

PharmaCyte Biotech Discusses Importance of Shrinking Pancreatic Cancer Tumors in Latest Q&A Series

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- [PharmaCyte Biotech, Inc.](#) (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature [live-cell encapsulation technology, Cell-in-a-Box®](#), today announced the latest in a series of Q&A articles that PharmaCyte conducts with some of the key team members of PharmaCyte's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC). Dr. Matthias Löhr, of the famed Karolinska Institute in Stockholm, Sweden, answers a host of questions related to PharmaCyte's upcoming clinical trial design. Dr. Löhr is the Chairman of PharmaCyte's Scientific Advisory Board, and he was the Principal Investigator of the two earlier clinical trials using the Cell-in-a-Box® technology in patients with advanced metastatic pancreatic cancer.

1. What are your impressions of PharmaCyte's final clinical trial design?

"When we as a team finalized this clinical trial design, the study design had to take into account the unmet medical need for patients with locally advanced pancreatic cancer that is both non-metastatic and inoperable and who have realized maximum antitumor response after undergoing first-line chemotherapy of Abraxane® plus gemcitabine or FOLFIRINOX. There are currently no effective treatment options for this patient population after first-line therapy. The study with comparator groups in our case reflects the state-of-the-art trial design as a true randomized controlled trial."

2. How do you feel this design can lend to PharmaCyte's success in the clinic?

"Success is not a given, but PharmaCyte's trial design plays to the advantage of the strengths of PharmaCyte's therapy perfectly with the selected patient population: local therapy and targeted delivery with the potential for an immunological effect systemically with virtually no side effects. It is foreseeable that the quality of life will be excellent in this group, from all we know from the two previous clinical trials.

"In the earlier Phase 1/2 clinical trial, the technology performed admirably with a population of patients that were in the final stages of the disease and of their lives, and we still managed to see a reduction in the size of advanced-stage tumors to the point where they would have been operable in 3 out of 14 patients (21.4%) in the Phase 1/2 trial. So, it is our feeling that with an improved technology, a better trial design, which includes more doses of the anticancer drug ifosfamide, and a better patient population (healthier to begin with than in the Phase 1/2 trial) that we can dramatically improve upon the statistics realized in the earlier clinical trials."

3. In your answer to the previous question, you mentioned that there may be an immunological effect associated with PharmaCyte's treatment. Given that immunotherapies for cancer is a "hot" area for study at the present time, how will we get data that shows PharmaCyte's treatment has immunological effects?

"One of the things that we will do as we carry out the LAPC clinical trial is to collect samples from patients undergoing treatment. These samples will then undergo a variety of tests to determine whether or not changes in the immunological system occur as the patients are treated. If changes are detected, just what they mean and exactly how they occur remains to be seen."

4. Explain more about what you were able to see in the earlier trials that you were involved with, and given what you know now about this design and an improved Cell-in-a-Box[®] technology, how can this trial potentially show more success?

"After just two rounds of low-dose ifosfamide treatment, we saw a significant effect on the tumor and hence, an improved survival (33% vs. 10% one-year survival when compared to a historical control group – gemcitabine, the standard of care at the time) together with an effect on remote liver metastasis. The quality of life was excellent. No side effects of the chemotherapy were recorded. The product (Cell-in-a-Box[®]) is now superior to the original CypCaps in that the quality is much better as is the stability of the ifosfamide converting cells. We now aim to give more ifosfamide to take full advantage of the improved, longer living encapsulated cells. It is common sense to expect a better outcome with a better product and longer therapy."

5. In the upcoming planned clinical trial in LAPC, PharmaCyte expects to address the critical unmet medical need for these pancreatic cancer patients you're speaking about by reducing the size of their tumor with reduced side effects. In your experience, what is the significance of these two things given the poor one-year and five-year survival rates of patients diagnosed with pancreatic cancer?

"This therapy has the potential to render patients suitable for surgery - resection of the pancreatic tumor. For all we know, those who could be operated on have a much better chance at survival compared to those where the primary tumor mass in the pancreas remains. This would be a fantastic outcome, if possible. In addition, offering chemotherapy for pancreatic cancer with practically no side effects would also represent a major advantage for these patients in terms of quality of life."

6. Isn't this what can really set PharmaCyte apart and advance this treatment being able to shrink tumors to the point of resectability?

"Yes indeed. If we are again successful in shrinking the size of the tumors in some of the patients in PharmaCyte's upcoming planned clinical trial like we were in earlier clinical trials, then we will be in a position to potentially offer surgery to remove the tumor in those patients. This is an area where PharmaCyte can dramatically address an unmet medical need by offering real hope to patients in this population that hasn't had any hope beyond the success of the first-line therapy."

7. Many people still ask why PharmaCyte switched to LAPC for the Phase 2b trial

instead of going head-to-head with Abraxane[®] plus gemcitabine or FOLFIRINOX as first-line treatment for advanced metastatic disease since the median survival and percentage of one-year survivors was nearly equivalent to those seen with today's standards of care for advanced disease, and additionally, the standards of care has significant side effects associated with them but with CapCells plus low-dose ifosfamide did not. With this in mind, can you give a reason for PharmaCyte switching the Phase 2b trial to LAPC?

“There are several reasons why PharmaCyte chose not to go head-to-head with Abraxane[®] plus gemcitabine or FOLFIRINOX as first-line treatment for advanced metastatic pancreatic cancer. One of the most obvious is a financial one. As to the pivotal trial where Abraxane[®] plus gemcitabine was compared head-to-head with gemcitabine alone, in the results reported in 2013, that trial needed about 850 patients for Abraxane[®] plus gemcitabine to show significant superiority (to the FDA) over gemcitabine. A trial that large would have been very expensive and most likely well beyond the capability of a company the size of PharmaCyte to pay for. PharmaCyte's trial may have had to be even larger than 850 patients.

“However, with LAPC, the Company has a unique opportunity to fulfill a clear unmet medical need and, if the Company's treatment can result in some patients having their tumors shrink in size to the point of going from inoperable to operable and their tumors can then be removed, these patients may see years and not just a few months added to their lives. Just think what this could mean to these patients and possible fast track approval by the FDA.”

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage 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 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, store and release insulin in response to the levels of blood sugar in the human body and/or beta

islet cells. 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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This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement because of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements due to the impact of numerous risk factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

More information about PharmaCyte Biotech can be found at www.PharmaCyte.com. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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Investor Relations:

PharmaCyte Biotech, Inc.

Dr. Gerald W. Crabtree, 917.595.2856

Investor Relations Department

Info@PharmaCyte.com

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