



Press Release
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OrganaBio launches decentralized support division for vaccine and cell and gene therapy clinical trials

Miami, Florida, US, October 9, 2023 - OrganaBio, the Contract Technology Development and Manufacturing Organization (CTDMO) specializing in solutions for cell and immunotherapy development, today announces the official launch of Cell Processing and Cryopreservation (CPC) Services, a new division of OrganaBio. CPC Services has been specifically developed to provide decentralized clinical trial support, including timely sample processing and data capture that are essential to accurately gauge the outcomes of clinical trials.

The number of vaccine clinical trials has grown in recent years, considerably increased by the response to the SARS-COV-2 global pandemic and subsequent recent increases in cases of influenza and respiratory syncytial virus (RSV). Currently, contract research organizations (CROs) are able to support this increased level of vaccine trials by obtaining clinical trial subject's blood at specified time points. However, there is still a lack of organizations with the capacity to support the full range of trial sponsor needs in collecting and processing participant samples. This includes sample processing to isolate cells of interest and cryopreservation capabilities, a critical intermediate manufacturing step. Cell isolation and cryopreservation often needs to be completed within the critical timeframe from collection, typically four to six hours. If this is not achieved, the risk of data and trial outcomes being inadvertently affected by undesirable phenotypic and functional changes is considerably increased.

There is also a growing and increasingly unmet requirement for rapid cryopreservation of apheresis material for the continually growing number of autologous cell and gene therapy trials. Many hospitals, cancer centers, clinical sites, and other translational centers included in Cell and Gene Therapy (CGT) product administration and patient apheresis currently lack cryopreservation capabilities, and pharmaceutical and CGT companies have limited bandwidth and resources to support these efforts in house. In addition, the transport of patient apheresis material to a central processing lab for cryopreservation and subsequent transport back to the hospital/cancer/treatment center introduces significant logistical challenges and risk of loss of patient material.

As a result of this demand from CGT and vaccine clinical development, OrganaBio has launched its CPC Services division to offer decentralized cell processing and cryopreservation services co-located to hospitals, cancer centers, and CGT healthcare facilities across the US. OrganaBio has, for the last 18 months, initially run an early access program to deliver these services to select multi-national big pharma partners, including the world's pre-eminent mRNA vaccine developer. Demand from these partners within the early access program has continued to grow with additional need anticipated in coming years. As a result, OrganaBio has launched CPC Services as a formalized division of the company to provide support to clinical trial sites across the wider biopharma sector. The CPC Services division will be initially focused on supporting clinical trials based in the US, but OrganaBio may expand the service internationally in a second phase when there is increased international market demand.

OrganaBio has invested significant resources in CPC Services to provide decentralized processing across the US, including in facilities and capital equipment. Justin Irizarry, CEO of OrganaBio and Dr. Priya Baraniak, CBO will oversee CPC Services, with dedicated project managers assigned to the department. Staffing numbers will continue to grow in line with the department.

"OrganaBio continually seeks to expand its CTDMO capabilities to support the development of therapies by providing solutions where they are required across the sector. OrganaBio's product and services portfolio now serves a therapy's entire development lifecycle," said Justin Irizarry, CEO, OrganaBio. "The continued demand for, and growth of, vaccine and CGT trials has led to areas where the market's ability to support these trials has fallen behind. This risks delays to the delivery of vital therapies to patients. This is why OrganaBio has and will continue to invest considerably in the launch of CPC Services to provide decentralized clinical trial support initially across the US, following the success of its early access program to select large pharma partners. OrganaBio hopes, as a result, to provide vital decentralized support to vaccine and CGT trials across the US and affect materially the delivery of a range of therapies to patients internationally."

About OrganaBio

OrganaBio is a robust and reliable biotech solutions provider for cell therapy and immunotherapy developers. OrganaBio has opened doors to a new Contract Technology Development and Manufacturing Organization (CTDMO) paradigm that involves a passionate commitment to ethically accelerating the deployment of cell therapies through making accessible critical resources that are essential for therapeutics development. The company's products and services span the full development lifecycle – from proprietary tissue supply chains (birth tissues and apheresis products) and cellular starting materials (e.g. MSCs (Mesenchymal Stromal Cells), PBMCs (Peripheral Blood Mononuclear Cells), HSCs (Hematopoietic Stem Cells), NK (Natural Killer) cells, T cells, etc.) to expert development, testing, and other support services that expedite the path to clinical translation within its state-of-the-art, ready-to-use cGMP (current Good Manufacturing Practices) manufacturing facility, enabling the rapid and economical manufacture of clinical materials.

OrganaBio believes in a paradigm where new CTDMO partnerships are needed to support a variety of organizations with a common mindset – one to accelerate the deployment of advanced therapies from its pre-clinical stages to scaling up towards global commercialization. OrganaBio's commitment to provide access to these critical resources essential for therapeutic development ensures its partners are given the flexibility and agility to significantly reduce manufacturing cost and timelines through its best-in-class donor management practices and tissue collection facilities. OrganaBio remains committed to a culture of ethically sourcing raw materials from healthy donors, fully consented under IRB (Institutional Review Board)-approved protocols and in accordance with US (United States) FDA (Food and Drug Administration) standards. More about OrganaBio and CPC Services can be found at www.organabio.com and www.cpcservices.com.