Scilex Holding Company, a Sorrento Therapeutics, Inc. Subsidiary Announces Expansion of Ztlido® Managed Care Coverage for Additional 33 Million Lives

August 19, 2021

PALO ALTO, Calif., Aug. 19, 2021 (GLOBE NEWSWIRE) -- Scilex Holding Company (SCILEX), a subsidiary of Sorrento Therapeutics, Inc. (NASDAQ: SRNE), announced that, effective September 1, 2021, ZTlido® (lidocaine topical system) 1.8% has been added to multiple formularies, including two national PBMs (Pharmacy Benefit Managers), a national health plan and two regional health plans – thereby expanding coverage by up to 33 million lives. ZTlido (zee-tee-lie-doh) is indicated for relief of pain associated with post-herpetic neuralgia (PHN), also referred to as post-shingles pain.

“With this expansion, up to 65% of lives nationally have covered or better access to ZTlido, with a reduction in need for prior authorization,” said Jaisim Shah, President and Chief Executive Officer of Scilex Holding Company. “ZTlido provides fast and significant PHN pain relief that can be sustained over time – without the trade-offs associated with other widely used options, notably impaired cognition and weight gain (seen with gabapentinoids), and analgesic tolerance and risk of addiction (seen with opioids). [1-4] In fact, ZTlido can be used in combination to optimize gabapentinoids by delivering additive, remarkable pain relief without adding to systemic adverse events – and the combination has the potential to reduce the use of opioids.”[1,5,6,*]

However, not all lidocaine patch products are created equal. ZTlido 1.8% uses proprietary ZTech advanced technology to provide 9x greater bioavailability versus 5% lidocaine patch and superior adhesion proven in head-to-head studies, and while showering, bathing or exercising.[7-12] This ensures that pain relief is delivered for the full treatment duration, without interrupting a patient’s routine.

ZTlido was approved by the U.S. Food and Drug Administration (FDA) in 2018 for relief of pain associated with post-herpetic neuralgia (PHN) in adults. Side effects of ZTlido include application site reactions such as, irritation, erythema, and pruritus.

About ZTlido® (lidocaine topical system) 1.8%

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

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. If application site reactions occur while the topical system is being worn, advise the patient to remove ZTLIDO and not to reapply until skin reactions subside.

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, eyeglasses/eyewear) 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.

***Less is More:** ZTlido 1.8% uses proprietary ZTech advanced technology for proven bioequivalence to 5% lidocaine patch, but with 9x greater bioavailability.[7-9] Data are from studies performed with 5% lidocaine patch.

About Sorrento Therapeutics, Inc.
Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers 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”), clinical stage immuno-cellular therapies (“CAR-T”, “DAR-T™”), antibody-drug conjugates (“ADCs”), and clinical stage oncolytic virus (“Seprehvir™”). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIGUARD™, COVI-AMG™, COVISHIELD™, Gene-MAb™, COVI-MSC™, COVIDROPS™; and diagnostic test solutions, including COVITRACK™, COVI-STIX™ and COVITRACE™.

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™), 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

post-herpetic neuralgia. RTX has completed a Phase IB trial for intractable pain associated with cancer and a Phase 1B trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 trial for the treatment of lumbosacral radicular pain, or sciatica. ZTlido® was approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.com.

About Scilex Holding

Scilex Holding Company, a subsidiary of Sorrento, is a commercial-stage, non-opioid pain management company focused on the development and commercialization of topical and injectable therapies. 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 1/2 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 post-herpetic 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™, 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%, or SP-103, a Phase 2, next-generation, 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, and chronic post-COVID syndrome ("long haul COVID" or "long COVID") in multiple Phase 1 programs planned 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 www.scilexpharma.com.

Forward-Looking Statement

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 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 advantages of ZTlido over other products, including with respect to trade-offs associated with other available options and its bioavailability and adhesive qualities; the use of ZTlido in combination with gabapentinoids and any potential reduction in the use of opioids; ZTlido's ability to deliver pain relief for the full treatment duration; and Scilex's and Sorrento's prospects and 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, 2020, 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 (SVP Corporate Development)
Email: mediarelations@sorrentotherapeutics.com
Telephone: 1.858.203.4120

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Source: Sorrento Therapeutics, Inc.