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Propanc Biopharma Submits Orphan Drug Designation Request to the US Food and Drug Administration for Treatment of Ovarian Cancer

MELBOURNE, AUSTRALIA -- (Marketwired) -- 10/25/17 -- 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 it has submitted a request for Orphan Drug Designation (ODD) to the US Food and Drug Administration (FDA) for PRP, a solution for once daily intravenous administration of a combination of two pancreatic proenzymes trypsinogen and chymotrypsinogen. The proposed orphan drug indication for PRP is the treatment of ovarian cancer.

"Obtaining orphan drug designation from the FDA for our PRP therapy for ovarian cancer is a significant regulatory milestone that we are looking forward to, and will be a positive step forward in Propanc Biopharma's ongoing efforts to develop effective treatments for metastatic cancer," said James Nathanielsz, Propanc Biopharma's Chief Executive Officer. "This will further reinforce our strategic investment in PRP, since we already achieved ODD status for pancreatic cancer, demonstrating significant progress in developing a potential best in class therapy that could transform treatment for patients with metastatic cancers, where limited treatment options are available. At the time the ODD is granted, we expect to be working closely with the regulatory authorities and clinical trial investigators to advance PRP promptly through the next stages of clinical development, ultimately filing a clinical trial application for First-In-Human studies in the UK early next year."

Ovarian cancer is a disease with the lowest survival rate of all gynecological cancers, making it the seventh most common cause of cancer death in women worldwide. More than 60% of women present with stage III or stage IV metastasized cancer at the time of first diagnosis and have a five-year survival of less than 20%. The therapy is very complex and presupposes expertise in both surgery and oncology. Thus, to date therapy of ovarian cancer is a challenge and prognosis is rather poor, creating a high unmet medical need for new efficacious and safe treatment options.

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 of the pancreatic proenzymes trypsinogen

and chymotrypsinogen for intravenous administration, in the proposed indication ovarian cancer is based on a set of *in-vitro* studies on cancer stem cells generated from various cancer cell lines as well as xenograft and orthotopic mouse models of ovarian 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 can not only reverse the EMT process with the implication to stop tumor progression and metastasis, but also seem to repress 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.

Further, recent scientific evidence demonstrates that EMT and CSCs play important roles in ovarian cancer chemoresistance, one of the main challenges in the treatment of recurrent ovarian cancer and responsible for the unfavourable outcome of this disease. Treatment of EMT and CSCs thus holds promise for improving current ovarian cancer therapies and prolonging the survival of recurrent ovarian cancer patients.

Preliminary early clinical data on the treatment of six patients with ovarian cancer have also been obtained using the two pancreatic proenzymes in the context of a UK "Specials" License treatment. Together, these data support the medical plausibility of the proposed indication and a distinctive benefit-safety profile of PRP for the treatment of ovarian cancer.

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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Source: Propanc Biopharma, Inc.