May 26, 2020

PharmaCyte Biotech Announces Final Major Study for IND Submission Has Begun

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a biotechnology company focused on developing cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, announced today that the final major study required by the U.S. Food and Drug Administration (FDA) for the submission of PharmaCyte's Investigational New Drug application (IND) has been initiated.

The study, referred to as the "Stability Study" is a rolling two-year study to demonstrate how the frozen clinical trial product manufactured by Austrianova Singapore (Austrianova) for patients with locally advanced, inoperable, pancreatic cancer (LAPC) performs over time after being frozen for certain periods of time and then thawed and tested for functionality. While the study will continue for 2 years, the FDA requires 3 months of stability data to be included in the IND for its submission.

The tests for the Stability Study started approximately 3 months (the first time point in the 2-year study) from the issuance of the Certificate of Analysis for the second successful manufacturing run and will continue for 24 months. Data from the balance of the Stability Study will be provided to the FDA as the data becomes available.

The Stability Study consists of many of the same tests that were performed as "release testing" that enabled Austrianova to issue to PharmaCyte a Certificate of Analysis for the second successful manufacturing run of the two back-to-back successful runs.

Various tests are taken at one or more of the following time points: month 0, 3, 6, 9, 12, 18 and 24. Month 0 represents the "release testing" for the Certificate of Analysis for the second manufacturing run that PharmaCyte previously announced earlier this year. For example, label integrity takes place on months 0, 3, 6, 9, 12, 18, and 24, while sequencing for the transgene marker takes place on months 0, 6, 12, and 24.

The parameters for testing are: (i) Identity (*Assay*: label integrity, polymerase chain reaction and sequencing for a transgene marker); (ii) Purity (*Assay*: appearance post thaw, pH, capsule integrity post-thaw and cultured 3 days) (iii) Viable Cell Number (*Assay*: determined by cell size); (iv) Potency (*Assay*: resorufin enzymatic activity) and (v) Integrity (*Assay*: container-closure integrity).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commented on commencement of the Stability Study saying, "While we had to wait for three months (the first time point in the 2-year study) from our receipt of the Certificate of Analysis for the second manufacturing run to begin the last major study required by the FDA to submit our IND, we are finally in the home stretch of studies we are required to conduct by the FDA. But

we do not have to wait until the 24- month Stability Study is completed to submit the IND. We are allowed to supplement the initial 3-months of data from the Stability Study to support the IND as the Stability Study runs its course. That data is currently in the process of being developed.

“We continue to remain laser focused on submitting PharmaCyte’s IND to the FDA. Our team continues to work every day to complete the necessary items that will allow PharmaCyte to submit an IND for its planned Phase 2b clinical trial in LAPC. As each test and item required for the IND is completed, our team of experts are compiling the data from these completed tests items and creating our IND package that will be submitted to the FDA.”

To learn more about PharmaCyte’s pancreatic cancer treatment and how it works inside the body to treat locally advanced inoperable pancreatic cancer, we encourage you to watch the company’s documentary video complete with medical animations at: https://www.PharmaCyte.com/Cancer.

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. (PharmaCyte) is a 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 little to 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 and release insulin in response to the levels of blood sugar in the human body. PharmaCyte is developing the use of genetically modified liver cells and stem cells, as well as beta islet cells, to treat diabetes. 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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