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

MELBOURNE, AUSTRALIA -- (Marketwired) -- 09/07/16 -- 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 pancreatic cancer, responsible for 338,000 cancer diagnoses and 331,000 deaths worldwide in 2012, and a major unmet medical issue.

"This is a critical step for Propanc and its plans for developing PRP as a treatment solution for aggressive, fast spreading solid tumors. Pancreatic cancer is an area where there is an urgent need for viable solutions and we remain determined to bring to market what could become a targeted and safer treatment approach, which we hope will meaningfully extend patient lives," said James Nathanielsz, Propanc's Chief Executive Officer. "We will work hard with the authorities to provide a strong rationale for why PRP qualifies for orphan medicinal product designation, which will provide exciting potential benefits to fast track the development process and provide attractive benefits for up to ten years when we achieve market approval."

The European Union (EU) grants Orphan Medicinal Product Designation (OMPD) status to products which treat rare diseases, providing a range of incentives to sponsors developing drugs or biologics. To stimulate the research and development of orphan drugs, in 2000, the EU introduced new legislation with the aim of providing incentives for the development of orphan and other medicinal products for rare disorders. Today, companies with an orphan designation for a medicinal product benefit from incentives such as fee waivers, a 10 year market exclusivity period post authorization for designated products; scientific assistance for marketing authorizations, and the possibility of a Community marketing authorization. The EMA grants OMPD to products that meet one of the following designation criteria:

- the life-threatening or debilitating nature of the condition;
- the medical plausibility of the proposed orphan indication;
- that the prevalence of the condition in the European Union is not more than five in 10,000; or that it is unlikely that marketing the medicinal product in the European Union, without incentives, would generate sufficient return to justify the necessary investment;
- that no satisfactory method of diagnosis prevention or treatment exists, or if such a method exists, that the medicinal product will be of significant benefit to those affected

by the condition.

The rationale for developing PRP, a formulation of the pancreatic proenzymes trypsinogen and chymotrypsinogen for intravenous administration, in 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***.

Preliminary early clinical data on the treatment of four patients with pancreatic cancer have been obtained with a rectal formulation of pancreatic proenzymes trypsinogen and chymotrypsinogen in the context of a UK "Specials" License treatment, administered by Dr Julian Kenyon, at the Dove Clinic Center for Integrated Medicine, back in the mid 2000's. Together, these data support the medical plausibility of the proposed indication and a distinctive benefit-safety profile of PRP for the treatment of pancreatic cancer.

To be added to the email distribution list, please emailPPCH@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.

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 Health Group Corporation