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# Propanc Biopharma Undertaking PRP Manufacturing & Development for Human Use

*Novel Proenzyme Pharmaceutical Formulation to be Administered by Intravenous (I.V.) Injection in World First, Phase I First-In-Human Study in Advanced Cancer Patients*

MELBOURNE, Australia--(BUSINESS WIRE)-- **Propanc Biopharma, Inc.** (OTCQB: PPCB) ("Propanc" or the "Company"), a biopharmaceutical company developing novel cancer treatments for patients suffering from recurring and metastatic cancer, today announced that the Company is undertaking manufacturing and development of PRP for human use. PRP is the Company's lead product candidate and is a novel pharmaceutical formulation consisting of two proenzymes to be administered by I.V. injection in a world first, First-In-Human (FIH) study in advanced cancer patients. It is a long-term therapy for the treatment and prevention of metastatic cancer in patients suffering from solid tumors.

To date, the Company has sourced the two proenzymes from a raw material supplier, where an isolation process for both ingredients have been established and scaled up. The proenzymes are extracted, precipitated and lyophilized (freeze dried by a low temperature dehydration process), serving as the raw materials for GMP (Good Manufacturing Practice) manufacture of the finished drug product. A proprietary purification process has been developed by Propanc and successful scale up of the bulk drug substances has been completed. Over 95% purity for each of the proenzymes was achieved to reach pharmaceutical standard for the final drug product. This reduces impurities, resulting in a more stable product with a longer shelf life, as the active enzymes have the potential to 'auto-catalyze' meaning they can potentially self-activate. Therefore, the novel formulation consists of two proenzymes prepared in individual vials ready to be mixed into a solution for I.V. injection for the upcoming Phase I, FIH study.

According to Dr. Linda Isaacs M.D., Integrative Cancer Therapies, January 2022, since the turn of the last century, based on the original hypothesis of Professor John Beard from Edinburgh University, the trophoblastic theory and the origin of cancer, numerous physicians have been injecting enzyme preparations into cancer patients with both startling, but also mixed success. One reason was attributed by Beard to the "wide variation" in the quality available enzymes that he believed explained why the treatment was sometimes unsuccessful. In the following years, there were numerous attempts at injection of enzymes, which led to the US Food and Drug Administration prohibiting intravenous and injectable enzymes, presumably due to the uncontrolled nature of the administration to patients. Despite this, Dr Isaacs concludes that an intravenous formulation for use in humans would offer "considerable advantages", whilst also acknowledging the considerable developmental costs.

Over the last decade, Propanc has undertaken the manufacturing and development of

proenzymes as an I.V. formulation and conducted several scientific advice meetings with the Medicines and Healthcare Products Regulatory Agency (MHRA) UK to determine the pathway for the clinical development of PRP. The Company has also sourced suitable quality proenzymes for the commercial scale quantities needed for global pharmaceutical distribution and is ready to undertake the full scale GMP manufacture of PRP in preparation for the upcoming Phase I FIH study in advanced cancer patients.

“We have spent significant time and resources on the manufacturing and development of PRP as we prepare for our Phase I, FIH study in advanced cancer patients,” said James Nathanielsz, Propanc’s Chief Executive Officer. “Undertaking the steps necessary to purify and scale up the bulk drug substances is critical to producing a quality product according to pharmaceutical standard, which we intend to seek regulatory approval for worldwide distribution. Our novel pharmaceutical formulation is a world-first approach using a technology with over 100 years of clinical experience, since Professor John Beard first proposed the use of enzymes as a novel way to treat cancer. By advancing PRP through the drug development process, we remain committed to achieving a vision of producing a long-term approach for the treatment and prevention of metastatic cancer from solid tumors, which remains the main cause of patient death for sufferers.”

Professor Klaus Kutz, Propanc’s Chief Medical Officer said, “Our lead product candidate, PRP, is a novel, targeted cancer therapy, free from the side effects normally associated with standard treatment approaches. That is why we have worked over several years to overcome the technical challenges to produce a novel pharmaceutical formulation to GMP standard for I.V injection, which is our preferred route of administration in order to increase systemic exposure to treat solid tumors, which may result in better therapeutic efficacy.”

PRP is a mixture of two proenzymes, trypsinogen and chymotrypsinogen from bovine pancreas administered by intravenous injection. A synergistic ratio of 1:6 inhibits growth of most tumor cells. Examples include kidney, ovarian, breast, brain, prostate, colorectal, lung, liver, uterine and skin cancers.

**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 www.propanc.com.

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: http://www.propanc.com/news-media/video

**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 periodic reports that are filed with the Securities and Exchange Commission and available on its website at http://www.sec.gov. 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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