November 12, 2019

PHARMACYTE BIOTECH

PharmaCyte Biotech's "Release Testing" Last Critical Event Before Submission of Investigational New Drug Application

NEW YORK, NY, Nov. 12, 2019 (GLOBE NEWSWIRE) -- PharmaCyte Biotech (OTCQB: PMCB) has reduced a long list of FDA-required items to just one last important component—release testing—before it can submit an Investigational New Drug application (IND) to the U.S. FDA. PharmaCyte's IND application will request permission from the FDA to conduct a Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer (LAPC). With the FDA's approval to begin a clinical trial, PharmaCyte's opportunities for funding improve dramatically.

PharmaCyte has already conducted and completed a long list of tests and entered the data from those tests into the IND application. PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of completing the IND for submission to the FDA, "Most of the work needed for PharmaCyte to submit an IND to the FDA has been completed."

PharmaCyte recently announced that it has encapsulated the live cells from its Master Cell Bank (MCB) into its live-cell encapsulation technology, Cell-in-a-Box®, in what is the second of two staggered and back-to-back manufacturing runs. In that announcement the company's CEO stated that after reviewing pictures of the growing cells, he is confident that those cells are growing as well as those in the first run, which ended successfully after a host of changes were implemented to improve the manufacturing process.

And, with the second manufacturing run well underway and growing as expected, this final run should end in success over the next week or so, and then the release testing for this second run combined with the release testing from the first run will complete what has been a long and arduous path to submitting the much-anticipated IND.

Now, let's walk through each of the tests (release testing) that are required by cGMP Validation, the company that is taking responsibility for "releasing" the clinical trial product into the U.S. for use in PharmaCyte's upcoming clinical trial. Many of these tests are also FDA-required tests that must be completed in order to obtain the data necessary to complete and submit the IND and for PharmaCyte to receive a Certificate of Analysis (CoA) from Austrianova. A CoA is a document issued by Austrianova's Quality Assurance and Quality Control Department (QA/QC) that confirms that PharmaCyte's product meets its product specifications. The CoA will contain the actual results obtained from the testing performed as part of the QA/QC of a representative sample of PharmaCyte's clinical trial product.

After a manufacturing run is completed successfully, 300 Cell-in-a-Box® capsules are placed into 400 of PharmaCyte's clinical trial syringes and then frozen. A representative sample of those syringes will be thawed and undergo release testing.

All release testing related to “safety” of the encapsulated cells is being outsourced by PharmaCyte to independent third-party laboratories in Europe. They include tests for sterility, endotoxin, pH, mycoplasma and cell identity.

A sterility test confirms that all syringes are free from the presence of viable microorganisms or microbial contamination.

An endotoxin test of a biologic product is necessary to ensure the product is endotoxin free. This means that the cells do not contain bacterial toxins.

A pH test will confirm how much hydrogen is in the product and that the product meets the specified pH balance for a human being.

A mycoplasma test confirms that the syringes are free from mycoplasma. Mycoplasma are small, simple bacteria which lack a cell wall and represent one of the most prevalent and serious sources of cell line contamination.

A cell identity test confirms that the cell line used in production is positively identified as the 22P1G cell line. This is the human cell line that PharmaCyte cloned from the original cell line used in the first two clinical trials using the Cell-in-a-Box® technology.

All release testing related to “functionality” of the encapsulated cells is being conducted by Austrianova at its GMP facility in Thailand. Those tests include enzymatic activity, cell viability, capsule count in each syringe, and capsule diameter.

An enzymatic activity test shows that the requisite enzymes are being produced by the cells inside the capsules to create the desired chemical reaction in the body. In PharmaCyte’s case, this means that the correct enzymes are being produced to convert the cancer-killing prodrug, ifosfamide, from its inactive form to its active form. Ifosfamide is the chemotherapy drug that PharmaCyte uses with the encapsulated cells that are implanted in a patient as close to the tumor as possible.

A cell viability test measures the number of cells that remain alive and viable after thawing a syringe of encapsulated cells.

A capsule count test confirms that each syringe contains 300 capsules. One syringe full of the encapsulated cells is implanted in a pancreatic cancer patient before ifosfamide is given intravenously to treat LAPC.

A capsule diameter test confirms that the diameter of each capsule inside a syringe of encapsulated cells meets a specified range.

Additionally, a pyrogenicity test must be completed to ensure that the capsules themselves do not produce a fever. This FDA-required test is not in the list of release tests. The pyrogenicity test is being conducted in the United States.

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.

About Stock Market Media Group

Stock Market Media Group is a Content Development IR firm offering a platform for corporate stories to unfold in the media with press releases, research reports, corporate videos, radio-style CEO interviews and feature news articles.

investment licenses and may not sell, offer to sell or offer to buy any security. Our publications about PMCB are not a recommendation to buy or sell a security.

Stock Market Media Group and its management may benefit from any increase in the share price of the profiled companies and hold the right to sell the shares bought at any given time including shortly after the release of the company's profile. Section 17(b) of the 1933 Securities and Exchange Act requires publishers who distribute information about publicly traded securities for compensation, to disclose who paid them, the amount, and the type of payment. Under the Securities Act of 1933, Section 17(b), Stock Market Media Group discloses that it expects to be remunerated fifteen thousand dollars monthly from September 2019 to September 2020, paid for by a third party via bank wire, to produce content related to PharmaCyte. This article is the opinion of Stock Market Media Group and was written based upon publicly available information and interviews conducted by SMMG.

Stock Market Media Group does not own any shares in PharmaCyte and never accepts compensation in free-trading shares for its marketing services of the company being profiled, however third parties that might have compensated Stock Market Media Group may hold free-trading shares of the company being profiled and could very well be selling, holding or buying shares of the company's stock at the same time the content is being disseminated to potential investors; this should be viewed as a definite conflict of interest and as such, the reader should take this into consideration.

If Stock Market Media Group ever accepts compensation in the form of free trading shares of the company being profiled and decides to sell these shares into the public market at any time before, during, or after the release of the company's profile, our disclaimer will be updated accordingly reflecting the current position of those free trading shares received as compensation for our services.

For more information: www.stockmarketmediagroup.com

Contact:

Stock Market Media Group

info@stockmarketmediagroup.com

PHARMACYTE BIOTECH

Source: PharmaCyte Biotech