

# ProPhase Labs Announces Successful Study Demonstrating Performance of BE-Smart<sup>™</sup> Test in Detecting Esophageal Cancer

BE-Smart represents a significant advance in diagnosis and management of Esophageal disease that affects an estimated 60 million people in the United States

Study shows >95% success rate, validating BE-Smart for use with esophageal brush cytology.

**UNIONDALE, NY, June 17, 2025 (GLOBE NEWSWIRE)** -- ProPhase Labs Inc. (NASDAQ: PRPH), (the "Company" or "ProPhase") a next generation biotech, genomics and consumer products company, today announced the successful completion of a key validation study evaluating the performance of the BE-Smart<sup>™</sup> molecular diagnostic test compatibility with samples obtained from esophageal brush cytology. The study demonstrated BE-Smart<sup>™</sup> achieved greater than a 95% technical success rate, confirming the BE-Smart's ability to reliably and accurately detect our panel of biomarkers, designed to assess progression risk in Barrett's esophagus and other distal esophageal conditions. Prophase will now move to accelerated commercialization of BE-Smart<sup>™</sup> with expected clinical launch in the next 2-3 quarters.

BE-Smart uses a proprietary panel of biomarkers and a multi-modal analysis method which together significantly increase detection of deadly cancer cells in one of the fastest growing cancer indications, esophageal denocarcinoma cancer or "EAC". EAC has a 5-year mortality rate of over 79% and surged in annual incidence over 750% since the 1970s. BE-Smart represents a technical advance in detection and prognosis which has the potential to change cost and outcomes for the large population affected by GERD, Barrett's and EAC globally.

"The ability to run BE-Smart on brush biopsy samples opens the door to much broader clinical use," said Ted Karkus, CEO at ProPhase Labs. "Many leading molecular diagnostics cannot be used with brush biopsies. BE-Smart now stands apart as the only advanced molecular test designed to work with both forceps biopsies and brush-based tissue collection. We are now working toward commercialization as a laboratory developed test (LDT) with a target market of roughly \$10 billion dollars, representing an exciting future for our Company."

The dual capability of BE-Smart now validated to analyze both "pinch" and "brush" standard of care biopsies enables a powerful tool for comprehensive esophageal disease surveillance and clinical management. Pinch biopsies enable detailed analysis of specific areas, while brush biopsies gather a wider sample of epithelial cells, improving detection of disease

across broader regions. Importantly, BE-Smart is commercially and clinically compatible with both of these broadly used approaches making it a dynamic and one-of-a-kind test.

Brush biopsies are rapidly emerging into mainstream clinical practice due to decreased cost and possibility of health complications associated with forceps biopsies. U.S. endoscopists perform approximately 6-7 million upper endoscopies (EGDs) each year, the majority of which still rely on traditional forceps biopsies alone. However, forceps sampling can miss up to 50% of focal areas of Barrett's esophagus, particularly when the disease is patchy or limited to the squamous epithelium.

This shift toward brush biopsies is driven by their improved diagnostic yield and safety profile, addressing some of the limitations of traditional forceps biopsies. As clinical evidence mounts, these non-invasive techniques are gaining traction in both the U.S. and abroad, transforming the landscape of esophageal diagnostics. With expanded payer coverage now reaching over 73 million U.S. lives, and inclusion in leading gastroenterology guidelines, brush biopsies are increasingly recognized for their ability to capture a broader, more representative cell population compared to forceps alone.

Brush biopsies continue to grow in popularity among gastroenterologists and endoscopists, particularly for patients with GERD, Barrett's esophagus, and other distal esophageal disorders. BE-Smart has been designed as the ideal molecular add-on testing platform for improving cancer risk stratification and disease monitoring. Improved measurement ability addresses the critical unmet need of early detection, treatment and improved outcomes.

## 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 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. <u>www.ProPhaseLabs.com</u>

## **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. 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.

The information contained in this press release is for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy any securities. The statements made herein reflect the Company's current views with respect to potential business opportunities and are based on currently available information, assumptions, and expectations. These statements are not guarantees of future performance or outcomes and are subject to risks and uncertainties. Comparisons to other companies or transactions, such as the referenced sale of 23andMe to Regeneron, are provided solely for illustrative purposes and do not imply any specific valuation or outcome for Nebula or any potential transaction involving it. No assurance can be given that any transaction will be pursued or consummated.

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