

# ProPhase Labs Announces Licensing of New Investigational Cancer Compounds

**Confirms Quarterly Growth continues year-over-year** 

Announces significant progress being made in Genomics Business

Company to Host Live Webcast to Discuss Business Developments Today at 11:30 a.m. EST

Garden City, NY, July 21, 2022 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH), a rapidly growing and diversified diagnostics, genomics and biotech company, today announced that its wholly owned subsidiary, ProPhase BioPharma, Inc. ("PBIO"), has executed a license agreement with Global BioLife, Inc. ("Global BioLife") for the Linebacker portfolio (LB-1 and LB-2), two patented small molecule PIM kinase inhibitors with significant potential across multiple therapeutic indications. The Company also announced continued year-over-year quarterly growth in revenues and earnings for Q2 2022 and projected year-over-year growth in Q3 2022. The Company is also making significant progress with a potential strategic partner for ProPhase Precision Medicine, Inc., its wholly owned genomics subsidiary, with plans to update shareholders further in the near future.

LB-1 is designed as an anti-cancer agent to be used as a co-therapy that targets PIM kinase receptors, a growth factor expressed in cancer. In preclinical laboratory studies, LB-1 inhibited PIM, which could potentially slow the growth of the cancer and allow for better efficacy of the co-therapy drug or treatment being used. Under the terms of the license agreement, PBIO has obtained exclusive rights worldwide to develop and commercialize LB-1 and LB-2 for the treatment of cancer, inflammatory diseases or symptoms and memory related syndromes, diseases or symptoms including dementia and Alzheimer's disease.

"We are excited to announce the second licensing agreement for ProPhase BioPharma (PBIO), our newly created subsidiary, whose goal is to license, develop and commercialize novel drugs and compounds," commented Ted Karkus, ProPhase Lab's Chief Executive Officer. "We believe the Linebacker platform has multi-billion dollar potential in oncology as well as significant potential in other fields. In the near term, we intend to initiate further development and studies of LB-1 as a potential cancer co-therapy."

ProPhase's initial focus for LB-1 is as a potential co-therapy for the following four drugs:

- *TAXOL*<sup>®</sup> (*Paclitaxel Injection*): TAXOL is among the most affordable and best-selling chemotherapy drugs, with annual sales over \$1 billion<sup>1</sup>.
- Doxorubicin: The global market for Doxorubicin is estimated at \$1.1 billion in 2022.
- *Topotecan*: Manufactured by GlaxoSmithKline as Hycamtin.
- Cisplatin: Market revenue for Cisplatin was \$326.0 million in 2019 and is projected to

reach \$547.0 million in 2025, with a CAGR of 8.95% during 2020-2025<sup>3</sup>.

## Findings From the Initial LB-1 Cell Line Proliferation in-vitro Studies

# LB-1 Co-Therapy with TAXOL

- LB-1 alone inhibited cell proliferation at 69.94% at 100uM
- TAXOL alone inhibited cell proliferation at 41.96% at 200nM
- LB-1 and TAXOL combined inhibited cell proliferation at 75.5% (100uM of LB1 + 200nM Taxol)

## LB-1 Co-Therapy with Doxorubicin

- LB-1 alone inhibited cell proliferation at 69.66% at 100uM
- Doxorubicin alone inhibited cell proliferation at 51.6% at 2000nM
- LB-1 and Doxorubicin combined inhibited cell proliferation at 86.95% (100uM of LB1 + 2000nM Doxorubicin)

## LB-1 Co-Therapy with Topotecan

- LB-1 alone inhibited cell proliferation at 69.54% at 100uM
- Topotecan alone inhibited cell proliferation at 58.27% at 2000nM
- LB-1 and Topotecan combined inhibited cell proliferation at 97.18% (100uM of LB1 + 2000nM Topotecan)

## LB-1 Co-Therapy with Cisplatin

- LB-1 alone inhibited cell proliferation at 72.33% at 100uM
- Cisplatin alone inhibited cell proliferation at 22.74% at 30uM
- LB-1 and Cisplatin combined inhibited cell proliferation at 82.48% (100uM of LB1 + 30uM Cisplatin)

Additional preclinical studies of the Linebacker portfolio with each of the four drugs described above is currently being conducted by a major U.S. university. ProPhase looks forward to the full results expected to be released in Q3 2022.

#### **About Linebacker**

Linebacker is a modified polyphenol. Polyphenols are substances found in many nuts, vegetables and berries. Linebacker compounds are modified Myricetin, which is a common plant-derived flavonoid. Myricetin exhibits a wide range of activities that include strong antioxidant, anticancer, antidiabetic and anti-inflammatory activities. It displays activities that are related to the central nervous system. Anecdotal evidence suggests that it may be beneficial to protect against diseases such as Parkinson's and Alzheimer's<sup>4</sup>.

LB-1 is Mono-chlorinated Myricetin with a Chlorine atom substituted for the Hydroxy group at 5' (position 5 on the B-ring). LB-2 is Di-chlorinated Myricetin with Chlorine atoms substituted for the Hydroxy groups at 5' and 7 (position 5 on the B-ring and position 7 on the A-ring).

LB-1 is being developed as a potential co-therapy to down-regulate PIM (proviral integration site for moloney murine leukemia virus) kinase, which plays a key role as an oncogene in various cancers including myeloma, leukemia, prostate and breast cancers.

Chemotherapy drugs alone, like TAXOL (chemically known as paclitaxel), kill healthy cells alongside tumorous ones. LB-1 is being developed to focus directly on the PIM expressions potentially rendering the cancer cell transcription and replication significantly less effective, so that chemotherapy drugs such as TAXOL can effectively kill the existing tumor cells. LB-1 may also be developed as a potential standalone post therapy to ensure cancer cells do not regenerate.

LB-1 and LB-2 were initially developed by Global BioLife, Inc. in partnership with Global Research and Development Group Sciences ("GRDG"). GRDG and Global BioLife created Linebacker, a multi-faceted therapeutic platform targeting metabolic, neurologic, cancer, and infectious diseases, to mirror the Panacea Project, a US Defense Advanced Research Projects Agency (DARPA) program that provides novel, multi-target therapeutics for unmet physiological needs.

ProPhase BioPharma has also formed an advisory board with Daryl Thompson as its founding member. Daryl Thompson is President and Director of Scientific Initiatives at GRDG and is a biochemist twice nominated for the Nobel Prize in 2015 and 2016 for his work in cutting-edge organic and carbohydrate chemistry.

ProPhase plans to work with Daryl Thompson and GRDG to continue the development of the Linebacker portfolio, as well as on other important compounds in the future.

"The compounds that ProPhase has licensed have enormous potential and represent years of scientific research. I truly believe that the Linebacker portfolio represents a potential breakthrough in cancer research. I am thrilled to continue to work on these compounds with ProPhase toward commercialization to ultimately improve the health and save the lives of so many," commented Daryl Thompson, President of GRDG.

A slide presentation dedicated to ProPhase BioPharma has been posted to the ProPhase Labs website. This is in addition to the company slide presentation. It is located at <a href="https://ir.prophaselabs.com/company-information/presentations">https://ir.prophaselabs.com/company-information/presentations</a>.

## **Additional Business Progress**

#### **ProPhase Diagnostics**

ProPhase's COVID-19 diagnostic testing business continues to experience year-over-year growth in revenues and earnings in Q2 2022 and is projecting continued growth in Q3 2022. Year over year growth is attributed to a larger and more diverse customer base of specimen collection companies, the acceleration of the BA.5 variant and the rise in overall COVID-19 cases across the country. Construction expanding the Company's state-of-the-art CLIA lab in Garden City, NY is almost complete and will enable ProPhase to diversify with traditional clinical lab testing. Plans are also being finalized for the build-out of a state-of-the-art genomics lab as part of the expansion.

#### **ProPhase Precision Medicine**

The Company continues to make significant progress with its ProPhase Precision Medicine subsidiary. The Company is actively negotiating a strategic partnership with a multi-billion dollar genomics company to collaborate across different geographic markets and joint venture opportunities focused on genomic sequencing, AI, sharing genomic data insights and related fields. The first initiative would include a deal for lower cost Whole Genome

Sequencing (WGS), which is expected to be finalized in the near future. The Company is also making significant progress with major retailers to potentially provide WGS in retail stores by the fourth guarter of 2022.

## **Shareholder Update Call**

ProPhase Labs' CEO and Chairman of the Board of Directors, Ted Karkus, will host a live webcast today, Thursday, July 21, 2022, at 11:30 a.m. EST / 8:30 a.m. PST to review these latest developments at ProPhase Labs and its subsidiaries.

To access the call, please use the following information:

Date: Thursday, July 21, 2022

Time: 11:30 a.m. Eastern time, 8:30 a.m. Pacific time

Participants can register for the webcast by navigating to:

https://www.renmarkfinancial.com/events/prophase-labs-reviews-latest-developments-2022-07-21-113000

Pre-registration required fields of information include name and email.

#### **About ProPhase Labs**

ProPhase Labs, Inc. (Nasdaq: PRPH) ("ProPhase") is a 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 data base to be used for further research. The Company continues to provide traditional CLIA molecular laboratory services, including COVID-19 testing. The Company also continues to operate a state-of-the-art contract manufacturing facility and the TK Supplements line of dietary supplements, 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 state-of-the-art polymerase chain reaction (PCR) testing for SARS-CoV-2 (COVID-19). 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. Announced plans for expansion of lab to include traditional clinical testing and genomics testing.

ProPhase Precision Medicine, Inc., a wholly owned subsidiary of ProPhase, focuses on genomics testing technologies, a comprehensive method for analyzing entire genomes, including the genes and chromosomes in DNA. The data obtained from genomic testing can 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. Currently selling 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 beginning with Equivir and Equivir G. PBIO announced a second licensing agreement for two small molecule PIM kinase inhibitors, Linebacker LB-1 and LB-2, in July 2022, with plans to pursue

development and commercialization of LB-1 as a cancer co-therapy.

ProPhase Labs has decades of experience researching, developing, manufacturing, distributing, marketing, and selling OTC consumer healthcare products and dietary supplements under the TK Supplements<sup>®</sup> brand and Phamaloz contract manufacturing subsidiary.

ProPhase actively pursues strategic investments and acquisition opportunities for other companies, technologies, and products.

For more information, visit www.ProPhaseLabs.com.

## **About Global Research and Development Group**

Global Research and Development Group ("GRDG") is a scientific think tank and private research and development organization that applies rapid analysis and problem-solving skills to quickly qualify, quantify, procure and test both applicable and accurate paradigms. GRDG works with BARDA (Biological Advance Research Development Authority), DARPA (Defense Advanced Research Projects Agency) and the Potomac Institute for Policy. It also has partnerships with major private sector research organizations including Charles River Laboratories.

#### About Global BioLife, Inc.

Global BioLife, Inc. ("Global BioLife") is a wholly owned subsidiary of DSS, Inc. Global BioLife strives to leverage its scientific know-how and intellectual property rights to provide solutions that have been plaguing the biomedical field for decades. By tapping into the scientific expertise of GRDG Sciences, LLC, Global BioLife pledges to undertake a concerted effort in the R&D, drug discovery and development for the prevention, inhibition, and treatment of neurological, oncological and immuno related diseases. For more information on Global BioLife visit <a href="http://impbio.com/">http://impbio.com/</a>.

#### **Forward Looking Statements**

Except for the historical information contained herein, this document contains forwardlooking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our strategy, plans, objectives and initiatives, including statements regarding our plans to develop Linebacker LB-1 and LB2, our ability to negotiate a strategic partnership for ProPhase Precision Medicine, Inc., to reduce costs for its WGS products and services and to expand into retail, our financial projections for Q2 and Q3 2022, our plans to expand our lab to include traditional clinical testing and genomics testing, to sell our whole genome sequencing products in food, drug and mass (FDM) stores and to provide testing for universities conducting genomic research. 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 forwardlooking statements. These risks and uncertainties include but are not limited to our ability to obtain and maintain necessary regulatory approvals, our ability to secure or maintain proprietary patent protection for products and technologies we develop or license, challenges relating to, entering into, and growing new business lines, general economic conditions, consumer demand for our products and services, 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.

<sup>®</sup> All brand names and trademarks are the property of respective owners.

#### References:

- 1. <a href="https://videocast.nih.gov/watch=35576#:~:text=Taxol%20is%20among%20the%20most,">https://videocast.nih.gov/watch=35576#:~:text=Taxol%20is%20among%20the%20most,</a>
- 2. <a href="https://www.reportlinker.com/p06031392/Global-Doxorubicin-Industry.html?">https://www.reportlinker.com/p06031392/Global-Doxorubicin-Industry.html?</a> utm source=GNW
- 3. <a href="https://www.marketwatch.com/press-release/cisplatin-market-size-in-2022-top-countries-data-competitive-landscape-corporate-strategy-share-industry-analysis-by-top-manufactures-growth-insights-and-forecasts-to-2029-128-report-pages-2022-06-07">https://www.marketwatch.com/press-release/cisplatin-market-size-in-2022-top-countries-data-competitive-landscape-corporate-strategy-share-industry-analysis-by-top-manufactures-growth-insights-and-forecasts-to-2029-128-report-pages-2022-06-07</a>
- 4. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4772053/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4772053/</a>

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