# Scilex Holding, a Subsidiary of Sorrento, Has Received From FDA a sNDA Approval for ZTlido® Label Expansion

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PALO ALTO, Calif., April 09, 2021 (GLOBE NEWSWIRE) -- Scilex Holding (“Scilex”), an over 99% owned subsidiary of Sorrento Therapeutics (NASDAQ: SRNE, “Sorrento”), has received a supplemental new drug application (sNDA) approval from the FDA for ZTlido® to make efficacy labeling change with clinical data.

ZTlido® is the only lidocaine topical system that has been studied under the water stress conditions, and now has FDA label reflecting its use while showering, swimming and bathing. It gives polymer-based ZTlido® a competitive edge as other systems, especially water-based or hydrogel-based formulations, cannot be used when wet and must be removed prior to water exposure.

In the previous clinical trial (NCT04784728), a randomized, crossover, adhesion performance and pharmacokinetic study under conditions of water exposure in healthy subjects, Scilex had demonstrated that upon immersing the lidocaine topical system 1.8% (ZTlido®) in water, wet topical systems can be successfully reapplied, if necessary, and remain adhered for up to the labeled administration period of 12 hours. The trial showed that the topical system may be used while showering and that this does not increase lidocaine plasma levels. The topical systems were well-tolerated under all conditions and the dermal irritation profile was benign.

"We are very pleased with the trial outcome and labeling revision that attests to characteristics of ZTlido superior to other topical systems, to give patients a more reliable and uninterrupted drug delivery to alleviate pain associated with post-herpetic neuralgia," said Dmitri Lissin, MD, Chief Medical Officer of Scilex.

**About Sorrento Therapeutics**

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®", “Seprehvec™”). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIDTRAP™, ACE-MAB™, COVI-MAB™, COVI-GUARD™, COVI-SHIELD™, COVI-AMG™ and T-VIVA-19™; and diagnosti solutions, including COVI-TRACK™, COVI-STIX™ and COVI-TRACE™

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 ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX has completed a phase 1B trial for intractable pain associated with cancer and a phase 1B trial in osteoarthritis patients. ZTlido® was approved by the FDA on February 28, 2018. SP-102 is undergoing a Phase 3 pivotal trial for the treatment of lumbosacral radicular pain/sciatica.

For more information visit www.sorrentotherapeutics.com

**About Scilex Holding**

Scilex Holding Company, a majority-owned 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 chronic 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 two Phase 2 candidates. 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’s three product candidates are SP-102 (10 mg, dexamethasone sodium phosphate viscous gel), 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, Delayed Burst Release Low Dose Naltrexone (DBR-LDN), for the treatment of chronic pain, fibromyalgia, and chronic post-COVID syndrome (“long haul COVID” or “long COVID”) in multiple Phase 2 programs planned to be initiated this year.

For more information visit www.scilexpharma.com

**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 Sorrento Therapeutics, Inc. 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 ZTlido®’s prospects, Sorrento’s products, technologies and prospects and Scilex’s products, technologies and 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 the risk that the results of a previous clinical trial (NCT04784728) for ZTlido® may not be replicated, regulatory and intellectual property risks and other risks set forth in Sorrento’s filings with the Securities and Exchange Commission. 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.

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