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Orgenesis Granted FDA Orphan Drug Designation for Autologous Insulin Producing Cells in the Treatment of Severe Hypoglycemia-Prone Diabetes Resulting from Total Pancreatectomy

FDA designation expected to reduce Orgenesis' time and costs of clinical development

GERMANTOWN, Md., June 17, 2019 (GLOBE NEWSWIRE) -- **Orgenesis Inc. (Nasdaq: ORGS)** ("Orgenesis" or the "Company"), a developer, manufacturer and service provider of advanced cell therapies, announced that the United States Food & Drug Administration ("FDA") has granted Orphan Drug designation for its Autologous Insulin Producing ("AIP") cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy ("TP") due to chronic pancreatitis ("CP"). The technology is exclusively licensed by Orgenesis Ltd. (Orgenesis' wholly-owned Israeli subsidiary) from Tel Hashomer Medical Research Infrastructure and Services Ltd. ("THM") in Israel and is based on the work of Professor Sarah Ferber, the Company's Chief Scientific Officer and a researcher at THM.

The incidence of diabetes following TP is 100%, resulting in immediate and lifelong insulin-dependence with the loss of both endogenous insulin secretion and that of the counter-regulatory hormone, glucagon. Glycemic control after TP is notoriously difficult with conventional insulin therapy due to complete insulin dependence and loss of glucagon-dependent counter-regulation. Patients with this condition experience both severe hyperglycemic and hypoglycemic episodes.

The Company's patented transdifferentiation (or cell reprogramming) process involves the conversion of one adult tissue or cell into another type of cell, with its distinct phenotype and function. Orgenesis has developed a novel therapy utilizing its transdifferentiation process and its Point of Care ("POCare") liver expansion technology to transform liver cells into AIP cells. The cells are first derived from a small sample of the patient's liver cells and expanded in a liver cell bank based on Orgenesis' unique POCare cell expansion capabilities. At the appropriate time, the cells may be converted into functional glucose-regulated AIP cells through the Company's proprietary transdifferentiation process and returned to the patient's liver via a transfusion. The goal is to provide a "practical cure" for various types of insulin-dependent diabetes, thus hopefully providing long-term insulin independence without the need for concomitant immunosuppressive therapy.

The FDA's Orphan Drug Designation Program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or

prevention of rare diseases/disorders that affect fewer than 200,000 people in the United States. Orphan designation qualifies the sponsor of the drug for various development incentives, including eligibility for seven years of market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and other potential assistance in the drug development process.

Vered Caplan, Chief Executive Officer of Orgenesis, commented, “We are honored to receive Orphan Drug designation from the FDA, as this represents a major milestone for both Orgenesis and patients who have to suffer the tremendous hardships associated with total pancreatectomy. Orphan Drug designation has the potential to reduce the time and costs required to bring our AIP cell therapy to market and should help streamline the approval process.”

“This therapy is a great example of what we hope to achieve on a broader scale and for numerous indications through our POCare strategy. By collaborating with multiple clinical sites to collect and process the liver biopsies from the relevant patient populations, we are building the framework for the creation and maintenance of our liver cell banks that will be the basis for the transdifferentiation process. Collaborations such as the NY Blood Center in the United States and the Medical University of Graz in Austria will allow us to maintain liver cell banks at a level required for clinical use and should become a vital resource for clinical development. While the treatment of patients with hypoglycemia-prone diabetes resulting from total pancreatectomy is our immediate focus, we see significant opportunities ahead to expand our indications to include treatment for other causes of diabetes.”

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 POCare cell therapy platform (“PT”) and (ii) a Contract Development and Manufacturing Organization (“CDMO”) platform conducted through its subsidiary, Masthercell Global Inc. (“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 S.A. in Belgium, Atvio Biotech Ltd. 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, LLC, 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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