



FOR IMMEDIATE RELEASE

OrganaBio Launches Portfolio of Novel Perinatal Tissue-Derived Products to Spur Rapid Development of Cell and Gene Therapies

Miami, FL, USA – September 29, 2020 – OrganaBio, LLC (“OrganaBio”) announces the launch of the **MesenPAC™** and **ImmunoPAC™** product lines, designed to support translational researchers in their quest to rapidly develop next generation cell-based therapies. These products provide a unique and timely solution to critical supply chain issues that are hindering the regenerative medicine, cell therapy, gene therapy, and immunotherapy arenas.

MesenPAC mesenchymal stem/stromal cells (MSCs) and ImmunoPAC natural killer cells (NKs) are derived from full-term placenta, umbilical cord tissue, and umbilical cord blood obtained from consented, non-compensated donors under IRB approved protocols. “OrganaBio’s focus on building its proprietary supply chain ensures donors are strictly qualified, screened, and enrolled, fresh tissues are used to manufacture the company’s cells, and robust, well-characterized cell banks are created in formats that cell and gene therapy developers can readily plug into their process and product development workflows,” said Mr. Justin Irizarry, CEO.

The MesenPAC-MSC product line consists of high-volume placenta and umbilical cord MSCs isolated and manufactured under xeno-free conditions. Paired with a high-efficiency bioprocess media system and supported by process recommendations for rapid expansion, the MesenPAC system generates lot sizes in the billions of cells in a matter of days, compared to the months of cell culture necessitated by traditional MSC culture regimens. MesenPAC-MSCs are also supported by a comprehensive quality data package elucidating the critical quality attributes of each lot manufactured, including expansion potential, population doubling level, differentiation potential, immunomodulatory potential, and cytokine secretion in vitro. The initial ImmunoPAC product offering consists of NK cells isolated via positive selection from fresh umbilical cord blood. Cells demonstrate high viability and purity post-thaw. In addition, all donors are HLA typed, and this information is provided with each cell lot manufactured.

“OrganaBio’s supply chain ownership gives us the unique ability to donor match MSCs from placenta and umbilical cord, and to further pair them with donor matched immune cells. Now, researchers may test the effects of tissue of origin on cell function, without the confounding effect of donor variability. For immunotherapy developers, our 2x resolution HLA typing also allows exploration of how donor matching or mismatching, and to what degree, affects preclinical outcomes. This is especially intriguing since clinical outcomes suggest that less stringent resolution HLA matching is sufficient with the transplantation of naïve immune cells compared to those from adult peripheral blood”, said Dr. Priya Baraniak, Vice President of Corporate Development and Process and Product Development

lead for OrganaBio. “We look forward to rapidly bringing additional cell types (including hematopoietic stem cells (HSCs), T cells and B cells) that the industry urgently needs for development of allogeneic therapies to market in the coming months.”

With the launch of the MesenPAC and ImmunoPAC product lines, OrganaBio is positioned to set new industry standards in cellular raw materials for therapeutics development. “Our steadfastness in building a robust, secure supply chain, coupled with our dedication to providing translational researchers high quality products that fit their process and product development needs, and further supporting this with a cGMP manufacturing solution via our multi-tenant GMP facility, provides much needed solutions to the cell, gene, and immunotherapy arenas and will rapidly move allogeneic product development through the preclinical pipeline and into First-in-Man studies,” said Justin Irizarry.

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ABOUT ORGANABIO

OrganaBio, LLC is a privately held solutions provider for the cell, gene, and immunotherapy fields. OrganaBio has a proprietary supply chain of perinatal tissue (including cord blood and cord tissue) from non-compensated donors and offers a range of starting cellular materials from these tissues. OrganaBio manufactures off-the-shelf research grade products for allogeneic cell therapy development and is building cGMP manufacturing capabilities, with a forecasted launch in Q3 2021. OrganaBio’s state-of-the-art, multi-tenant cGMP facility will not only be used to manufacture the company’s cellular raw materials for therapeutics development but will also offer the industry cleanrooms and support services to rapidly manufacture clinical materials. This new paradigm in cGMP manufacturing affords companies flexibility and agility, significantly reducing manufacturing costs and timelines. For more information, visit www.organabio.com and follow the company on LinkedIn and twitter (@organabio).

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