

# Propanc Biopharma's Management Explains Why They Believe Cancer Patients Are Likely to Respond to PRP Treatment

*Clinical Knowledge Obtained Increases Probability of Success Compared to Drug Products Entering Phase I without Human Experience*

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 why the Company's management team believes that cancer patients are likely to respond to PRP treatment. PRP is the Company's lead product candidate for the treatment and prevention of metastatic cancer from solid tumors, which is the main cause of death for sufferers. PRP is currently advancing towards a Phase I, First-In-Human (FIH) study, in advanced cancer patients. 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.

**Clinical knowledge of proenzymes obtained demonstrates an increased likelihood of success compared to drug products entering Phase I without prior human experience.** For any new molecule entering Phase I clinical trials without any prior human experience, or clinical testing, the probability of success can be relatively small at only around 10%, as discussed by Derek Lowe, *Science journal*, May 2019. However, the clinical efficacy of a suppository formulation containing bovine pancreatic proenzymes trypsinogen and chymotrypsinogen was evaluated via a compassionate use study and the results published in a peer reviewed journal, *Scientific Reports*. Clinical effects were studied in 46 patients with advanced metastatic cancers of different origin (prostate, breast, ovarian, pancreatic, colorectal, stomach, non-small cell lung, bowel cancer and melanoma) after treatment with a rectal formulation of both pancreatic proenzymes. No severe or serious adverse events related to the rectal administration were observed. Patients did not experience any hematological side effects as typically seen with classical chemotherapy regimens. No allergic reactions after rectal administration of suppositories were observed.

In order to assess the therapeutic activity of rectal administration, overall survival of patients under treatment was compared to the life expectancy assigned to a patient prior to treatment start. Nineteen from 46 patients (41.3%) with advanced malignant diseases, most of them suffering from metastases, had a survival time significantly longer than their expected, in fact, for the whole set of cancer types, mean survival (9.0 months) was significantly higher than mean life expectancy (5.6 months). Although the number of patients per cancer indication is quite low, 3 out of 8 patients with prostate cancer and 5 out of 11 patients with

gastrointestinal cancers appear to particularly benefit from the treatment with the proenzyme suppositories.

Furthermore, Novak and Trnka reported 19 terminal patients pronounced incurable or released from traditional cancer care were treated with a proenzyme suppository formulation (2005). Eight of these patients responded by a multiyear survival, free of the major complications seen with traditional drug therapies.

**PRP will be administered by intravenous injection at higher doses which is expected to increase the exposure of the proenzymes at the tumor site, and may result in increased therapeutic efficacy.** PRP has undergone extensive preclinical and safety toxicology testing, resulting in the identification of a maximum tolerated and feasible dose in order to establish a safe starting dose in the FIH study in advanced cancer patients. As a result, the identified safe starting dose is much higher than the original dose administered via the suppository formulation. Furthermore, the 1:6 ratio of trypsinogen to chymotrypsinogen in the PRP formulation exhibits highly synergistic anti-cancer effects against solid tumors. Finally, administration by intravenous injection will maximize exposure in the blood, versus per rectal administration via a suppository, which can result in patient-to-patient variability as a result of absorption across a mucous membrane.

**PRP is a targeted cancer therapy and leaves healthy cells alone.** Most standard treatment approaches take advantage of the uncontrolled proliferation of cancer cells and kill these cells by targeting the cell division machinery. These therapies are effective, but affect healthy cells as well, particularly those with a high rate of cell turnover, inducing undesirable side effects. Since PRP does not target replicating cells, it is unlikely to affect healthy cells and will suppress undesirable effects from cancer.

**Trypsinogen and chymotrypsinogen are pancreatic proenzymes which are also produced by the pancreas and therefore endogenous (originating from) within the human body.** PRP is a biological formulation and the pancreatic proenzymes are therefore less likely to induce toxic effects compared to standard treatments which are synthetic and therefore induce toxic effects. However, PRP active ingredients are extracted and purified from bovine sources to over 95% purity, to ensure it can be accepted to pharmaceutical standards and administered by intravenous injection. Given the source of the proenzymes, the potential for immunogenicity due to cross species reactivity will need to be monitored carefully. However, no evidence of immunogenicity was observed during the compassionate use study or the preclinical safety toxicology studies undertaken.

Dr Kenyon, Propanc's Chief Scientific Officer said, "After many years of research, I believe patients are likely to respond to PRP treatment based on my clinical experience with late-stage cancer patients who had exhausted treatment options, as well as the extensive preclinical activities undertaken to establish the science, the mode of action, and the optimal formulation identification, resulting in our lead product candidate, PRP, which is set to advance into a FIH study."

"Early-stage clinical development of new oncology drugs are often associated with a relatively small success rate, but we are excited about the potential of PRP, where our management team believes the scientific and clinical evidence reduces these risks considerably," said James Nathanielsz, Propanc's Chief Executive Officer. "We look forward to entering early-stage clinical development of PRP and believe in the potential of PRP as a

long-term therapeutic approach for the treatment and prevention of metastatic cancer.”

### **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](http://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 successfully 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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