

Propanc Biopharma Advances Bioanalytical & Immunogenicity Assay Development for Phase 1b First-In-Human Study in up to 50 Advanced Cancer Patients

MELBOURNE, Australia, Oct. 30, 2026 (GLOBE NEWSWIRE) -- Propanc Biopharma, Inc. (Nasdaq: PPCB) ("Propanc" or the "Company"), a biopharmaceutical company focused on developing novel treatments for chronic diseases including recurrent and metastatic cancer, today announced that key analytical development activities are underway, including immunogenicity assay feasibility, pharmacokinetic method optimization and stability testing, supporting preparations for the planned Phase 1b, First-In-Human study of the Company's lead clinical candidate, PPC-001, in up to 50 advanced cancer patients with solid tumors.

"Propanc continues to advance its analytical development activities in parallel with preparations for its Phase 1b First-In-Human study," said Dr. Ralf Brandt, Propanc's Research & Development Director. "The ongoing feasibility assessment of immunogenicity assays, together with the planned optimization of pharmacokinetic bioanalytical methods and stability testing, represents an important component of the Company's clinical development strategy."

Key achievements include:

- **Encouraging stability results for PPC-001 in human blood matrices:** Bioanalytical studies demonstrated that the two proenzyme components of PPC-001, trypsinogen and chymotrypsinogen, remained detectable without evidence of significant degradation over the investigated sample-handling periods.
- **Stability demonstrated across three human donors:** Follow-up experiments conducted by FyoniBio evaluated serum and plasma samples from three individual donors, strengthening the initial feasibility findings.
- **Stability over 60 minutes at room temperature:** The September study demonstrated recovery results generally exceeding 85% after 60 minutes, supporting the feasibility of clinical blood sample collection and processing procedures.
- **Successful application of mass spectrometry:** LC-MS-based analytical methods were used to measure both proenzyme components in human serum and plasma, providing a foundation for further development of pharmacokinetic assays.
- **Progress in immunogenicity assay development:** Laboratory experiments demonstrated successful preparation of biotin- and sulfoTAG-labelled trypsinogen and chymotrypsinogen reagents, with no degradation observed by SDS-PAGE under the

tested labelling conditions.

- **Additional evidence of short-term reagent stability:** Labelled assay reagents showed no detectable degradation by SDS-PAGE following storage for one day at 4°C under the tested conditions, supporting continued development of anti-drug antibody (ADA) assays.

Advancement toward clinical bioanalytical readiness – together, these findings support continued assay optimization and pre-validation activities required for the planned clinical development of PPC-001 and are structured in the three key areas based on the unique properties of treatment. These activities are expected to provide the analytical foundation required to support the evaluation of PPC-001 during its clinical development program.

1. **Anti-Drug Antibody Assay Development:** The feasibility assessment for the development of two ADA assays, targeting the individual proenzyme components trypsinogen and chymotrypsinogen, is currently underway. The feasibility program is evaluating the suitability of existing positive control antibodies to support the development of reliable immunogenicity assays. Following successful feasibility assessment, the program is scheduled to progress to assay establishment and subsequent validation.
2. **Pharmacokinetic Bioanalytical Method Development:** The Company has established a structured analytical development program aimed at optimizing the sensitivity and performance of bioanalytical methods for measuring PPC-001 components in clinical samples. The program includes the evaluation of stable isotope-labelled peptides as internal standards, strategies to minimize biological matrix effects, and optimization of sample volumes to improve analytical sensitivity. Additional activities will focus on reducing sample analysis time and establishing a suitable analytical method for subsequent clinical application.
3. **Stability Assessment and Analytical Support:** Stability testing activities covering the drug product and its analytical characteristics are included in the development program. The analytical program is intended to generate the data necessary to support appropriate sample handling, analytical reliability and clinical bioanalytical assessments.

“The work undertaken led by Dr Ralf Brandt, our R&D Director, his team, and our partner CRO is of a high standard and provides an excellent framework for our world-first study for PPC-001 in advanced cancer patients,” said Mr. James Nathanielsz, Propanc’s Chief Executive Officer. “PPC-001, a combination therapy consisting of two pancreatic proenzymes from naturally derived sources is a unique approach to cancer treatment which has the capacity to reverse the effects of cancer cell dissemination and recurrence. By undertaking these important bioanalytical activities, we are going to obtain great insight into the effects of PPC-001.”

About Propanc Biopharma, Inc.

Propanc Biopharma, Inc. (Nasdaq: PPCB) is developing a novel approach to preventing cancer recurrence and metastasis by targeting and eradicating cancer stem cells through

proenzyme activation. The Company's lead product candidate, PRP, is designed to address the underlying drivers of cancer proliferation and spread.

More information: www.propanc.com

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to the Company's expectations regarding its market position and market opportunity, expectations and plans as to its product development, manufacturing and sales, and relations with its partners and investors, made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections regarding its business, operations and other similar or related factors. Words such as "may," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expect," "intend," "plan," "project," "believe," "estimate," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond the Company's control. Forward-looking statements are not guarantees of future actions or performance. Actual results may differ materially from those in the forward-looking statements because of several factors, including, without limitation, risks and uncertainties related to market conditions, as well as those risks described under "Risk Factors" in the prospectus related to the proposed offering and those described in the Company's filings with the SEC. The Company undertakes no obligation to revise or update information in this release to reflect events or circumstances in the future, even if new information becomes available.

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