Sorrento Therapeutics Completes Enrollment of Phase 2 Clinical Trial of Resiniferatoxin (RTX) for Treatment of Knee Pain in Moderate to Severe Osteoarthritis of the Knee (OAK) Patients

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- Phase 2 trial of RTX for OAK pain completed enrollment with last patient (n=120) dosed
- No limiting toxicities have been encountered during the trial to date. Patients are now being monitored for long-term safety and efficacy outcomes measures (6 and 12 months timepoints)
- Initial efficacy data on pain relief parameters expected to be available in Q2 2023
- Sorrento plans to conduct an end of phase 2 meeting with the FDA for the RTX program as soon as initial top line data is available
- As a non-opioid treatment for severe intractable pain, RTX has the potential to become a key therapeutic in a market segment estimated to exceed $10B by 2025[1]

SAN DIEGO, Sept. 26, 2022 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") announced today that the company has completed enrollment of its latest Phase 2 clinical study of RTX for treating moderate-to-severe osteoarthritis of the knee pain (OAK).

This Phase 2 study follows the analysis of the positive observations from the Phase 1b/2 trial results (NCT03542838) of RTX Day 84 patient data, for which Sorrento completed the one year following up of last patient visit in February 2021.

The phase 2 trial, a multi-center, double blind, placebo- and active-controlled study, assesses the efficacy and safety of several dose groups of RTX to manage pain in patients with moderate-to-severe osteoarthritis of the knee pain (OAK) (clinicaltrials.gov: NCT04885972). Given the durability of OAK pain relief response to RTX demonstrated in earlier phase 1/2 trials, Sorrento has decided to include an active comparator (injectable corticosteroid) in the current trial protocol. If superiority is demonstrated by RTX against this widely used approved drug, this could be supportive data for accelerated international registrations and would enable pricing discussions with regulatory authorities in Europe.

The RTX clinical development program in OAK pain continues to deliver as planned, with an end of phase 2 meeting with the FDA and concurrent phase 3 clinical trials planned in larger patient populations in the first half of 2023.

About RTX

A thousand times “hotter” than pure capsaicin (16 billion Scoville units versus 16 million), and with a high affinity for afferent sensory pain nerves, RTX binds to TRPV1 receptors present and selectively ablates the nerve endings responsible for pain signals experienced by patients[2]. Delivered peripherally (into the joint space) the transient nerve ending ablation effect can have profound clinical benefits lasting for months to years (as shown in canine studies[3]).

The first arthritis pain clinical trial in humans was completed in 2021. That study was a multicenter, placebo-controlled Phase 1b/2 study to assess the safety and define the maximally tolerated dose of RTX administered in the knee joint in patients with moderate to severe pain associated with osteoarthritis of the knee. The study was a dose-escalation trial in which cohorts of patients receive increasing doses of RTX until the maximum tolerated dose (MTD) was achieved. The primary objective of the study was to evaluate the safety of RTX and identify the recommended Phase 3 dose. The secondary objective was to assess the preliminary efficacy of RTX measured by assessing changes in the intensity of pain using the A1 score from the WOMAC, a widely used proprietary validated pain questionnaire.

The second arthritis pain phase 2 clinical trial in humans completed enrollment in September 2022. This study is expected to confirm the phase 3 doses and demonstrate long-term effectiveness of RTX in controlling osteoarthritis pain when compared to placebo or active steroid intra-articular injections.

Sorrento continues to progress as planned on all clinical fronts of the RTX program, including exploring additional orphan indications with breakthrough potential.

RTX is an extremely potent compound used therapeutically in very small concentrations. It is very challenging to formulate and keep stable long-term when made in large quantities. Sorrento has been working on process optimization of RTX manufacturing for several years and continues to advance the validation and scale up, with the expectation to have final validated batches completed in 2023. Ensuring the company can meet market demands from API to finished product once phase 3 trials have been completed has been identified as a critical priority, which Sorrento is addressing early on.

The osteoarthritis treatment market and in particular the Knee Osteoarthritis and injectable markets have historically seen healthy growth and are expected to continue the trend as populations age and present excessive weight. Multiple sources estimate the 2020 market to be around 50M patients and $7B.

More information on this completed trial can be found at www.clinicaltrials.gov (NCT03542838).

About Sorrento Therapeutics, Inc.

Sorrento is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease 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 next-generation tyrosine kinase inhibitors ("TKIs"), fully human antibodies ("G-MAB™ library"), immuno-cellular therapies ("DAR-T™"), antibody-drug conjugates ("ADCs"), and oncolytic virus ("Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including STI-1558, COVISHIELD™ and COVIDROPS™; and diagnostic test solutions including COVIMARK™.

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a (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 postherpetic neuralgia (PHN). RTX has been cleared for a Phase II trial for intractable pain associated with cancer and a Phase II trial in osteoarthritis patients. Positive final results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. ZTlido® was approved by the FDA on February 28, 2018. For more information visit www.sorrentotherapeutics.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), the clinical potential of RTX, including the potential for RTX to address long-term control of pain associated with osteoarthritis of the knee, RTX's potential to become a key therapeutic in the knee osteoarthritis and injectable markets, expected timing of initial efficacy data on pain relief parameters and initial topline data, the potential superiority of RTX over any active comparators, timing for conducting an end of phase 2 meeting with the FDA and concurrent phase 3 clinical trials, completion and submission of a request to proceed with any Phase 3 trial for RTX, the possibility of proceeding to a Phase 3 trial, the possibility of obtaining accelerated international registration for RTX, any potential additional orphan indications for RTX with breakthrough potential and the expected timing for having final validated batches for 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 technologies and prospects, including, but not limited to risks related to seeking regulatory approval for RTX; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risk of difficulties or delays in obtaining regulatory approvals; risks that clinical study results may not meet any or all endpoints of a clinical study and that any data generated from such studies may not support a regulatory submission or approval; risks that prior test, study and trial results may not be replicated in continuing or future studies and trials; risks of manufacturing and supplying drug product; risks related to leveraging the expertise of its employees, subsidiaries, affiliates and partners to assist Sorrento in the execution of its product candidates strategies; risks related to the global impact of COVID-19; 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, 2021, 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] Osteoarthritis Market Size, Share, Value and Competitive Landscape 2021-2025. MarketWatch Report

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC398431/

[3] Sorrento Therapeutics (Ark Animal Health) internal data (on file)

Source: Sorrento Therapeutics, Inc.