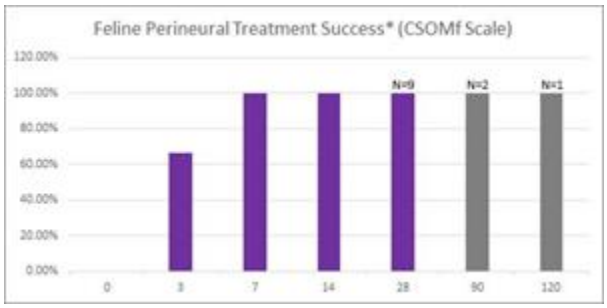
Sorrento Therapeutics Logo

Positive Feline Clinical Trial Outcome Motivates Sorrento Therapeutics to Accelerate Human IND Filing of Resiniferatoxin (RTX) for Prolonged Non-Opioid Control of Post-Amputation Neuropathic Pain

June 10, 2019

SAN DIEGO, June 10, 2019 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), announced that review of early results from an on-going “declawed cat pain trial” (run by its Ark Animal Health division) prompted management to assign a high priority to exploring the use of resiniferatoxin as a local nerve block injection for the control of neuropathic post-amputation residual limb pain in humans. A full IND package is being prepared for FDA submission in the second half of 2019.



Treatment Success* as measured by Client Specific Outcome Measures feline scale (CSOMf)

Declawing is the amputation of the last digit in a cat’s paws. Although currently falling out of favor, this procedure used to be commonplace. The population of “aging amputee cats” living with the sequalae of surgeries performed years ago is quite large making it a valuable “model” when looking at residual limb pain which affects about 30% of the 1.6 million American amputees, or phantom limb pain which affects up to 70% of those human patients[1].

“Chronic distal limb pain in declawed cats is common in varying degrees, especially in older cats. For some, the pain is very difficult to control and often causes limping, aggressive behavior, litter box avoidance, and decreased quality of life. I was elated that the veterinarians at ARK contacted me and showed interest in helping treat this population of cats as they don’t otherwise receive much attention. I was hopeful but still cautiously optimistic that these cats could improve and be made more comfortable. My expectations were met as both cats I treated did well during the treatment and showed improvement that lasted for months afterwards. I was initially hesitant since the treatment involved anesthesia and direct injections in the paw nerves. However, experiencing the cat’s improved demeanor and reduction in negative behavior was worth the effort. Reducing or eliminating the need for daily systemic medications positively affected not only the cat’s quality of life, but also the human-animal bond with the owner,” (Dr M, Feline Specialist, Principal Investigator).

Nine cats that have been living for years with debilitating neuropathic post-declaw pain were included to date in the on-going ARK clinical trial. Every cat treated was considered a treatment success at Day 28, regardless of dose group, as defined by FDA Center for Veterinary Medicine guidance using a validated feline pain and behavior scale (see figure 1). No failures noted through Day 120, but only 2 cats have completed the follow-up visits so far. Andy, the cat with the longest follow-up to date, is still doing well and enjoying a much-improved quality of life 7 months after treatment (see video).

For humans, Residual Limb Pain is a common and difficult to control condition in amputees. Often the condition is managed with the use of opioids despite the high potential for addiction and the unclear long-term clinical benefits. Delivering RTX peripherally as a nerve block just like what is done with local anesthetics, is an easy and precise technique that puts the drug exactly in the area we believe might be the most effective. Any convenient to administer non-opioid solution that could provide long-term relief to amputees and potentially reduce the use for drugs or more complex procedures in their pain control strategy, would address a clear unmet need for that patient population.

“We are looking at RTX in cats as a good long-term pain control approach given that felines do not tolerate non-steroidal anti-inflammatory drugs well (there are no NSAIDs approved in cats for chronic use) and opioids are not a viable approach for daily at home pain control. The local nerve block as a route of administration for RTX presents numerous advantages and a convenient way for veterinarians to help their feline patients without relying on off-label chronic use of daily oral medications. Given the clear clinical benefits we have seen in cats, and confirmed in some dogs, we decided to explore the same direct nerve application approach for the RTX human clinical development program,” stated Alexis Nahama, DVM, President of Ark Animal Health and Head of the RTX program.

“In addition to our marketed product ZTlido ® (lidocaine topical system) 1.8% for postherpetic neuralgia and our Phase 3 SP-102 product for sciatica back pain, RTX provides another powerful tool in our expansive arsenal of non-opioid pain management,” added Dr. Henry Ji, Chairman and CEO of Sorrento Therapeutics. “The clinical data generated by our animal health division is very exciting and motivates us to accelerate the work needed to file a human IND later this year. We hope to confirm the long-term potential of RTX in helping control residual limb pain and assess the clinical benefits in reducing phantom limb pain in people”.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/a98449dc-9b89-416f-a9e1-2dd09cb33663

* CSOMf. Validated Scale taking into account 3 pet owner selected parameters measured (from 1 to 5) over time. Success defined as a reduction of at least 2 in total CSOMf score compared to Day 0 with no increase in any individual activities. Two treated cat patients were followed at Day 90 and one at Day 120.

About Resiniferatoxin (RTX)

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 experienced by patients. Delivered peripherally (into the joint space, the epicardial space or as a nerve block) the transient nerve ending ablation effect can have profound clinical benefits lasting for months to years (as shown in canine joint pain studies). Delivered spinally the effect can be profound and lasting (as shown in canine cancer pain studies).

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 and Osteoarthritis (OA) patients is also demonstrated by its effort to advance Resiniferatoxin (“RTX”), a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, ZTlido® and SP-102, a non-opioid corticosteroid gel. Resiniferatoxin is completing a Phase 1b trial in terminal cancer patients and a Phase 1b trial for OA. ZTlido was approved by US FDA on 02/28/18. SP-102 is in Phase 3 pivotal study for the treatment of lumbar radicular pain/sciatica.

For more information visit www.sorrentotherapeutics.com

More information on Sorrento clinical trials can be found at www.clinicaltrials.gov

About Ark Animal Health, Inc.

Ark Animal Health is a wholly owned subsidiary of Sorrento Therapeutics, Inc. 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. and Ark Animal Health, 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), ZTlido® (lidocaine topical system) 1.8% for postherpetic neuralgia and our Phase 3 SP-102 product for sciatica back pain. 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, ZTlido® (lidocaine topical system) 1.8% for postherpetic neuralgia and our Phase 3 SP-102 product for sciatica back pain; risks related to seeking regulatory approvals and conducting and obtaining results of clinical trials, including, but not limited to, any prior RTX studies in animals; the clinical and commercial success of RTX and SP-102; the viability and success of using RTX for treatments in certain therapeutic areas, including cardiovascular diseases and osteoarthritis, ZTlido® (lidocaine topical system) 1.8% for postherpetic neuralgia pain, our Phase 3 SP-102 product for sciatica back pain 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, 2018, 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

Head of RTX Program and President ARK Animal Health

Telephone: 1.858.203.4120

Email: mediarelations@sorrentotherapeutics.com

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References:

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3198614/

A video accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/929fa479-a377-4f60-87da-49c7e0ff8fd5

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