FDA Clears Sorrento Phase 2 Trial Of Non-Opioid Product Candidate Resiniferatoxin (RTX) For Treatment of the Knee Pain in Osteoarthritis (OA) Patients

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- Phase 2 trial of RTX for OA pain to proceed following FDA clearance.
- Phase 1b data demonstrated RTX safety for a single intra-articular administration without dose limiting toxicity (DLT) at any doses tested up to 30 ug.
- Phase 1b data demonstrated significant efficacy supporting RTX as an ideal candidate for long-term control of refractory OA pain: significant pain relief observed in patients with advanced OA disease (Kellgren-Lawrence grade 3/4) and sustained pain relief last beyond 6 months.
- Sorrento believes RTX has the potential to become a key therapeutic in a market segment estimated to continue to grow and exceed $10B by 2025[1]

SAN DIEGO, July 06, 2021 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento") announced today that the company has received FDA clearance to proceed with a Phase 2 clinical study of RTX for treating moderate-to-severe osteoarthritis of the knee pain (OAK).

The phase 2 trial, a multi-center, double blind, placebo- and active-controlled study, will assess 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 OA pain relief response to RTX demonstrated thus far, Sorrento has decided to include an active comparator (injectable corticosteroid) in the current trial protocol. Superiority data potentially generated by RTX against a widely used approved drug could be supportive for accelerated international registrations (Europe) and is required for pricing purposes in Europe.

This Phase 2 study follows the analysis of the significant observations from the Phase 1b trial results (NCT03542838) of RTX Day 84 patient data which completed the one year following up of last patient visit in February 2021. This Phase 1b study was a double-blinded, placebo-controlled ascending dose study in 94 patients and included an open-label expansion cohort to assess the long-term safety and preliminary efficacy of a single intra-articular administration of RTX or saline control (as placebo group) for the treatment of moderate-to-severe pain due to osteoarthritis of the knee. The magnitude of the difference in the treatment effect (RTX versus saline control) at 12 weeks exceeded what is traditionally considered sufficient to support regulatory approval based on greater than 2 points reduction in WOMAC A1 10-point scale question “pain at walking on flat surface” compared to placebo. RTX met this requirement in this study.

The Phase 1b study was designed to follow patients to day 84 (primary endpoint). Patients were also given the option to be followed for up to a year. Pain relief appeared to be very consistent among patients responding to the initial treatment, with a large proportion of the patients followed past Day 84 showing pain relief sustained beyond all time points assessed through one year follow-up. Fast relief (starting within days, with optimal pain relief level achieved within weeks) and durability of the effect (past 84 days) confirm the clinical potential of the RTX drug for long-term control of pain associated with osteoarthritis of the knee.

The RTX clinical development program continues, with Phase 2 and 3 clinical trials planned in larger patient populations. The first Phase 2 trial will focus on identifying the recommended Phase 3 dose.

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[1] Osteoarthritis Market Size, Share, Value, And Competitive Landscape 2021-2026 - MarketWatch

About RTX

A thousand times “hotter” than pure capsaicin (16 billion Scoville units versus 16M), 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]).

PTVA-OA-001 was a multicenter, placebo-controlled Phase 1b 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 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).

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

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

About Sorrento Therapeutics, Inc.

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™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIGUARD™, COVI-AMG™, COVISHIELD™, Gene-MAb™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, inclu COVITRACK™, COVISTIX™ and COVITRACE™

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 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 post-herpetic neuralgia. RTX has completed a Phase IB trial for intractable pain associated with cancer and a Phase 1B trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 trial for the treatment of lumbosacral radicular pain, or sciatica. 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 major therapeutic in the knee osteoarthritis and injectable markets, timing for commencing additional Phase 2 and 3 clinical trials for RTX, timing for completion and submission of a request to proceed with any Phase 3 trial for RTX, the possibility of proceeding to a Phase 3 trial, and the possibility of obtaining accelerated international registration for RTX in Europe. 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 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 therapeutic antibody product candidate 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, 2020, 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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