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New Cell Therapy Trial Launches for Patients with Severe COVID-19

FOR IMMEDIATE RELEASE: APRIL 9, 2020

After a lightening round of proposals and reviews, an international team of scientists led by Dr. Camillo Ricordi was granted immediate FDA authorization for a 24-patient clinical trial to test the safety and exploratory efficacy of umbilical cord-derived mesenchymal stem cells (UC-MSCs) to block the life-threatening lung inflammation that accompanies severe cases of COVID-19.

Dr. Ricordi, the principal investigator, is the Stacy Joy Goodman Professor of Surgery and Director of the Diabetes Research institute (DRI) and Cell Transplant Center at the University of Miami Miller School of Medicine.“ We are very grateful to the FDA’s Center for Biologics Evaluations and Research, Office of Tissues and Advanced Therapies for performing four rounds of reviews in a record time — one week.”

“There is no time to waste,” said Dr. Ricordi, “patients who die from COVID-19 have a median time of just 10 days between first symptoms and death. In severe cases oxygen levels in the bloodstream drop, and the inability to breathe pushes patients towards their end very quickly; any intervention that might prevent that trajectory would be highly desirable.”

The trial will be based in Miami, at the University of Miami Health System and Jackson Health System in Miami, Florida. It is the result of a collaborative, international, academic initiative sponsored by The Cure Alliance, a non-profit group of scientists and innovators dedicated to sharing knowledge and accelerating cures for all diseases. In response to the COVID-19 pandemic, The Cure Alliance has pivoted all resources to fighting the virus. The clinical protocol has been already shared with other academic institutions throughout the world who want to test similar treatment strategies in the fastest and most efficient way possible.

One hundred per cent of the philanthropic contributions raised by The Cure Alliance (www.thecurealliance.org) are being directed to this clinical trial and to expand manufacturing of UC-MSC products. If the clinical trial proves to be safe and effective, The Cure Alliance will continue to direct any contribution received for this initiative, to support future manufacturing and distribution of these cellular therapies

The FDA had previously authorized the testing of UC-MSC cell products in patients with Type 1 Diabetes and Alzheimer’s Disease at the University of Miami as part of other clinical trials. For the

COVID-19 trial, Dr. Ricordi enlisted additional experts from around the world with extensive experience in infectious diseases, pulmonary medicine and critical care, while others provided expertise in cell-based product development and their use in clinical trials. The cell therapy is administered intravenously.

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Acknowledgments: We thank the supporters of The Cure Alliance for this COVID-19 initiative, especially Barilla, the Italian Food Company, that has been our major philanthropic supporter since the beginning of this initiative. We also thank the Diabetes Research Institute Foundation for supporting the DRI Team and the DRI cGMP Advanced Cell and Biologic Product Manufacturing Facility, that will provide the UC-MSC products used in this clinical trial.

Shelley Ross is president of The Cure Alliance, a 501 (c)(3) non-profit organization, founded in 2009 by Dr. Camillo Ricordi.