

## Scilex Announces ZTlido® Insurance Coverage for ~100 Million Insured Lives(1)

January 14, 2019

SAN DIEGO, Jan. 14, 2019 (GLOBE NEWSWIRE) -- Scilex Pharmaceuticals Inc. (SCILEX), a subsidiary of Sorrento Therapeutics, Inc. (NASDAQ: SRNE), today announced that ZTlido® (lidocaine topical system) 1.8% (ZTLIDO) is covered by nearly 100M U.S. insured lives<sup>1</sup>. ZTLIDO is indicated for relief of pain associated with postherpetic neuralgia (PHN), also referred to as post-shingles pain.



"SCILEX has been working closely with pharmacy benefit managers (PBMs) and health plans to help ensure patients and providers have access to ZTLIDO, a non-opioid, non-abusive treatment option for post-herpetic neuralgia," said Mike Sweeting, Vice President, Market Access, Scilex. "Having launched ZTLIDO less than 90 days ago, we think achieving 47%<sup>1</sup> commercial coverage this quickly is a testament that health plans and pharmacy benefit managers (PBMs) believe ZTLIDO can be part of the solution as we fight the opioid epidemic."

ZTLIDO is a topical system product that 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 of lidocaine patches,<sup>2</sup> and based on clinical data, ZTLIDO has proven adhesion superiority over Lidoderm®.<sup>3</sup> PHN is the most common complication of shingles, a condition caused by the herpes zoster virus.<sup>3</sup> PHN affects an estimated 1 million people in the United States each year.<sup>4</sup>

ZTLIDO was approved by the U.S. Food and Drug Administration (FDA) in February 2018 for relief of pain associated with PHN.

### 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

#### **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 we serve. We are uncompromising in our focus to become the global pharmaceutical leader in pain management through social, environmental, economic and ethical principles. Dedicated to valued partnerships, we strive to deliver next-generation products that are Responsible By Design. Our product, ZTlido<sup>®</sup> (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 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<sup>™</sup> library"), clinical stage immuno-cellular therapies ("CAR-T"), intracellular targeting antibodies ("ITAbs"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Seprehvir<sup>®</sup>").

Sorrento's commitment to life-enhancing therapies for cancer patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule in Resiniferatoxin ("RTX") and ZTlido<sup>®</sup>. Resiniferatoxin is completing a phase IB trial in terminal cancer patients.

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

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

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sorrento Therapeutics, Inc. and its subsidiaries, including, but not limited to, Scilex Pharmaceuticals Inc., 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 advantages of ZTlido<sup>®</sup> over other products, health plan and pharmacy benefit manager (PBM) coverage, intentions and strategy, Scilex's strategy, plans and prospects, Sorrento's strategy and other forward-looking statements. 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: that ZTlido<sup>®</sup> may not be commercially successful and other risks that are described in Sorrento's most recent periodic reports filed with the Securities and Exchange Commission, including Sorrento's Annual Report on Form 10-K for the year ended December 31, 2017, as amended, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, and if applicable, as amended, 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.

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

\*Lidoderm<sup>®</sup> is a registered trademark of Hind Health Care, Inc.

#### **References**

1. MMIT Analytics, Accessed January 13, 2019. ZTLIDO has 98.6M of 302.1M (33%) of insured lives with Preferred or Unrestricted coverage across all books of business of which 87.7M of 187.4M (47%) are commercially insured lives.
2. U.S. Food and Drug Administration. FDA Adverse Events Reporting System (FAERS) Public Dashboard. Data as of March 31, 2018. Accessed July 27, 2018.
3. Data on File. SCILEX Pharmaceuticals Inc.
4. CDC. Shingles (Herpes Zoster). Clinical Overview. <https://www.cdc.gov/shingles/hcp/clinical-overview.html>. Accessed November 30, 2018.

Source: Sorrento Therapeutics, Inc.