Sorrento Therapeutics Logo

Sorrento Therapeutics Presents Interim Positive Results of Phase 1b Resiniferatoxin (RTX) in Cancer Pain Trial

February 27, 2020

- Fourteen subjects with advanced cancer pain received epidural RTX (04 to 15 ug)
- Most common treatment-related adverse event was transient post-procedure related pain
- Three subjects at the higher doses had rapid and marked pain reduction after treatment
- One additional cohort was added to further evaluate a 25 ug dose for upcoming Phase 3 studies

SAN DIEGO, Feb. 27, 2020 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") announced that an interim analysis of an ongoing Phase 1b study of resiniferatoxin (RTX) administered via epidural route in patients with intractable cancer pain has generated positive data. The study is completing enrollment of an additional 25 ug expansion dose cohort. Based on full study results a dose will be selected for RTX to proceed to Phase 3 pivotal trials in patients with advanced cancer pain.

Safety in the higher dose cohort is expected to be supportive for testing RTX epidural administration in other advanced non-cancer disease related unmet clinical needs (with a choice of starting dose at 15 or 25 ug depending on the indication considered).

Results as planned in the original study (to 15 ug) are being presented at the American Academy of Pain Medicine Annual Meeting on February 27, 2020.

The Phase 1b open-label study was used for dose escalation to assess the safety and preliminary efficacy of a single epidural administration of resiniferatoxin for the treatment of intractable pain due to cancer. Initial expectations for safety and efficacy have been met for the Phase 1b study, though optimal dose selection will follow assessment of the additional dose group in which 25 ug is also being evaluated. Thus far, after Institutional Review Board approval was obtained, and with oversight by an independent data monitoring committee, data is available from 14 subjects with intractable cancer-related pain who received a single epidural injection of RTX from 0.4 to 15 ug.

Safety Outcomes

No dose limiting toxicities or notable adverse events unrelated to progression of underlying disease were encountered for any of the subjects. The most common treatment-related adverse event was transient post-procedural pain: 7 of 14 subjects (50%) reported moderate severity. Two additional treatment-related adverse events of moderate severity were back pain and increase in blood pressure in a patient. All events resolved in less than two days following drug administration.

Efficacy Outcomes

The ongoing trial will follow subjects for at least 84 days. The lower doses of 0.4, 1.0, 2.0, 4.0 ug did not demonstrate notable pain relief, but permitted dose escalation to the next designated dose level based on how well the drug was tolerated.

Three patients had marked pain relief starting shortly after initial administration that were still observed weeks after treatment: 1 of 3 subjects who received 8 ug (a 58-year-old woman with gastrointestinal stromal cancer with severe lower back pain reported a decrease in numerical pain rating scale (NPRS) scores from >6/10 to 2/10), and 2 of 3 subjects who received 15 ug (a 62-year-old man with rectal cancer noted significant improvement in pain, physical strength, mood, and appetite with NPRS scores reduced from 7-8/10 to 3/10; and a 57-year-old man with multiple myeloma and severe pain in his back, hips, and lower extremities subsequently reported mild pain in the target areas after RTX injection). Improvement in pain and mobility within 24 hours of dosing in the three responders at the higher dose levels of RTX suggests the clinical potential of the drug for intractable cancer pain.

Sorrento intends to present the detailed results of the completed study upon completion of the additional expansion cohort later this year. A pivotal Phase 3 trial is being planned using epidural RTX for severe pain states associated with advanced disease.

“We are encouraged by the benefits of using RTX to treat intractable pain in patients with metastatic cancer,” said Associate Professor of Anesthesia, Srdjan S. Nedeljkovic, M.D. from the Department of Anesthesiology, Perioperative and Pain Medicine, Brigham and Women’s Hospital at Harvard Medical School. “Even in patients with high levels of pain, RTX given via an epidural injection has been found to reduce pain intensity without having any long-term adverse safety consequences. The addition of RTX to existing cancer pain therapies represents a positive step forward in improving the care of patients with intractable cancer pain and offers the hope of enhancing the overall quality of life experienced by this population.”

For access to the scientific presentation (AAPM poster) please visit
http://investors.sorrentotherapeutics.com/events-and-presentations/presentations

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[1]. 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[2]).

RTX-001 is a multicenter, open-label dose escalation Phase 1b study to assess the safety and define the maximally tolerated dose of resiniferatoxin administered via the epidural route for the reduction of moderate to severe pain signal intensity associated with advanced cancer. The Phase 1b study is a dose-escalation protocol in which cohorts of patients receive increasing doses of resiniferatoxin until the maximum tolerated dose is achieved. The primary objective of the study is to evaluate the safety of resiniferatoxin and identify the recommended Phase 3 dose. The secondary objective is to assess the preliminary efficacy of resiniferatoxin measured by assessing changes in the intensity of pain using the NPRS score, a widely used proprietary validated pain scale.

RTX is not approved for clinical use by regulatory authorities. Safety and efficacy have not been established.

More information on this trial can be found at www.clinicaltrials.gov (NCT03226574).

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 its 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 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.

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, timing for completion and providing detailed results from the Phase 1b study and the potential timing and dose selection for any Phase 3 trial for RTX for the treatment of intractable pain associated with cancer. 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 obtaining results of clinical trials, including, but not limited to, the Phase 1b study and any prior RTX studies in animals; costs associated with clinical trials, the clinical and commercial success of RTX; the viability and success of using RTX for treatments in certain therapeutic areas, including for the treatment of intractable pain associated with cancer 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.

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1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC398431/

2 Sorrento Therapeutics (Ark Animal Health) internal data (on file)

Source: Sorrento Therapeutics, Inc.