TriSalus Life Sciences Technology Featured in Two Presentations at the Society of Interventional Radiology Annual Scientific Meeting

March 26, 2024 12:00 PM EDT

– New safety and feasibility data from Phase 1/1b PERIO-03 trial for locally advanced pancreatic cancer supports further development of the novel TriSalus Infusion System for therapeutic delivery via retrograde venous delivery –

– A retrospective clinical study of the Pressure-Enabled Drug Delivery™ (PEDD™) method supports selection of the TriNav® Infusion System fo treatment-refractory hypovascular tumors –

DENVER & SALT LAKE CITY--(BUSINESS WIRE)--Mar. 26, 2024-- Technology from 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, was featured in two oral presentations at the Society of Interventional Radiology Annual Scientific Meeting.

PERIO-03 Phase 1/1b Update

TriSalus is studying an investigational class C toll-like receptor-9 (TLR9) agonist, nelitolimod (formerly 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, nelitolimod is delivered via the PEDD method with the TriSalus Infusion System using a retrograde venous approach, leveraging established interventional radiology access techniques.

Early safety and feasibility data from the PERIO-03 trial for locally advanced pancreatic adenocarcinoma showed technical success in all five patients who had received eight treatment interventions at data cutoff. There were no immediate complications from the procedure, and there was no evidence of hemorrhage or thrombosis. This follows a previous report indicating evidence of encouraging immune signals such as decreases in myeloid derived suppressor cells (MDSC) in the treated pancreatic tumors with evidence of T-cell activation.

PEDD Performance in Hypovascular Solid Tumors

In a retrospective study, investigators from The University of Texas MD Anderson Cancer Center reported on a variety of tumor types, the majority of which were notable for being hypovascular metastases and for which embolization may be clinically challenging. Technical success for embolization using the TriNav microcatheter was 100%. Tumors were treated in the liver (88%), bone (9.4%), and adrenal gland (3.1%). Local tumor progression-free survival rates across organs at one month, six months, and one year were 94%, 80%, and 70%, respectively.

"The data presented at the Society of Interventional Radiology meeting provide further evidence that the Pressure Enabled Drug Delivery method has the potential to improve therapeutic uptake and clinical outcomes at multiple disease sites, including the liver and pancreas. The data, which suggest the PEDD method can address solid tumor delivery challenges, align well with the 2024 outcomes research study from Current Medical Research and Opinion, which provides support for the recently awarded Centers for Medicare & Medicaid Services reimbursement code for procedures involving the TriNav system," said Steven C. Katz, M.D., FACS, Chief Medical Officer at TriSalus.

Both TriSalus presentations from SIR are available here.

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, nelitolimod, 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 nelitolimod 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 nelitolimod 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 nelitolimod 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. Nelitolimod, 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 nelitolimod delivered via PEDD may have favorable immune effects within the liver and systemically. The target for nelitolimod, TLR9, is expressed across cancer types and the mechanical barriers addressed by PEDD are commonly present as well. Nelitolimod 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.

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