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# PharmaCyte Discusses Pancreatic Cancer Clinical Trial with Medpace's Medical Monitor Dr. Lyon Gleich

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a biotechnology company focused on developing targeted treatments for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, released an interview with Lyon Gleich, M.D., of Medpace, a global full-service clinical contract research organization (CRO). Dr. Gleich serves as the Medical Monitor and key team member of PharmaCyte's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

Dr. Gleich is Vice President, Medical Oncology, at Medpace headquartered in Cincinnati, Ohio. Dr. Gleich has provided medical leadership over oncology trials at Medpace for nearly 15 years. He has extensive expertise in new drug development in oncology—specifically, pancreatic cancer.

**Why is Medpace well suited to conduct PharmaCyte's clinical trial in locally advanced, non-metastatic, inoperable pancreatic cancer?**

**Dr. Lyon Gleich:** "Medpace is experienced in managing oncology trials of new molecular entities for our biotech partners and our full-service, scientific-model aligns well with innovative companies such as PharmaCyte. Oncology is a clear and well-established focus of Medpace with multiple recent trials in pancreatic cancer. We have strong relationships with oncology sites and site investigators who will help us recruit the best site investigators for this trial. This will also provide patients access to the trial by having multiple sites throughout the United States. Medpace will work with the Principle Investigator and site investigators to maximize their regional referral networks, as well as to support recruitment for PharmaCyte's study.

"Conducting a pancreatic cancer study is not like managing a study in more benign conditions, where you can advertise for patients. Working with established cancer centers of excellence that have access to pancreatic cancer patients will be critical to the trial's success. Our relationships with these sites and site investigators, as well as our processes, will enable us to support the site relationships while making sure that the data quality is high and that the trial is run correctly. Medpace will also support the site's recruitment efforts and trial management to make it as easy as possible for each site and its patients to participate in the trial."

**What is unique about PharmaCyte's signature live-cell encapsulation technology, Cell-in-a-Box®?**

**Dr. Lyon Gleich:** “Given the severe mortality rate associated with pancreatic cancer as well as the morbidity of the locally advanced disease, we are eager to work with PharmaCyte to advance their live-cell encapsulation therapy that can potentially improve local morbidity as well as impact survival for patients suffering from this aggressive disease. The Cell-in-a-Box or ‘CypCaps’ capsules that are implanted into each patient will activate the chemotherapy agent ifosfamide in the pancreatic tumor bed specifically, which will permit an infusion of only a low dose of the chemotherapeutic agent PharmaCyte uses for its pancreatic cancer therapy. This is a novel way to take an older and effective chemotherapeutic product and make it even more efficacious. PharmaCyte’s therapy offers LAPC patients a drug with proven anti-cancer activity that is delivered locally to their advanced cancer.

“The CypCaps will require angiographic administration into the pancreatic cancer feeding vessel. Medpace will train each trial site regarding the implantation of the capsules into the patient to ensure proper and consistent methodologies across the study. This will help ensure that the implantation is done without any adverse events and maximize the potential for efficacy of the chemotherapy agent ifosfamide.”

**What are your thoughts about PharmaCyte and Medpace teaming up with well-known and respected pancreatic cancer experts such as Dr. Manuel Hidalgo?**

**Dr. Lyon Gleich:** “PharmaCyte and the experience of Medpace with pancreatic cancer experts will be key to driving success in this trial. It is important to have the support of the thought leaders in pancreatic cancer that have already been involved with PharmaCyte so that the best sites are recruiting appropriate patients for the study and the quality of the CypCaps administration is done consistently.

“Manuel Hidalgo, M.D., of Beth Israel Deaconess Medical Center, is the Principal Investigator and a well-known expert in pancreatic cancer with whom Medpace is experienced. This is an excellent example of teaming and collaborating with the best resources in treating pancreatic cancer.”

**How do the CRO and the PI work together during clinical trials?**

**Dr. Lyon Gleich:** “Medpace works to be as supportive and transparent as possible with the Principle Investigator and the site investigators alike. This includes providing training on all protocol procedures and helping sites understand the purpose and details of the study to present it accurately to potential patients. Medpace physicians and staff are readily available to the sites to support and answer trial-related questions and concerns, and thereby help continuously with enrollment and patient treatment in accordance with the protocol. Of course, one of our main responsibilities is also site monitoring to ensure that data is entered in a timely manner and supported at all times by proper site documentation to support any future applications for Marketing Authorization.”

**What are some of the biggest challenges you anticipate and are planning for in this trial?**

**Dr. Lyon Gleich:** “Any trial in pancreatic cancer is a difficult trial because of the severity and morbidity of the disease. Many patients enrolled in these studies, even if they have a

good performance status and high activity level, are patients with advanced cancer with a very high mortality rate. Patients can turn the corner at any moment, in a very negative way, in terms of having a severe worsening of their disease such as an increase in ascites, a blockage of their biliary duct, and even in some cases, a quick descent to death. This is a huge hurdle for any trial in pancreatic cancer. Even during the couple of weeks during the screening period, LAPC patients can see a rapid progression of the disease and are no longer able to respond to any therapy.

“In this trial, we are hopeful that we won’t experience too much of that. The trial is designed for patients with locally advanced non-metastatic unresectable pancreatic cancer. Many patients with pancreatic cancer do have metastatic disease, meaning the spread of the cancer elsewhere in the body, not just a locally advanced disease. This therapy won’t offer a benefit to those patients and is designed for the non-metastatic locally advanced patient. We need to find locally advanced patients without metastases who still have an acceptable performance status and haven’t, so to speak, gone over the precipice where the disease takes off in a way that therapies can no longer help.

“The support of the patients by the treating physicians, their teams and nurses are key to this. Medpace will work closely with PharmaCyte to provide support and education to the teams so that they can provide that needed support and education to the patients to help them through this terrible disease.

“Based on Medpace’s experience in trials with pancreatic cancer and our experience in working with sites in similar difficult studies for late stage advanced pancreatic cancer, we are well positioned to know what the sites expect from us regarding support. Through this important trial, our hope is being able to advance the treatment of pancreatic cancer, which is greatly needed.”

**About Medpace**

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical, and medical device industries. The mission of Medpace is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

**About PharmaCyte Biotech**

PharmaCyte Biotech 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 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. The cell lines being studied are human liver cells, stem cells and 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 are designed to function as a “bio-artificial pancreas” for purposes of insulin production.

**Safe Harbor**

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that express the current beliefs and expectations of the management of PharmaCyte, including statements regarding the timing and commencement of our planned Phase 2b clinical trial in LAPC. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. Factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof, and we undertake no obligation to update or revise the forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

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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