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Servier Appoints MaSTherCell for the Development of its CAR-T Cell Therapy Manufacturing Platform

GERMANTOWN, MD -- (Marketwired) -- 01/20/17 -- ***Orgenesis Inc.*** (OTCQB: ORGS), a fully-integrated cell therapy and contract development and manufacturing company, announced that its wholly-owned subsidiary, MaSTherCell S.A., specializing in the delivery of optimized process industrialization capacities to cell therapy organizations, has signed a master service agreement with Servier for the development of a manufacturing platform for allogeneic cell therapies. Under the master service agreement, MaSTherCell is developing a CAR-T cell therapy manufacturing platform, which will enable industrial and commercial manufacturing of Servier's cell therapy products. This is a critical step in the development of these products for later stage clinical trials.

Cell therapies have shown promising results in treating cancers. However so far, successful development has been mainly limited to autologous therapies. This approach, where the patient's cells are collected and then used to create a drug for that specific patient, is limited by the lack of possibility of industrialized manufacturing, thus restricting its access to few patients. Allogeneic therapies, or off-the-shelf treatments, potentially offering the technology to a higher number of patients, are developing very rapidly. However, the challenges of their manufacturing scale-up still lie ahead.

One of the most advanced cell therapies is based on CAR-T technology, where the T-cells are armed with a Chimeric Antigen Receptor. Servier is developing UCART-19 (see below About UCART-19 for more information), with two clinical trials currently ongoing in Europe, in relapsed or refractory B cell acute lymphoblastic leukemia (B-ALL), in pediatric and adult patients.

Servier selected MaSTherCell because of its leading global cell therapy CDMO position, as well as its essential broad expertise in immunotherapy products. MaSTherCell has a track record of designing and delivering cost-effective cell therapy manufacturing platforms. MaSTherCell anticipates that it will complete the development of the initial CAR-T platform in 2018. This will then be an efficient complement to the bioproduction facilities that Servier is developing at its site at Gidy (France), which will mainly focus on the production of antibodies.

"This partnership will result in developing solutions for one of the biggest challenges to the ongoing development of the cell therapy sector. MaSTherCell has quickly built the most extensive CDMO experience in manufacturing and process industrialization development in the cell therapy industry," said Denis Bedoret, CBO at MaSTherCell. "This enables MaSTherCell to leverage that experience to deliver solutions to contribute to the Servier cell therapy pipeline. We will thus be able to directly contribute to delivery of life-saving cell therapy treatments to patients."

"The scale up of manufacturing for late scale clinical trials still remains one of the biggest industry-wide challenges in the cell therapy sector, and especially in a CAR-T field still in its infancy," said Marielle Anger-Leroy, Director of Biotechnology Industrial Development at Servier. "Being pioneers with these innovative therapies means that we have to find the best partners to maximize the chances of delivering these therapies to patients with few alternative options."

About Servier

Servier is an international pharmaceutical company governed by a foundation and headquartered in France. With a strong international presence in 148 countries and a turnover of 4 billion Euros in 2016, Servier employs over 21,000 people worldwide. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular diseases, diabetes, cancers, immune-inflammatory diseases, and neurodegenerative diseases, as well as by its activities in high-quality generic drugs. Being completely independent, the Group reinvests 25% of Servier's products turnover in research and development and uses all its profits for growth.

Becoming a key player in oncology is part of Servier's long-term strategy. Currently, there are nine molecular entities in clinical development in this area, targeting gastric and lung cancers and other solid tumors, as well as various leukemias and lymphomas. This portfolio of innovative cancer treatments is being developed with partners worldwide, and covers different cancer hallmarks and modalities, including cytotoxics, proapoptotics, targeted, immune and cellular therapies to deliver life-changing medicines to patients. For more information, visit www.servier.com.

About UCART19

UCART19 is an allogeneic CAR T-cell product candidate developed for treatment of CD19-expressing hematological malignancies, gene edited with TALEN®. UCART19 is initially being developed in acute lymphoblastic leukemia (ALL). Cellectis' approach with UCART19 is based on the preliminary positive results from clinical trials using autologous products based on the CAR technology, and has the potential to overcome the limitation of the current autologous approach by providing an allogeneic, frozen, "off-the-shelf" T-cell based medicinal product.

In November 2015, Servier acquired the exclusive rights to UCART19 from Cellectis. Following further agreements, Servier and Pfizer began collaborating on a joint clinical development program for this cancer immunotherapy. Pfizer has exclusive rights from Servier to develop and commercialize UCART19 in the United States, while Servier retains exclusive rights for all other countries.

About MaSTherCell S.A.

MaSTherCell is a dynamic and global Contract Development and Manufacturing Organization (CDMO) on a mission to deliver optimized process industrialization capacities to cell therapy organizations, and speed up the arrival of their therapies onto the market. The company is the subsidiary of Orgenesis Inc. (OTCQB: ORGS), a cell therapy and regenerative medicine company that is committed to developing a cure for Type 1 diabetes. The heart of MaSTherCell is a team of more than 80 highly dedicated experts combining strong experience in cGMP cell therapy manufacturing with a technology-focused approach

and a substantial knowledge of the industry. From technology selection to business modeling, GMP manufacturing, process development, quality management and assay development, MaSTherCell's teams are fully committed to helping their clients fulfill their objective of providing sustainable and affordable therapies to their patients. The company operates in a validated and flexible facility located in the strategic center of Europe within the Walloon healthcare cluster, Biowin. For more information visit www.masthercell.com.

Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial uncertainties and risks. These forward-looking statements 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 expectations of management regarding the success of the joint ventures and expanding our market penetration in the CMDO field in Europe and Asia; the successful integration of our clinical and CDMO strategy; the development of our regeneration technology as therapeutic treatment for diabetes which could, if successful, be a cure for Type 1 Diabetes; our limited financial resources and our ability to raise the working capital needed to fund the commitments of our CDMO business, various joint ventures, development projects and business generally; our technology not working as well as expected; our ability to retain key employees; our ability to satisfy the rigorous regulatory requirements for new medical procedures; our competitors developing better or cheaper alternatives to our products and the risks and uncertainties discussed under the heading "RISK FACTORS" in Item 1 of our Annual Report on Form 10-K for the fiscal year ended November 30, 2015, 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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