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PharmaCyte Biotech's CEO Explains How New Clinical Trial Design Changed the GMP Certification Process

NEW YORK, NY -- (Marketwired) -- 04/06/16 -- PharmaCyte Biotech (OTCQB: PMCB) expects to begin its clinical trial in advanced pancreatic cancer in 2016; however, locking down an exact date has been a challenge given the company dramatically changed course with its clinical trial design. While the new trial design offers PharmaCyte a much better shot at success with FDA and EMA approval, it has also been an exercise in patience for the company's leadership and its shareholders.

After visiting Austrianova's live-cell encapsulation facility in the Thai Science Park, we were impressed with all of the work being done to outfit a "one-of-a-kind" state of the art manufacturing facility, which at that time was being made GMP-compliant for a clinical trial to be held solely in Australia and to meet the guidelines of that country's drug regulatory agency -- the Therapeutic Goods Administration or TGA. In fact, the Thai facility where PharmaCyte's signature live-cell encapsulation technology, Cell-in-a-Box®, and the live cells contained inside that make up the company's pancreatic cancer therapy, would have been ready for a clinical trial to begin in Australia months ago using the old trial design.

But, as Kenneth L. Waggoner, the Chief Executive Officer of PharmaCyte, tells us, moving the clinical trial to the United States with sites in Europe meant that Austrianova's facility had to now comply with the far more stringent regulations of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

"I don't think most people are aware that our change in trial design also led to a change in GMP requirements at Austrianova's facility. When we changed our clinical trial design to meet what our 'world-renowned' oncologists felt was a therapy that can address a critical unmet medical need for pancreatic cancer patients, we moved the trial and trial sites predominantly to the U.S. so that Translational Drug Development (TD2) could head up the trial and do so under the watchful eyes of the FDA and EMA. Of course, this meant that Austrianova would now have to complete a great deal more documentation and processes than required by the TGA to comply with the GMP requirements of these two new regulatory agencies.

"There has been an incredible amount of work that has gone on at Austrianova's facility since Chamow & Associates visited in December 2015, and we're confident that we are getting close to announcing the facility is GMP-compliant. Getting the facility ready to conduct a clinical trial in the United States with a few study sites in Europe versus in Australia alone, has required the generation of volumes of documentation and procedures. It's a slow and tedious process, but one where we'll benefit in the end. After all, this new trial design gives us the greatest shot at success where there is a real need in the pancreatic cancer community for an effective therapy when the 'gold-standard' no longer works. So,

while it may be an exercise in patience on this side of the clinical trial, we feel that the advantages of the new trial design and the addition of TD2 as our lead CRO with most of the trial sites in the U.S. give us a real shot at getting our therapy approved."

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