Sorrento Therapeutics and Scilex Holding, a Majority Owned Subsidiary, Have Entered Into an Exclusive Licensing Term Sheet With Aardvark Therapeutics to Acquire Its ARD-301 For the Treatment of Chronic Pain, Fibromyalgia, and Chronic Long Haul Covid Syndrome

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SAN DIEGO, Calif., March 01, 2021 (GLOBE NEWSWIRE) — Sorrento Therapeutics (NASDAQ: SRNE, "Sorrento") and Scilex Holdings Company ("Scilex"), a majority owned subsidiary of Sorrento, have entered into an exclusive licensing term sheet with Aardvark Therapeutics ("Aardvark") to acquire Aardvark's proprietary formulation, Delayed Burst Release Low Dose Naltrexone (DBR-LDN), or ARD-301, 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.

Following execution of the definitive agreement between the parties, Scilex plans to work with Aardvark to initiate a new Phase 2 trial this year for fibromyalgia, which Scilex believes will be an important milestone for treating physicians, and most importantly for the estimated 10 million U.S. adults suffering from this chronic, frequently debilitating central pain condition with limited treatment options.[1] Approximately one-third of those diagnosed with fibromyalgia in the U.S. are reported to receive chronic prescription opioids, which is part of the opioid crisis, since opioids are not believed to be an effective solution for chronic central pain.[2] ARD-301 is comprised of a non-opioid, non-addictive therapy option that has been shown to have activity for improving a broad array of fibromyalgia symptoms in prior clinical studies with LDN. Currently, there are only three FDA approved pharmacologic treatments for fibromyalgia, but they have demonstrated limited efficacy and burdensome side effects in many patients.

COVID-19 is a global public health crisis with severe and potentially long-lasting effects. COVID-19 patients around the world have reported persistent suffering, including serious complications that can last for months after the acute infection resolves, and – even with vaccines – there is great a need for treatment options for Long Haul COVID. According to a research letter published in the Journal of the American Medical Association (JAMA), more than 40 percent of COVID-19 survivors assessed in an Italian study still reported shortness of breath an average of 60 days following symptom onset.[3] These data suggest that a significant percentage of COVID-19 survivors may be at risk for respiratory complications and other sequelae, which is a condition that is now colloquially referred to as "Long COVID." "I look forward to working with Sorrento, Scilex Holding, and Aardvark Therapeutics to initiate a Phase 2 trial to explore potential benefit of ARD-301 for patients suffering from the sequelae of chronic post-COVID syndrome," said Stephen Faraone, Ph.D., Distinguished Professor and Vice Chair for Research, Department of Psychiatry, SUNY Upstate Medical University, Syracuse, New York.

"We at Scilex are very excited to license from Aardvark a meaningful non-opioid therapeutic option that is desperately needed for millions of people in the US and around the world who will develop fibromyalgia or the critical complications of COVID-19 disease where very few treatments exist," said Jaisim Shah, President and CEO of Scilex. "As increasing numbers of patients suffer from uncontrolled chronic pain resulting from dysregulation of pain signaling, we look forward to helping advance both clinical programs with Scilex's team to address these high unmet needs," commented Tien Lee, MD, Chief Executive Officer of Aardvark Therapeutics. Dr. Brian Johnson, professor of psychiatry and anesthesia at SUNY Upstate Medical University, states, "it is very encouraging to see development of an innovative low-dose naltrexone formulation to address fibromyalgia, a condition for which there is a need for better pharmacotherapies."

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 Company

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 a Phase 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 postherpetic neuralgia, which is a form of post-shingles nerve pain. Scilex's two 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, and 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.

For more information visit www.scilexpharma.com.

About Aardvark Therapeutics

Aardvark Therapeutics is a clinical stage biotechnology company focused on the development of novel small molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases, inflammation, and other indications.

For more information visit www.aardvarktherapeutics.com.

About Fibromyalgia

Fibromyalgia is a chronic condition associated with widespread pain and tenderness, as well as general fatigue. Fibromyalgia is considered by many to be a condition that is largely mediated in the central nervous system, given that fibromyalgia sufferers often present without a direct peripheral insult or injury. People suffering from fibromyalgia also often experience sleep disruption, depressed mood, and cognitive impairment. It is estimated that, in the United States, fibromyalgia affects more than 10 million people. Currently, there are only three FDA-approved pharmacologic treatments for fibromyalgia, but they have limited efficacy and burdensome side effects in many patients.

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 the proposed agreement between Sorrento, Scilex and Aardvark regarding the proposed license and acquisition ARD-301 for the treatment of chronic pain, fibromyalgia, and chronic post-COVID syndrome, the prospects for ARD-301 and Scilex's plans to initiate [a] new Phase 2 trial[s] this year for fibromyalgia. 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 parties do not enter into a definitive agreement or close the proposed transaction, the risk that ARD-301 does not meet the parties' objectives and the risk that Scilex does not commence [a] Phase 2 trial[s] for fibromyalgia in 2021 or at all. 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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