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OrganaBio Manufactures First GMP Cryopreserved Leukopaks for Two New Biopharma Partners' Allogeneic Cell Therapies

- **OrganaBio began cryopreservation of clinical-grade leukopaks for two new clinical-stage cell therapy partners following many successful regulatory and client audits and inspections of its Miami GMP facility and leukapheresis operations**
- **cGMP-grade cryo leukopaks will allow advanced therapy companies to translate and scale preclinical work into clinical allogeneic cell therapy manufacturing, improving patient access to cell-based therapies**
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Miami, Florida, August 13, 2024 – OrganaBio, the cell and gene therapy industry's hub for tissue sourcing, cell isolation, cryopreservation and clinical sample processing, today announces two new partners that will utilize its current Good Manufacturing Practice (cGMP)-grade cryopreserved (cryo) leukopaks for clinical manufacturing of cell and cell-based therapies. Apheresis material was cryopreserved at OrganaBio's FDA-registered GMP manufacturing facility, and the cGMP cryo leukopaks are now being shipped to three partners in the United States and abroad with ongoing active studies at pre-clinical and clinical stages.

As the cell therapy space expands into new modalities, disease areas and approaches, so too are developers' requirements for starting material. Many of OrganaBio's partners are moving beyond patient-derived materials to donor-derived, allogeneic cell therapies. New technologies are needed to address nontraditional blood cancer indications like autoimmune indications, such as rarer cell types than the more established pan T cells initially used for cell-based immunotherapies. This means that long-term donor recruitment, retention and recall strategies, coupled with robust, compliant manufacturing processes, are needed to ensure that a sustainable and scalable supply of cellular starting materials will meet developers' specific needs as their programs progress through clinical trials and into the commercial realm.

"The cell and gene therapy field is in need of reliable partners for effective donor screening, selection, and recallability to transition from preclinical to clinical scale-up of ATMPs," said Justin Irizarry, CEO of OrganaBio. "Multiple biopharma companies have now found OrganaBio to be the partner of choice in order to source consistent materials for research and development use, as well as clinical manufacturing."

Three partners with allogeneic cell therapies at clinical stages – two cell therapy companies (one in the US and one in APAC) and a large cap global pharmaceutical company – are utilizing OrganaBio's cGMP cryo leukopaks to manufacture drug products for clinical trials. These partners are exploring autoimmune disease and solid tumor indications and utilizing a variety of T cell populations, including γδ T cells and iNKT cells, that are rare and found in low numbers in healthy donors. OrganaBio collects and isolates the desired advanced therapy medicinal product (ATMP) starting material from donors who were recruited and screened through its wholly owned leukapheresis business, HemaCenter.

OrganaBio has extensive experience in providing cryopreserved leukopaks to drug developers, and increasingly from its GMP facility in Miami, which has been successfully audited and inspected by regulatory agencies and clients. In April, the company launched on-demand GMP-compliant hematopoietic stem cells as a starting material for clinical manufacturing. This added to the company's existing suite of GMP isolation, manufacturing, and cryopreservation capabilities for other tissues and cells, including cord blood, placenta and cord tissue, and their derivatives.

Added Priya Baraniak, Ph.D, OrganaBio's Chief Business Officer and Laboratory Director: "Consistency is key to ensure the highest quality starting materials throughout development, which means not only utilizing the same donor pool but the same protocols and procedures for tissue collection and subsequent manufacturing and cryopreservation. With our experience and capabilities at both our Miami GMP facility and our cell processing facility in Irvine, California, OrganaBio is uniquely positioned to support the development of the next generation of cell-based therapies, which hold tremendous potential to treat more patients than ever before."

About OrganaBio
OrganaBio is a robust and reliable biotech solutions provider for cell therapy and immunotherapy developers. The company has pioneered a new paradigm for ethically accelerating the deployment of cell therapies, making critical resources that are essential for therapeutics development accessible, and marrying this to manufacturing capabilities. OrganaBio spans the full development lifecycle – from proprietary tissue supply chains and cellular starting materials to expert support services including development and testing. Its state-of-the-art, ready-to-use cGMP manufacturing facility supports the rapid, economical, and ethical manufacture of clinical materials from birth tissues, apheresis products, and their components (including HSCs, PBMCs, NK cells, T cells, and subsets of these cells).

Strategic partnerships are needed to accelerate advanced therapies from the lab to global commercialization. OrganaBio's flexibility and agility allow partners to significantly reduce manufacturing cost and timelines, with best-in-class donor management practices and tissue collection facilities. OrganaBio sources donor tissues under fully consented institutional review board (IRB)-approved protocols, and in accordance with US FDA standards. More about OrganaBio can be found at www.organabio.com.