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PharmaCyte Biotech's Pancreatic Cancer Therapy Production in Final Days of Key Manufacturing Run

NEW YORK, NY, Sept. 23, 2019 (GLOBE NEWSWIRE) -- PharmaCyte Biotech (OTCQB: PMCB) and its partner, Austrianova, along with the company's cellular biologist, David Judd, are all more confident than ever that they have a product that can succeed in a U.S. FDA clinical trial for locally advanced, inoperable pancreatic cancer (LAPC). It's now up to the company to produce its signature live-cell encapsulation product, Cell-in-a-Box®, successfully, test it, and then use the data from those tests to complete an Investigational New Drug application (IND). The aim, of course, is to submit the IND to the FDA to gain approval to begin its planned Phase 2b clinical trial in the United States.

During a conference call with shareholders late last week, PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, told shareholders that the company is in the final days of the first of two back-to-back, staggered manufacturing runs, and that he is "very encouraged" by the reports he's getting from Austrianova—the company conducting the manufacturing runs to produce the Cell-in-a-Box® capsules for PharmaCyte's upcoming clinical trial.

Once this first manufacturing run is completed successfully, the final stage in the process—testing those capsules and the live cells inside that make up the Cell-in-a-Box® technology—can begin. The capsules will be placed into syringes and then those syringes will be frozen and stored in a freezer at Austrianova's manufacturing facility in Thailand. Soon thereafter, a representative sample of the Cell-in-a-Box® syringes will be thawed and a series of tests (release testing) will begin. These FDA-required tests are necessary for PharmaCyte to be able to use its product in human beings in a clinical trial.

Also, PharmaCyte informed shareholders that Austrianova scheduled the second of two manufacturing runs to begin last Friday. This news confirms the extreme confidence that both PharmaCyte and Austrianova have in the many changes they've made to the production process this past year, and it also marks the first time that a second manufacturing run has received the go-ahead to begin. There were 7 changes that were incorporated into the manufacturing process and each of those "tweaks" or changes to the production process were also discussed on the company's shareholder conference call.

Regarding an upcoming second manufacturing run, PharmaCyte said, "If the first run is successful from start to finish, and all things are mimicked from the first run in this upcoming second run, then we're confident that we'll see a successful second run. From there, the company will move to a second round of release testing."

Why is the company insisting on two manufacturing runs? Well, PharmaCyte's CEO explained to shareholders that cGMP Validation, the company that is taking responsibility for releasing the company's clinical trial product into the U.S., believes PharmaCyte's chances

for FDA approval of its IND are much more likely with the successful completion of these two runs.

“Releasing clinical trial product” means that cGMP Validation will be taking responsibility for the product’s GMP compliance with the manufacturing standards that apply to the company’s clinical trial product, which will be placed inside human beings.

The FDA wants a “reliable” and a “reproducible” clinical trial product. To demonstrate those two components, PharmaCyte believes that conducting a second staggered and back-to-back manufacturing run – which means the second run is being conducted while the first run is finishing up – optimizes its chances for a successful IND submission.

In last week’s conference call, Kenneth Waggoner explained to shareholders, “We have a product that we’re completely satisfied with — meaning that the cells we have genetically engineered do exactly what they were designed to do and our encapsulation process is exactly how we want it to be.”

The CEO stated, "The viability of the cells from our Master Cell Bank is well within the normal range. Cells from our Master Cell Bank produce the amount of enzymatic activity we designed them to produce and that is necessary to convert the prodrug we currently use to treat pancreatic cancer from its inactive form to its cancer killing form. We are satisfied with everything in the 'design' of the manufacturing process.”

The confidence shown by PharmaCyte’s CEO during last week’s conference call will only continue to grow, if, in the coming days, the first manufacturing run is completed successfully, and testing can begin.

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

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. 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 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.

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