TriSalus Life Sciences Appoints Steven Katz, M.D., Chief Medical Officer

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- Renowned surgeon, clinician, and researcher to advance work to combine novel immuno-oncology therapies with regional drug delivery to improve outcomes in metastatic liver and pancreatic tumors

DENVER and CHICAGO, September 29, 2020 (BUSINESS WIRE) —TriSalus Life Sciences (TriSalus), an emerging immuno-oncology Company committed to transforming outcomes for patients with solid tumors, announced today the appointment of Steven Katz, M.D., as its Chief Medical Officer. Katz will oversee the Company's clinical development strategy as it seeks to overcome poor outcomes in the treatment of solid tumors by combining TriSalus' proprietary, FDA-cleared intravascular, regional drug delivery technology with immuno-oncology therapeutics. Katz has served as the Company's Chief Medical Advisor and as Chairman of its Scientific Advisory Board since 2018.

Mary Szela, Chief Executive Officer and President of TriSalus Life Sciences, said, "We are thrilled to have Steven join TriSalus as a member of our leadership team and one who will advance our goal of improving outcomes for patients with solid pancreatic and liver tumors. Steven's scientific acumen and clinical experience are second to none, but it's his relentless commitment to eradicating solid tumors by embracing new approaches that will make the most lasting impact on overcoming one of the greatest challenges in cancer care."

Steven Katz, M.D., Chief Medical Officer of TriSalus Life Sciences, said, "Joining TriSalus will allow me to leverage my experiences as a surgeon, clinician and scientist to realize my ultimate goal – transforming outcomes for solid tumor patients with metastatic disease. New therapies are improving the way in which we treat cancer, but critical barriers in solid tumors prevent optimal delivery and performance of therapeutics."

"I can't wait to continue our work as a member of the TriSalus team. We're focused on integrating delivery technology that can deliver therapeutic directly to the site of disease with therapeutic agents that both kill cancer cells and stimulate the body's immune system in the fight. Through our relationships with exceptional academic clinical sites, we can rapidly initiate and execute clinical trials using this novel approach."

Katz attended the New York University School of Medicine, receiving the Alpha Omega Alpha Award. He completed his general surgery residency at the New York University Medical Center. Dr. Katz completed Fellowships in Immunology and Surgical Oncology at the Memorial Sloan-Kettering Cancer Center, where he served as the Chief Administrative Fellow. Katz maintains a part-time clinical practice focused on liver tumors, pancreas cancer, sarcoma, and melanoma. His laboratory research endeavors focus on immunotherapy for solid tumor metastases and he has led a cGMP cell therapy facility. He has served as the principal investigator for five solid tumor CAR-T trials, including four for liver metastases and one for peritoneal carcinomatosis. Dr. Katz has invented numerous cell therapy products and methods currently under testing or development.

TriSalus was formed to investigate treatments to help stimulate the immune system to overcome immunosuppression by delivering a combination of immuno-oncology therapies directly to the site of disease. We are researching this multi-pronged approach to reprogram the immunosuppressive tumor microenvironment, harness the power of tumor killing agents, and deliver these therapies directly to the tumor through its Pressure-Enabled Drug Delivery™ (PEDD™) approach. The Company has identified validated, IND-ready targets to acquire through license agreements, collaborations, or joint ventures. TriSalus is initially focused on the goal of successfully treating intractable solid tumors including uveal melanoma liver metastases and pancreatic cancer.

About SD-101

TriSalus recently acquired SD-101, an investigational Toll-Like receptor 9 (TLR9) agonist that has been tested in Phase 2 clinical trials for advanced cutaneous melanoma and head and neck cancer, evaluating efficacy, safety, and the ability to increase responsiveness to checkpoint inhibitors in PD-L1 negative tumors.

By combining SD-101 with TriSalus' proprietary FDA cleared, drug delivery technologies, TriSalus will deliver the agent into the local vasculature of solid tumors. The Company intends to begin evaluating SD-101 in patients with uveal melanoma liver metastases followed by testing in patients with pancreatic ductal adenocarcinoma and colorectal cancer liver metastases. In addition, a separate program for locally advanced pancreatic ductal adenocarcinoma is in progress.

SD-101 is an investigational proprietary short sequence of synthetic deoxyribonucleic acid (DNA) which binds to the Toll-Like receptor 9 (TLR9) found on suppressive immune cells including myeloid-derived suppressor cells and antigen presenting cells.[1] SD-101 has been evaluated in numerous clinical studies to assess safety and efficacy. Investigational studies suggest responsiveness to checkpoint inhibitors in PD-L1 negative tumors as well as inducing an influx of cytotoxic T cells and interferon gamma production.[2]

SD-101 will be evaluated in multiple visceral organ tumor types to assess its safety and activity via PEDD as well as in combination with other immunotherapies and modalities. For more information on SD-101 clinical trials that are currently recruiting patients, please visit www.clinicaltrials.gov.

About Pressure-Enabled Drug Delivery™ (PEDD™)
Pressure-Enabled Drug Delivery (PEDD) approach with SmartValve™ technology features a self-expanding, nonocclusive, one-way valve which can infuse therapeutics into solid tumor vasculature.[3] The FDA cleared SmartValve devices have been shown to deliver more therapy into the tumor while preventing embolic reflux.[4]

About TriSalus Life Sciences
TriSalus Life Sciences is a revenue generating, emerging immuno-oncology Company dedicated to developing immunotherapy treatments for liver and pancreatic tumors using our novel delivery technologies to improve patient outcomes. TriSalus intends to pursue multiple solid tumor indications with investigational SD-101 and acquire other immuno-oncology agents to combine with our proprietary Pressure-Enabled Drug Delivery™ technology

for the administration of therapeutics intravascularly into visceral organ solid tumors. In combination with checkpoint inhibitors, our focus is to reprogram the dominant immunosuppressive cell population in liver and pancreatic tumors. This innovative approach in development has the potential to leverage multiple mechanisms that can work together with the goal to overcome inherent immune suppression within the solid tumor microenvironment. For more information, please visit www.trisaluslifesci.com.

References:

[1]NCI Drug Dictionary, Definition of TLR9 Agonist SD-101, National Cancer Institute Accessed June 17, 2020.

[2]Ribas, A., et al. SD-101 in Combination with Pembrolizumab in Advanced Melanoma: Results of a Phase Ib, Multicenter Study. Cancer Discov. 2018 Oct;8(10):1250-1257.

[3]Data on file (CEA 001 trial) Study Design: Single patient infusion. Pressure continuously monitored during initial positioning at target site, deployment of the PEDD™ device, and infusion of 3 cc saline bolus. TriSalus™ Life Sciences, 2019.

[4]Titano et al Study Design: A retrospective, single-center study included 88 treatment-naive patients with solitary HCC tumors <6.5 cm who underwent treatment utilizing either SIS (n = 18) or standard EH microcatheters (n = 70). Twenty-three patients (5 SIS, 18 EH) received a liver transplant during the study, with 1 SIS and 6 EH patients excluded from the tumor necrosis analysis for receiving subsequent therapies prior to transplant. A pathologist performed a blinded review of the liver explant specimens to assess tumor necrosis and treatment distribution. Pathological analysis of explanted livers showed greater concentrations of microspheres within the tumor relative to the surrounding tissue in SIS explants (88.7 ± 10.6%) versus the EH explants (55.3 ± 32.7%) (p = 0.002). Titano JJ, et al. Cardiovasc Intervent Radiol. 2019;42:560-568.