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ProPhase Labs Announces Study Validating BE-Smart Esophageal Cancer Test Accepted by Journal of Clinical Gastroenterology and Hepatology

Study Acceptance Supports and Provides the Catalyst for Upcoming Commercial Rollout and Revenue-Generating Potential

UNIONDALE, NY, Oct. 22, 2025 (GLOBE NEWSWIRE) -- ProPhase Labs Inc. (NASDAQ: PRPH) ("ProPhase" or the "Company"), a next generation biotech, genomics and consumer products company, announced today that its pivotal clinical study by *Hartley et al.* (2025) validating the BE-Smart™ esophageal cancer test has been accepted for publication in *Clinical Gastroenterology and Hepatology*, the official journal of the American Gastroenterological Association.

This milestone marks a crucial turning point as ProPhase moves from validation to commercialization of the BE-Smart™ assay. With approximately 7 million upper endoscopies performed annually in the U.S. for GERD and Barrett's Esophagus surveillance, BE-Smart is positioned to address a total addressable market of roughly $7–$14 billion. The company is now advancing regulatory preparations and scaling laboratory efforts to support clinical testing in partnership with leading gastroenterology practices. In parallel, ProPhase is pursuing collaborations with key opinion leaders and health-system partners to integrate BE-Smart into patient-care workflows and clinical decision-making. These efforts will enable physicians to order the test through standard pathology channels, with a phased rollout planned to begin in 2026.

The study, titled "*Assessing Risk of Progression in Barrett's Esophagus Using a Mass-Spectrometry-Based Proteomic Panel*," presents peer-reviewed clinical evidence supporting BE-Smart, a novel, 8-protein, mass spectrometry-based assay developed through a collaborative research effort between ProPhase Labs and the Mayo Clinic that stratifies the risk of progression from Barrett's Esophagus (BE) to high-grade dysplasia or esophageal adenocarcinoma (EAC).

In a blinded cohort of 100 patients, BE-Smart achieved 100% sensitivity in identifying those who later progressed to cancer and demonstrated a strong correlation between predicted molecular risk and time to progression. In independent testing, the model showed strong discriminative performance (AUC 0.89–1.0 in test cohorts), comparable to leading commercial molecular assays and especially effective for identifying patients likely to progress within three years. These results exceeded the pre-specified performance threshold and further highlight BE-Smart's value as a screening and triage tool for early cancer prevention.

“Acceptance of this work by a top-tier gastroenterology journal marks an important milestone for ProPhase and for the clinical management of Barrett’s Esophagus,” said Ted Karkus, CEO of ProPhase Labs. “This is the same journal that published a seminal molecular classifier that helped catalyze the molecular screening era for esophageal disease. With BE-Smart, we are advancing that legacy with a more streamlined, tissue-sparing, and highly scalable solution. The gastroenterology market has spoken, and clinicians are asking for enhanced molecular profiling to guide surveillance in esophageal precancers. With our partners at the Mayo Clinic, we have established a solution that is accurate, highly sensitive, and requires no additional tissue, making it both physician and patient friendly. We believe BE-Smart represents the next evolution in esophageal disease surveillance and management.”

Key Findings

- **Perfect sensitivity** in detecting patients who later developed cancer
- **High predictive accuracy** (AUC up to 1.0 in test cohorts) for near-term disease progression
- **Strong association** between quantitative proteomic scores and time-to-progression
- **Strongest performance** in non-dysplastic and “indefinite for dysplasia” (IND) cases, where histology is least reliable
- **Compatible with FFPE biopsy tissue** and integrates seamlessly with standard pathology workflows
- **High-throughput and multiplex design** suitable for clinical laboratory adoption and scalability

Why It Matters

Barrett’s Esophagus affects millions of adults in the U.S., yet only a small percentage will ever develop cancer, making it one of the most challenging conditions to manage in gastroenterology. Current surveillance strategies rely on subjective histologic grading and frequent endoscopies, which are invasive, expensive, and often unnecessary.

BE-Smart fills this critical diagnostic gap. By delivering objective, molecular risk stratification, the test empowers gastroenterologists to:

- Escalate care for patients at highest risk
- Avoid unnecessary procedures and costs in low-risk cases
- Improve clinical workflow and cost efficiency

“This is a game-changer for gastroenterologists,” said Dr. Joe Abdo, Scientific Advisor at ProPhase Labs. “BE-Smart allows clinicians to visualize the proteomic hallmarks of disease progression, showing real-time expression of proteins linked to cellular proliferation and immune signaling directly within standard biopsy tissue. BE-Smart is now established as a new tool for the early detection of esophageal cancer, with implications that are immediate, actionable, and long overdue for patients and clinicians alike. This brings unprecedented molecular clarity to patient management in Barrett’s Esophagus.”

About BE-Smart

BE-Smart is a multiplex proteomic assay developed using quantitative mass spectrometry on microdissected esophageal biopsy specimens. It quantifies the expression of eight proteins associated with the risk of progression in Barrett's Esophagus and is fully compatible with routine FFPE tissue. BE-Smart represents the first publication from ProPhase Labs' **STLA (Stratify-to-Limit-Advance)** precision oncology pipeline.

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, manufacture, 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

Forward-Looking Statements

Except for the historical information contained herein, this document contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our strategy, plans, objectives and initiatives, including our expectations regarding the future revenue growth potential of each of our subsidiaries, our expected timeline for commercializing our BE-Smart Esophageal Cancer Test, our expectations regarding future liquidity events, the success of our efforts to collect accounts receivables and anticipated timeline for any payments relating thereto, and our ability to successfully transition into a consumer products company. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to our ability to obtain and maintain necessary regulatory approvals, general economic conditions, consumer demand for our products and services, challenges relating to entering into and growing new business lines, the competitive environment, and the risk factors listed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any other SEC filings. These forward-looking statements are subject to risks and uncertainties and actual results may differ materially. Details about these risks and uncertainties can be found in our filings with the SEC. The Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws. Readers are cautioned that forward-looking statements are not guarantees of future performance and are cautioned not to place undue reliance on any forward-looking statements.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities.

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