

PharmaCyte Biotech's Live-Cell Encapsulation Facility is Commissioned for GMP Manufacture

SILVER SPRING, Md., April 25, 2016 (GLOBE NEWSWIRE) -- PharmaCyte Biotech, Inc. (OTCQB:PMCB), a clinical stage biotechnology company focused on developing targeted treatments for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box[®], today reported that the encapsulation facility for its pancreatic cancer therapy is ready to manufacture PharmaCyte's biologic product under current Good Manufacturing Practices (GMP) standards. The facility will be used to encapsulate the live cells used for PharmaCyte's pancreatic cancer therapy. The assessment was issued by Chamow & Associates, the biopharmaceutical consulting firm that specializes in the inspection of facilities for GMP compliance.

Dr. Steven Chamow of Chamow & Associates stated, "Use of the live-cell encapsulation technology is very complex with many manufacturing steps and processes. GMP readiness of a biologic manufacturing facility such as the Bangkok site is no exception. In a relatively short period of time, with the relentless and determined cooperation we received from Austrianova, the facility is ready for GMP manufacture to produce the encapsulated cells that are a major part of PharmaCyte's pancreatic cancer therapy."

PharmaCyte Biotech's Chief Executive Officer, Kenneth L. Waggoner, commented, "We are delighted to announce this exciting milestone in the development of our therapy for pancreatic cancer. This is a major step in generating the overall Chemistry, Manufacturing and Controls (CMC) information, which makes up a large part of the pre-IND package we will be submitting to the U.S. Food and Drug Administration (FDA). We would like to thank Chamow & Associates and Austrianova for completing this process. With the facility ready for cGMP manufacture, we are now in a position to engage with the FDA to discuss our clinical investigational plan and initiate our first clinical trial."

Over the last few months, following an initial on-site audit of the facility by Chamow & Associates, numerous detailed documents were required to be prepared, reviewed and approved by Chamow. These documents include the quality management system manual and a variety of facility-related standard operating procedures (SOPs). In addition, all facility-related equipment has successfully completed the necessary Installation Qualifications (IQ) and Operational Qualifications (OQ).

Dr. Brian Salmons, the Chief Executive Officer of Austrianova, said, "We are exceedingly pleased that we were able to have our unique state-of-the-art live-cell encapsulation facility assessed as ready for GMP manufacture by Chamow & Associates. Both of the teams from Austrianova and Chamow worked together seamlessly and virtually nonstop to ensure that the facility is ready for GMP manufacture of PharmaCyte's biologic product. We did so to enable PharmaCyte to reach the clinic with its novel therapy for pancreatic cancer at the

earliest opportunity."

The Austrianova facility will be used to encapsulate the genetically engineered live human cells that, together with low doses of the cancer prodrug ifosfamide, make up PharmaCyte's pancreatic cancer therapy. PharmaCyte's cancer therapy attacks the pancreas tumor with "targeted chemotherapy," resulting in significant tumor shrinkage, the ability to convert some tumors from inoperable to operable, a reduction in the pain associated with the disease and an improvement to a patient's overall quality of life.

PharmaCyte's upcoming clinical trial in advanced inoperable pancreatic cancer involves placing the genetically modified live cells near the blood supply to the pancreas. The cancer prodrug ifosfamide is then given at one-third the normal dose. The prodrug is converted to its active form at the site of the tumor. In an earlier Phase 1/2 clinical trial, this "targeted chemotherapy" demonstrated far greater efficacy than the then "gold-standard" of care with no meaningful side-effects from the chemotherapy. Patients enrolled in PharmaCyte's clinical trial will have non-metastatic, locally advanced and inoperable pancreatic cancer. They will be eligible for the trial if their tumors are either stable or progressing after 4-6 cycles of treatment with either of the two most commonly used chemotherapies for these cancers - the two-drug combination of Abraxane[®] plus gemcitabine or the four-drug combination known as FOLFIRINOX. PharmaCyte's therapy will be compared in such patients with the current "standard of care," which consists of the combination of the anticancer drug capecitabine plus radiation.

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage biotechnology company focused on developing and preparing to commercialize treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®". This unique and patented technology will be used as a platform upon which treatments for several types of cancer and diabetes are being developed. PharmaCyte's treatment for cancer involves encapsulating genetically modified live cells that convert an inactive chemotherapy drug (ifosfamide) into its active or "cancer-killing" form. The encapsulated live cells are placed as close to a cancerous tumor as possible. Once implanted in a patient, ifosfamide is given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated live cells have been placed. When the ifosfamide, which is normally activated in the liver, comes in contact with the encapsulated live cells, activation of the chemotherapy drug takes place at the source of the cancer without any side effects from the chemotherapy. This "targeted chemotherapy" has proven remarkably effective and safe to use in past clinical trials.

In addition to developing a novel treatment for cancer, PharmaCyte is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. PharmaCyte plans to encapsulate 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.

Safe Harbor

This press release may contain forward-looking statements regarding PharmaCyte and its future events and results that involve inherent risks and uncertainties. The words "anticipate", "believe", "estimate", "expect", "intend", "plan" and similar expressions, as they

relate to PharmaCyte or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of PharmaCyte, could cause actual results to differ materially from those set forth in the forward-looking statements. They include PharmaCyte's ability to continue as a going concern, delays or unsuccessful results in preclinical and clinical trials, flaws or defects regarding its product candidates, changes in relevant legislation or regulatory requirements, uncertainty of protection of PharmaCyte's intellectual property and PharmaCyte's continued ability to raise capital. PharmaCyte does not assume any obligation to update any of these forward-looking statements.

More information about PharmaCyte Biotech can be found at<u>www.PharmaCyte.com</u>. It can also be obtained by contacting Investor Relations.

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