

Orgenesis Signs Master Service and Joint Venture Agreement with TheraCell Advanced Biotechnology for the Development of Cell and Gene Therapies

GERMANTOWN, Md., March 28, 2019 (GLOBE NEWSWIRE) -- [Orgenesis Inc.](#) (NASDAQ: ORGS), a developer of advanced cell therapies, manufacturer and service provider, today announced that it has entered into a Master Service and Joint Venture Agreement (the "JV") with TheraCell Advanced Biotechnology ("TheraCell"), for the clinical development and commercialization of cell and gene therapies. The JV will implement Orgenesis' point-of-care ("POCare") cell therapy strategy with a goal to bring Advanced Therapy Medicinal Products (ATMPs) to patients at the therapeutic setting by leveraging Orgenesis' and TheraCell's combined technical, regulatory and commercial expertise in Greece, Cyprus, Balkan region and Turkey.

Under the Master Service Agreement, Orgenesis will provide regulatory consultancy services, pre-clinical studies, intellectual property (IP) services including IP life cycle management, and POCare services including training and technical runs, quality management systems and operational support.

TheraCell is a regenerative biotechnology company with operations in Greece, where its laboratories and primary facilities are located. The Company focuses in the areas of autologous cell therapy and regenerative medicine.

TheraCell has extensive experience in the isolation, processing and application of adipose derived stem cells (ADSCs), as well as somatic cells and has developed a patented platform for tissue engineering and cell therapies in the areas of dermatology, chondral defects and chronic kidney injury.

Chronic Kidney Disease (CKD) is an important clinical problem with a significant socioeconomic impact affecting more than 10% of the global population, which continues to increase. Despite advances in renal replacement therapies and organ transplantation, poor quality of life for dialysis patients and long transplant waiting lists remain major concerns for nephrologists treating this condition.

ADSCs secrete a variety of biologically active cytokines, growth factors, extracellular matrix proteins and tissue remodeling enzymes that play an important role in various aspects of tissue function, repair and homeostasis. The secreted factors have demonstrated the potential to suppress local inflammation/immune responses, reduce oxidative stress, fibrosis and cell death, stimulate angiogenesis and induce the recruitment, proliferation and differentiation of endogenous stem cells.

Fotis Sakellaridis, CEO of TheraCell, commented, "We are delighted to partner with Orgenesis, as they bring extensive clinical, regulatory and manufacturing capabilities, along with unique IP that will support the development, and ultimately commercialization of this advanced cell therapy. CKD is a prevalent condition that is associated with high cardiovascular mortality and can progress towards end-stage renal diseases requiring renal replacement therapy. We look forward to collaborating with Orgenesis to advance this therapy, which holds the potential to save many lives."

Vered Caplan, CEO of Orgenesis, further noted, "TheraCell is an innovator and pioneer in the fields of cell therapy and regenerative medicine. We are pleased to partner with them on this project focused on kidney regeneration, and by our joint venture partnership, our goal is to advance this breakthrough technology through the clinic and into commercialization. ADSCs, being multipotent cells, have numerous therapeutic benefits, given their ability to self-renew and differentiate. Multiple preclinical studies have demonstrated that the administration of exogenous ADSCs holds the potential to prevent progression of renal injury and promote renal recovery. We look forward to leveraging our cell therapy platform in order to accelerate their timeline of bringing this innovative treatment to market."

About Orgenesis

Orgenesis is a biotechnology company specializing in the development, manufacturing and provision of technologies and services in the cell and gene therapy industry. The Company operates through two platforms: (i) a point-of-care ("POCare") cell therapy platform ("PT") and (ii) a Contract Development and Manufacturing Organization ("CDMO") platform conducted through its subsidiary, MaSTherCell Global. Through its PT business, the Company's aim is to further the development of Advanced Therapy Medicinal Products ("ATMPs") through collaborations and in-licensing with other pre-clinical and clinical-stage biopharmaceutical companies and research and healthcare institutes to bring such ATMPs to patients. The Company out-licenses these ATMPs through regional partners to whom it also

provides regulatory, pre-clinical and training services to support their activity in order to reach patients in a point-of-care hospital setting. Through the Company's CDMO platform, it is focused on providing contract manufacturing and development services for biopharmaceutical companies. The CDMO platform operates through MaSTherCell Global, which currently consists of MaSTherCell in Belgium, Atvio in Israel and subsidiaries in South Korea and in the United States, each having unique know-how and expertise for manufacturing in a multitude of cell types. Additional information is available at: 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, 2018, 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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