TriSalus Life Sciences Presents Data for SD-101 Delivered by TriSalus Infusion System for Pancreatic Adenocarcinoma at the Society for Immunotherapy of Cancer (SITC) Annual Meeting

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– New data from PERIO-03 clinical trial indicates PEDD™ method resulted in modulation of the tumor microenvironment by enabling performance of a TLR9 agonist in pancreatic tumors –

DENVER & SAN DIEGO--(BUSINESS WIRE)--Nov. 3, 2023-- TriSalus Life Sciences® Inc., (Nasdaq: TLSI), an oncology company integrating its novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors, today announced initial positive safety and feasibility data from a Phase 1 trial at the Society of Immunotherapy for Cancer (SITC) 2023 Annual Meeting.

TriSalus is studying an investigational class C toll-like receptor-9 (TLR9) agonist, SD-101, delivered intravascularly using the Company's proprietary Pressure-Enabled Drug Delivery™ (PEDD™) method of administration in three Phase 1 trials (periotrial.com). In PERIO-03, SD-101 is delivered via PEDD with the TriSalus Infusion System® using a retrograde venous approach, leveraging established interventional radiology access techniques.

The TriSalus Infusion System has an expandable SmartValve® and can interface with standard invasive blood pressure transducers for continuous pressure monitoring during infusion of a therapeutic. During infusion, the device blocks retrograde flow and modulates pressure in the vessel, resulting in the perfusion of the venous and capillary network isolated by the device.

Early safety and feasibility data from the PERIO-03 locally advanced pancreatic adenocarcinoma trial revealed that in three patients who received SD-101 via retrograde venous infusion PEDD at the lowest dose level (0.5 mg), there were no serious grade 3/4 adverse events related to treatment. This is a first-in-human experience for use of PEDD and retrograde venous infusion for delivery of an immunologic agent into pancreatic tumors. Immune signals pointed to a decrease in myeloid derived suppressor cells (MDSC) activity in the treated pancreatic tumors, with declines in MDSC associated genes, including arginase-1, nitric oxide synthetase-2, and S100A9 (n=3). Signals associated with T cell activation were also noted in pancreatic tumor biopsy specimens.

"There is a critical need for novel treatments and approaches in locally advanced pancreatic cancer. The PERIO-03 trial is a highly innovative and multidisciplinary approach of delivery of a novel immunotherapy into the pancreas through pancreatic retrograde venous infusion," stated Michael S. Lee, M.D., associate professor of Gastrointestinal (GI) Medical Oncology at The University of Texas MD Anderson Cancer Center. "The treatments have been well tolerated and the translational studies show intriguing changes in immune markers. We are excited to continue enrolling patients in this study."

"These data offer additional validation of our innovative immunotherapy approach for pancreatic tumors. SD-101 was selected based on its mechanism of action, which has the potential to reverse immunosuppression in the pancreas through depletion of MDSC in concert with broad stimulation of immune cells in the tumor microenvironment," said Steven C. Katz, M.D., FACS, Chief Medical Officer at TriSalus. "TriSalus delivery systems, which use the PEDD method, are designed to overcome mechanical barriers to immunotherapy success, which may be underappreciated factors in limiting performance of TLR agonists in liver and pancreas tumors. Pancreatic tumors in particular contain very dense stromal tissue, which may accentuate the mechanical barriers to effective drug delivery in these patients."

Overall, the data emerging from PERIO-03 trials indicate immunologic changes are occurring within the pancreas, with a favorable safety profile. Additionally, pre-clinical data presented by TriSalus at SITC indicates that SD-101 administered via PEDD can enable both intravenously and subcutaneously administered checkpoint inhibitors.

TriSalus will also present data from its PERIO-01 trial for uveal melanoma liver metastases at a SITC late breaker session on Saturday, November 4 at 11:25 am PT. All TriSalus presentations from SITC are available here following their respective sessions.

About Pressure-Enabled Regional Immuno-Oncology (PERIO) clinical trials

The Pressure-Enabled Regional Immuno-Oncology (PERIO) clinical trials are studying an investigational class C toll-like receptor-9 agonist, SD-101, delivered intravascularly by TriSalus' TriNav® Infusion System (TriNav) using the Company's proprietary Pressure-Enabled Drug Delivery™ (PEDD™) method of administration in three Phase 1 trials.

The PERIO-01 Phase 1 clinical study for uveal melanoma with liver metastases (UMLM), is studying SD-101 delivered via PEDD with TriNav in combination with intravenous checkpoint inhibitors.

The PERIO-02 Phase 1b clinical study for hepatocellular carcinoma and intrahepatic cholangiocarcinoma, is studying SD-101 delivered via PEDD with TriNav in combination with intravenous checkpoint inhibitors.

The PERIO-03 Phase 1 clinical study for locally advanced pancreatic adenocarcinoma, is studying SD-101 delivered via PEDD with TriNav in combination with intravenous checkpoint inhibitors.

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology company integrating novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors.

The Company's platform includes devices that utilize a proprietary drug delivery technology and a clinical stage investigational immunotherapy. The Company's two FDA-cleared devices use its proprietary Pressure-Enabled Drug Delivery™ (PEDD™) approach to deliver a range of therapeutics: the TriNav® Infusion System for hepatic arterial infusion of liver tumors and the Pancreatic Retrograde Venous Infusion System for pancreatic tumors. PEDD is a novel delivery approach designed to address the anatomic limitations of arterial infusion for the pancreas. The PEDD approach modulates

pressure and flow in a manner that delivers more therapeutic to the tumor and is designed to reduce undesired delivery to normal tissue, bringing the potential to improve patient outcomes. SD-101, the Company's investigational immunotherapeutic candidate, is designed to improve patient outcomes by treating the immunosuppressive environment created by many tumors and that can make current immunotherapies ineffective in the liver and pancreas. Patient data generated during Pressure-Enabled Regional Immuno-Oncology™ (PERIO) clinical trials support the hypothesis that SD-101 delivered via PEDD may have favorable immune effects within the liver and systemically. The target for SD-101, TLR9, is expressed across cancer types and the mechanical barriers addressed by PEDD are commonly present as well. SD-101 delivered by PEDD will be studied across several indications to address immune dysfunction and overcome drug delivery barriers in the liver and pancreas.

In partnership with leading cancer centers across the country – and by leveraging deep immuno-oncology expertise and inventive technology development – TriSalus is committed to advancing innovation that improves outcomes for patients. Learn more at trisaluslifesci.com and follow us on Twitter and LinkedIn.

For Patients

To learn more about the clinical trial treatment protocol and enrollment, visit http://www.periotrial.com or http://www.clinicaltrials.gov and search NCT04935229, NCT05220722, and NCT05607953.

Forward Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the benefits and potential benefits of the Company's PEDD drug delivery technology and SD-101 investigational immunotherapy. Risks that could cause actual results to differ from those expressed in these forward-looking statements include risks associated with clinical development and regulatory approval of drug delivery and pharmaceutical product candidates, including that future clinical results may not be consistent with patient data generated during the Company's PERIO clinical trials, and other risks described in the Company's filings with the Securities and Exchange Commission under the heading "Risk Factors." All forward -looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

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