

May 9, 2018



PharmaCyte Biotech Successfully Completes Pore Size Studies in Cell-in-a-Box® Capsules Used in Pancreatic Cancer Therapy

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- [PharmaCyte Biotech, Inc.](#) (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature [live-cell encapsulation technology, Cell-in-a-Box®](#), today announced that it has successfully completed the “pore size studies” on its Cell-in-a-Box® capsules that are required by the U.S. Food and Drug Administration (FDA).

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, explained the significance of the study saying, “PharmaCyte’s treatment for locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC) utilizes genetically engineered live human cells that produce a particularly potent cytochrome P450 enzyme that is able to activate the chemotherapy prodrug ifosfamide. These cells are encapsulated using the Cell-in-a-Box® technology, and the capsules are implanted near the cancerous tumor so that a high local concentration of the cancer-killing ifosfamide metabolite is produced near the tumor.

“Therefore, it is essential that the ifosfamide can easily and quickly enter the capsules so that it can be efficiently converted into the ifosfamide tumor-killing metabolite. It is equally important that this metabolite can then exit the capsules and destroy the tumor. The completed studies clearly demonstrate that this is the case and underscore the stability of the capsules over the freezing, transport and storage cycle.”

As part of PharmaCyte’s Investigational New Drug Application (IND) for its clinical trial in patients with LAPC, the FDA required PharmaCyte to provide data showing that the size of the pores in the outer shell of the Cell-in-a-Box® capsules is appropriate to allow ifosfamide to enter the interior of the capsules where the ifosfamide-activating cells are located. Additionally, PharmaCyte is required to provide data showing that the pores are also of appropriate size to allow the activated form of ifosfamide to leave the capsules.

The FDA also required PharmaCyte to conduct experiments to demonstrate that the pore size was not affected by the freezing and thawing process of the capsules. To provide the information required by the FDA, a series of laboratory experiments were performed with non-frozen and freshly thawed capsules that were previously frozen and that contained labelled particles. Each set of samples studied contained particles of a particular size, and the appropriate size range was covered by the series of experiments.

Both the release of the particles from the capsules over time and the accumulation of the particles outside the capsules over time were evaluated. The experiments clearly demonstrated that molecules of the size of ifosfamide or its activated cancer-killing form

could pass through the capsule's pores virtually instantaneously. Further, there was no difference detected in the release parameters between freshly produced capsules and those that had been frozen and then thawed.

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage biotechnology company developing cellular 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. For pancreatic cancer, these encapsulated cells are implanted in the blood supply to the patient's tumor as close as possible to the site of the tumor. 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 flows through pores in the capsules, the live cells inside act as a "bio-artificial liver" and activate the chemotherapy drug at the site of the cancer. This "targeted chemotherapy" has proven effective and safe to use in past clinical trials and results in no treatment related side effects.

PharmaCyte's therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes involves encapsulating 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 and/or beta islet cells. 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 because 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 due to the impact of numerous 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. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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