PharmaCyte Ships Clinical Trial Cells to Austrianova for Encapsulation

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®, announced that vials of cells from PharmaCyte’s Master Cell Bank (MCB) have been shipped by Eurofins Lancaster Laboratories (Eurofins) to Austrianova’s encapsulation facility in Thailand. The cells from the MCB will be encapsulated and then tested by Austrianova after encapsulation. This post-encapsulation testing will generate the remaining data required by the U.S. Food and Drug Administration (FDA) to be included in PharmaCyte’s Investigational New Drug Application (IND). For the cells to be shipped and accepted into Austrianova’s GMP encapsulation facility, they had to pass mandatory sterility and mycoplasma testing by Eurofins.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, stated, “We are extremely pleased to make this announcement. It represents a major step forward in preparations for our planned clinical trial to treat locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC). After encapsulation, further testing will be done by Austrianova. The data from these tests, along with data from the tests done by Eurofins and its subcontractors, will be included as an integral part of our IND.”

Austrianova’s Chief Executive Officer, Brian Salmons, said, “We are excited to receive vials of cells from the MCB produced by Eurofins. The next step will be the encapsulation of these cells followed by another round of sterility testing and numerous quality control tests. After this is completed, the encapsulated cells in a syringe will be shipped to PharmaCyte for use in its planned clinical trial.”

Before the cells were shipped, they had undergone and passed numerous tests completed by Eurofins and its subcontractors. Several tests are still ongoing. The large number of tests that PharmaCyte must complete on the cells are necessary to meet the FDA’s requirements. The lengthy amount of time it has taken to complete these tests is because PharmaCyte is using genetically modified live human cells as part of its combination product that utilizes the Cell-in-a-Box® technology plus low dose ifosfamide as a novel therapy to treat LAPC.

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. 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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