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# Propanc Biopharma Advances towards GMP Manufacture of PRP for Human Trials

## Purification Process Achieves Pure and Stable Active Drug Substances, Engineering Runs to Commence

MELBOURNE, Australia, Dec. 4, 2017 /PRNewswire/ --Propanc Biopharma Inc. (OTCQB: PPCB) ("Propanc Biopharma" or "the Company"), a clinical stage biopharmaceutical company focusing on development of new and proprietary treatments for cancer patients suffering from solid tumors such as pancreatic, ovarian and colorectal cancers, today announced that the Company has made significant recent progress towards full scale Good Manufacturing Process (GMP) manufacture of its lead product, PRP, for First-In-Human studies, expected to commence in 2018. Research and development activities conducted with its European Contract Manufacturing Organization (CMO) experienced in the production of biopharmaceuticals, have been successful in developing a process capable of purifying and stabilizing the two active drug substances of the PRP formulation, trypsinogen and chymotrypsinogen, which is an important requirement during the manufacturing process. As a result, the Company is set to commence engineering runs of manufacturing the finished drug product, prior to full scale GMP manufacture of PRP for human trials. PRP is a solution for once-daily intravenous administration of a combination of two pancreatic proenzymes trypsinogen and chymotrypsinogen.

"We are delighted with the excellent progress made with our CMO in progressing PRP to its current stage of development and we are excited about our plans to move into First-In-Human studies next year," said Dr Julian Kenyon, Propanc Biopharma's Chief Scientific Officer. "Purifying and stabilizing each active drug substance of PRP has been technically challenging. This is due to the nature of the proenzymes which are able to auto-activate themselves, which is not unexpected for biological molecules of this nature. The work conducted by our research and development team to meet this challenge has been first class and we look forward to progressing PRP through to clinical development."

The Company expects to file its first Clinical Trial Application (CTA) for a First-In-Human study in the UK next year, initially treating late stage cancer patients with solid tumors, before progressing into two larger Phase II Proof of Concept studies in both pancreatic and ovarian cancer patients. Preclinical animal studies demonstrating proof of concept, *in vivo*, as well as the completion of a GLP-compliant, 28-day repeat-dose toxicology study, which helps to confirm the starting dose in humans by identifying the No Observable Adverse

Effect Level (NOAEL) in an animal species, has the management team confident it has undertaken the steps necessary to achieve the best possible results in its planned human studies. This is further supported by the FDA granting Orphan Drug Designation of PRP for the treatment of one of its lead indications, pancreatic cancer, with a second application filed for ovarian cancer under evaluation.

"I am pleased with the progress of PRP and look forward to preparing our lead product for First-In-Human studies next year," said Professor Klaus Kutz, Propanc Biopharma's Chief Medical Officer. "The Company has undertaken significant work to prepare for this important milestone, and believe the product can benefit patients suffering from aggressive solid tumors, which are most often incurable. Extending life meaningfully, but without compromising the quality of life for patients, without the side effects normally associated with standard treatment regimens, remains a high priority. We remain hopeful that PRP can become a breakthrough product for many patients worldwide."

Currently progressing towards First-In-Human studies, PRP aims to prevent tumor recurrence and metastasis from solid tumors. Eighty percent of all cancers are solid tumors and metastasis is the main cause of patient death from cancer. According to the World Health Organization, 8.2 million people died from cancer in 2012. Consequently, a report by IMS Health states innovative therapies are driving the global oncology market to meet demand, which is expected to reach $150 billion by 2020. The Company's initial target patient populations are pancreatic, ovarian and colorectal cancers, representing an estimated combined market segment of $14 billion in 2020, according to GBI Research.

To view Propanc Biopharma's "Mechanism of Action" video on anti-cancer product candidate, PRP, please click on the following link: http://www.propanc.com/news-media/video

To be added to Propanc Biopharma's email distribution list, please click on the following link: http://ir.propanc.com/email-alerts and submit the online request form.

**About Propanc Biopharma:**
Propanc Biopharma is a clinical stage biopharmaceutical company developing new cancer treatments initially for patients suffering from pancreatic, ovarian and colorectal cancers. We have developed a formulation of anti-cancer compounds, which exert a number of effects designed to control or prevent tumors from recurring and spreading throughout the body. Our products involve or employ pancreatic proenzymes, which are inactive precursors of enzymes. In the near term, we intend to target patients with limited remaining therapeutic options for the treatment of solid tumors. In future, we intend to develop our lead product to treat (i) early stage cancer and (ii) pre-cancerous diseases and (iii) as a preventative measure for patients at risk of developing cancer based on genetic screening. For more information, visit: www.propanc.com.

**Forward-Looking Statements:**
All statements other than statements of historical fact contained herein are "forward-looking statements" for purposes of federal and state securities laws. Forward-looking statements may include the words "may," "will," "estimate," "intend," "continue," "believe," "expect," "plan" or "anticipate" and other similar words. Although we believe that the expectations reflected in our forward-looking statements are reasonable, actual results could differ materially from those projected or assumed. Our future financial condition and results of

operations, as well as any forward-looking statements, are subject to change and to inherent risks and uncertainties including those regarding our earnings, revenues and financial condition, our ability to implement our plans, strategies and objectives for future operations, our ability to execute on proposed new products, services or development thereof, our ability to establish and maintain the proprietary nature of our technology through the patent process, our ability to license from others patents and patent applications, if necessary, to develop certain products, our ability to implement our long range business plan for various applications of our technology, our ability to enter into agreements with any necessary manufacturing, marketing and/or distribution partners for purposes of commercialization, the results of our clinical research and development, competition in the industry in which we operate, overall market conditions, and any statements or assumptions underlying any of the foregoing. Other risks, uncertainties and factors that could cause actual results to differ materially from those projected may be described from time to time in reports we file with the Securities and Exchange Commission, including our reports on Forms 10-K, 10-Q and 8-K. We do not intend, and undertake no obligation, to update any forward-looking statement contained herein, except as required by law.

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