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Orgenesis Subsidiary Masthercell Global Announces Manufacturing Services Agreement with Iovance Biotherapeutics in Europe

GERMANTOWN, Md., Oct. 18, 2018 (GLOBE NEWSWIRE) -- Orgenesis Inc. (NASDAQ: ORGS), a manufacturer, service provider and developer of advanced cell therapies, today announced that its subsidiary, Masthercell Global ("Masthercell"), has entered into a new three-year Manufacturing Services Agreement with Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. Using Iovance's proprietary technology and process, Masthercell plans to manufacture tumor infiltrating lymphocytes (TIL) for Iovance's European late-stage clinical trials in its commercial-ready cGMP manufacturing suites.

"We are pleased to be expanding our clinical and manufacturing capacity in Europe through this new collaboration with Masthercell. We have been dosing patients with lifileucel in Europe for the treatment of metastatic melanoma and LN-145 for the treatment of cervical cancers. As part of our global development plan for our TIL product, we are initiating the IOV-COM-202 trial in Europe as well and have received approval from Medicines and Healthcare products Regulatory Agency (MHRA). This newly established relationship with Masthercell will add additional commercial-ready capacity to support our ongoing and upcoming trials," said Dr. Maria Fardis, PhD, MBA, president and chief executive officer of Iovance Biotherapeutics. "Masthercell specializes in clinical and commercial manufacturing of cell therapy as well as process development which brings valuable expertise and capabilities to our development program. We look forward to working with them to deliver our TIL product to patients with solid tumors across Europe."

"We are glad that Iovance called on our expertise to accelerate the development of their TIL products. By addressing the unmet needs for solid tumor treatment, the outcome of this project could represent potential hope for a considerable number of patients," commented Dr. Denis Bedoret, General Manager of Masthercell Global. "Masthercell is really pleased to welcome Iovance in its new commercial plant for advanced cell therapy manufacturing."

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The Company's lead product candidate is an adoptive cell therapy using TIL technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck, recurrent, metastatic or persistent cervical cancer and locally advanced or metastatic non-small cell lung cancer. For more information, please visit <http://www.iovance.com>.

About Orgenesis

Orgenesis is a vertically-integrated biopharmaceutical company with expertise and unique experience in cell therapy development and support services. Through its Israeli subsidiary, Orgenesis Ltd., Orgenesis is developing technology designed to successfully reprogram human liver cells into glucose-responsive, fully functional, Insulin Producing Cells (IPCs). Orgenesis believes that converting the diabetic patient's own tissue into insulin-producing cells has the potential to overcome the significant issues of donor shortage, cost and exposure to chronic immunosuppressive therapy associated with islet cell transplantation.

Through its Masthercell Global subsidiary, a global contract development and manufacturing organization (CDMO), Orgenesis is able to deliver optimized process industrialization capacities to cell therapy organizations and speed up the arrival of their therapies onto the market. From technology selection to business modeling, GMP manufacturing, process development, and quality management, Masthercell's teams are fully committed to helping their clients fulfill their objective of providing sustainable and affordable therapies to their patients. Masthercell operates in a validated and flexible facility located in the strategic center of Europe within the Walloon healthcare cluster, Biowin. This integrated approach supports the Company's business philosophy of bringing to market significant life-improving medical treatments. For more information, visit www.orgenesis.com.

Orgenesis 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, 2017, 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.

Iovance Notice Regarding Forward-Looking Statements

Certain matters discussed in this press release are "forward-looking statements" of Iovance Biotherapeutics, Inc. (the "Company"). The Company may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans,"

“intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company’s statements regarding clinical trials and manufacturing capabilities and collaborations in Europe are examples of such forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current and future product candidates (including both Company-sponsored and collaborator-sponsored trials), such as statements regarding the timing of initiation and completion of these trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority (including regulatory authorities in the United Kingdom and elsewhere in Europe) approval of, or other action with respect to, our product candidates; the strength of the Company’s product pipeline; the successful implementation of the Company’s research and development programs and collaborations; the success of the Company’s manufacturing, license or development agreements; the acceptance by the market of the Company’s product candidates, if approved; and other factors, including general economic and international trade conditions and regulatory developments, not within the Company’s control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. A further list and description of the Company’s risks, uncertainties and other factors can be found in the Company’s most recent Annual Report on Form 10-K and the Company’s subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or www.iovance.com. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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