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## PharmaCyte Biotech CEO Addresses IND Submission Questions

LAGUNA HILLS, Calif., March 17, 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<sup>®</sup>, today released a statement by Chief Executive Officer Kenneth L. Waggoner that addresses the company's position on releasing a date for filing its Investigational New Drug application (IND). Mr. Waggoner's statement can be read below:

PharmaCyte does not plan to publish a date for the filing of its IND. At the current time, it's extremely difficult for the company to supply a development timeline that will accurately predict when the IND will be filed. It would be irresponsible of the company to release what, at this point, would be a "hopeful" date for filing the IND. This date could change from day-to-day and week-to-week based upon several unforeseen variables – many of which are beyond PharmaCyte's control. This means that we cannot give an accurate timeline for filing the IND because we too are awaiting a list of items to be completed by others.

What can be said with certainty is that PharmaCyte is on the right track for filing its IND at the earliest opportunity. With the help of Facet Life Sciences and TD2, the company is committed to doing everything the right way by following the guidance given to the company by the FDA during the pre-IND meeting. In doing that, PharmaCyte will maximize the possibility of preparing a successful IND rather than having the company's IND put on clinical hold or even outright denied because it didn't follow the FDA's guidance. Getting to a point where the IND can be filed is not an overnight or even a one-month process. During the company's conference call, I tried to convey this point to shareholders. Any shareholder who thought that the pre-IND meeting would be held one day and then the IND would be filed the next had completely unrealistic expectations. This never occurs.

PharmaCyte's pre-IND meeting with the FDA was the best possible way for the company to introduce its pancreatic cancer therapy, past clinical trial results and trial design to the FDA, and, in turn, received invaluable feedback from the FDA and suggestions and ideas to best advance our therapy in the clinical trial. The pre-IND meeting served as the starting point of getting PharmaCyte and the FDA on the same page for the company to properly prepare for a clinical trial in inoperable locally advanced pancreatic cancer (LAPC).

The pre-IND meeting represented a critical point in the regulatory process for PharmaCyte and allowed the company to establish a strong relationship with the FDA. It also provided PharmaCyte and the FDA the opportunity to agree on a development strategy that should lead to a successful IND and, hence, the start of the clinical trial. The discussions held during the pre-IND meeting have the potential to save PharmaCyte both time and money in the long run, and have definitively shaped the overall strategy for the development of PharmaCyte's therapy for LAPC.

If you're wondering how the pre-IND meeting could have meaningfully benefited PharmaCyte and possibly reduce time to market, the FDA has addressed this question on its website, indicating the following benefits pertaining to PharmaCyte:

- Identifying and avoiding unnecessary studies;
- Ensuring that necessary studies are designed to provide useful information to the FDA;
- Gaining FDA support for PharmaCyte's proposed strategy;
- Minimizing the chance for a clinical hold being issued by the FDA after filing the IND which would, of course, delay the start of the clinical trial;
- Providing an opportunity for PharmaCyte and the FDA to creatively embark upon an exchange of ideas about all aspects of the clinical trial;
- Obtaining regulatory insight from the FDA into the proposed clinical trial, particularly about PharmaCyte's cell therapy for LAPC;
- Minimizing costs so PharmaCyte doesn't unnecessarily spend money on its development program;
- Defining acceptable endpoints and goals that the FDA finds acceptable; and
- Allowing early interactions and ongoing negotiations with the FDA related to the clinical trial.

The company now has the guidance it needs to complete what is expected to be a successful IND process. PharmaCyte was charged with completing numerous tasks identified by the FDA during the pre-IND meeting. Many of these tasks came about because PharmaCyte's treatment for LAPC is novel in that it is a live cell-based therapy that also involves a unique form of cell encapsulation technology. When these tasks are completed by PharmaCyte, Austrianova, TD2 and others, PharmaCyte will file its IND. It will be then that the public is notified the IND has been filed.

### **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<sup>®</sup>." 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 because 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 Biotech can be found at [www.PharmaCyte.com](http://www.PharmaCyte.com). It can also be obtained by contacting Investor Relations.

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