New TriNav Data in JVIR

TriSalus Announces Journal of Vascular and Interventional Radiology Publication of Data that Demonstrate Improved Therapeutic Delivery of Glass Microspheres to Solid Tumors With PEDD™ Method via the TriNav® Infusion Systems

September 23, 2024

Pressure enabled drug delivery (PEDD) method significantly increased penetration of glass microspheres into porcine liver tumors (117%; p=0.004 and 39%; p=0.032) with lobar infusions and selective infusions, respectively

TriSalus Life Sciences®, Inc. ("TriSalus" or the "Company") (Nasdaq: TLSI), an oncology company integrating its novel delivery technology with standard of care therapies and immunotherapy to transform treatment for patients with liver and pancreatic tumors, announced today the publication of research titled, "Intra-arterial Pressure-Enabled Drug Delivery Significantly Increases Penetration of Glass Microspheres in a Porcine Liver Tumor Model," in the peer-reviewed Journal of Vascular and Interventional Radiology. The article illustrates that the PEDD method via the TriNav Infusion System significantly improved delivery of glass microspheres (GM) with deeper penetration into liver tumors and the peritumoral tissue, when compared to delivery of GM with a conventional microcatheter in a transgenic (oncopig) model.

"This is another example of how our PEDD approach effectively tackles a significant challenge in cancer care by ensuring the selective and increased delivery of therapeutics to the tumor. This research advances and validates our understanding of the PEDD method, providing high-resolution evidence of enhanced delivery," said Bryan F. Cox, Ph.D., Chief of Research for TriSalus. "With both proximal and distal placements of the PEDD device, we observed significantly improved delivery of glass microspheres to the tumor, quantified on a millimeter scale. The strength of the proximal infusion data suggests an opportunity to selectively target multiple tumors simultaneously in patients with heavy disease burdens."

"These results contribute to the substantial and expanding body of pre-clinical and clinical evidence supporting the wide-ranging potential applicability of the PEDD approach," said Mary Szela, Chief Executive Officer and President of TriSalus. "Efficient delivery of therapeutics into tumor cells without causing harm to off-target normal tissue remains a real-world challenge in cancer care, and the PEDD approach aims to overcome this obstacle. This publication strengthens our current understanding that, regardless of placement of the technology, either lobar or selective infusions, the PEDD method increased glass microspheres delivery uptake compared to conventional microcatheters. The TriNav device signifies a potential breakthrough in delivering glass microspheres and other drugs into tumors in a highly controlled and targeted manner."

"This study shows the potential of PEDD method to address an unmet need in liver cancer therapy – achieving the same safety profile of selective Y90 treatment to those performed for more advanced diffuse disease using lobar injections. This study suggests that the use of PEDD method alters hemodynamics and the microenvironment in a manner resulting in higher concentrations of microspheres in the tumor compared to the adjacent liver parenchyma, thereby offering the ability to increase efficacy and improve safety. If further validated in human models, this may represent a significant advancement in the management of liver cancer," said Dr. Riad Salem, Chief of Interventional Radiology, and Professor of Radiology, Surgery, and Medicine in Chicago.

The research involved transgenic pigs (oncopigs) with induced liver tumors. These tumors were intra-arterially infused with fluorescently labeled GM. The PEDD method with the TriNav device was compared to the use of conventional microcatheter delivery in both lobar and selective infusions. Near-infrared (near IR) imaging was utilized to detect the GM fluorescent signal in tumors. The results showed significant increases in GM signal intensity in and around tumors after delivery with the PEDD method, with a 117% increase in tumor penetration with lobar infusions and a 39% increase with selective infusions compared to conventional delivery. Lobar PEDD delivery of GM to the tumor was statistically equivalent to conventional selective delivery (p=0.497).

A copy of the full abstract can be accessed here.

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology focused medical technology business providing disruptive drug delivery technology with the goal of improving therapeutics delivery to 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

Certain statements made in this press release are "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created thereby under the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words such as "become," "may," "intend," "will," "expect," "anticipate," "believe" or other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements may include, but are not limited to, statements regarding the consummation of the Offer and Consent Solicitation, the timing of the Expiration Date, the future effectiveness of the registration statement on Form S-4, the approval by the holders of Warrants of the Warrant Amendment and subsequent entry into the Warrant Amendment, the effects of the Offer on our capital structure and expected changes to the dilutive impact of the Warrants. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by any investor as, a guarantee, an assurance, a prediction or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including, without limitation: the Company's ability to successfully complete the Offer and Consent Solicitation; the number of holders of Warrants that approve the Warrant Amendment in the Consent Solicitation; the timing and results of the SEC review of the registration statement on Form S-4 filed on May 24, 2024, if any; the Company's ability to attract and retain customers and expand customers' use of the Company's products; risks relating to market, financial, political and legal conditions; risks relating to the uncertainty of the projected financial and operating information with respect to the Company; risks related to future market adoption of the Company's offerings; risks related to the Company's marketing and growth strategies; risks related to the Company's ability to acquire or invest in businesses, products or technologies that may complement or expand its products, enhance its technical capabilities or otherwise offer growth opportunities; the effects of competition on the Company's future business; the risks discussed in the Company's quarterly report on Form 10-Q for the period ended March 31, 2024 under the heading "Risk Factors"; and the risks discussed in the Company's Registration Statement on Form S-4 filed on May 24, 2024, under the heading "Risk Factors" and other documents of the Company filed, or to be filed, with the SEC. If any of these risks materialize or any of the Company's assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that the Company presently does not know of or that the Company currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect the Company's expectations, plans or forecasts of future events and views as of the date of this press release. The Company anticipates that subsequent events and developments will cause the Company's assessments to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by applicable law. These forward-looking statements should not be relied upon as representing the Company's assessments as of any date subsequent to the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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Indications
For Use The TriNav Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.[1]

Contraindications
TriNav is not intended for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature).

Rx Only. For the safe and proper use of the TriNav Infusion System, refer to the Instructions for Use.

References
1. TriSalus™ TriNav® Infusion System, Instructions for Use