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Orgenesis Announces Planned Study to Confirm Suitability of Liver Cells as a Source for Personalized Cell Replacement Therapy for Insulin-Dependent Diabetic Patients

Receives IRB Approval to Collect Liver Biopsies for Future Clinical Use at Israel's Rambam Medical Center

GERMANTOWN, Md., April 30, 2019 (GLOBE NEWSWIRE) -- Orgenesis Inc. (NASDAQ: ORGS), a developer, manufacturer and service provider of advanced cell therapies, today announced it has received Institutional Review Board (IRB) approval to collect liver biopsies from patients at Rambam Medical Center located in Haifa, Israel for a planned study to confirm the suitability of liver cells for personalized cell replacement therapy for patients with insulin-dependent diabetes resulting from total or partial pancreatectomy. The liver cells are intended to be bio-banked for potential future clinical use.

The goal of the study, entitled "Collection of Human Liver Biopsy and Whole Blood Samples from Type 1 Diabetes Mellitus (T1DM), Total or Partial Pancreatectomy Patients for Potential use as an Autologous Source for Insulin Producing Cells in Future Clinical Studies," is to confirm the suitability of the liver cells for personalized cell replacement therapy, as well as eligibility of patients to participate in a future clinical study, as defined by successful Autologous Insulin Producing (AIP) cell production from their own liver biopsy. The secondary objective of the study is to evaluate patients' immune response to AIPs based on the patient's blood samples and followed by subcutaneous implantation into the patients' arms, which would represent the first human trial.

During the study, liver samples will be collected and then processed and stored in specialized, clinical grade tissue banks for potential clinical use. The study will enroll 20 patients and is expected to commence in May 2019. The propagated cells will be maintained in a tissue bank and are intended to be utilized in a future clinical study, in which the cells will be transdifferentiated and administered back to the patients as a potential treatment. This personalized autologous process will be performed under our Autologous Point of Care (POCare) model, in which the patient liver samples are processed, cryopreserved and potentially re-injected, all in the medical center, under clinical grade/GMP level conditions.

Pancreatectomy involves the surgical removal of all or part of the pancreas, which can be required for the treatment of a variety of conditions. The incidence of diabetes following a total pancreatectomy is one hundred percent, resulting in immediate and lifelong insulin-dependence with loss of both endogenous insulin secretion and that of the counter-regulatory hormone, glucagon. Currently, Islet Autologous Transplant (TP-IAT) is considered the standard of care following TP, but this is not always a feasible treatment due to insufficient quantity of potential functional harvested islets.

Orgenesis has developed a novel technology based on technology licensed from Tel Hashomer Medical Research Infrastructure and Services Ltd., utilizing liver cells as a source for Autologous Insulin Producing Cells (AIP cells) as replacement therapy for islet transplantation. AIPs are derived from liver cells that are taken by sampling from the patient liver to be treated and then converted into functional glucose-regulated IPCs and returned to the patient via injection. Due to the assumption that some of the patients, following TP or PP, will develop severe diabetes, Orgenesis' therapy has the potential to provide a long-term treatment.

The study's principal investigator, Professor Naim Shehadeh, is the Director of the Institute of Diabetes, Endocrinology and Metabolism at the Rambam Health Care Campus, and is a member of the Israel National Diabetes Council, Ministry of Health, and President of the Israel Diabetes Association. Professor Shehadeh's main research and clinical interests are pathogenesis and prevention of Type 1 Diabetes and the effect of oral insulin on the gastrointestinal tract. The study's principal surgeon and pancreatectomy specialist, Professor Yoram Kluger, is the director of the division of general surgery and the medical director of the pancreatic surgery service at Rambam Health Care Campus.

Prof. Shehadeh, Rambam Medical Center, noted, "We are excited and proud to be one of the first research sites to advance this breakthrough technology that could provide patients in the future a potential cure that could

dramatically improve their quality of life."

Prof. Sarah Ferber, Orgenesis Chief Scientific Officer, commented, "We believe that this key study, our first human trial, will allow us to better understand the autologous immune response following AIP cell implantation in different patient populations (autoimmune or not), *ex-vivo* and *in-vivo,* as well as the potency of transdifferentiation as a novel precision medicine platform to predict treatment success."

Dr. Efrat Assa-Kunik, General Manager of Orgenesis Ltd, commented, "We believe that this IRB approval is a significant milestone in our product development process as we prepare to commence a key study, which is intended to confirm the suitability of patients' liver cells to be used as a personalized cell replacement therapy. Based on the outcome of this study, our goal is to utilize these cells in a future clinical phase I/IIa study, in which the cryopreserved cells would be administered back to the patient. If successful, we believe that both of these studies could represent major milestones for the company and, most importantly, could be transformative for patients worldwide."

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 a 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.

Contact for Orgenesis:
David Waldman
Crescendo Communications, LLC
Tel: 212-671-1021
ORGS@crescendo-ir.com

Source: Orgenesis Inc.