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Koligo Therapeutics to develop personalized cell therapy for the treatment of COVID-19

- **KT-PC-301 is an autologous cell therapy derived from a patient's own adipose (fat) tissue**
- **Pre-IND consultation with FDA completed on April 27**
- **Randomized, placebo-controlled, phase 2 trial planned**

New Albany, IN. -- May 21, 2020 -- Koligo Therapeutics, Inc. (Koligo), a privately-held regenerative medicine company, today announced its progress in developing an autologous cell therapy for the treatment of moderate to severe COVID-19. On April 27, 2020, Koligo completed a pre-IND (Investigational New Drug) consultation with the U.S. Food and Drug Administration for KT-PC-301 to treat COVID-19 Acute Respiratory Distress Syndrome (ARDS) symptoms. Koligo expects to file an IND for this therapeutic candidate in the coming weeks. A phase 2 clinical trial is expected to start in the summer of 2020 (subject to the FDA review and clearance of the IND submission).

KT-PC-301 is a cell therapy that is derived from a patient's own adipose (fat) tissue. A small amount of fat is collected from the patient and sent to Koligo's manufacturing facility in Indiana to make KT-PC-301. The product is manufactured within hours and sent back to the hospital for intravenous administration. 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. Published 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 believes that the multiple mechanisms of action of KT-PC-301 are important to treat ARDS symptoms of moderate to severe COVID-19.

The planned phase 2 trial will enroll 75 patients and evaluate the safety and efficacy of KT-PC-301 as compared to placebo. 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.

Dr. Saad commented, "COVID-19 can lead to serious, sometimes fatal, pulmonary complications due to a lack of oxygenation and a hyperinflammatory response. We believe there is strong scientific rationale for the development of KT-PC-301 to treat moderate to severe COVID-19. The autologous approach (using a patient's own cells) is expected to be safe and well tolerated. The multi-functionality of the cells in KT-PC-301 may mitigate the complications and ARDS symptoms associated with COVID-19 and lead to improved clinical outcomes for patients."

With KT-PC-301, Koligo is building on its history of successful development and commercialization of autologous cell therapies. Over the past two years, Koligo has rolled out a commercial pilot program for KYSLECEL®, its autologous pancreatic islet cell therapy used in the treatment of chronic or recurrent acute pancreatitis. To date, Koligo has deployed KYSLECEL at two hospitals, treating over 30 patients, and has worked out important logistical considerations for widespread distribution. This pilot program has generated approximately US$1.6 million in revenue for Koligo. KYSLECEL will be available at increasing numbers of hospitals throughout the United States, over the coming months.

Matthew Lehman, CEO of Koligo said, “We are excited to start clinical testing of KT-PC-301 for ARDS symptoms of moderate to severe COVID-19. Koligo is dedicated to developing and commercializing transformative cell therapies for patients with serious diseases. The KT-PC-301 program fits squarely within our mission and our core compe-tencies. The promise of cell therapy and regenerative medicine is to treat complex diseases such as COVID-19. We believe the autologous approach, using a patient’s own cells, will prove to be safe and effective for treatment.”

About KT-PC-301
KT-PC-301 is a potential cell therapy in development for patients with moderate to severe COVID-19. Derived from a patient’s own adipose (fat) tissue, KT-PC-301 con-tains a population of a patient’s own (autologous) cells, including endothelial cells, hematopoietic and mesenchymal stem cells, and white blood cells (T regulatory cells and T and B lymphocytes). The product has been evaluated for safety and tolerability in several phase 1 studies to date. KT-PC-301 is for investigational use only in the con-text of an approved clinical trial.

About Koligo Therapeutics
Koligo Therapeutics, Inc. is a 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. www.koligo.net.