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PharmaCyte Biotech engages cGMP validation to assist in preparation of IND for Pancreatic Cancer Trial

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PharmaCyte Biotech, a biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box has announced that it has engaged cGMP Validation L.L.C. (cGMP Validation) to assist in the preparation of the Investigational New Drug application (IND) that must be submitted to and approved by the U.S. Food and Drug Administration (FDA) before PharmaCyte can begin its planned clinical trial in patients with locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC).

cGMP Validation is playing a pivotal role for PharmaCyte and will continue to do so as it moves forward with the preparation of its IND. The role of cGMP Validation and its President and Chief Executive Officer, Jesse Gillikin, in particular, is to ensure that each and every step of the manufacturing process of PharmaCyte's encapsulated cells completely complies with the FDA's cGMP regulations and all other FDA requirements requested by the U.S. drug regulatory agency. In addition to ensuring that PharmaCyte's clinical trial product meets regulatory compliance throughout the production process, cGMP Validation will also serve as a resource to Austrianova in its manufacturing process related to cGMP requirements with which it must adhere. For example, cGMP Validation will examine cGMP required documents prepared by Austrianova that concern all "production runs" of the manufacturing process and work with Austrianova to ensure compliance in every respect.

cGMP Validation will also serve, on behalf of PharmaCyte, as the agent for the "release" of the final product that will be implanted into patients before the chemotherapy prodrug ifosfamide is given during the planned clinical trial in LAPC.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commented, "We are extremely fortunate to have been able to retain cGMP Validation as our outside cGMP compliance/validation expert and to have Mr. Gillikin work directly with us and the principals at Austrianova to make certain that the very important manufacturing portion of our IND is complete and compliant with the FDA's stringent cGMP regulations.

As I mentioned in an interview last summer, we're almost there. Our checklist of items to be completed has been whittled down to just a few remaining items, and cGMP Validation provides us with the confidence moving forward to get across the finish line. It is imperative that our submission of the IND to the FDA is done flawlessly; therefore, cGMP Validation's efforts will play a major role in ensuring that the IND we plan to submit to the FDA is as complete and accurate as possible."

cGMP Validation was established in 1997 as a full-service validation/compliance firm offering services for the pharmaceutical, biotechnology, biologics, medical device and medical diagnostic sectors. It has served new and repeat clients across the U.S., Puerto Rico and Canada and has international experience in Europe, Egypt, Korea, Indonesia and Vietnam. cGMP is headquartered in North Carolina, and it has an operational office in Missouri.

Mr. Gillikin is a co-founder of cGMP Validation and serves as its President and Chief Executive Officer. He has been in the pharmaceutical industry since 1978 and has experience in validation, managing QC laboratories, field auditing, and compliance, including interactions with the FDA and international regulatory agencies. His experience has included working with numerous companies in establishing validation and compliance practices. Mr. Gillikin's experience enables him to provide clients with a wide array of validation resources, such as manufacturing equipment validation, process validation, cleaning validation and computer validation. His extensive work with other companies, as well as his long-standing relationship and experience with the FDA, also enables him to provide auditing, compliance/validation program building and the writing/execution of validation protocols.

Because of the intense efforts that PharmaCyte, cGMP Validation, and PharmaCyte's clinical team of consultants are currently engaged in with respect to the preparation of the IND, as well as difficulty in coordinating and scheduling travel with everyone involved during the holiday season, PharmaCyte has decided to postpone its planned shareholder meeting until the first quarter of 2019.