1st Patient Treated for Osteoarthritis Knee Pain in Sorrento Resiniferatoxin Phase 1B Trial Meets Both Safety and Efficacy Expectations

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SAN DIEGO, Aug. 13, 2018 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), announced that the first enrolled patient in the phase 1b study of its non-opioid, afferent nerve ablating drug candidate (resiniferatoxin or “RTX”) for the treatment of pain from osteoarthritis in the knee (intra-articular route of administration) received treatment on July 31, 2018. In a planned safety assessment, the data monitoring committee (DMC) found no safety concerns, and the study will continue as planned.

“Joint pain affects over 30 million patients in major markets, half of which suffer from knee osteoarthritis pain [1]. A clear unmet need for a single administration long-lasting non-opioid and non-steroidal pain control solution exists for this degenerative joint disease” stated Dr. Jerome Zeldis, Chief Medical Officer for Sorrento. “We believe resiniferatoxin has the potential to adequately address this need and may help limit chronic use of other pain medications including opioids.”

This “Phase 1b double-blind study to assess the safety, tolerability and preliminary efficacy of intra-articular administration of resiniferatoxin (Potent Transient Vanilloid Receptor 1 Ablator, PTVA) versus placebo for the treatment of pain due to moderate to severe osteoarthritis of the knee,” is expected to continue recruiting until planned 40 patients have been enrolled in up to 5 dose level cohorts or until a maximum tolerated dose (MTD) is reached. The study could be stopped early if a clearly effective dose or a maximum tolerated dose is reached prior to the highest dose scheduled to be received. It is anticipated this trial will be completed within the first half of 2019.

In this first patient a response suggestive of a pharmaceutically active dose was noted. Prior to resiniferatoxin, the pain score for this patient ranged from 4 to 8 (median 6) on a 10 points scale. During the one-week period following treatment, the patient’s pain score was reported to be between 0 and 2 with no individual pain score above 2. The patient also reported not taking any pain medications since the day of the resiniferatoxin treatment. No conclusion can be drawn from a single patient outcome and the hope is to see consistent and similar results for the next patients treated. Duration of pain relief has not yet been established and will be tracked as the study progresses.

Dr Harold Minkowitz, Director of Clinical Investigation, HD Research Corporation and an investigator for the first patient, stated, “I am very excited with the very promising effect of resiniferatoxin. Our patient had a dramatic reduction of pain and improved quality of life following treatment with resiniferatoxin. She had been suffering from severe ongoing knee pain, despite her use of NSAIDs and opioid containing analgesics. She is now not needing any pain medications. The only notable adverse effect from the resiniferatoxin injection was post injection pain, which resolved within a few hours. I think this drug has the potential to improve the quality of life for patients like this and totally shift the treatment paradigm.”

A thousand times “hotter” than pure capsaicin (16 Billion Scoville units versus 16M), and with a high affinity for afferent pain nerves, resiniferatoxin binds to TRPV1 receptors and selectively ablates the nerve endings responsible for pain signals felt by patients.

“Treating the first patient in the PTVA-OA-001 trial represents a milestone for the resiniferatoxin development program. We are translating valuable lessons gathered from companion animals afflicted with naturally occurring chronic diseases (such as OA joint pain) to our human programs. By doing so, we significantly decrease our risk of unexpected outcomes and can accelerate our human trial time to completion. Our first human patient’s pain relief the day following injection is very similar to what was observed in dogs with joint pain. If all continues to go as planned, we could expect functional pain relief that lasts months with a single intra-articular injection. In a dog study that followed 8 pets treated for about a year, the median duration of pain relief was 150 days with one dog having no signs of pain for 370 days. A larger study in dogs is currently on-going and continues to provide valuable insights as we proceed with human trials” said Dr Alexis Nahama (veterinarian), Project Lead for RTX human development program and President of Ark Animal Health, a wholly owned subsidiary of Sorrento focusing on veterinary medicine.

About the PTVA-OA-001 Study

PTVA-OA-001 is a multicenter, placebo-controlled phase 1b study to assess the safety and define the maximally tolerated dose of resiniferatoxin administered in the knee joint for the reduction of moderate to severe pain signal intensity associated with osteoarthritis. The study is a dose-escalation protocol in which cohorts of patients will receive increasing doses of resiniferatoxin until the maximum tolerated dose (MTD) is achieved. The primary objective of the study is to evaluate the safety of resiniferatoxin and identify the recommended phase 2 dose. The secondary objective is to assess the preliminary efficacy of resiniferatoxin measured by assessing changes in the intensity of pain using the WOMAC Index, a widely used proprietary validated pain questionnaire.

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 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. Resiniferatoxin is completing a phase IB trial in terminal cancer patients and a phase 1B trial in osteoarthritis patients. ZTlido was approved by the FDA on 02/28/18.

For more information visit www.sorrentotherapeutics.com

About Ark Animal Health, Inc.

Ark Animal Health is a fully owned subsidiary of Sorrento Therapeutics. The company was formed in 2014 to bring to the companion animal market innovative solutions issued from Sorrento's human research and development activities. Ark is shifting the paradigm of treatment of veterinary pain management with the development of a multi-species multi-indications resiniferatoxin (RTX), a purified chemical originally discovered in cactus-like Euphorbia plants with unique properties and potential to help treat previously intractable pain. This ultra-potent non-opioid molecule selectively binds to and deletes the afferent nerves responsible for transmitting the chronic inflammatory pain signals to the brain. The company's lead program evaluating RTX for the control of canine pain associated with bone cancer, has received FDA/CVM MUMs designation (orphan type designation). Other pipeline projects include indications for RTX in chronic articular pain in companion animals, neuropathic pain in horses, and idiopathic cystitis in cats. Development opportunities leveraging Sorrento human immuno-oncology expertise and clinical assets (antibodies, oncolytic virus, cell therapies) are being assessed for translation into the companion animal health market.

For more information about Ark Animal Health or Sorrento's translational program visit http://www.arkanimalhealth.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., under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the expectations for Sorrento's and its subsidiaries' technologies and product candidates, including, but, not limited to, resiniferatoxin (RTX). 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: risks related to Sorrento's and its subsidiaries' technologies and prospects, including, but not limited to, RTX; risks related to seeking regulatory approvals and conducting and results of clinical trials, including, but not limited to, the PTVA-OA-001 study or trial and any prior RTX studies in animals; the clinical and commercial success of RTX; the viability and success of using RTX for treatments in certain therapeutic areas, including osteoarthritis (OA) 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, 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.

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[1] GlobalData Epicast (2017 report) states for year 2016: 17M cases of symptomatic hand OA (7 Major Markets, 7.6M in the USA) + 15.2M symptomatic Knee OA (4.4M in the US) + 3.34M symptomatic hip OA (1.7M in the US)

Source: Sorrento Therapeutics, Inc.