58% stake in Scilex Holding. With Scilex's lead product ZTlido® (lidocaine topical system 1.8%) ramping rapidly in the early months of commercial launch and Semnur's lead compound (non-opioid corticosteroid gel) in Phase 3 pivotal studies for the treatment of lumbar radicular pain/sciatica with Fast Track status from the FDA, Scilex Holding is well positioned to become a global leader in non-opioid pain management.

"This transaction is highly synergistic. Scilex has built up a commercial organization with over 100 highly experienced sales representatives, fully staffed marketing, market access, and medical liaison teams while Semnur has a very exciting Phase 3 compound in non-opioid pain management. The synergy is compelling on multiple fronts. With Semnur's SP102, ZTlido and the RTX product lines, Sorrento is now well positioned to address an approximately \$63 billion pain therapeutics market," stated Dr. Henry Ji, Chairman and CEO of Sorrento. "Semnur CEO Jaisim Shah and his team are bringing a tremendous amount of industry knowledge and an impressive proven record in pharmaceutical commercialization to the combined company. I am confident that under Jaisim's leadership, Scilex Holding will emerge as a preeminent force in the industry."

Mahendra Shah, Chairman of Semnur, which was backed by leading healthcare venture capital firms including Canaan Partners, Frazier Healthcare Partners, and Vivo Capital, commented, "We are very excited for Semnur to be part of the Sorrento family. With the ongoing opioid crisis, both companies have been in active dialogue with local, state and federal agencies on best strategies and methods to treat a continuum of chronic and acute pain conditions using non-addictive non-opioid therapies. We are confident that Scilex Holding can take full advantage of the opportunities created in this paradigm shift." Newly appointed Scilex Holding CEO Jaisim Shah added "I am delighted to be a part of this strategic combination which collectively underscores our mission to provide innovative non-opioid therapies to as many patients as possible. It also addresses alternative approaches to pain management mandated due to the epidemic overuse of opioids."

Semnur's lead compound SP102 has been awarded fast track status by the FDA. It is the first non-opioid corticosteroid formulated as a viscous gel injection in development for the treatment of lumbar radicular pain/sciatica, containing no neurotoxic preservatives, surfactants, solvents or particulates. The FDA's Fast Track program was implemented to expedite the development and regulatory review of therapeutic programs that seek to address significant unmet medical needs. As Scilex Holding develops SP-102 for lumbar radicular pain, the company will be eligible for more frequent communication with the FDA related to the drug development plan and data necessary to expedite the development of this novel non-opioid pain treatment. SP-102 is currently in a pivotal trial "Corticosteroid Lumbar Epidural Analgesia for Radiculopathy (C.L.E.A.R.)." The CLEAR study is a randomized, double-blind, placebo-controlled Phase 3 trial that will enroll 400 patients with lumbar radicular pain at 40+ sites across the U.S. The primary endpoint is mean change in the Numerical Pain Rating Scale for leg pain in patients receiving SP-102 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. Lifetime prevalence of lower back pain with radiculopathy ranges from 12% to 43%. (2)

ZTlido® (lidocaine topical system 1.8%) uses an advanced adhesion technology, providing more efficient lidocaine delivery than Lidoderm® (lidocaine patch 5%) over a full 12 hours. Poor adhesion is the most common complaint associated with lidocaine patches and ZTlido® has proven adhesion superiority over Lidoderm®. Post-herpetic neuralgia (PHN) is the most common complication of shingles, a condition caused by the herpes zoster virus. PHN affects an estimated 1 million people in the United States each year. ZTlido® received its FDA approval through a 505(b)(2) regulatory pathway, which required establishment of its bioequivalence to Lidoderm® in two separate pharmacokinetic studies. ZTlido® was approved by the FDA in February 2018 for relief of pain associated with PHN. Also under development is a topical system with a three-fold higher concentration of lidocaine, which takes advantage of ZTlido's thinner and more efficient delivery system to potentially address other types of pain.

(1) IQVIA National Sales Audit 2018 and Sorrento Pain Management Research

(2) Konstantinou; Spine 2008;33(22):2464-2472

## About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to turn malignant cancers into manageable and possibly curable diseases. 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"), intracellular targeting antibodies ("iTAb"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Seprehvir®").

Sorrento's commitment to life-enhancing therapies for cancer patients is also demonstrated by its effort to advance Resiniferatoxin ("RTX"), a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, ZTlido® and SP-102, a non-opioid corticosteroid gel. Resiniferatoxin is completing Phase 1b trials in terminal cancer patients and knee osteoarthritis patients. ZTlido was approved by US FDA on 02/28/18. SP-102 is in Phase 3 pivotal study for the treatment of lumbar radicular pain/sciatica. RTX Phase 3 studies in osteoarthritis knee pain are scheduled to start later in 2019.

For more information visit [www.sorrentotherapeutics.com](http://www.sorrentotherapeutics.com)

## About Scilex Pharmaceuticals Inc.

Scilex, a majority-owned subsidiary of Sorrento located in San Diego, California, responsibly develops and brings branded products to market using technologies designed to maximize quality of life for the patients it serves. Scilex is uncompromising in its focus to become the global pharmaceutical leader in pain management through social, environmental, economic and ethical principles. Dedicated to valued partnerships, Scilex strives to deliver next-generation products that are Responsible By Design. Its product, ZTLido® (lidocaine topical system) 1.8%, is a branded lidocaine topical system formulation for the treatment of relieving the pain of post-herpetic neuralgia, also referred to as after-shingles pain. For more information visit [www.scilexpharma.com](http://www.scilexpharma.com).

## **About ZTLido® (lidocaine topical system 1.8%)**

### **Indication**

ZTLIDO is indicated for relief of pain associated with post-herpetic neuralgia (PHN).

### **Important Safety Information**

#### **Contraindications**

ZTLIDO is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

#### **Warnings and Precautions**

Accidental exposure can occur even after a ZTLIDO patch has been used. Small children or pets could suffer serious adverse effects from chewing or ingesting a new or used ZTLIDO patch. Store and dispose of patches properly and keep out of reach of children and pets.

Excessive dosing or overexposure to lidocaine can occur. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increased blood concentration levels of lidocaine. If lidocaine overdose is suspected, check drug blood concentration. Management of overdose includes close monitoring, supportive care, and symptomatic treatment.

Cases of methemoglobinemia have been reported with local anesthetic use, although patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, or concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. Signs and symptoms include cyanotic skin discoloration and/or abnormal coloration of the blood and may occur immediately or may be delayed after exposure. Methemoglobin levels may continue to rise leading to more serious central nervous system and cardiovascular adverse effects. Discontinue ZTLIDO and any other oxidizing agents. Depending on severity of the symptoms, patients may respond to supportive care or may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Application site reactions can occur during or immediately after treatment with ZTLIDO. This may include development of blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours. Inform patients of these potential reactions and that severe skin irritation may occur with ZTLIDO if applied for a longer period than instructed.

Hypersensitivity cross-reactions may be possible for patients allergic to PABA derivatives. Manage hypersensitivity reactions by conventional means.

Eye exposure with ZTLIDO should be avoided. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye (such as, eye glasses/eye wear) until sensation returns.

#### **Adverse Reactions**

Side effects of ZTLIDO include application site reactions such as, irritation, erythema, and pruritus. These are not all of the adverse reactions that may occur. Please see Full Prescribing Information for more information.

#### **Use in Specific Populations**

Use of ZTLIDO during lactation should be used with caution as lidocaine is excreted into breast milk. The limited human data with lidocaine in pregnant woman is not sufficient to inform drug-associated risk for major birth defects and miscarriage.

To report SUSPECTED ADVERSE REACTIONS, contact SCILEX Pharmaceuticals Inc. at 1-866-SCILEX3 or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please click here for full Prescribing information: <https://www.ztlido.com/prescribing-information.pdf>

#### **Forward-Looking Statements**

This press release and any statements made for and during any presentation or meeting contains forward-looking statements related to Sorrento Therapeutics, Inc. and its subsidiaries, including but not limited to Scilex Pharmaceuticals Inc., Semnur Pharmaceuticals, Inc. and Scilex Holding Company, 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 developments of and prospects for SP-102, RTX and ZTLido; Sorrento's, Scilex Holding's, Scilex's and Semnur's products and technologies, including their antibody products and technologies and non-opioid pain products; outcome of the data from clinical trials for SP-102 and RTX; Scilex Holding's ability to continue to accelerate the development of SP-102 and RTX; expectations for Sorrento's and its subsidiaries' technologies and product candidates and financing prospects. 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 Sorrento's and its subsidiaries' technologies and prospects; the possibility that ZTLido may not be commercially successful; risks that SP-102 and RTX may not meet any or all endpoints of a clinical study and that any data generated from such studies may not support a regulatory submission or approval; risks related to seeking regulatory approvals and conducting clinical trials; and other matters that are described in Sorrento's Annual Report on Form 10-K for the year ended December 31, 2018, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, including the risk factors set forth in those filings. 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 required by law.

#### **Media and Investor Relations**

Contact: Alexis Nahama, DVM

Telephone: 1.858.203.4120

Email: [mediarelations@sorrentotherapeutics.com](mailto:mediarelations@sorrentotherapeutics.com)

Website: [www.sorrentotherapeutics.com](http://www.sorrentotherapeutics.com)

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SEMDEXA™ (SP-102) is a trademark owned by Semnur Pharmaceuticals, Inc. A proprietary name review by the FDA is planned.

Seprehvir®, is a registered trademark of Virtu Biologics Limited, a wholly-owned subsidiary of TNK Therapeutics, Inc. and part of the group of companies owned by Sorrento Therapeutics, Inc.

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