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PharmaCyte Biotech Moves Closer to Filing IND with Naming of Comparator Arm for Upcoming Clinical Trial and Discusses Pivotal Trial Opportunity

LAGUNA HILLS, Calif., Feb. 13, 2017 (GLOBE NEWSWIRE) -- PharmaCyte Biotech, Inc. (OTCQB:PMCB), a clinical stage biotechnology company focused on developing targeted treatments for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, today discussed the comparator arm for its upcoming clinical trial and provided additional clarification on its recent pre-IND meeting with the U.S. Food and Drug Administration (FDA) regarding its upcoming clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

In the company's upcoming trial, the comparator arm that PharmaCyte's pancreatic cancer therapy will be compared to is the combination of the cancer drug 5-fluorouracil (FU) and the compound leucovorin (LV). The necessary and quick decision was made by Dr. Manuel Hidalgo, the Principal Investigator for the upcoming clinical, Dr. Daniel Von Hoff with Translational Drug Development (TD2), the CRO for PharmaCyte's clinical trial, and Dr. Matthias Löhr, the Chairman of PharmaCyte's Medical and Scientific Advisory Board.

"After our pre-IND meeting I am more confident and enthusiastic than ever about PharmaCyte's ability to validate its therapy for locally advanced, inoperable pancreatic cancer in a human clinical trial," stated PharmaCyte's Chief Executive Officer, Kenneth L Waggoner.

He continued, "And I am quite gratified that the FDA sees enough potential in our product to consider our trial a pivotal one under the right circumstances. Now the mission for our entire team is to work diligently towards the submission of our IND to the FDA. We all feel that the suggested changes we received from the FDA should not take long to make and will certainly be well worth it in the long run. For example, we quickly gained agreement on the comparator arm for the trial and, in doing so, we've moved closer to filing our IND with the FDA."

PharmaCyte's management, Dr. Manuel Hidalgo, TD2 and TD2's consulting statistician are actively working to finalize the number of patients that will be included in the trial. This is the final element and will complete the adjustments necessary for a newly designed trial.

In PharmaCyte's recent pre-IND meeting with the FDA, the FDA stated that it would be willing to change PharmaCyte's clinical trial from an "exploratory" trial to a "pivotal" trial under certain conditions. A pivotal trial is a clinical trial intended to provide evidence for a drug marketing approval by the FDA.

This indeed is a landmark moment in PharmaCyte's history. Generally, a pivotal trial must be a Phase 3 trial (which PharmaCyte's upcoming trial could be labeled); in such a trial several hundred patients can be treated. However, the FDA indicated that: (i) if PharmaCyte's therapy shows real promise; (ii) includes a sufficient number of patients; and (iii) includes primary endpoints of overall survival (OS) and safety rather than progression free survival (PFS) and safety, the trial may be considered a pivotal trial.

Mr. Waggoner said of this opportunity, "This is good news for PharmaCyte shareholders since the change from an "exploratory" trial to a "pivotal" trial can eliminate one or two lengthy and costly trials and potentially make PharmaCyte's Cell-in-a-Box®-based product, CypCaps™, "market-ready" in a much shorter period of time than anticipated. It may also accelerate the overall development timeline if the results are very positive, thus making the therapy more attractive to potential investors or suitors."

To be a pivotal trial, the FDA wants at least 100 patients treated with CypCaps™ for purposes of determining the safety of PharmaCyte's therapy. In the trial's original design only 40 or so patients would have received CypCaps™ and been evaluated for safety.

Other highly positive news provided by Mr. Waggoner concerning the pre-IND meeting with the FDA included:

- agreement with the FDA that PharmaCyte is on the "right track" in its development program;
- agreement with the FDA on the cell line that will be used in the clinical trial;
- agreement with the FDA on the patient population to be studied in the clinical trial;
- agreement with the FDA on the secondary endpoints of the clinical trial, except that PFS will be added to the list of secondary endpoints if the trial becomes a pivotal trial;
- agreement with the FDA on the number of patients needed to comprise an adequate safety database for a Biologics Licensing Application for CypCaps™;
- agreement that the FDA believes CypCaps™ is a drug/device combination product;
- agreement with the FDA that it will assist PharmaCyte in its development program; and
- agreement with the FDA that the next step for PharmaCyte is to submit an IND.

There is still a "hard stop" at the six-month mark after a certain number of patients have been enrolled in the trial to review the data generated to that point. The timing of this hard stop may change, however, to the point in time when 50% of the patients have been treated. Because the clinical trial is an "open-label" trial (the trial is not a "blinded" study), this interim analysis should give PharmaCyte an important indication of the successfulness of its CypCaps™ therapy for LAPC.

Mr. Waggoner commented on the significance of following the FDA's guidance moving forward stating, "We have one shot at this, and we intend to get it right. We greatly appreciate the continued patience and support of our shareholders during this process."

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage biotechnology company developing therapies for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." This technology will be used as a platform upon which therapies for several types of cancer and diabetes are being

developed. PharmaCyte's therapy for cancer involves encapsulating genetically engineered human cells that convert an inactive chemotherapy drug into its active or "cancer-killing" form. These encapsulated cells are implanted as close to the patient's cancerous tumor as possible. Once implanted, a chemotherapy drug that is normally activated in the liver (ifosfamide) is given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide comes in contact with the encapsulated cells they act as an artificial liver and activate the chemotherapy drug at the source of the cancer. This "targeted chemotherapy" has proven effective and safe to use in past clinical trials and results in no side effects.

In addition to developing a novel therapy for cancer, PharmaCyte is developing a treatment for Type 1 diabetes and insulin-dependent Type 2 diabetes. PharmaCyte plans to encapsulate a human cell line that has been genetically engineered to produce, store and release insulin in response to the levels of blood sugar in the human body. The encapsulation will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient they will function as a "bio-artificial pancreas" for purposes of insulin production.

Safe Harbor

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of risk factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

More information about PharmaCyte can be found atwww.PharmaCyte.com. It can also be obtained by contacting Investor Relations.

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