

September 29, 2020



Orgenesis Announces Agreement to Acquire Koligo Therapeutics, a Leader in Personalized Cell Therapies

Acquisition to support accelerated commercialization of Koligo's KYSLECEL[®], a personalized islet cell therapy available in the U.S. for chronic and recurrent acute pancreatitis

Goal to rapidly advance KT-PC-301, an autologous cell therapy under investigation for the treatment of COVID-19-related Acute Respiratory Disease Syndrome ("ARDS")

Orgenesis to leverage Koligo's 3D-V bioprinting technology across its POCare Platform

GERMANTOWN, Md., Sept. 29, 2020 (GLOBE NEWSWIRE) -- [Orgenesis Inc. \(NASDAQ: ORGS\)](#) ("Orgenesis" or the "Company"), a global biotech company working to unlock the full potential of cell and gene therapies, and Koligo Therapeutics, Inc. ("Koligo"), a regenerative medicine company, today announced that the two companies have entered into a definitive merger agreement, subject to final closing conditions, with expected completion before year-end ("Transaction").

Koligo is a leader in developing personalized cell therapies utilizing the patient's own (autologous) cells. Koligo has successfully launched its first commercial product, KYSLECEL, and plans to commence a phase 2 trial of KT-PC-301 for COVID-19-related ARDS. Koligo's development stage technology utilizes 3D bioprinting and vascularization with autologous cells ("3D-V" technology) to create biodegradable and shelf-stable three-dimensional cell and tissue implants. The 3D-V technology is being developed for diabetes and pancreatitis, with longer term applications for neural, liver, and other cell/tissue transplants.

Following closing of the Transaction, Orgenesis plans to accelerate the commercial scaleup of KYSLECEL throughout the United States and, subject to regulatory and logistical considerations, in international markets as well. After closing of the Transaction, and subject to FDA review and clearance of the Company's Investigational New Drug application, Orgenesis expects to start patient recruitment for a phase 2 randomized clinical trial of KT-PC-301 in COVID-19 patients. Orgenesis also plans to leverage Koligo's 3D-V bioprinting technology across its POCare platform.

Under the terms of the merger agreement, Orgenesis will acquire all of the outstanding stock of Koligo from its shareholders (the founders and staff of Koligo and a subsidiary of Bergen Special Opportunity Fund, LP, an institutional investor managed by Bergen Asset Management, LLC). The agreed consideration terms are an aggregate of \$15 million in shares of Orgenesis' common stock valued at \$7.00 per share which shall be issued to Koligo's accredited investors (with certain non-accredited investors to be paid solely in cash) and an assumption of \$1.3 million in Koligo's liabilities, estimated to be substantially all of

Koligo's liabilities. Additional details of the Transaction will be available in the Company's Form 8-K, which will be filed with the Securities and Exchange Commission, and will be available at www.sec.gov.

KYSLECEL®

Koligo's KYSLECEL is commercially available in the United States for chronic and recurrent acute pancreatitis in a surgical procedure commonly called Total Pancreatectomy with Islet Autologous-Transplant ("TPIAT"). TPIAT has been proven to provide significant pain relief, improved quality of life, and a reduction in the need for pain medication for patients suffering from chronic or recurrent acute pancreatitis. KYSLECEL infusion after a total pancreatectomy helps preserve insulin secretory capacity and reduce the risk of diabetic complications. KYSLECEL is made from a patient's own pancreatic islets – the cells that make insulin to regulate blood sugar.

Koligo has commenced its commercial pilot program for KYSLECEL at six U.S. hospitals, treating 40 patients to date. The KYSLECEL pilot program has generated approximately \$2 million in sales revenue. KYSLECEL has also been shown to result in significant savings to payors over traditional chronic pancreatitis management. Following the closing of the Transaction, Orgenesis plans to make KYSLECEL available to an increasing number of hospitals throughout the United States through its POCare Network.

KT-PC-301

Koligo's lead clinical development program is for KT-PC-301, an autologous cell therapy under investigation for the treatment of COVID-19-related Acute Respiratory Disease Syndrome (ARDS). KT-PC-301 is comprised of autologous stromal and vascular fraction cells ("SVF") derived from each patient's adipose (fat) tissue. KT-PC-301 contains a population of mesenchymal stem cells, vascular endothelial cells, and immune cells which migrate to the patient's lungs and other peripheral sites of inflammation. Nonclinical and clinical evidence demonstrate that KT-PC-301 may: (1) stabilize microcirculation to improve oxygenation; (2) maintain T and B lymphocytes to support antibody production; and (3) induce an anti-inflammatory effect.

Koligo has completed a pre-IND (Investigational New Drug) consultation with the U.S. Food and Drug Administration to start clinical trials of KT-PC-301 in COVID-19-related ARDS. Following the closing of the Transaction, and subject to FDA review and clearance of the Company's Investigational New Drug application, Orgenesis expects to start patient recruitment for a phase 2 randomized clinical trial of KT-PC-301 in COVID-19 patients. As currently planned, the phase 2 trial is expected to enroll 75 patients and evaluate the safety and efficacy of KT-PC-301. Mohamed Saad, MD, Chief of Division of Pulmonary, Critical Care, and Sleep Disorders Medicine at the University of Louisville, will be the lead clinical investigator on the trial.

3D-V Technology

Koligo's 3D-V bioprinting technology is designed to support development of a number of product candidates for the treatment of diabetes, cancer, neurodegenerative disease, and other serious diseases. The 3D-V technology platform is able to print three-dimensional cell and tissue constructs with a vascular network. Key benefits of the 3D-V approach include: faster revascularization/inosculation of cell/tissue transplant to improve engraftment; host tolerance of the graft while minimizing need for immune suppressive drugs; better site of

transplant administration of such products; and scaffolding to keep cell/tissue in place in vivo. These solutions are ideally suited for islet transplant and other cell/tissue transplant applications.

Koligo Management

Following the closing of the Transaction, Koligo's management team will be joining Orgenesis to continue commercial and development activities. Koligo's CEO, Matthew Lehman, is an accomplished executive in the biotech and regenerative medicine fields. Prior to co-founding Koligo, he was CEO of Prima Biomed Ltd (now Immuteq Ltd, a Nasdaq (IMMP) and ASX (IMM) listed biotech company). Stuart Williams, PhD, Chief Technology Officer, is a bioengineer and thought leader in regenerative medicine, with over 300 publications and 20 issued patents in the field. Dr. Williams has co-founded three other biotech companies and is an experienced academic-industry collaborator. Michael Hughes, MD, Chief Medical Officer, is a transplant surgeon who started the islet transplant program at University of Louisville which was the genesis of Koligo's KYSLECEL program. He has successfully treated nearly 50 chronic pancreatitis patients with islet autologous transplant after pancreatectomy. Balamurugan Appakalai, PhD, has more than 20 years of islet isolation experience, having processed more than 800 human pancreases. He is a leader in the field of islet transplant with 100+ publications.

Vered Caplan, Chief Executive Officer of Orgenesis, stated, "We are pleased to announce this transformative acquisition, which we expect will add broad capabilities to our therapeutic and technology platform, and will further our leadership in the cell and gene therapy field. Based on several phase 1 studies, Koligo's KT-PC-301, using a patient's own cells, has demonstrated safety and tolerability, and has shown signs of efficacy to support continued development in COVID-19-related ARDS. If successful for the treatment of COVID-19-related ARDS, KT-PC-301 is likely to have applications in other acute and chronic respiratory indications, areas that represent significant unmet medical need. In addition, we see significant potential in KYSLECEL, a commercial stage asset for the treatment of chronic and acute recurrent pancreatitis, which we plan to introduce through our global network of hospitals. Finally, Koligo's 3D-V bioprinting technology is highly complementary to our POCare Platform, as we implement new technologies to improve efficacy and lower the costs of cell and gene therapies. I would like to personally welcome Matthew and the rest of the Koligo team to the Orgenesis organization when the Transaction closes. We believe that their skills and experience will be an important addition as we execute on our strategy to unlock the power of cell and gene therapies and make them accessible to all."

Matthew Lehman, Chief Executive Officer of Koligo Therapeutics, stated, "The merger with Orgenesis marks a major milestone for our company and builds on our recent progress, including the Pre-IND package submitted to the U.S. FDA for KT-PC-301 and our pilot commercial program for KYSLECEL. The Orgenesis team brings extensive clinical, regulatory, and manufacturing expertise well suited to supporting Koligo's goals. Orgenesis' intellectual property is highly complementary to Koligo's technology and the combined companies will work to advance a robust commercial and development product portfolio. Orgenesis' POCare technologies are also ideally suited for low-cost and efficient production of autologous cell therapies at the point of care, which we believe will considerably enhance the delivery of these therapies to patients. Additionally, we believe Orgenesis' global network of leading hospitals and healthcare institutions will enable us to accelerate the commercial rollout of KYSLECEL. We are quite encouraged by the outlook for the business and look

forward to leveraging Orgenesis' POCare Platform in order to accelerate the timeline to bringing our innovative cell therapies to market. Through this merger, we believe we can maximize value for all shareholders and we are grateful to Orgenesis for this opportunity."

Pearl Cohen Zedek Latzer Baratz LLP and KPMG advised Orgenesis on the Transaction. Maxim Group LLC acted as a finder and Nelson Mullins Riley & Scarborough, LLP advised Koligo on the Transaction.

About Koligo Therapeutics

Koligo Therapeutics, Inc. is a US regenerative medicine company. Koligo's first commercial product is KYSLECEL[®] (autologous pancreatic islets) for chronic and acute recurrent pancreatitis. Koligo's 3D-V technology platform incorporates the use of advanced 3D bioprinting techniques and vascular endothelial cells to support development of transformational cell and tissue products for serious diseases. More information is available at www.koligo.net.

About Orgenesis

Orgenesis is a global biotech company working to unlock the full potential of cell and gene therapies (CGTs) in an affordable and accessible format at the point of care. The Orgenesis POCare Platform is comprised of three enabling components: a pipeline of licensed **POCare Therapeutics** that are processed and produced in closed, automated **POCare Technology** systems across a collaborative **POCare Network**. Orgenesis identifies promising new therapies and leverages its POCare Platform to provide a rapid, globally harmonized pathway for these therapies to reach and treat large numbers of patients at lowered costs through efficient, scalable, and decentralized production. The Network brings together patients, doctors, industry partners, research institutes and hospitals worldwide to achieve harmonized, regulated clinical development and production of the therapies. Learn more about the work Orgenesis is doing at www.orgenesis.com.

Notice Regarding Forward-Looking Statements

The information in this release is as of September 29, 2020. Orgenesis assumes no obligation to update forward-looking statements contained in this release as a result of new information or future events or developments. This release contains forward looking statements about Orgenesis, Koligo, Koligo's technology, and potential development and business opportunities of Koligo and Orgenesis following the closing of the Transaction, each of which involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of the Company's products; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any such regulatory authorities may approved the Company's development products, and, if approved, whether such product candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of the Company's products; uncertainties

regarding the impact of COVID-19 on the Company's business, operations and financial results and competitive developments.

A further description of risks and uncertainties can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov.

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