



Press Release
Media Contacts:
IB Communications
Tel +44 (0)20 89434685
organabio@ibcomms.agency

OrganaBio Expands Cell and Gene Therapy Donor Base to Include Patients with Lupus, Other Autoimmune Diseases

- **OrganaBio is responding to sharply rising demand from pharmaceutical companies for donor material from patients with chronic diseases like lupus and psoriatic arthritis, to enable advanced therapies for autoimmune diseases**
- **OrganaBio is now cleared to safely collect from donors with over 200 diseases and conditions, with plans to add more to increasingly support cell therapy-relevant disease areas, including cancer**

Miami, Florida, September 17, 2024 – OrganaBio, the cell and gene therapy industry’s hub for tissue sourcing, cell isolation, cryopreservation and clinical sample processing, today announced an expansion of its cell and gene therapy (CGT) starting materials donor base to include patients with over 200 diseases and conditions, including lupus and more than a dozen of the most common autoimmune diseases. The company can now provide fresh and frozen leukopaks and cells isolated from peripheral blood to clients that require patient material to develop chimeric antigen receptor (CAR)-T cell and other cellular therapies for autoimmune conditions, a fast-growing sector of the advanced therapies market.

Following the publication of groundbreaking clinical results earlier this year¹, excitement is building for the potential of CGTs, like CAR-T, for autoimmune diseases like systemic lupus erythematosus (SLE), systemic sclerosis, and idiopathic inflammatory myositis. Commercial CAR-T therapies have been proven to be curative for patients with blood cancers, and drugmakers have been eager to replicate that success in other areas. Until now, however, developers have largely been limited to development with material from healthy donors, which can differ from cells impacted by autoimmune diseases.

“Interest from major pharmaceutical companies has skyrocketed for material donated by patients with autoimmune diseases, who themselves are often eager to contribute to potential cures for diseases like theirs,” said Dr. Priya Baraniak, Chief Business Officer and Laboratory Director of OrganaBio. “Safely collecting cells from patients with serious illnesses like lupus and rheumatoid arthritis will unlock the next wave of cell therapies. That’s why it is imperative that we build on this moment and expand our capabilities to include donors with other serious diseases, such as cancer.”

By safely sourcing donor material from patients with chronic autoimmune conditions, OrganaBio is addressing several challenges. This population is more likely to produce cells that behave like those of future recipients of an autologous (patient-derived) CAR-T therapy, given natural similarities such as epigenetic memory. Additionally, since different conditions can make apheresis – the process of isolating material – more complex, the company is expanding their expertise and experience with this donor population that will contribute to the development of specialized protocols that can optimize and standardize the collection process for these future patients.

Further, because of OrganaBio’s GMP manufacturing capabilities, stringent ethical framework and commitment to donor safety, donors with an autoimmune disease may also form the basis of a pool for next-generation allogeneic cell therapies, which are derived from donors instead of patients.

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 costs 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.

1. Müller F, Taubmann J, Bucci L, Wilhelm A, Bergmann C, Völkl S, et al. CD19 CAR T-Cell Therapy in Autoimmune Disease — A Case Series with Follow-up. *The New England Journal of Medicine*. 2024 Feb 22;390(8):687–700.