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# **ProPhase Labs Seeks to Transform Esophageal Cancer Detection and Management with Launch of its BE-Smart Test in H2 2024**

Garden City, NY, April 10, 2024 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH) ("ProPhase" or the "Company"), a next-generation biotech, genomics, and diagnostics company, today reported its progress on the commercialization of its breakthrough BE-Smart test for esophageal cancer. The Company is aiming for commercial launch in the second half of 2024.

Ted Karkus, CEO of ProPhase Labs, commented, "The BE-Smart test is more than an advancement in medical technology; it is providing a critical solution to esophageal cancer by enabling early and cost-effective detection. Early detection offers patients the opportunity for more favorable outcomes and a brighter, healthier future. This groundbreaking diagnostic test is a patent-protected method for identifying esophageal cancer markers and a key component of ProPhase Labs' mission to enhance early detection and facilitate personalized treatment strategies and reflects our commitment to saving lives and improving patient care."

The BE-Smart test constitutes a major innovation in the detection and management of esophageal adenocarcinoma ("EAC") and stands at the forefront of a diagnostic revolution. ProPhase intends to pursue and seeks to capture a significant share of a multi-billion-dollar market for EAC diagnostics. The Company anticipates reimbursement rates ranging between \$1,000 and \$2,000 per test based on CPT codes (as defined below) of similarly complex tests<sup>[1]</sup>. By addressing the annual estimated demand for 7 million endoscopies in the U.S. alone for severe GERD and Barrett's Esophagus cases, the BE-Smart test targets an initial market size of \$7 billion to \$14 billion.

ProPhase Labs, in collaboration with mProbe Inc., a precision health and medicine company utilizing clinical proteomics in the oncology space, is nearing completion of rigorous validation studies of the BE-Smart test, which at its core aims to accurately implement our patent-protected method for identifying esophageal cancer markers. This phase of analytical validation is being completed in parallel with clinical verification by institutions including the Mayo Clinic and Genesis Clinical, a leader in statistical analysis and algorithm development.

"Once completed, we anticipate that the analytical validation studies will demonstrate to the scientific and medical community the BE-Smart test's reliability, accuracy, and readiness for widespread clinical use," said Igor Ban, PhD, director of Research and Development at ProPhase. "Understanding the critical role of extensive data in improving diagnostic tools, we are reaching out to research hospitals across the US and Europe to form partnerships. These collaborations will provide BE-Smart with access to a wider array of esophageal tissue samples, including those from diverse patient demographics and various stages of

Barrett's Esophagus and EAC. Following commercialization, this invaluable data pool will enable BE-Smart to conduct more nuanced analyses, continuously advancing the test's sensitivity, specificity, and overall utility."

Within the coming months, the Company anticipates submitting the documentation required for BE-Smart's Advanced Diagnostic Laboratory Test (ADLT) application, a subclass of the Current Procedural Terminology ("CPT") Proprietary Laboratory Analyses ("PLA") coding system. ProPhase plans to commercially launch BE-Smart following CPT code approval, which is anticipated in the second half of 2024, paving the way for a new era in cancer diagnostics.

Obtaining CPT codes is important for billing purposes, enabling ProPhase Labs to bill for providing the test services and receive reimbursement from insurance companies. The Company is diligently preparing and compiling all necessary documentation to ensure compliance with regulatory standards.

Developed over six years, the BE-Smart test leverages sophisticated proteomics to improve early detection of EAC, a valuable tool given that EAC is among the deadliest cancers with no effective currently available targeted treatments. This unfortunate situation, where approximately 80-90% of EAC patients face a fatal outcome, highlights the important need for a groundbreaking diagnostic tool like BE-Smart.

Through its partnership with Genesis Clinical, the Company is bolstering BE-Smart's capability to stratify esophageal cancer risk accurately, a development of immense value to patients and insurance providers. The test's innovative approach not only promises early detection but also promises to stratify patients into low or high-risk groups with remarkable accuracy.

Mr. Karkus continued, "This risk assessment is crucial, offering peace of mind to those at low risk and potentially sparing them from unnecessary and costly annual endoscopies. For high-risk individuals, it facilitates timely interventions, such as ablation procedures reimbursed by insurance, offering a lifesaving and cost-effective solution compared to the management of advanced disease. Being able to provide targeted patient care strategies, we believe that the BE-Smart test stands at the forefront of transforming patient management in EAC, embodying a holistic approach to enhancing patient outcomes through state-of-the-art early detection and personalized care plans. And the beauty of the test is that it is performed on slivers of tissue specimens that are already being extracted during routine endoscopy procedures."

## **About ProPhase Labs**

ProPhase Labs, Inc. (Nasdaq: PRPH) ("ProPhase") is a next-generation biotech, genomics, therapeutics and diagnostics company. Our goal is to create a healthier world with bold action and the power of insight. We're revolutionizing healthcare with industry-leading Whole Genome Sequencing solutions, while developing potential game changer diagnostics and therapeutics in the fight against cancer. This includes a potentially life-saving cancer test focused on early detection of esophageal cancer and potential breakthrough cancer therapeutics with novel mechanisms of action. Our world-class CLIA labs and cutting-edge diagnostic technology provide wellness solutions for healthcare providers and consumers. 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 multi-billion-dollar potential.

Footnotes –

1. <https://bassett.testcatalog.org/catalogs/191/files/6843>

## **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 to grow our subsidiaries and build a multi-billion dollar company, our anticipated timeline for developing and commercializing the BE-Smart test, our estimates regarding the target market for esophageal cancer, and the anticipated reimbursement rates for the Be-Smart test. 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.

For more information, visit [www.ProPhaseLabs.com](http://www.ProPhaseLabs.com)

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