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**OrganaBio launches on-demand GMP-compliant hematopoietic stem cell source for advanced therapy manufacturing**

- **First commercial source of on-demand GMP CD34+ hematopoietic stem cells for clinical manufacturing in the industry**
- **OrganaBio leveraging years of in-house tissue sourcing and cell isolation experience to produce high-quality GMP-compliant cells**

**Miami, Florida, April 3, 2024** – **OrganaBio**, the cell and gene therapy industry's hub for tissue sourcing, cell isolation, cryopreservation, contract manufacturing services, and clinical sample processing, today announced the launch of HematoPAC™-HSC-CB-GMP, on-demand current good manufacturing practice (cGMP)-compliant CD34+ hematopoietic stem cells (HSCs) ethically derived from fresh human cord blood. The new product relies on OrganaBio's experience in cell isolation and GMP manufacturing to rapidly produce exceptional yields of highly viable CD34+ HSC cells for use in the development of next-generation cell therapies.

HSCs have long been used to treat blood cancers and have more recently been deployed in gene therapies for blood disorders, such as sickle cell disease and beta thalassemia. HSCs are in increasing demand for cutting-edge advanced therapies since they are the progenitor cell for blood cells, including immune cells. They are promising for the next generation of therapies that have proven difficult to scale, such as therapeutics using invariant natural killer (iNKT) and γδ T cells, which are in low frequency in the body. HSCs can be readily reprogrammed into induced pluripotent stem cells (iPSCs), expanded, and differentiated into iNKT, γδ T cells, and many other cell types with therapeutic potential, circumventing issues of primary cell isolation and expansion. However, HSCs are also infrequent in the blood and are challenging to collect in large numbers, especially since cell viability and function can degrade quickly if manufacturing processes are not optimized.

Leveraging over five years of cord blood collection and processing experience, OrganaBio has developed a robust and reproducible GMP manufacturing process that optimizes HSC yield and post-thaw viability and purity. The company continues to utilize its in-house tissue sourcing capabilities and manufacturing expertise to drive quality – this includes its industry-best processing time of under 24 hours to maintain high cell viability – to offer the first on-demand, GMP-compliant HSCs to the industry.

"Traditionally, acquiring GMP-compliant HSCs has been a time-consuming and complex process," said Priya Baraniak, Ph.D., Chief Business Officer of OrganaBio. "HematoPAC-HSC-CB-GMP streamlines this process by offering readily available, ethically sourced cells with unmatched processing times. This empowers researchers to focus on developing innovative cell therapies, not on securing the raw materials they need, and has the potential to expedite the development of life-saving treatments for patients with blood cancers, genetic diseases, and other conditions."

HematoPAC-HSC-CB-GMP are manufactured from cord blood collected immediately following birth from consenting, healthy donors under ethically approved protocols. OrganaBio prioritizes donor safety and ethical sourcing throughout the collection process. Key features include:

- **Rigorous donor screening:** Donors undergo comprehensive screening for infectious diseases according to US FDA regulations and eligibility determination following completion of a comprehensive FDA and AABB approved donor history questionnaire.
- **IRB-approved protocols:** All collections adhere to Institutional Review Board (IRB)-approved protocols to ensure informed consent and donor well-being.
- **Experienced OB/GYN team:** Collections are performed by a trained OB/GYN team under the purview of a Chief of Obstetrics and OrganaBio's Medical Director, ensuring safe and efficient cord blood collection. Physicians adhere to best practices for delayed cord blood clamping to ensure newborn well-being.
- **Meticulous processing:** HSCs are isolated and cryopreserved within hours of collection using best-in-class methods to maintain high cell viability and function.

HematoPAC-HSC-CB-GMP are available for purchase by qualified researchers and manufacturers and are for further manufacturing use only. These high-quality stem cells are ideal for developers of advanced therapies, including cell and gene therapies, immunotherapies, tissue engineering, and drug discovery and development. The launch of HematoPAC-HSC-CB-GMP further demonstrates OrganaBio's commitment to accelerating the development of life-saving treatments for patients in need, by providing innovative tools and resources to advance scientific discovery.

**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 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.