Sorrento Therapeutics Logo

Scilex Announces Addition of ZTlido® to Express Scripts National Formularies

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SAN DIEGO, Jan. 14, 2019 (GLOBE NEWSWIRE) -- Scilex Pharmaceuticals Inc. (SCILEX), a subsidiary of Sorrento Therapeutics, Inc. (NASDAQ: SRNE), today announced that Express Scripts has added ZTlido® (lidocaine topical system) 1.8% to its commercial national formularies representing nearly 30 million lives. ZTLIDO is indicated for relief of pain associated with postherpetic neuralgia (PHN), also referred to as post-shingles pain.

"SCILEX worked diligently with Express Scripts to ensure that patients and providers will have access to ZTLIDO, a non-opioid, non-abusive treatment option for post-herpetic neuralgia," said Mike Sweeting, Vice President, Market Access, Scilex. "Express Scripts' decision to include ZTLIDO on its national formularies in recognition of the benefit it can provide to patients with post-herpetic neuralgia, or PHN, is an important milestone for SCILEX. It underscores our efforts to be part of the solution to the nation's opioid epidemic, which has reached crisis proportions with overdose deaths setting a record last year, mainly due to opioids."

Research presented at the Academy of Managed Care Pharmacy (AMCP) Managed Care & Specialty Pharmacy Annual Meeting in 2016 showed that only 8 percent of patients are started on a lidocaine patch when diagnosed with PHN.[1] In contrast, more than one in five patients (22 percent) is started on an opioid when diagnosed with PHN, although opioids are not specifically indicated for PHN.[1]

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,[2] and ZTLIDO has proven adhesion superiority over Lidoderm®.[3] PHN is the most common complication of shingles, a condition caused by the herpes zoster virus.[3] PHN affects an estimated 1 million people in the United States each year.[4]

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.

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® (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.

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 ("iTAbs"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Seprehvir®").

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 ®. Resiniferatoxin is completing a phase IB trial in terminal cancer patients.

For more information visit 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 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® over other products and its potential position as a first-line therapy, Scilex' 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® 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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References
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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.