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ProPhase Labs Esophageal Cancer Early Detection Test (BE-smart) Featured in Peer-Reviewed Article in the International Journal of Molecular Science

Garden City, NY, Feb. 16, 2023 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH), a growth oriented and diversified diagnostics, genomics and biotech company, today announced that its flagship diagnostic test, which is undergoing clinical validation as a laboratory developed test (LDT) for esophageal cancer screening, was featured in *International Journal of Molecular Science* (MDPI Open-Access Publishing), volume 24, no. 4 edition. The article highlights the current clinical limitations and future molecular innovations of Barrett's esophagus-related cancer. The authors note that progress has been made regarding genomic, transcriptomic, and proteomic approaches for molecular diagnostics of Barrett's-related esophageal cancer as some of these research innovations and findings could be translated into full clinical adoption.

The senior author, Dr. Devendra Agrawal, has over 500 peer-reviewed publications as a clinical and translational researcher with a focus on bench-to-bedside projects. Dr. Agrawal is the Director of Research & Biotechnology and Professor in Translational Research at Western University of Health Sciences. The second author, Dr. Joe Abdo, is a scientific advisor for ProPhase Labs and is a key opinion leader in the molecular biology of advanced reflux disease transformation into cancer and the treatment of esophageal adenocarcinoma. Dr. Abdo has over a decade of experience researching molecular oncology mechanisms in gastrointestinal diseases and has published dozens of peer-reviewed articles on esophageal cancer.

The article explains that cancerous mechanisms are the body's natural response to areas of the body in need of cellular debris removal and reconstruction and that when these processes are dysfunctional or overactive, carcinogenesis can occur. The article recognizes ProPhase Labs' BE-smart assay as a mass spectrometry-based test that, once clinically validated, may offer a fully quantitative analysis of these markers and other proteins indicative of disease progression from formalin-fixed, paraffin-embedded forceps biopsies, with the potential to demonstrate the predictability of carcinogenesis, as traditional oncogenes have failed to yield consistent prognostic results.

To date, the BE-Smart test has been tested on over 200 human samples by mProbe, Inc. ("mProbe"), a precision health and medicine company utilizing clinical proteomics in the oncology space in conjunction with Dr. Christopher Hartley of the prestigious Mayo Clinic, and has shown greater than 99% sensitivity and specificity to detect protein expressions in cells that are at high risk of becoming cancerous.[1] The initial data appears to demonstrate accuracy and reproducibility as well as identification of potential biomarkers for therapeutic

drug discovery to treat esophageal cancer.

Dr. Abdo notes that "[t]he current standard diagnostic protocols suffer from a lack of interobserver agreement and descriptive molecular assessment tools to inform the efficient cadence of endoscopic screening and the effective use of therapeutic options for millions of patients with precancerous esophageal disease."

Ted Karkus, CEO of ProPhase Labs added, "Further development of novel therapies and the increased use of molecular diagnostics will promote informed decision-making for clinicians to help mitigate the threats presented by Barrett's-related esophageal cancer. In the coming weeks, we plan to further update our shareholders as to our progress and development timelines for our BE-Smart Esophageal Cancer Test. We currently believe, but cannot assure, that we will be able to commercialize the BE-Smart diagnostic tool within 12 to 18 months based on the completion of testing of a total of 1,000 specimens with mProbe in coordination with specimens provided by the Mayo Clinic. The future for this diagnostic test is very exciting and could save countless lives by diagnosing pre-cancerous cells years earlier than current standard diagnostic protocols for esophageal cancer. We believe the BE-Smart diagnostic tool, once fully clinically validated, has the potential to be commercialized in 2024 with multi-billion-dollar potential."

The full article can be accessed ahead-of-print on the journal's website: https://www.mdpi.com/1422-0067/24/4/3316

[1] Abdo, J., Wichman, C. S., Dietz, N. E., Ciborowski, P., Fleegel, J., Mittal, S. K., & Agrawal, D. K. (2018). Discovery of Novel and Clinically Relevant Markers in Formalin-Fixed Paraffin-Embedded Esophageal Cancer Specimen. Frontiers in Oncology, 8. https://doi.org/10.3389/fonc.2018.00157

About ProPhase Labs

ProPhase Labs, Inc. (Nasdaq: PRPH) ("ProPhase") is a growth oriented and diversified diagnostics, genomics and biotech company that seeks to leverage its CLIA lab services to provide whole genome sequencing and research direct to consumers and build a genomics database to be used for further research. The Company provides traditional CLIA molecular laboratory services, including COVID-19 testing. The Company also operates a contract manufacturing subsidiary and offers the TK Supplements line of dietary supplements, which are distributed in food, drug and mass stores throughout the country.

ProPhase Diagnostics, Inc., a wholly owned subsidiary of ProPhase, offers a broad array of clinical diagnostic and testing services at its CLIA certified laboratories including polymerase chain reaction (PCR) testing for SARS-CoV-2 (COVID-19) and Influenza A and Influenza B. Critical to COVID-19 testing, ProPhase Diagnostics provides fast turnaround times for results. ProPhase Diagnostics also offers best-in-class rapid antigen and antibody/immunity tests to broaden its COVID-19 testing beyond RT-PCR testing. The Company has announced plans for the expansion of the lab to include traditional clinical testing and genomics sequencing.

Nebula Genomics, a wholly owned subsidiary of ProPhase, focuses on genomics sequencing and testing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic

sequencing may help to identify inherited disorders and tendencies, help predict disease risk, help identify expected drug response, and characterize genetic mutations, including those that drive cancer progression. The Company currently offers Nebula Genomics whole genome sequencing products direct-to-consumer online, with plans to sell in food, drug and mass (FDM) stores and to provide testing for universities conducting genomic research.

ProPhase BioPharma, Inc. (PBIO), a wholly owned subsidiary of ProPhase, was formed for the licensing, development and commercialization of novel drugs and compounds. Licensed compounds currently include Equivir (OTC/dietary supplement) and Equivir G (Rx), two broad based anti-virals, and Linebacker LB-1 and LB-2, two small molecule PIM kinase inhibitors. The company is collaborating with the Dana Farber Cancer Institute to develop LB-1 as a cancer co-therapy. In January 2023, the Company acquired exclusive rights to BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets. The BE-Smart test is focused on the early detection of esophageal cancer, and is intended to provide health care providers and patients with data to help determine treatment options.

ProPhase Labs has decades of experience researching, developing, manufacturing, distributing, marketing, and selling OTC consumer healthcare products and dietary supplements under the TK Supplements® brand and Pharmaloz contract manufacturing subsidiary.

ProPhase actively pursues strategic investments and acquisition opportunities for other companies, technologies, and products.

For more information, visit 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 statements related to our anticipated timeline for commercializing the BE-Smart Esophageal Cancer Test and its market potential, as well as our plans to expand our New York lab to include traditional clinical testing and genomic sequencing, to sell our whole genome sequencing products in food, drug and mass (FDM) stores and to provide testing for universities conducting genomic research, and our ability to develop and commercialize LB-1 as a cancer co-therapy. 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. 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.

Media Relations and Institutional Investor Contact:
ProPhase Labs, Inc.
267-880-1111
investorrelations@prophaselabs.com

Retail Investor Relations Contact:
Renmark Financial Communications
John Boidman
514-939-3989
Jboidman@renmarkfinancial.com

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