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# Kangstem Biotech Selects Orgenesis' Subsidiary Masthercell for GMP Manufacturing of Furestem-AD® in Europe

SEOUL and GERMANTOWN, Md., Oct. 01, 2018 (GLOBE NEWSWIRE) -- **Orgenesis Inc. (NASDAQ: ORGS)**, a manufacturer, service provider and developer of advanced cell therapies, today announced that Kangstem Biotech Co., Ltd. (KOSDAQ: 217730), a biotechnology company specializing in developing cell therapies using mesenchymal stem cells derived from human umbilical cord blood, has selected Orgenesis' subsidiary, Masthercell Global Inc. (Masthercell), as its contract manufacturing partner for the European clinical trials of **Furestem-AD®**, a cell therapy designed to treat atopic dermatitis.

Masthercell is a leading cell therapy Contract Development and Manufacturing Organization (CDMO) with facilities in Europe, Asia and the Middle East, which has been selected to manufacture **Furestem-AD** for Kangstem's European clinical trial utilizing both Kangstem's proprietary process, as well as cell manufacturing technologies/processes developed by Masthercell.

Kangstem is moving into late phase clinical trials on **Furestem-AD®** in Korea, and in order to build on this foundation, Kangstem plans to enter Europe with its innovative cell therapy products. **"The European clinical trial of Furestem-AD will be a milestone for our company. We believe that Masthercell's expertise and experience are key to enabling our entry into this sizable market,"** said Mr. Taehwa Lee, CEO of Kangstem.

"Kangstem's allogeneic human umbilical cord blood-derived stem cell-based project fits perfectly with Masthercell's long term strategy—to provide services across all segments within the cell therapy field," said Romain de Rauville, Business Development Manager for Masthercell Global. "Our selection by a leading Korean cell therapy company further validates Masthercell's expertise and agility in assisting our partners with their globalization strategy."

Vered Caplan, CEO of Orgenesis, further commented, "This partnership provides Kangstem access to Masthercell's cell therapy manufacturing expertise, capabilities and state-of-the art facility in Belgium. This facility will provide Kangstem with the most efficient set-up for its unique and large-scale manufacturing process. Not only do we have local market experience in Korea and Europe, but Masthercell's global platform could allow Kangstem to expand to other continents. We look forward to building upon this partnership, which we believe will help Kangstem accelerate its commercial program, in order to provide its innovative cell therapy products to more patients around the world."

## About KangStem Biotech

Kangstem Biotech Co., LTD. (KSB) is developing stem cell therapeutic products which target autoimmune diseases. KSB has developed methods to isolate and to mass culture high

purity human umbilical cord blood-derived stem cells (hUCB-SCs). Based on these platform technologies, KSB was able to establish immune-modulating mechanisms of hUCB-SCs and is currently conducting clinical trials for the development of stem cell therapeutic products targeting atopic dermatitis (Furestem-AD®), rheumatoid arthritis (Furestem-RA®), and Crohn's disease (Furestem-CD®). A therapeutic product targeting osteoarthritis (Furestem-OA®) is currently in the pre-clinical trial stage. KSB is also conducting research on directly converted neural stem cells (dcNSC) to provide patient specific regenerative medicine for neurological disorders.

## **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 advancing to clinical stage significant life-improving medical treatments. For more information, visit [www.orgenesis.com](http://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, 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.*

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