TriSalus Life Sciences Highlights Clinical Data from Phase 1b PERIO-02 Trial, Studying Delivery of Nelitolimod via Pressure-Enabled Drug Delivery in Patients with Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma at 2024 ASCO Annual Meeting

June 3, 2024 11:00 AM EDT

– Hepatic arterial infusion (HAI) of nelitolimod has been well tolerated and associated with encouraging immunologic activity in patients with HCC and ICC

– 4 mg dose demonstrated 3 of 3 patients achieving disease control, with one complete response in the liver (5L ICC), one partial response (-31%), and one stable disease (SD) when combined with checkpoint inhibition

– Follow up of patients is ongoing to determine next steps in the program

– Poster presentation on Saturday, June 1, 2024, at 9:00 a.m. to 12 p.m. CT

DENVER--(BUSINESS WIRE)--Jun. 3, 2024-- TriSalus Life Sciences, Inc. (Nasdaq: TLSI), an oncology company integrating its novel Pressure Enabled Drug Delivery™ (PEDD™) technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors, today announced that data from its Phase 1b PERIO-02 clinical trial was presented in a poster session at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting, taking place May 31-June 4, 2024, in Chicago, Illinois.

The PEDD approach is a proprietary delivery mechanism developed by TriSalus that aims to overcome challenges of the tumor microenvironment (TME) by modulating pressure and flow to enhance local drug concentrations in tumors by improving intravascular therapeutic delivery. The PERIO-02 clinical trial is the hepatic arterial infusion (HAI) of nelitolimod with the PEDD method to enhance tumor response in combination with intravenous checkpoint inhibition in adults with Hepatocellular Carcinoma (HCC) or Intrahepatic Cholangiocarcinoma (ICC).

“The PEDD approach represents a promising new delivery method that addresses the limitations of intravenous infusions or needle injections to deliver therapeutics such as nelitolimod to immune cells throughout and surrounding the tumor microenvironment,” said Mary Szela, Chief Executive Officer and President of TriSalus. “The findings from the PERIO-02 clinical trial demonstrate the potential of the PEDD method to treat patients with HCC and ICC and provide initial clinical validation that HAI of nelitolimod is well tolerated with encouraging immunologic activity. We look forward to presenting these data and engaging with the medical community at ASCO.”

Key Findings from the Phase 1b PERIO-02 Clinical Trial

- At the 4 mg dose in cohort C, three of three patients had disease control as best on-treatment response, with one complete response (CR) in the liver (5L ICC), one partial response (PR) (-31%), and one stable disease (SD). For patient 101-017, investigators noted decreases in the target liver lesion (31.3 to 17.5 mm), non-target liver lesion, and extra-hepatic lymph nodes on days 53 and 84 with CR of target liver lesions and stability of extra-hepatic nodal lesions reported on day 154.
- Median progression-free survival (PFS) in the Cohort C 4 mg dose level is > 120 days. Median overall survival (OS) for this group has not been reached (range 120-170 days).
- Immune effects of nelitolimod included increases in liver tumor CD4 and CD8 T cells and an increase in the CD8 T cell:MDSC ratio.
- Gene expression changes revealed increased Th1 programming as well as increased expression of granzyme A, IFNγ, and CXCL10 in both liver tumor and surrounding normal liver.
- Changes among plasma marker levels included increased IL-2R and CXCL10 expression, with decreased IL-17A, IDO, and NT5E (CD73).

“The PERIO-02 data presented by Dr. Sunyoung Lee from the University of Texas MD Anderson Cancer Center illustrate that SD-101 is well tolerated when given by the PEDD method in patients who often have underlying liver disease, in association with encouraging biologic activity. The effects noted in PERIO-02 patients, including liver myeloid derived suppressor cell depletion and broad tumor microenvironment immune stimulation, are consistent with previously reported data in metastatic liver tumors (PERIO-01) and locally advanced pancreatic adenocarcinoma (PERIO-03),” said Steven C. Katz, MD, FACS, Chief Medical Officer at TriSalus.

PERIO-02 is an open-label phase 1 trial of nelitolimod given by the PEDD method in HCC and ICC. The study consists of dose-escalation cohorts of nelitolimod alone (Cohort A), with IV pembrolizumab (Cohort B), or IV nivolumab + ipilimumab (Cohort C). Nelitolimod is delivered over two cycles, with three weekly doses per cycle. Blood, liver tumor, and normal liver biopsies are collected for correlative studies.

Details about the presentation can be found below and on the ASCO website. Additionally, a copy of the poster will be available on the publications

page of the TriSalus website.

Title: PERIO-02: Phase 1b Pressure Enabled Regional Immuno-oncology Trial of nelitolimod (SD-101), a Class C TLR9 agonist, delivered via hepatic artery infusion +/- checkpoint inhibition in intrahepatic cholangiocarcinoma and hepatocellular carcinoma
Presenter: Dr. Sunyoung Lee, associate professor of Gastrointestinal (GI) Medical Oncology at the University of Texas MD Anderson Cancer Center
Date: Saturday, June 1, 2024
Session Time: 9:00-12:00 p.m. CT/10:00-1:00 p.m. ET
Poster Session: Developmental Therapeutics—Immunotherapy
Abstract: 2622

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 which 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 in an effort 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 X (formerly Twitter) and LinkedIn.

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 nelitolimod investigational immunotherapy, the Company's ability to achieve the revenue milestones under the credit facility, the Company's expectations about its cash runway, and the Company's ability to execute on its strategy. 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 clinical trials, the cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, the risks associated with the credit facility, including the Company's ability to remain in compliance with all its obligations thereunder to avoid an event of default, the risk that the Company will continue to raise capital through the issuance and sale of its equity securities to fund its operations, the risk that the Company will not be able to achieve the applicable revenue requirements to access additional financing under the credit facility, changes in expected or existing competition or market conditions, changes in the regulatory environment, unexpected litigation or other disputes, unexpected expensed costs, 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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