

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

Germfree and Orgenesis announce asset purchase and strategic partnership intended to revolutionize cell and gene therapy through decentralized production and global accessibility

**Ormond Beach, Florida and Germantown, Maryland, April 10, 2024** - **Germfree,** a leading innovator in modular cleanroom infrastructure and services, and **Orgenesis Inc. (Nasdaq: ORGS)**, a global leader in decentralizing cell and gene therapies (CGTs), today announced an asset purchase and strategic partnership aimed at advancing Orgenesis' therapeutic programs and its suite of product development and GMP cell processing services. The collaboration's goal is to transform the production of cell and gene therapies, making these vital treatments more affordable and accessible to patients worldwide.

By combining Germfree's expertise in designing, manufacturing, and maintaining advanced manufacturing facility environments with Orgenesis' cutting-edge processes and analytical development capabilities, the partnership seeks to significantly reduce the production costs of cell and gene therapy products. The ultimate goal is to enable broader adoption of life-saving treatments.

Vered Caplan, CEO of Orgenesis, stated, "Under the agreement, Orgenesis and Germfree will join forces to co-market Orgenesis' decentralized Octomera service platform, and its Octomera Mobile Processing Units and Labs (OMPULs™) globally. The partnership marks a significant milestone in the biomanufacturing industry, as the industry begins to pivot to the paradigm-shifting distributed processing of cell and gene therapies (CGTs). Germfree will be marketing, manufacturing, and servicing OMPULs as part of its modular cleanroom fleet, enabling Orgenesis to focus on its therapeutic pipeline with an emphasis on immuno-oncology. We are delighted to work with Germfree to meet the growing demand for our platform."

Victor Miller, CFO of Orgenesis, remarked on the financial and strategic significance of the partnership, stating, "This collaboration significantly supports Orgenesis' infrastructure growth requirements while immediately providing a commercial footprint that will significantly impact market expansion opportunities for the partnership."

Carol Houts, Chief Strategy Officer at Germfree, highlighted the innovative potential of the partnership, "Our collaboration with Orgenesis transcends traditional boundaries, setting a new standard for the industry. By harnessing the power of digital workflows and advanced quality management systems, we believe that we are not just streamlining production but revolutionizing it. This partnership is expected to foster innovation, particularly in how we approach and execute cell and gene therapy manufacturing. Moreover, our joint efforts with regulatory authorities worldwide are expected to ensure that our advancements not only meet, but exceed, global standards. The synergy between Germfree and Orgenesis paves the way for a future where regulatory collaboration and digital innovation ensure that life-saving therapies are developed and delivered with high efficiency and quality."

Kevin Kyle, CEO of Germfree, shared his insights on the collaboration, "Our strategic partnership with Orgenesis is a cornerstone in the continuation of our mission to advance healthcare solutions globally. By integrating Germfree's modular cleanroom technology with Orgenesis' innovative cell and gene therapy programs, we are setting a new benchmark for efficiency and accessibility in the treatment of lifethreatening conditions. This collaboration is not just about enhancing production capabilities; it's about creating a paradigm shift in how cell therapies are developed, produced, and delivered to those in dire need. Together, we are building the foundation for a future where advanced medical treatments are no longer a privilege, but a right, accessible to everyone, everywhere."

For more information about Germfree and Orgenesis and their strategic partnership, please visit www.germfree.com and www.orgenesis.com.

## **About Germfree**

Germfree is a global leader in the design, manufacture, and maintenance of modular cleanroom environments. With decades of global expertise in serving the biopharmaceutical industry, Germfree specializes in providing advanced solutions that enhance the safety, efficiency, and sustainability of

critical healthcare manufacturing processes. Germfree is continuing to invest in cleanroom design and manufacturing solutions and is committed to providing innovative solutions, with the goal of improving patient access to critical medicines. Germfree is backed by the healthcare growth equity investor, EW Healthcare Partners. www.germfree.com

## **About Orgenesis**

Orgenesis is a global biotech company that has been committed to unlocking the potential of cell and gene therapies (CGTs) since 2012 as well as a paradigm-shifting decentralized approach to processing since 2020. This new model allows Orgenesis to bring academia, hospitals, and industry together to make these essential therapies a reality sooner rather than later. Orgenesis is focusing on advancing its CGTs toward eventual commercialization, while partnering with key industry stakeholders to provide a rapid, globally harmonized pathway for these therapies to reach and treat a larger number of patients more cost effectively and with better outcomes through great science and decentralized production.

## Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. These forward-looking statements involve substantial uncertainties and risks and are based upon our current expectations, estimates and projections and reflect our beliefs and assumptions based upon information available to us at the date of this release. We caution readers that forward-looking statements are predictions based on our current expectations about future events. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict. Our actual results, performance or achievements could differ materially from those expressed or implied by the forwardlooking statements as a result of a number of factors, including, but not limited to, our reliance on, and our ability to grow, our decentralized cell therapy platform and OMPUL business, our ability to achieve and maintain overall profitability, our ability to manage our research and development programs that are based on novel technologies, our ability to control key elements relating to the development and commercialization of therapeutic product candidates with third parties, the timing of completion of clinical trials and studies, the availability of additional data, outcomes of clinical trials of our product candidates, the potential uses and benefits of our product candidates, the sufficiency of working capital to realize our business plans and our ability to raise additional capital, the development of our decentralized cell therapy processing, our ability to further our CGT development projects, either directly or through our JV partner agreements, and to fulfill our obligations under such agreements, our license agreements with other institutions, our ability to retain key employees, our competitors developing better or cheaper alternatives to our products, risks relating to legal proceedings against us, our ability to remain listed on Nasdaq and the risks and uncertainties discussed under the heading "RISK FACTORS" in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and in our other filings with the Securities and Exchange Commission. We undertake no obligation to revise or update any forwardlooking statement for any reason.