



Press Release
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Orgenesis announces collaboration agreement with SCTbio to expand POCare sites in the Czech Republic and enhance capabilities for the production of lentivirus vectors

Germantown, Maryland, US and Prague, Czech Republic – May 18, 2023 – Orgenesis Inc. (NASDAQ: ORGS) (“Orgenesis”), a global biotech company working to unlock the full potential of cell and gene therapies (CGT) through its US-based point-of-care (POCare) services subsidiary, Morgensis LLC (“Morgensis”), has signed a collaboration agreement with **SCTbio**, a full-service contract development and manufacturing organization (CDMO) specializing in cell-based therapy and viral vectors. The goal of the collaboration is to open new point-of-care (POCare) sites within the Czech Republic and leverage SCTbio’s GMP facility for the production of lentivirus vectors to support Morgensis’ POCare worldwide customers, including use in CAR-T cell and gene therapies (CGTs).

Orgenesis’ POCare Platform, including its Orgenesis Mobile Processing Units and Labs (OMPULs), overcomes conventional processing challenges by enabling high-quality standards and sterile, scalable onsite processing of CGTs, near local hospitals and treatment facilities. The POCare centres and OMPULs are designed to shorten the implementation time of new production, while offering a more cost-effective environment and enabling local scalability.

Lentiviral vectors are part of the family of retroviral vectors and are a fundamental component of the cell therapy manufacturing process, ensuring the delivery of the therapeutic genes into the patient’s cells. SCTbio brings expertise in retroviral vector GMP production with a deep knowledge of state-of-the-art manufacturing technologies and quality control (QC) methods.

Ludek Sojka, Chief Executive Officer at SCTbio, stated, “We are looking forward to collaborating with Orgenesis. Its POCare Platform is a unique technology supporting the development of potentially breakthrough CGTs, and we recognize the great potential for utilizing long-term experience of our team and our GMP lentiviral vector manufacturing capabilities to support Orgenesis-powered breakthroughs in Central Europe and beyond.”

Vered Caplan, CEO of Orgenesis, commented, “This partnership reflects our commitment to helping bring potential breakthrough cell therapies to market in a cost-effective, high-quality and scalable manner. We look forward to teaming with SCTbio to expand our POCare CGT production services to the region, as well as leveraging their lentiviral vector production as a key element supporting our CAR-T customers in the EU.”

About SCTbio

SCTbio is a cell-based therapy and retroviruses vector CDMO spun out from SOTIO Group in 2021, led by a tight-knit team that has been through every stage of process and product development over the last decade, bringing SOTIO’s autologous cell therapies into phase III. From its 2,000 sqm facility in Central Europe, SCTbio offers personal attention through long-term manufacturing partnerships, offering strategic development and regulatory guidance alongside full services covering GMP production, testing and logistics of advanced therapy medicinal products, including genetically modified and viral vectors.

The breadth of its experience means that SCTbio delivers the highest quality collaboration through a range of services ensuring GMP compliance for the full life cycle of drug development, that include technology transfers, process development, clinical manufacturing services, fill and finish, quality control, QA/QP release, storage and logistics.

SCTbio is member of PPF Group.
To learn more, visit [SCTbio.com](https://www.sctbio.com).

About Orgenesis

Orgenesis is a global biotech company working to unlock the full potential of cell and gene therapies (CGTs) in an affordable and accessible format at the point of care. The Orgenesis POCare Platform is comprised of three enabling components: a pipeline of licensed POCare Therapeutics that are processed and produced in closed, automated POCare Technology systems across a collaborative POCare Network. Orgenesis identifies promising new therapies and leverages its POCare Platform to provide a rapid, globally harmonized pathway for these therapies to reach and treat large numbers of patients at lowered costs through efficient, scalable, and decentralized production. The POCare Network brings together

patients, doctors, industry partners, research institutes and hospitals worldwide to achieve harmonized, regulated clinical development and production of the therapies. www.orgenesis.com.

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 forward-looking statements as a result of a number of factors, including, but not limited to, our reliance on, and our ability to grow, our point-of-care 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, our ability to manage potential disruptions as a result of the COVID-19 pandemic, the sufficiency of working capital to realize our business plans and our ability to raise additional capital, the development of our POCare strategy, our trans differentiation technology as therapeutic treatment for diabetes, the technology behind our in-licensed ATMPs not functioning as expected, 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 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, 2021, and in our other filings with the Securities and Exchange Commission. We undertake no obligation to revise or update any forward-looking statement for any reason.