

## Propanc Files Application for Orphan Medicinal Product Designation in the EU for Ovarian Cancer

MELBOURNE, AU -- (Marketwired) -- 11/01/16 -- [Propanc Health Group Corporation](#) (OTCQB: PPCH) ("Propanc" or "the Company"), an emerging healthcare 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 an application for Orphan Medicinal Product Designation (OMPD) to the European Medicines Agency (EMA) for PRP, a solution for intravenous administration of pancreatic proenzymes trypsinogen and chymotrypsinogen. The proposed orphan drug indication for PRP is for the treatment of ovarian cancer.

"Obtaining orphan medicinal product designation from the EMA 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's ongoing efforts to develop effective treatments for metastatic cancer," said James Nathanielsz, Propanc's Chief Executive Officer. "This will reinforce our strategic investment in PRP, demonstrating progress in developing a potential best-in-class therapy that could transform treatment for patients with metastatic cancers, where there are limited treatment options. Once the OPMD is granted, we will work closely with the regulatory authorities and our clinical investigators to advance PRP promptly through the next stages of clinical research and development."

Ovarian cancer is a disease with the lowest survival rate of all gynecological cancers (Quaglia et al. 2009), 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 (Roett and Evans, 2009). 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.

Orphan medicinal product designation is granted by the European Commission, following a positive opinion from the Committee for Orphan Medicinal Products (COMP), to a medicinal product that is intended for the diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition affecting not more than five in 10,000 persons in the European Community when the application for designation is submitted. An orphan designation allows a company to benefit from incentives from the European Union to develop a medicine for a rare disease, such as reduced fees and protection from competition once the medicine is placed on the market.

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 ovarian 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.

Preliminary early clinical data on the treatment of six patients with ovarian cancer have been obtained with PRP 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.

To be added to the email distribution list, please email [PPCH@kcsa.com](mailto:PPCH@kcsa.com) with "Propanc" in the subject line.

### **About Propanc:**

Propanc is developing new cancer treatments 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](http://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.

Investor Contacts:

KCSA Strategic Communications  
Philip Carlson / Elizabeth Barker  
[propanc@kcsa.com](mailto:propanc@kcsa.com)

Media Contacts

Jon Goldberg / Lisa Lipson  
[propanc@kcsa.com](mailto:propanc@kcsa.com)

Source: Propanc Health Group Corporation