TriSalus Life Sciences Announces Launch of PREDICTT Clinical Trial Evaluating Pressure-Enabled Drug Delivery in Liver Tumors

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WESTMINSTER, Colo.--(BUSINESS WIRE)--May 4, 2026-- TriSalus Life Sciences, Inc. (Nasdaq: TLSI) (the “Company”), an oncology company integrating novel delivery technology with standard of care therapies, and its investigational immunotherapeutic to transform treatment for patients with solid tumors, today announced the initiation of patient enrollment for the **PREDICTT clinical trial (NCT07444645)**, a prospective study designed to evaluate its novel Pressure-Enabled Drug Delivery™ (PEDD™) approach in patients with primary or metastatic liver tumors.

The PREDICTT trial is an investigator-led single-arm, prospective, interventional study designed to evaluate how PEDD impacts tumor targeting and radiation dose distribution. Investigators at The University of Texas MD Anderson Cancer Center will assess the use of the TriNav® Infusion System in conjunction with Y90 radioembolization therapy. Specifically, the trial will measure changes in CT-based tumor-to-normal liver ratios and assess how these changes correlate with tumor dose and treatment outcomes.

Advancing Precision Delivery in Liver-Directed Therapy

Y90 radioembolization is a widely used treatment for unresectable liver tumors. However, optimizing delivery to maximize tumor dose while minimizing exposure to healthy liver tissue remains a critical challenge. The PREDICTT study aims to address this by evaluating the TriNav Infusion System, a Pressure-Enabled Drug Delivery device designed to improve microsphere distribution within tumors.

Study Design and Objectives

The PREDICTT (Prospective Evaluation of Pressure-Enabled Delivery and Alterations in CT-Based Tumor-to-Normal Liver Ratio and Tumor Dose) trial is an investigator-led study evaluating the impact of pressure-enabled delivery using the TriNav Infusion System in patients undergoing Y90 radioembolization for liver tumors. The PREDICTT trial will enroll approximately 20 adult patients with unresectable primary or metastatic liver tumors who are eligible for Y90 radioembolization. The trial is led by principal investigator Peiman Habibollahi, M.D., associate professor of Interventional Radiology at UT MD Anderson.

Key objectives include:

- Evaluate changes in CT-based tumor-to-normal liver enhancement ratios using the TriNav Infusion System
- Correlate imaging-based measurements with tumor dose and microsphere distribution
- Evaluate relationships between imaging metrics and post-treatment SPECT/CT findings
- Assess safety of the TriNav Infusion System [with Y90] in liver directed therapy

Strengthening Clinical Collaboration

The launch of PREDICTT underscores the continued collaboration between TriSalus Life Sciences and UT MD Anderson.

“This study represents an important step toward optimizing locoregional therapies through advanced delivery technologies,” said Richard Marshall, MD at Chief Medical Officer, TriSalus Life Sciences. “We are proud to collaborate with UT MD Anderson to generate clinical evidence that could redefine how Y90 therapies are delivered.”

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology focused medical technology company seeking to transform outcomes for patients with solid tumors by integrating its innovative delivery technology with standard-of-care therapies, and with its investigational immunotherapeutic, nelitolimod, a class C Toll-like receptor 9 agonist, for a range of different therapeutic and technology applications. The Company’s platform includes devices that utilize a proprietary drug delivery technology and a clinical stage investigational immunotherapy. The Company’s three FDA-cleared devices use its proprietary Pressure-Enabled Drug Delivery™ (PEDD) approach to deliver a range of therapeutics: the TriNav® Infusion System and TriNav Infusion System LV for hepatic arterial infusion of liver tumors and the Pancreatic Retrograde Venous Infusion System for pancreatic tumors. The PEDD technology 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 the PEDD technology 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 the PEDD technology are commonly present as well. The Company is in the final stages of data completion for a number of phase 1 clinical trials and will begin exploring partnership opportunities for development.

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. Risks that could cause actual results to differ from those expressed in these forward-

looking statements include the risk 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, 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, TriNav ® system and nelitolimod investigational immunotherapy, 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, the risk that the Company will not become profitable on its expected timeline, if at all, the risk that the reported financial results will differ from the estimates provided in this press release, 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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