TriSalus Life Sciences Receives FDA Clearance for TriNav® Advance, Strengthening Comprehensive Pressure-Enabled Drug Delivery™ (PEDD™) Portfolio for Liver Embolizatio

September 22, 2026 8:15 PM EDT

WESTMINSTER, Colo.--(BUSINESS WIRE)--Sep. 22, 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 it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for TriNav® Advance, the newest addition to its Pressure-Enabled Drug Delivery™ (PEDD) portfolio.

TriNav® Advance expands TriSalus' portfolio of PEDD devices, adding access to small, distal vessels, via a compatible delivery microcatheter, while preserving PEDD's enhanced therapeutic delivery and off-target protection. Interventional radiologists can now pair TriNav Advance with a compatible microcatheter of their choice, giving them flexibility across a broader range of procedures and anatomies.

With this addition, TriSalus offers a complete portfolio addressing liver-directed therapy cases and its indication supports a broader range of embolization procedures beyond the liver. The Company intends to initiate a limited market release of the TriNav Advance device over the coming weeks.

TriNav Advance can be used in two configurations to match vessel anatomy and treatment goals:

- Telescoping: Used with a compatible microcatheter, with the TriNav Advance SmartValve positioned proximal to the delivery site - enabling selective delivery to smaller, distal vessels while maintaining the benefits of PEDD.
- High-flow: Used like a standard TriNav device, without an additional microcatheter, for easy infusion through a large lumen.

“TriNav® Advance enhances our Pressure-Enabled Drug Delivery™ portfolio in support of the full range of liver embolization procedures,” saidMary Szela, President and Chief Executive Officer of TriSalus. “We are proud of the range of tools we offer to physicians and believe TriNav Advance will catalyze further adoption across these procedures. We’re excited to broaden our portfolio in a way that can meaningfully benefit both physicians and patients.”

“The TriNav® Advance clearance marks a seminal moment for TriSalus Life Sciences, enabling us to expand our impact, particularly in cases involving tortuous anatomies,” said Richard Marshall, M.D., Chief Medical Officer of TriSalus. “We believe that physicians can now optimize therapeutic delivery in difficult cases while limiting exposure to unaffected anatomical structures, which has been central to what makes PEDD clinically meaningful. This is a natural extension of the technology into cases we haven’t been able to fully address before.”

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 has completed three 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. 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, 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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