TriSalus Life Sciences Announces Real-World Data Demonstrating the Ability of TriNav® to Successfully Treat Patients with Higher Disease Burden and to Improve Delivery of Therapeutics to Liver Tumors

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– Data published in Current Medical Research and Opinion provide a comparison of the TriNav Infusion System vs. standard drug delivery and show the ability of TriNav to successfully treat sicker, treatment refractory, and higher disease burden patients, further validating previous data in the real-world setting –

DENVER--(BUSINESS WIRE)--Feb. 29, 2024-- 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 the publication in *Current Medical Research and Opinion* a manuscript detailing a real-world study of the use of the pressure-enabled drug delivery (PEDD™) method with the TriNav® device for trans-arterial chemoembolization (TACE) and trans-arterial radioembolization (TARE) in patients with hepatocellular carcinoma (HCC) and liver metastases.

The data presented in this study captured real-world safety and clinical outcomes data for TriNav in its launch phase (2020-2022) utilizing a large, 300 million patient dataset covering 98% of US payers. These data provide valuable insights into the important benefits of this technology that would otherwise take many years to accumulate through alternative approaches using clinical trials. Key findings include that TriNav patients, despite a higher baseline disease burden and clinical complexity, showed overall clinical results comparable to patients with lower disease burden. The study also revealed that:

- In TACE procedures, interventional radiologists could deliver significantly more chemotherapeutic to the tumor when using TriNav vs. the amount delivered using standard catheters, a critical treatment goal.
- In a matched cohort comparison, TriNav patients had fewer 30-day inpatient visits post-procedure than non-TriNav patients.
- TriNav HCC patients were more likely to have a post-procedure liver transplant in a matched cohort comparison.
- TriNav TARE patients with liver metastases had fewer clinical complications post-procedure vs. non-TriNav patients in a matched cohort comparison.
- TriNav TARE patients with liver metastases had lower rates of post-procedure fatigue vs. non-TriNav patients.

These study data clearly demonstrate that TriNav is preferentially selected to treat patients with a higher burden of disease than patients treated with standard catheters, yet these patients show similar results post-treatment compared to patients with a lower disease burden. TriNav patients showed impressive trends toward better outcomes in matched cohort comparisons, including an increased rate of liver transplants. The results also demonstrate how real-world data complement traditional clinical trials to provide a more robust and timely understanding of the benefits realized by patients. TriSalus is committed to updating this data set continuously and affirming the benefit TriNav and the PEDD approach bring to patients, providers, and payers.

“Analyses of real-world data are critical to obtaining a holistic understanding of the benefits of treatment with TriNav. The ability of the PEDD method to impact more complex patients when compared to standard-of-care drug delivery systems is potentially game-changing and brings us closer to addressing the limitations of current treatment options for HCC and other liver cancer patients,” said Mary Szela, Chief Executive Officer of TriSalus. “This important, peer-reviewed, real-world study speaks to our commitment to improve patient care and outcomes. These data, together with the recent, new Centers for Medicare and Medicaid (CMS) Healthcare Common Procedure Coding System (HCPCS) code effective as of this year, are a testament to TriNav’s continued emergence as a potentially best-in-class and cost-effective drug delivery method for patients with liver and pancreatic tumors.”

“These new population-based findings resonate well with previously published clinical studies that indicate PEDD improves therapeutic uptake, accuracy of therapeutic delivery, and clinical outcomes in liver cancer patients. The ability of the TriNav’s SmartValve™ to favorably modulate drug delivery pressure and flow within target blood vessels gives liver cancer patients, even those with major medical co-morbidities and large tumor burdens, the opportunity to achieve better outcomes,” said Steven C. Katz, M.D., FACS, Chief Medical Officer at TriSalus. “This large sample size study underscores the particular benefits of the TriNav device compared to standard drug delivery systems.”

About the TriNav Infusion System

TriNav is a flexible, ultra-thin therapy delivery system with SmartValve technology, a self-expanding, nonocclusive one-way dynamic microvalve that opens and closes in synchrony with the patient’s heart to modulate pressure and flow. This system uses the Pressure-Enabled Drug Delivery approach and has demonstrated the ability to overcome intratumoral pressure in solid tumors and potentially improve distribution and penetration of therapy during Transcatheter Arterial Chemoembolization (TACE) and Transcatheter Arterial Radioembolization (TARE) procedures. For more information, please visit www.trinavinfusion.com.

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 to 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, 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 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 LinkedIn and X, formerly Twitter.

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