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Propanc Biopharma Awaits FDA Response to Orphan Drug Designation Request for Treatment of Pancreatic Cancer, as PRP Progresses to First-In-Human Studies

Welcomes Appointment of Dr Scott Gottlieb as New FDA Commissioner

MELBOURNE, AUSTRALIA -- (Marketwired) -- 05/16/17 -- Propanc Biopharma Inc. (OTCQB: PPCHD) ("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 the Company awaits a response from the FDA to an Orphan Drug Designation (ODD) request for the use of its lead product, PRP, a solution for once daily intravenous administration of a combination of two pancreatic proenzymes trypsinogen and chymotrypsinogen. Submitted in February 2017, the proposed orphan drug indication for PRP is the treatment of pancreatic cancer, one of the most lethal malignancies with a median survival of 6 months and a 5-year survival rate of less than 5%. The lethal nature of this disease stems from its propensity to rapidly disseminate to the lymphatic system and distant organs, and is a major unmet medical issue.

"We remain committed to providing a first-in-class treatment which can halt the growth and spread of aggressively spreading cancers like pancreatic cancer, but safer compared to standard treatment approaches," said Dr Julian Kenyon, Propanc's Chief Scientific Officer. "We will work with the FDA to provide a strong rationale why PRP qualifies for orphan drug designation, which provides exciting potential benefits to fast track the development process and provide attractive benefits for up to seven years when we achieve market approval."

Responsible for 331,000 deaths worldwide in 2012, the aggressive biology and resistance to conventional therapeutic agents leads to a typical clinical presentation of incurable disease at the time of diagnosis. Propanc Biopharma intends to introduce a new therapy which targets and eradicates cancer stem cells, the cells responsible for the aggressive dissemination, resulting in a meaningful life extension for patients.

"Propanc Biopharma is an innovative, entrepreneurial organization dedicated to the development of targeted and safer cancer therapeutics and we look forward to receiving a response from the FDA in the next two months regarding our orphan drug designation request, as we head towards First-In-Human studies for our lead product, PRP," said James Nathanielsz, Propanc's Chief Executive Officer. "We are also pleased to acknowledge the recent appointment of Dr Scott Gottlieb as the new commissioner at the FDA, who supports and welcomes innovation from industry, whilst continuing to protect the interests of public health. We believe there is an opportunity to set a new agenda for healthcare reform at the FDA, which could help drive change worldwide for future generations."

Under the Orphan Drug Act (ODA), drugs, vaccines, and diagnostic agents qualify for orphan status if they are intended to treat a disease affecting less than 200,000 American citizens. Under the ODA, orphan drug sponsors qualify for seven-year FDA-administered market Orphan Drug Exclusivity (ODE), tax credits of up to 50% of R&D costs, R&D grants, waived FDA fees, protocol assistance and may get clinical trial tax incentives.

The rationale for developing PRP, a formulation combining pancreatic proenzymes trypsinogen and chymotrypsinogen for intravenous administration for the proposed indication pancreatic cancer, is based on a set of in-vitro studies on cancer stem cells generated from pancreatic cancer cell lines as well as xenograft and syngeneic mouse models of pancreatic cancer. In summary, these data indicate that the dramatic reduction of cellular markers associated with the process of ***epithelial-mesenchymal transition (EMT)*** as a consequence of PRP treatment, could not only reverse the EMT process with the implication to stop tumor progression and metastasis, but also seem to suppress the ***development of cancer stem cells (CSCs)***. Consequently, these results are strong indicators of the therapeutic potential of PRP that could be categorized as an ***anti-CSC therapeutic drug***.

Recent development progress for PRP includes successful completion of a GLP-compliant, 28-day repeat-dose toxicity study with no toxicological findings after administration, indicating a broad safety margin and providing sufficient data to support a safe starting dose in First-In-Human studies. The Company has also commenced development of the GMP-compliant investigational medicinal product (IMP) manufacture of PRP to support preparation of a planned clinical trial application in the UK.

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 a combined market segment of $14 Billion predicted in 2020, by 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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