

OrganaBio Named Translation Award Finalist for Supporting CAR-NKT Cell Therapies into Clinical Trials

- OrganaBio has developed GMP-quality supply chains and processes to ensure ample availability of donor-derived cells for clinical trials of first-in-class allogeneic CAR-NKT cell therapies
- The Translator of the Year award winner will be announced this Thursday at Phacillitate's Advanced Therapies Week

Miami, Florida, January 16, 2024 – [OrganaBio](#), the hub for tissue sourcing, cell isolation, clinical sample processing, cryopreservation, and contract manufacturing services to support cell therapy and immunotherapy development globally, has been named a Translator of the Year finalist at the upcoming Advanced Therapies Awards for its work to support a chimeric antigen receptor natural killer T-cell (CAR-NKT) therapy as it progresses into clinical trials. The new award category honors companies that help translate novel science from the lab to clinical-quality manufacturing. OrganaBio was selected after developing and refining processes to identify and isolate the number and type of cells required for manufacturing from human umbilical cord blood and adult apheresis material.

CAR therapies made from T cells have shown remarkable curative, if imperfect, results in thousands of patients with advanced B cell malignancies. Two persistent limitations have been certain resistance mechanisms and the difficulty in manufacturing these therapies at scale, but NKT cells – a rare subtype of T lymphocytes – have the potential to overcome these issues. NKT cells can be like needles in blood cell haystacks, but OrganaBio provides access to this rare population of donor-derived starting materials from its proprietary tissue supply chains.

In addition to identifying adult donors who produce high numbers of NKT cells for leukapheresis, OrganaBio also provides access to hematopoietic stem cells (HSCs) from umbilical cord blood. HSCs can be reprogrammed to a pluripotent state and then differentiated back to NKT and other immune cell lineages. OrganaBio will provide clinical-grade starting materials for four NKT cell therapy developers this year, from both its birth tissue and adult peripheral blood businesses.

To prepare for clinical trials, developers of NKT cell therapies and others need a process to isolate enough cells to manufacture therapies under current good manufacturing practices (cGMP), and to secure a sufficient supply that will scale with their program as they move from clinical trials into commercial scale manufacturing. For the project that has been recognized by Phacillitate, OrganaBio has:

- created GMP-compliant protocols for tissue procurement and isolation of the cellular starting materials
- defined processes to proactively identify peripheral blood donors and umbilical cord blood units that will yield enough cells to support clinical manufacturing
- isolated up to three times as many cells as historical manual processes

- secured access to a robust supply of GMP HSCs and GMP peripheral blood by expanding its network of donors
- provided cell bank access for development of process and product characterization assays

In total, partnering with OrganaBio has given developers' scientists sufficient volumes of critical cellular starting materials to support internal process design and manufacturing, define critical process parameters and critical quality attributes of the starting materials and final cell therapy product, and transfer these processes from the lab to cleanrooms for clinical manufacturing. The isolation protocols can also be automated and scaled to further expand throughput in support of late-stage clinical trials and commercialization.

"We are honored to have our development work recognized by Phacilitate's expert panel, drawing attention to the promise of this new wave of therapies for patients as it progresses through human testing," said Dr. Priya Baraniak, Chief Business Officer of OrganaBio. "This project demonstrates how we have developed our unrivaled expertise in the burgeoning NKT cell space, and for cell and gene therapies more broadly. We have leveraged our flexible, customer-centric approach to quickly meet the needs of several new technologies by building on fresh blood supply chains and providing a full range of services to support partners from early development through GMP-ready starting materials to enable rapid scale-up for clinical trials. In fact, we have taken one partner from research and discovery to clinical manufacturing in less than 3 years, an impressive timeline for clinical translation of a novel cell therapy."

The [Advanced Therapies Awards](#) ceremony will be held this Thursday, January 18 in Miami at Phacilitate's Advanced Therapies Week.

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 accessible critical resources that are essential for therapeutics development 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 allows partners to significantly reduce manufacturing cost and timelines, with best-in-class donor management practices and tissue collection facilities. OrganaBio sources materials 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.