

ProPhase Labs Announces Data Presentation its BE-Smart Esophageal Cancer Test

Presentation to be given in Collaboration with the Mayo Clinic at the United States and Canadian Academy of Pathology (USCAP) Annual Meeting

Company's findings to be presented in a headline Poster on March 14th at the premiere global pathology conference.

Garden City, NY, March 13, 2023 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH) ("ProPhase"), a growth oriented and diversified diagnostics, genomics and biotech company, today announced it will be giving a data presentation at the United States and Canadian Academy of Pathology (USCAP), which is being held March 11 – 16, 2023, at the Ernest N. Morial Convention Center in New Orleans, LA.

The senior author of the presentation is Christopher P. Hartley, MD of the Mayo Clinic, a board-certified pathologist, and principal investigator of the Collaborative Research Agreement with the Mayo Clinic to assess the performance of the Company's BE-smart Test that detects and quantifies hallmarks of cancer development in tissue of patients diagnosed with Barrett's esophagus, a precancerous condition with high incidence in the United States. The Director of Norton Thoracic Institute, Dr. Sumeet Mittal, Dr. Catherine Hagen of the Mayo Clinic, Dr. Sheeno Thyparambil of mProbe Inc. and Dr. Joe Abdo, scientific advisor to ProPhase Labs, serve as co-authors of the study. Dr. Andrew Cannon, an anatomic and clinical pathology resident at the Mayo Clinic serves as first author and will be giving the presentation to attendees of USCAP on Tuesday, March 14th.

Details of the presentation are as follows:

Abstract #: 1946 Poster Board #: 113

Abstract Title: Targeted Mass Spectrometry of Barrett's Esophagus Reveals High-Fidelity Combinatorial Molecular Correlates Along the Metaplasia-Dysplasia-Adenocarcinoma Spectrum

Presentation Date and Time: March 14, 2023, from 1:00 PM - 4:30 PM

Presentation Location: New Orleans Ernest N. Morial Convention Center in Exhibit Hall B

Presenting Author: Andrew Cannon, MD, PhD (Mayo Clinic Pathology)

USCAP is known as the largest gathering of M.D. pathologists in the world, the annual conference attracts more than 4,700 attendees and 136 exhibitors, with 28 percent of its attendees coming from outside of North America, according to conference officials. According to USCAP only a low percentage of submitted papers get

accepted for presentation at the conference. USCAP's leading-edge pathology education is the main attraction of the event and a natural extension of the Academy's panorama of year-round continuing medical education for its 10,000 pathologist members across the globe.

Ted Karkus, ProPhase Lab's Chief Executive Officer, commented, "We are very excited to be sharing our data at the high impact USCAP annual meeting, which is one of the most prestigious conferences of the year because of the hyper-focus of clinical research in the advancement of molecular pathology. The USCAP annual meeting is a great opportunity to introduce the science behind our early cancer detection assay and observe novel advances that have been made in the global pathology community. We look forward to showcasing the clinical advantages of our diagnostic assay that illuminate the carcinogenic proteomic milieu in precancerous tissues that leads to an increase in cellular proliferation, invasion, migration, metastasis, and cell survival. Presentations at conferences like this contribute to the ultimate goal of receiving CPT codes next year for commercialization and broad adoption of this life saving pre-cancer test."

Esophageal adenocarcinoma is the fastest rising cancer in the United States, with a 700% increase in incidence over the last four decades (Thuy-Van P. Hang, et al). The majority of these patients are diagnosed with gastroesophageal reflux disease (GERD) and Barrett's esophagus before their cancer is detected. Even though Barrett's patients are screened routinely for disease progression, the detection of cancer is too late. Four out of five esophageal cancer patients still present to their oncologist in the advanced stages when the disease is no longer curable.

About the BE-Smart Test

The BE-Smart Esophageal Pre-Cancer Diagnostic Screening test is aimed at early detection of esophageal cancer. It has already been tested by an independent test lab, mProbe, Inc. on over 200 human samples and has shown an area under curve of greater than 99% in distinguishing highly impactful histologic classifications. ^[1] ProPhase Labs plans to pursue initial commercialization of the BE-Smart test as an LDT (Laboratory Developed Test) and RUO (Research Use Only). The goal of widespread adoption of the BE-Smart diagnostic test would allow health care providers to initiate potentially lifesaving early treatment processes such as an ablation procedure to remove the precancerous cells and could also significantly reduce unnecessary endoscopies.

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 Pharmaloz, a rapidly growing 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 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 rapidly growing and 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. The Company also owns the exclusive rights to the BE-Smart Esophageal Pre-Cancer Diagnostic Screening test and related IP assets. The BE-Smart test remains under validation as a LDT. The 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 <u>www.ProPhaseLabs.com</u>.

References

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

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 plans for developing and commercializing the BE-Smart diagnostic test, our estimates regarding the target market for esophageal cancer, 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.

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