

## Propanc Biopharma Completes Development of Bioanalytical Assay Method to Quantify PRP's Active Ingredients in Preparation for First-In-Human Study

Allows Propanc to Move to Pre-Validation Stage and Facilitate Discussion with Investigators at Peter Mac Center, Australia's Largest Cancer Hospital

MELBOURNE, Australia--(BUSINESS WIRE)-- <u>Propanc Biopharma, Inc.</u> (OTC: PPCB) ("Propanc"), a biopharmaceutical company developing new cancer treatments for patients suffering from recurring and metastatic cancer, announced today it has developed a method to quantify the active ingredients of Propanc's lead product candidate, PRP, in preparation for the company's First-In-Human ("FIH") study, planned for early 2020. The work was conducted by Propanc's research partner based in Berlin, Germany, who has extensive experience in the development of functional assays for unique bio-therapeutics. This bioanalytical method development and validation plays a significant role in evaluation and interpretation of the systemic absorption of PRP in clinical studies including its distribution, and clinical effects throughout the body.

PRP is a mixture of two proenzymes, trypsinogen and chymotrypsinogen, administered by intravenous injection. The naturally derived proenzymes are very large and complex protein structures that can be broken down into different fragments that can be difficult to separate and analyze from human serum. The remarkable achievement to identify and develop a suitable method to measure four key analytes from PRP, the two proenzymes, trypsinogen and chymotrypsinogen, as well as the activated enzymes, trypsin and chymotrypsin, is particularly significant due to the close structural similarity of each protein structure. By using a highly sensitive detection system like Liquid Chromatography/Mass Spectrometry, a suitable method was developed that could separate, identify and quantify all four analytes. Moreover, a strong correlation between the concentration and signal intensity was established with a R<sup>2</sup> = 0.9996, where 1.0000 represents a linear, straight line, indicating a direct correlation between the two variables measured. This is especially important when measuring the concentration of the analytes within a certain range over time, providing valuable information regarding dosing and the clinical effects of a drug, like PRP, when administered to patients. Lower limits of quantification and detection were also established.

"This is an important step for the advancement of PRP towards commencing our First-In-Human study. Understanding clinical effects and their relationship to the concentration of the drug over time is especially important so that we can optimize dosing of PRP when administered to patients," said Dr. Julian Kenyon, Propanc's Chief Scientific Officer. "We think measuring all four analytes, the two proenzymes and their activated enzymes is critical, because it is the activated enzymes which exert their effects on cancerous cells, so this will provide an important link to the action of PRP and its clinical effects."

The development of the bioanalytical assay is also an important step for the clinical development of PRP, as Propanc evaluates sites to conduct the FIH study in advanced cancer patients, such as the Peter Mac Center, Australia's largest cancer hospital, which has significant experience in early stage clinical development. Propanc is evaluating Australia as a potential destination where it may commence the Phase Ib clinical trial because of its research and development tax incentives, as well as a simplified regulatory environment. As part of such incentives, eligible companies conducting clinical trials in Australia may receive up to 43.5% "cash-back" benefit in the form of a refund of their qualified research and development costs and expenses.

"Since we have completed the development of bioanalytical assay and are commencing the pre-validation stage, we look forward to presenting the data package in the near future to the Director at the Peter Mac Center, Parkville Cancer Clinical Trials Unit, and his investigators, to discuss further details about the upcoming FIH study," said Professor Klaus Kutz, Propanc's acting Chief Medical Officer.

## About Propanc Biopharma, Inc.

Propanc Biopharma, Inc. (the "Company") is developing a novel approach to prevent recurrence and metastasis of solid tumors by using pancreatic proenzymes that target and eradicate cancer stem cells in patients suffering from pancreatic, ovarian and colorectal cancers. For more information, please visit <a href="https://www.propanc.com">www.propanc.com</a>.

The Company's novel proenzyme therapy is based on the science that enzymes stimulate biological reactions in the

body, especially enzymes secreted by the pancreas. These pancreatic enzymes could represent the body's primary defense against cancer.

To view the Company's "Mechanism of Action" video on its anti-cancer lead product candidate, PRP, please click on the following link: <a href="http://www.propanc.com/news-media/video">http://www.propanc.com/news-media/video</a>

## **Forward-Looking Statements**

All statements other than statements of historical facts contained in this press release are "forward-looking statements," which may often, but not always, be identified by the use of such words as "may," "might," "will," "will likely result," "would," "should," "estimate," "plan," "project," "forecast," "intend," "expect," "anticipate," "believe," "seek," "continue," "target" or the negative of such terms or other similar expressions. These statements involve known and unknown risks, uncertainties and other factors, which may cause actual results, performance or achievements to differ materially from those expressed or implied by such statements. These factors include uncertainties as to the Company's ability to continue as a going concern absent new debt or equity financings; the Company's current reliance on substantial debt financing that it is unable to repay in cash; the Company's ability to successfully remediate material weaknesses in its internal controls; the Company's ability to reach research and development milestones as planned and within proposed budgets; the Company's ability to control costs; the Company's ability to obtain adequate new financing on reasonable terms; the Company's ability to successfully initiate and complete clinical trials and its ability to successful develop PRP, its lead product candidate; the Company's ability to obtain and maintain patent protection; the Company's ability to recruit employees and directors with accounting and finance expertise; the Company's dependence on third parties for services; the Company's dependence on key executives; the impact of government regulations, including FDA regulations; the impact of any future litigation; the availability of capital; changes in economic conditions, competition; and other risks, including, but not limited to, those described in the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the U.S. Securities and Exchange Commission (the "SEC") on June 14, 2019, and in the Company's other filings and submissions with the SEC. These forward-looking statements speak only as of the date hereof and the Company disclaims any obligations to update these statements except as may be required by law.

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