Orgenesis Announces Collaboration with the New York Blood Center for Tissue Collection, Processing and Biobanking U.S. Cell Therapy Development Program

GERMANTOWN, Md., Nov. 21, 2018 (GLOBE NEWSWIRE) -- Orgenesis Inc. (NASDAQ: ORGS), a developer, service provider and manufacturer of advanced cell therapies, today announced that it has entered into a collaboration agreement with the New York Blood Center (NYBC), one of the largest independent, community-based blood centers in the world. Under the agreement, NYBC will be responsible for establishing the infrastructure to collect, process, test, cryopreserve and biobank sampling materials, including liver biopsies. The samples are intended for use as source of autologous insulin producing (AIP) cells for patients that may be eligible for future clinical trials.

Orgenesis' transdifferentiation (TD) process is a platform technology with potential applications across multiple indications. The first indication the company is pursuing is for the treatment of severe diabetes following Total Pancreatectomy (TP). The Company also plans to target insulin dependent diabetes. Both of these therapies involve the use of the TD technology that transforms the patient's own liver cells into functional and physiologically glucose-responsive insulin-producing cells (IPC), with the goal of providing long-term insulin independence.

Orgenesis has invested significant time and effort in developing processes that include effective processing of liver biopsies and manufacturing of batch sizes that may be utilized for human clinical trials. Orgenesis has leveraged the expertise and technologies developed by Prof. Sarah Ferber, a global thought leader in the field of cell therapy, and inventor of the TD technology.

Professor Sarah Ferber, whom continues to head the research efforts, commented, “This agreement marks an important milestone toward initiating our US clinical activities. We have utilized human biopsy samples in a wide range of animal trials, and this agreement will now enable us to collect the biopsies from patients for potential clinical use once we receive the appropriate regulatory approvals.”

Vered Caplan, CEO of Orgenesis, noted, “We view the New York Blood Center (NYBC) as an ideal strategic partner for the expansion of our activity in the U.S. NYBC is well equipped to provide the necessary infrastructure to collect, process and biobank materials for both our diabetes program as well as for other development programs. They have well established relationships with hundreds of hospitals in the U.S., which will be valuable during both the development and the commercial phases of our programs. Moreover, this infrastructure provided by NYBC and their expert development team complements our cell
collection and processing activities for research purposes in Belgium, Israel and South Korea, where we have set up similar programs."

Beth Shaz, MD, Executive Vice President, of NYBC, commented, “We are delighted to partner with Orgenesis in advancing these disruptive cell therapies. We look forward to leveraging both our infrastructure and hospital relationships to help accelerate the path to market and are looking forward to partnering on a broad range of projects.”

**About New York Blood Center**

Founded in 1964, New York Blood Center (NYBC) is a nonprofit organization that is one of the largest independent, community-based blood centers in the world. NYBC, along with its partner organizations Community Blood Center of Kansas City, Missouri (CBC), Innovative Blood Resources (IBR), Blood Bank of Delmarva (BBD), and Rhode Island Blood Center (RIBC), collect approximately 4,000 units of blood products each day and serve local communities of more than 45 million people in the Tri-State area (NY, NJ, CT), Mid Atlantic area (PA, DE, MD), the Kansas City metropolitan area, Minnesota, Nebraska, Rhode Island, and Southern New England. NYBC and its partners also provide a wide array of transfusion-related medical services, including Comprehensive Cell Solutions, the National Center for Blood Group Genomics, the National Cord Blood Program, and the Lindsley F. Kimball Research Institute, which — among other milestones — developed the Hepatitis B vaccine and a patented solvent detergent plasma process innovating blood-purification technology worldwide.

**About Orgenesis**

Orgenesis is a vertically-integrated biopharmaceutical company with expertise and unique experience in cell therapy development and support services. Through its Israeli subsidiary, Orgenesis Ltd., Orgenesis is developing technology designed to successfully reprogram human liver cells into glucose-responsive, fully functional, Insulin Producing Cells (IPCs). Orgenesis believes that converting the diabetic patient's own tissue into insulin-producing cells has the potential to overcome the significant issues of donor shortage, cost and exposure to chronic immunosuppressive therapy associated with islet cell transplantation. Through its Masthercell Global subsidiary, a global contract development and manufacturing organization (CDMO), Orgenesis is able to deliver optimized process industrialization capacities to cell therapy organizations and speed up the arrival of their therapies onto the market. From technology selection to business modeling, GMP manufacturing, process development, and quality management, Masthercell’s teams are fully committed to helping their clients fulfill their objective of providing sustainable and affordable therapies to their patients. Masthercell operates in a validated and flexible facility located in the strategic center of Europe within the Walloon healthcare cluster, Biowin. This integrated approach supports the Company's business philosophy of advancing to clinical stage significant life-improving medical treatments. For more information, visit 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, the success of our reorganized CDMO operations, the success of our partnership with Great Point Partners, our ability to achieve and maintain overall profitability, the sufficiency of working capital to realize our business plans, the development of our transdifferentiation technology as therapeutic treatment for diabetes which could, if successful, be a cure for Type 1 Diabetes; our technology not functioning as expected; our ability to retain key employees; our ability to satisfy the rigorous regulatory requirements for new procedures; our competitors developing better or cheaper alternatives to our products 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 November 30, 2017, 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.

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