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ProPhase Labs Announces Formation of Clinical Science Advisory Board to Accelerate Commercialization of BE-SmartTM Esophageal Disease Diagnostic Platform

UNIONDALE, NY, June 06, 2025 (GLOBE NEWSWIRE) -- ProPhase Labs Inc. (NASDAQ: PRPH), (the "Company" or "ProPhase") a next generation biotech, genomics and consumer products company, today announced the formation of its Clinical Science Advisory Board to support the clinical adoption and commercialization of its breakthrough BE-Smart™ molecular test for esophageal disease. The advisory board will provide expert strategic guidance as ProPhase leads the regulatory and commercialization pathway for BE-Smart, with the goal of establishing a new clinical and economic standard in the early detection and management of esophageal cancer risk. A full data package detailing the test's validation and clinical utility is currently under peer review.

The advisory board includes Dr. Joe Abdo, the inventor of the BE-Smart test and a nationally recognized leader in molecular oncology. Dr. Abdo looks to leverage his deep relationships with academia, the Mayo Clinic GI Path department, KUMC gastroenterology and KOLs in the esophageal cancer space. Also joining the advisory board is Mr. James McCullough, founder and CEO of Renalytix and former Chief Executive Officer of Exosome Diagnostics Inc., a pioneer in liquid biopsy diagnostics. Additional key opinion leaders and experts in the field will be added to the advisory board in the near future as the Company plans for its initial commercial launch.

"We believe BE-Smart has the potential to redefine how some severe esophageal disease progressing to cancer is detected and managed," said Ted Karkus, Chief Executive Officer of ProPhase Labs. "This advisory board brings together the scientific leadership, clinical insight, and operational expertise needed to scale this innovation and bring it into widespread clinical use. It's a major step toward realizing the full value of BE-Smart for patients, physicians, and payers. Our target market is roughly 7 million endoscopies performed each year in the United States alone on patients at risk of esophageal cancer, with a reimbursement goal of $1,000 - $2,000 per test. This equates to a $7 - $14 billion target market that is virtually untapped. We believe that our test will significantly enhance the accuracy of the endoscopy, which will in turn save thousands of lives and save the insurance companies billions of dollars."

BE-Smart offers a distinct advantage in the molecular diagnostics landscape for esophageal disease. Unlike imaging-based or DNA methylation approaches, BE-Smart measures real-time protein activity, capturing the dynamic biological signals of disease progression. It

requires only a single 10 µm FFPE biopsy section, minimizing tissue burden and simplifying lab workflows. The test integrates seamlessly into existing endoscopy and pathology procedures, delivering results in under 7 days with no added complexity for providers.

Its versatility extends beyond progression prediction. BE-Smart can help stratify risk across a spectrum of patients with GERD and Barrett's Esophagus, including those with non-dysplastic or indefinite dysplasia, areas where current tools often fall short. This broad clinical utility, coupled with its scalable, cost-efficient design, makes BE-Smart a compelling option for both frontline clinicians and healthcare systems aiming to optimize care pathways and reduce unnecessary interventions.

While other technologies like TissueCypher (Castle Bioscience) and EsoGuard (Lucid Diagnostics) have established early momentum in the esophageal diagnostics space, each has helped pave the way for broader adoption of molecular tools in GI practice. TissueCypher has been instrumental in introducing pathologists and gastroenterologists to the value of tissue-based molecular insights, while EsoGuard's less invasive disease monitoring method shows potential to expand the addressable patient population and encourage earlier engagement. BE-Smart builds on this progress by offering a next-generation approach that combines real-time biological precision with streamlined clinical integration. Its high-throughput, multiplexible design, enabled by advanced mass spectrometry, allows for deep protein-level analysis from minimal tissue input, positioning it to deliver both depth of insight and operational ease across a wide range of care settings.

The BE-Smart molecular test is strengthened by robust intellectual property protection centered on eight key proteins identified as critical biomarkers for esophageal adenocarcinoma progression. ProPhase Labs, Inc. has secured exclusive patents covering the proprietary methods for detecting and analyzing the expression of these proteins, which are uniquely associated with the molecular mechanisms driving this esophageal disease and its progression to malignancy. This IP portfolio not only safeguards the innovative approach of BE-Smart in measuring real-time protein activity through advanced mass spectrometry but also establishes a significant competitive advantage in the molecular diagnostics market.

The latest BE-Smart clinical validation manuscript, "Assessing Risk of Progression in Barrett's Esophagus Using a Mass-Spectrometry-Based Proteomic Panel" is under review at the Journal of Clinical Gastroenterology and Hepatology. A preprint may be available in the coming weeks.

Dr. Joe Abdo is a molecular oncology scientist with over 15 years of experience in cancer diagnostics, translational research, and biotech business development. He has held leadership roles across public and private biotechnology companies, with a focus on early cancer detection, immunotherapy response prediction, and clinical utility studies. He has authored more than 30 peer-reviewed publications and teaches graduate-level courses at Georgetown University Medical Center. Mr. James McCullough brings decades of leadership experience in precision medicine, having successfully launched and scaled diagnostic technologies in both the public and private sectors.

The Clinical Science Advisory Board will focus on accelerating clinical adoption, guiding payer education, and supporting evidence development and regulatory advancement.

About ProPhase Labs Inc.

ProPhase Labs Inc. (Nasdaq: PRPH) ("ProPhase") is a next-generation biotech, genomics and consumer products company. Our mission is to build a healthier world through bold innovation and actionable insight. We're revolutionizing healthcare with industry-leading Whole Genome Sequencing solutions, groundbreaking diagnostic development – such as our potentially life-saving test for the early detection of esophageal cancer – and a world class direct-to-consumer marketing platform for cutting edge OTC dietary supplements. We develop and commercialize health and wellness solutions to enable people to live their best lives. We are committed to executional excellence, smart diversification, and a synergistic, omni-channel approach. ProPhase Labs' valuable subsidiaries, their synergies, and significant growth underscore our potential for long-term value. www.ProPhaseLabs.com

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