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## PharmaCyte Biotech Updates Progress of cGMP Facility for the Production of Cell-in-a-Box for Clinical Trials

SILVER SPRING, Md., Aug. 06, 2015 (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<sup>®</sup>, announced an update on the progress of completing the certification of Austrianova's cGMP (current Good Manufacturing Practices-compliant) facility in the Thai Science Park in Bangkok, Thailand. This is the facility that will encapsulate genetically modified human cells in the Cell-in-a-Box<sup>®</sup> capsules PharmaCyte Biotech will use in its clinical trials in both cancer and diabetes.

Austrianova is in the process of completing installation qualification, operational qualification and performance qualification on each of the machines required for the manufacturing process and cleanroom at the cGMP facility. After completion, Austrianova will need to carry out the engineering or "shake-down" runs at the facility, which will involve running through the production process and generating data on the qualified equipment. These tests are required before the facility can pass inspection by drug regulatory authorities.

Prof. Walter H. Günzburg, Chief Technical Officer at Austrianova, said of the current cGMP process, "Depending on how the engineering runs go, we may have to do two or three runs. The data generated will be used to set the 'Specifications' that will be used for the cGMP encapsulation process. Then we will have to carry out three 'Validation Runs' which we refer to as production runs. The data from all three runs need to meet the Specifications. If one of these runs does not meet the predefined Specifications, cGMP regulations require us to carry on doing runs until at least three consecutive runs meet the Specifications."

He continued, "In parallel with this, two new staff, including a head of quality control, have recently joined our team. In addition, we are completing our Quality Documentation on all aspects of the machinery used in the facility, the environment within it, operations conducted and the encapsulation process itself, as well as on materials used in the facility, finished goods produced, cleaning procedures, personnel who will work in the facility, etc. To enable this process to be completed to international standards, we have arranged for an on site inspection by a former-World Health Organization (WHO) cGMP inspector. Her findings will give us guidance on which parts, if any, of the Quality System may require additional fine-tuning."

PharmaCyte Biotech's Chief Executive Officer, Kenneth L. Waggoner, commented on the progress of Austrianova, "The very laborious, rigorous and intensive procedures that are necessary to have a facility such as the encapsulation facility in Bangkok deemed 'cGMP-compliant' are proceeding well on all fronts. Our colleagues at Austrianova are working exceedingly hard to ensure that the facility passes inspection by regulatory authorities in as

timely a fashion as possible. We are confident that this entire process is in very good hands.”

## **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<sup>®</sup>.” This unique and patented technology will be used as a platform upon which treatments for several types of cancer, including advanced, inoperable pancreatic cancer and its related symptoms, as well as diabetes are being developed.

PharmaCyte Biotech’s treatment for pancreatic cancer involves encapsulating genetically modified human cells that convert the prodrug ifosfamide into its active or “cancer-killing” form. These encapsulated live cells are placed as close to the tumor as possible to enable the delivery of the highest levels of the cancer-killing drug at the source of the cancer. Ifosfamide is then given intravenously at one-third the normal dose to eliminate the side effects normally associated with chemotherapy. When the ifosfamide comes in contact with the encapsulated live cells through the circulatory system, the activation of ifosfamide takes place at or near the tumor. This “targeted chemotherapy” has proven remarkably effective and safe to use in past clinical trials.

PharmaCyte Biotech is also developing treatments for cancer based upon the encapsulation of chemical constituents of the *Cannabis* plant. It is examining ways to exploit the benefits of the Cell-in-a-Box<sup>®</sup> technology in optimizing the anticancer effectiveness of *Cannabis*, while at the same time minimizing or outright eliminating the debilitating side effects often associated with cancer treatments.

In addition to developing treatments for pancreatic and other cancers, PharmaCyte Biotech is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. PharmaCyte Biotech plans to encapsulate a human cell line which has been genetically engineered to produce, store and secrete insulin on demand at levels in proportion to the levels of blood sugar in the human body. The encapsulation of the insulin producing live cells will be done using the Cell-in-a-Box<sup>®</sup> technology.

## **Safe Harbor**

This press release may contain forward-looking statements regarding PharmaCyte Biotech 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 Biotech or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of PharmaCyte Biotech, 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 Biotech’s intellectual property and PharmaCyte Biotech’s continued ability to raise capital. PharmaCyte Biotech does not assume any obligation to update any of these forward-looking statements.

More information about PharmaCyte Biotech can be found at [www.PharmaCyte.com](http://www.PharmaCyte.com). It can

also be obtained by contacting Investor Relations.

Investor Relations:  
PharmaCyte Biotech, Inc.  
Investor Relations Department  
Telephone: 917.595.2856  
Email: [Info@PharmaCyte.com](mailto:Info@PharmaCyte.com)



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