Sorrento Therapeutics Logo

Sorrento Therapeutics Autologous Anti-CEA CAR-T Cell Therapy for Liver Metastases Demonstrates Therapeutic Activity in Stage IV Pancreas Cancer in a Phase 1b HITM-SURE Trial (NCT02850536)

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One subject with stage IV pancreas cancer has no viable liver metastases by PET scan 11 months after treatment

SAN DIEGO, March 05, 2018 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (NASDAQ:SRNE) ("Sorrento"), cellular therapy focused subsidiary, TNK Therapeutics, Inc. ("TNK"), and Surefire Medical, Inc., announced today initial results from the **H**epatic **I**mmuno**T**herapy for **M**etastases-**S**urefire, or HITM-SURE (NCT02850536), a Phase 1b single arm trial testing its autologous anti-CEA CAR-T cells administered regionally by hepatic artery infusion (HAI) via pressure directed microvalve infusion (MVI) technology (Surefire Infusion System, Surefire Medical, Inc., Westminster, Colorado) in heavily pre-treated patients with refractory CEA-positive liver metastases (LM). This Phase 1b trial follows the HITM (NCT01373047) and HITM-SIR (NCT02416466) Phase 1 studies we believe demonstrated the safety and biological activity of the anti-CEA CAR-T administered with hepatic artery infusions (HAI) alone or with selective internal radiotherapy.

The data of HITM-SURE were provided by Dr. Steven Katz, the Principal Investigator of the Study and Associate Professor of Surgery at The Roger Williams Medical Center (CharterCare Health Partners and Prospect Medical Holdings). The study is also open at Colorado University and funded in part by the Colorado Office for Economic Development and International Trade.

In total, three patients have completed the ongoing HITM-SURE protocol, two with stage IV pancreatic cancer and one with colorectal cancer (LM). All patients presented with unresectable, chemotherapy refractory CEA+ liver metastases. Patients received three HAI of anti-CEA CAR-T cells (1e10 cells per dose) along with low dose IL-2 infusion (50,000 IU/kg/day, Proleukin, Prometheus). CAR-T HAI were administered via a Surefire MVI technology. The primary objective of the study was to establish the safety of the CAR-T HAI with the pressure directed MVI device. Secondary objectives included response assessed by modified RECIST (mRECIST), immune-related response criteria (irRC), and tumor marker kinetics. Reduction in post-treatment serum CEA was noted in all patients (average change 19 ng/mL, range 3.1-39 ng/mL). Two patients have progressive disease, with a pancreatic cancer patient alive at 7 months and a colorectal cancer patient alive at 4.8 months. A patient with stage IV pancreas adenocarcinoma has no evidence of liver metastases 11 months on PET scan following three CAR-T HAIs. In the phase III MPACT study, treatment of stage IV pancreas adenocarcinoma patients with gemcitabine plus albumin-bound paclitaxel resulted in a median overall survival time of 8.7 months. It will be of interest to determine if the results from upcoming phase 2 liver metastasis HITM studies will confirm the encouraging results from our small number of patients.

The initial findings from the currently enrolling HITM-SURE trial follows the results of two other trials. In one of the previous trials, a patient survived 51 months following 3 anti-CEA CAR-T HAIs and a patient from another trial is alive 25 months after treatment.

Dr. Katz noted, "In 15 patients in the Phase 1 and 1b studies, our CAR-T hepatic artery infusion method has resulted in highly selective delivery of CAR-T to liver tumors, with avoidance of severe cytokine release syndrome and neurotoxicity. We have observed encouraging clinical outcomes in heavily pre-treated patients. Future trials will test our novel delivery strategies for pancreatic and peritoneal tumors, in addition to novel combinatorial approaches to reverse organ-specific immunosuppressive pathways. We have developed a pipeline and delivery methods specifically tailored to address barriers to effective solid tumor CAR-T therapy, including the use of Surefire's pressure-directed microvalve infusion technology to help overcome the high interstitial pressure of these tumors. The combination of CAR-T cells and this novel delivery mechanism are powerful tool for enhancing solid tumor uptake of CAR-T cells. Regional delivery of CAR-T cells has promise to be an important component of a multifaceted approach for advanced solid tumor patients."

"It is gratifying to observe that local infusion of CAR-T cells is very well tolerated and active in treating solid tumor metastases in the liver," said Dr. Jerome Zeldis, Sorrento Chief Medical Officer and President of TNK Therapeutics. "Based on these exciting data, we are now working on strategies to enhance the anti-solid tumor activity while lessening the complications typical of CAR-T therapy. In addition, we are planning on performing combination therapy studies using our CAR-T programs, including anti-CEA CAR-T, together with other Sorrento assets, such as our immuno-oncology checkpoint antibodies as well as Seprehvir®, our clinical-stage oncolytic virus. The combination studies of anti-CEA CAR-T and Seprehvir should initiate the second half of 2018."

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 is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule in Resiniferatoxin ("RTX") and ZTlido™. Resiniferatoxin is completing a phase Ib trial in terminal cancer patients. ZTlido is approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.com

About TNK Therapeutics, Inc.

TNK Therapeutics is a subsidiary of Sorrento Therapeutics that is focused on the development and commercialization of cellular therapies to address unmet medical needs in oncology. TNK technologies harness the adaptive and innate immune system by reprogramming immune cells to recognize and efficiently kill cancer cells.

About Surefire Medical, Inc.

Surefire Medical develops infusion technologies that help physicians deliver therapy deeper into liver tumors while protecting healthy tissue, giving

patients greater confidence in their cancer care. For more information, visit www.surefiremedical.com.

Forward-Looking Statements

This press release contains forward-looking statements related to Sorrento Therapeutics, Inc. and its subsidiaries, 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, among others, those relating to statements about Sorrento's and its subsidiaries' prospects, including, but not limited to any statements about the chimeric antigen receptor (CAR) T cell programs; potential combination therapies or use with medical devices; Sorrento's expectations for CAR-T immunotherapies, antibody technology and oncolytic viral technology, Sorrento's and its subsidiaries' collaborations with Roger Williams Medical Center and Surefire Medical, Inc., and their respective technologies, products and employees, and the development of CAR-T, antibody and oncolytic viral technologies and programs; Sorrento's and its subsidiaries' abilities to leverage the expertise of its employees and partners to assist the company and its subsidiaries in the execution of their strategies; Sorrento's and its subsidiaries' advances made in developing CAR-T, antibody and oncolytic viral technologies and products, including the results of any clinical studies using the company's and its subsidiaries' CAR-T, antibody and oncolytic viral technologies and products. Risks and uncertainties include whether Sorrento and its subsidiaries will continue the development of clinical studies for its assets; regulatory risks and risks in seeking and obtaining US and non-US regulatory approvals of Sorrento's and its subsidiaries' product candidates; risks associated with conducting clinical trials of product candidates; whether ongoing or planned clinical trials are implemented and conducted on the timelines Sorrento and/or its subsidiaries currently expect; whether any product candidates will be shown to be safe and efficacious in clinical trials; whether Sorrento and/or its subsidiaries will have access to sufficient capital to fund their respective planned development and clinical activities; risks regarding competitors' products and product candidates; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this letter to stockholders. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

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