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Propanc Biopharma to Initiate World-First Phase 1b First-in-Human Study of PRP in February 2027

Open-label, two-part dose-escalation and dose-expansion study planned in up to 50 patients with advanced solid tumors across Australia

MELBOURNE, Australia, Sept. 09, 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 plans to commence a world-first Phase 1b first-in-human (FIH) study of PRP in February 2027.

The multicenter, open-label study will enroll up to 50 patients with advanced solid tumors, including pancreatic, ovarian, and refractory prostate cancers, at trial centers across Australia. The two-part design, dose escalation (Part A) followed by dose expansion (Part B), is intended to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary antitumor activity of PRP.

Several workstreams are advancing in parallel to support study start:

- **Manufacturing:** GMP manufacture of finished drug product is underway. A small-scale technology transfer run has been completed. Two scale-up runs are scheduled this month, with an engineering run planned for late October. Raw drug substance supply for the PRP formulation is secured after recent audit and vendor qualification processes were successfully completed.
- **Bio-analytics:** PK method validation has commenced. Development of an anti-drug antibody assay is underway, and in-use stability testing of the finished PRP formulation is scheduled.
- **Regulatory and ethics:** Supporting documentation for Human Research Ethics Committee (HREC) submission is in preparation, including the Investigator’s Brochure (IB), a briefing document drawn from the IB, and the clinical trial protocol. Documents will be provided to investigators at Australian trial sites for feasibility assessment ahead of the planned HREC submission in November 2026.

PRP will be administered as a weekly intravenous infusion on Days 1, 8, 15, and 22 of each 28-day cycle. Treatment may continue until a withdrawal criterion is met.

Part A will use a Bayesian Optimal Interval (BOIN) design with backfill (BF-BOIN) and a predefined target dose-limiting toxicity (DLT) probability to identify the maximum tolerated dose (MTD), if reached, and/or up to two recommended doses for optimization and expansion (RDO). Up to five dose levels are planned. Following selection of the RDO(s) in

Part A, Part B will further evaluate safety, tolerability, and preliminary antitumor activity in one or more tumor-specific expansion cohorts.

“We are making meaningful progress toward a pivotal milestone for Propanc as we prepare to advance PRP into the clinic,” said James Nathanielsz, Chief Executive Officer of Propanc. “Our team is diligently executing planned manufacturing, analytical, and regulatory work required to initiate a world-first Phase 1b first-in-human study of PRP. Our objective is a therapy that can extend survival and improve quality of life for patients with limited remaining options — without the severe toxicities often associated with standard regimens. After years of research, that clinical milestone is now coming into view.”

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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