Sorrento Therapeutics Anti-CEA CAR-T Demonstrates Significant Therapeutic Activity With Increased Overall Survival in Pancreatic Cancer Patients With Liver Metastases

November 6, 2018

- Two out of four patients showed complete resolution of liver metastases on PET scan
- Median overall survival (OS) 8.3 months and mean OS 9.8 months, compared to the standard of care 3 to 6 months
- Meeting scheduled with FDA for discussion on the path towards Licensure

SAN DIEGO, Nov. 06, 2018 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (NASDAQ: SRNE) ("Sorrento") announced today the release of data from a phase 1b clinical trial administering anti-CEA CAR-T by utilizing a unique Pressure-Enabled Drug Delivery (PEDD) manufactured by TriSalus™ Life Sciences. The preliminary data for the Hepatic Immunotherapy for Metastases (HITM-SURE) clinical trial results will be presented in a poster at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, being held November 7-11 in Washington, DC.

Five patients, four pancreatic and one colorectal, with carcinoembryonic antigen–positive (CEA+), unresectable stage IV adenocarcinoma with liver metastases, who had failed one or more lines of systemic chemotherapy, each received three hepatic artery infusions of Sorrento autologous anti-CEA CAR-T cells using the Hepatic Immunotherapy for Metastases (HITM) method. The immunotherapy was delivered by means of PEDD technology, which overpowers the high pressure within solid tumors that limits the reach and efficacy of therapeutic agents.

Two out of the four pancreatic cancer patients had no viable liver metastases by PET scan after treatment. After 12 months, one patient with stage IV pancreatic carcinoma still showed no evidence of liver metastases on PET imaging, and his primary pancreatic tumor was well-controlled. A second patient with stage IV pancreatic cancer also had no evidence of liver metastases six weeks after CAR-T/PEDD infusions. Median overall survival (OS) post-treatment is 8.3 months and the mean OS is 9.8 months to date. No patient suffered any severe adverse event related to the CAR-T infusions.

"PEDD significantly increased CAR-T, more than five-fold, within liver metastases when compared with low-pressure microcatheters, and serum CEA levels declined on-study in all subjects," said Steven Katz, MD, director of the Office of Therapeutic Development at the Roger Williams Medical Center, and the principal investigator of the trial. "These early results suggest we may be able to achieve a therapeutic dose in solid tumors and avoid the severely limiting systemic side effects, such as neurotoxicity and cytokine release syndrome, that are prevalent with conventional systemic CAR-T administration methods. Furthermore, our delivery approach limits the number of circulating CAR-T cells compared to systemic delivery, which has the potential to improve the safety profile of CAR-T therapies for solid tumors in several critical organs."

"With our CD38 and CEA CAR-T programs, we are addressing the challenges of treating both liquid and solid tumors," stated Henry Ji, PhD, President and CEO. "We are scheduled to discuss with the FDA the continued development of this program towards Licensure."

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 clinical stage fully human antibodies ("G-MAB™ library"), immuno-cellular therapies ("CAR-T"), antibody-drug conjugates ("ADC"), and oncolytic virus ("Seprehvir®").

Sorrento’s commitment to life-enhancing therapies is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule in Resiniferatoxin ("RTX") as well as to promote newly-launched ZTlido™. Resiniferatoxin is completing a Phase 1b trial in terminal cancer patients as well as in trial for osteoarthritis (OA) pain management. ZTlido was approved by the FDA on February 28, 2018 for the treatment of post-herpetic neuralgia.

For more information visit www.sorrentotherapeutics.com

Forward-Looking Statements

This press release contains 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 developments of and prospects for Sorrento’s and its subsidiaries’ and affiliates’ products and technologies, including their respective antibody and CAR-T products and technologies (including, but not limited to, CEA CAR-T cell therapy program), and expectations for Sorrento’s and its subsidiaries’, affiliates’ and joint ventures’ technologies and product candidates. 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, its subsidiaries’, affiliates’ and partners’ technologies and prospects; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risks that prior clinical results and outcomes will not be replicated; risks of difficulties or delays in obtaining regulatory approvals; risks that clinical study results, including, but not limited to, data from our phase 1b clinical trial administering anti-CEA CAR-T, 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 related to seeking regulatory approvals and conducting clinical trials; risks of supplying drug product; risks related to Sorrento’s ability to leverage the expertise of its employees, subsidiaries, affiliates and partners to assist the company in the execution of its strategies; risks related to Sorrento’s M&A and licensing strategy; risks related to Sorrento’s and its’ subsidiaries’ abilities to supply drug product; and other matters that are described in Sorrento’s Annual Report on Form 10-K for the year ended December 31, 2017, 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.