February 20, 2024

ProPhase Labs Announces Significant Progress in BE-Smart Esophageal Cancer Test Development USPTO grants additional broad patents for BE-SMART

Garden City, NY, Feb. 20, 2024 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH), a next generation biotech, genomics and diagnostics company, today announced important developments in the Company's efforts to commercialize its novel BE-SMART esophageal cancer diagnostic test.

BE-Smart is a novel diagnostic test that is intended to detect and quantify early signs of certain types of cancer in individuals with Barrett's esophagus, a condition known to significantly increase the risk of developing esophageal cancer. This breakthrough test, in development for nearly five years, is nearing completion of clinical studies. If the clinical trial results are successful, the Company will be aiming for commercial launch during 2024. Recently, an additional 139 specimens were analyzed in collaboration with The Mayo Clinic, for the purposes of assessing the test's precision and reliability in identifying esophageal adenocarcinoma risk. These additional specimens continue to achieve consistently positive preliminary results. All tested samples are currently under review by Genesis Biotechnology Group ("Genesis"), a leading independent statistical analysis firm, for independent verification of the results.

Key Milestones and Innovations:

-BE-Smart is the only mass spectrometry-based diagnostic intended for cancer progression surveillance in Barrett's esophagus patients. The test is believed to have both high diagnostic (disease type and stages confirmation) and prognostic (molecular analysis of tissue indicative of disease progression or stability) capabilities. Subject to successfully completing the testing phase and regulatory compliance, both aspects of the test will be bundled into one offering for use by gastroenterologists, and GI pathologists and other health care professionals. The ability to identify whether an individual is at high-risk would offer a transformative approach in diagnosing and managing this deadly disease, potentially saving lives and reducing healthcare costs.
- The United States Patent and Trademark Office (USPTO) has granted ProPhase Labs a patent safeguarding the BE-Smart technology and extending protection to similar biomarker discovery processes for various diseases.
- The test has demonstrated molecular precision in excess of 99%[1], which is a remarkably precise accomplishment in cancerous tissue analysis.
- Recent studies on additional samples using a brush technique appear to confirm the test's versatility and effectiveness compared to traditional biopsy methods.
-As a laboratory-developed test ("LDT"), BE-Smart will continue to develop and adapt to new

potential protein markers that may arise after the completion of the RNA-Seq data analysis currently being conducted at the Mayo Clinic.

Future Directions and Impact:

As an LDT, BE-Smart's flexibility allows for the incorporation of emerging protein markers, enhancing its diagnostic power. ProPhase anticipates the completion of Genesis Biotechnology Group's analysis by early Q2, followed by subsequent strategic collaborations to then secure reimbursement rates and enable wide-scale adoption of the test. BE-Smart uses high throughput mass spectrometer technology that we believe will enhance national deployment, targeting over 20 million Americans monitored for Barrett's esophagus.

“A recent Wall Street Journal op-ed from February 2, 2024 spoke about early cancer detection and improving survival rates, but BE-SMART does one better, it detects hallmarks of carcinogenesis before it even develops, allowing for a simple procedure to remove the potentially dangerous cells, a true game changer for gastroenterology, “said Ted Karkus, CEO of ProPhase Labs. “We believe that BE-Smart potentially solves many of the problems that plague other tests in the field, our test doesn’t need multiple samples and the test isn’t limited by staining and subjective diagnosis. BE-Smart requires only a small amount of tissue for testing and allows for extremely high throughput. Once commercialized, our goal is for this to be the standard of care test used on the over 20 million people being monitored by gastroenterologists for Barrett’s esophagus. If we are able to attain reimbursement rates of just $1,000 - $2,000, which cannot be assured, the initial addressable US market alone represents an enormous market for us.” Mr. Karkus concluded.

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%[1] in distinguishing highly impactful histologic classifications. ProPhase Labs plans to pursue initial commercialization of the BE-Smart test as an LDT. 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 next-generation biotech, genomics 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.

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 anticipated timeline for developing and commercializing the BE-Smart Esophageal Cancer Test and our estimates regarding the target market for esophageal cancer. 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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