TriSalus Life Sciences Receives Approval from the World Health Organization and the American Medical Association's Adopted Name Council for "Nelitolimod" as the Nonproprietary Drug Name for SD-101

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– Nelitolimod, a class C TLR-9 agonist formerly called SD-101, is the Company's therapeutic candidate designed to overcome biologic barriers in liver and pancreatic tumors

– Nelitolimod is currently being evaluated in three Phase 1/1b studies in adults with liver and pancreatic cancers in combination with TriSalus' proprietary Pressure Enabled Drug Delivery™ technology

DENVER--(BUSINESS WIRE)--Mar. 7, 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 that the International Nonproprietary Names (INN) Expert Committee of the World Health Organization (WHO) and the United States Adopted Names (USAN) Council have approved the use of the nonproprietary name of "*nelitolimod*" for SD-101, a class C TLR-9 agonist. Nelitolimod is the Company's novel lead drug candidate that is currently being studied in three Phase 1/1b trials for the treatment of uveal melanoma with liver metastases, hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and locally advanced pancreatic ductal adenocarcinoma.

"The WHO INN and USAN approval of nelitolimod is an important milestone in the continued progress we are making with our nelitolimod program," said Mary Szela, Chief Executive Officer and President of TriSalus. "This accomplishment, along with the recent assignment of a new technology HCPCS Code for our TriNav® Infusion System, further positions TriSalus to deliver on our mission to overcome key treatment barriers in liver and pancreatic tumors and make a meaningful difference in the lives of patients suffering from cancer."

TriSalus' unique approach leverages its innovative delivery device together with its immunotherapeutic drug to overcome the mechanical and biologic barriers present in the tumor microenvironment. This approach has the potential to enable more durable responses by patients to other immunotherapeutics, thereby facilitating better patient outcomes. Data from TriSalus' Phase 1/1b trials indicates that the Company's approach in liver and pancreatic tumors is well tolerated with encouraging efficacy and immune signals, with evidence of nelitolimod being delivered by the TriNav system into difficult to reach tumors, potentially overcoming limitations posed by intravenous or direct needle injection approaches.

Information on nelitolimod will be posted on the USAN website (www.ama-assn.org/go/usan) and will be published in the Chemical Abstracts Service and in the U.S. Pharmacopeia. The WHO provides the INN to the Organization's Member States (at present 191), to national pharmacopoeia commissions, and to other bodies designated by WHO's Member States.

The name, nelitolimod, is ready for use in labelling and publications. It will serve to identify SD-101 during its lifetime worldwide. Going forward, TriSalus will use the name in publications and public statements, at conferences and other forums, and in corporate-related materials.

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 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.

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