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# Orgenesis Announces Publication of an Independent Study “The Role of The Vasculature Niche on Insulin Producing Cells Generated by Transdifferentiation of Adult Human Liver Cells” in the Stem Cell Research and Therapy Journal

GERMANTOWN, Md., April 03, 2019 (GLOBE NEWSWIRE) -- Orgenesis Inc. (NASDAQ: ORGS), a developer of advanced cell therapies, manufacturer and service provider, today announced the publication of an independent study, entitled “The Role of The Vasculature Niche on Insulin Producing Cells Generated by Transdifferentiation of Adult Human Liver Cells,” which was published in the February 2019 issue of Journal of Stem Cell Research and Therapy, a leading peer-reviewed journal in the field of stem cell therapy. The study publication is available at: https://doi.org/10.1186/s13287-019-1157-5.

Insulin dependent diabetes is a multifactorial disorder that could be theoretically cured by functional pancreatic islets and autologous insulin producing cells (AIP cells) implantation. Regenerative medicine approaches include the potential for growing tissues and organs in the laboratory and transplanting them when the body cannot heal itself. There are several obstacles that remain to be overcome in order to bring regenerative medicine approaches for diabetes closer to clinical implementation; the cells generated in-vitro are typically of heterogenic and immature nature and the site of implantation should be readily vascularized for the implanted cells to survive in vivo. The study was able to address these two limitations by analyzing the effect of co-implanting AIP cells with vasculature promoting cells in an accessible site such as subcutaneous. It further analyzed the effects of reconstituting the in-vivo environment in-vitro on the maturation and function of insulin producing cells.

The study results show that co-implantation of mesenchymal stem cells (MSCs) and endothelial colony forming cells (ECFCs) with AIP cells led to doubling the survival rates and a three-fold increase in insulin production, in-vivo. ECFCs and MSCs co-culture, as well as conditioned media of co-cultures resulted in significant increased expression of pancreatic specific genes and an increase in glucose-regulated insulin secretion, compared with AIP cells alone. Mechanistically, the study demonstrated that ECFCs and MSCs co-culture increases the expression of CTGF and ACTIVINβα, that play a key role in pancreatic differentiation.

Professor Sarah Ferber, Chief Scientific Officer of Orgenesis, stated, “We are pleased to have this study published in a leading peer reviewed journal, which further validates that the transdifferentiation process, which is the conversion of one adult tissue or cell into another type of cell, with its distinct phenotype and function, works. In this study, we were able to uncover that vasculature is an important factor in generating regenerative properties and is a fitting approach for the treatment of diabetes. Vasculature enacts cell-to-cell communication, inducing a change of the maturation of insulin producing cells and their survival upon implantation. The reconstitution of the in-vivo niche is expected to promote liver to pancreas transdifferentiation, which brings this cell therapy approach closer to clinical implementation.”

This recent study is preceded by another study that identified human liver cells that are predisposed to undergo transdifferentiation into AIP cells. This transdifferentiation capacity has been extended to most of the liver cells using epigenetic modifications and Wnt signaling activation. The combined effect of epigenetic modifications and canonical Wnt signaling activity has been published in Hepatology.

**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 a guarantee 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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