TRISALUS LIFE SCIENCES' PRESSURE-ENABLED DRUG DELIVERY (PEDD) SIGNIFICANTLY INCREASED THERAPEUTIC EFFECT OF ANTI-CEA CAR-T IN PANCREATIC CANCER PATIENTS WITH LIVER METASTASES

- **PEDD overpowers intratumoral high pressure, significantly increasing CAR-T into solid tumors**
- **Median overall survival (OS) 8.3 months and mean OS 9.8 months vs. 3 to 6 months standard of care**
- **Two of four stage IV patients who failed systemic chemotherapy showed metabolic complete response (CR); no visible liver metastases on PET**

WASHINGTON, DC—November 7, 2018—A phase 1b clinical trial shows that administering a concentrated dose of anti-CEA CAR-T cells precisely at the site of a solid tumor by means of TriSalus™ Life Sciences' unique Pressure-enabled Drug Delivery (PEDD) is safe, with encouraging clinical responses. The preliminary 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. A separate preclinical study will also be presented which highlights specific delivery within the pancreas itself with minimal side effects.

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 Therapeutics (NASDAQ: SRNE) autologous anti-CEA CAR-T cells. The immunotherapy was delivered by means of TriSalus Life Sciences' PEDD technology, which overpowers the high pressure within solid tumors that limits the reach and efficacy of therapeutic agents.

"PEDD significantly increased CAR-T within liver metastases when compared with low-pressure microcatheters, and this was associated with encouraging clinical activity in two 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 severe side effects, such as neurotoxicity and cytokine release syndrome, that are prevalent with conventional systemic CAR-T administration methods."

Two out of four pancreatic cancer patients had no viable liver metastases by PET scan after the treatment. After 12 months, one patient with stage IV pancreatic carcinoma showed no evidence of liver metastases on PET imaging, and his primary pancreatic tumor was stable. A second patient with stage IV pancreatic cancer also had no evidence of liver metastases six weeks after CAR-T/PEDD infusions. The median overall survival (OS) posttreatment for four stage IV pancreatic cancer patients is 8.3 months. One patient died of causes unrelated to the study. No patient suffered a severe adverse event related to the CAR-T or device.

"Although this is an early study, we are hopeful CAR-T immunotherapy in combination with our PEDD technology can help prolong the lives of patients with pancreatic and other high-pressure solid tumors," said Mary T. Szela, CEO and president of TriSalus Life Sciences. "Localized infusion with the company's technology has been used in nearly 8,000 procedures worldwide for liver cancer, with proven ability to improve tumor uptake."

Preclinical study: pancreatic PEDD delivery safe, effective

A preclinical porcine study to be presented at SITC showed an approximately 150-fold increase in CAR-T cell delivery efficiency after Venous Pressure-enabled Drug Delivery (V-PEDD) directly to the pancreas, as compared to penetration after systemic infusion. There was no evidence of pancreatic or systemic toxicity.

The clinical study was funded by TriSalus Life Sciences, Sorrento Therapeutics, and the Colorado Office of Economic Development and International Trade.

About Pressure-enabled Drug Delivery (PEDD)

The high intratumoral pressure created by the tumor microenvironment limits the flow and accumulation of therapy in solid tumors. Pressure-enabled Drug Delivery (PEDD) can improve drug delivery to the tumor by creating a favorable pressure gradient that penetrates the hostile tumor microenvironment and increases drug concentration in the tumor without increasing systemic toxicity.

About TriSalus™ Life Sciences

Founded in 2009, TriSalus Life Sciences (previously known as Surefire® Medical, Inc.) is a privately held oncology drug delivery company headquartered in Westminster, CO, focused on developing technologies that overcome the high-pressure tumor microenvironment to expand the therapeutic index. The company created the proprietary Pressure-enabled Drug Delivery (PEDD) technology and is committed to advancing other applications of the technology for use in other solid tumors and the administration of immuno-oncology (I-O) therapies. For more information visit www.trisaluslifesci.com.

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. For more information visit www.sorrentotherapeutics.com.

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