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ProPhase Labs Announces Plans to Initiate Clinical Trial of Equivir (OTC)

Goal to launch commercially in Q4 2023

Garden City, NY, Feb. 22, 2023 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH) ("ProPhase"), a growth oriented and diversified diagnostics, genomics and biotech company, today announced that its wholly-owned subsidiary, ProPhase BioPharma, Inc. (PBIO), is initiating a randomized, placebo-controlled clinical trial of Equivir (OTC) to evaluate its effect on upper respiratory tract infections. Vedic Lifesciences, a leading clinical research organization, is contracted to conduct the combination prophylactic and therapeutic study, which will be conducted at 12 sites, with enrollment planned to commence in March 2023.

Ted Karkus, ProPhase Lab's Chief Executive Officer, commented, "Today marks an important milestone for ProPhase BioPharma and for Equivir (OTC), which we believe has significant potential to improve human health outcomes worldwide. We look forward to reporting our initial progress from this study mid-year and anticipate launching Equivir in the United States toward the end of this year, leveraging our infrastructure and deep relationships with over 40,000 food, drug and mass retail stores as well as our direct-to-consumer platform for distribution. Given our prior success with anti-viral OTC products, we are quite optimistic regarding the launch of Equivir later this year."

ProPhase BioPharma announced a licensing agreement for Equivir (OTC) in the second quarter of 2022. In the second half of 2022, PBIO completed Equivir compound formulation and claim aggregation to optimize future commercialization and marketing initiatives. PBIO also completed compound claim substantiation, clinical trial protocol development and initiated its contract research organization recruitment protocol in late 2022.

The Company expects trial completion in the third quarter of 2023 and will seek to launch Equivir as an over-the-counter dietary supplement in the fourth quarter of 2023.

About Equivir

Equivir is a blend of FDA Generally Recognized as Safe (GRAS) eligible polyphenols. The composition is projected to come in capsule form and be taken much like a multivitamin, or at the onset of initial symptoms. The composition is believed to work by potentially blocking the entry of a virus into host cells, which prevents infection and replication in those host cells. Since 2019, the Equivir portfolio has received two U.S. patents as a treatment against viral infections as well as a positive patentability report opening the door for international patent possibilities.

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. The Company is also developing the 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 our anticipated timeline for patient enrollment in the Equivir (OTC) clinical trial, providing updates regarding our clinical progress, trial completion and product launch, 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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