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FIRST PATIENT RECEIVES NOVEL COVID-19 THERAPY IN CELULARITY CLINICAL TRIAL LED BY SEATTLE’S INFECTIOUS DISEASE RESEARCH INSTITUTE

The first patient was treated on Sept. 3 with a novel therapy for COVID-19 in California as part of a national clinical trial that seeks to treat approximately 100 patients across the United States utilizing Celularity’s CYNK-001 investigational immunotherapy.

SEATTLE, WASH. – Sept 8, 2020 – The Infectious Disease Research Institute (IDRI) has announced that the first COVID-19 patient has received treatment using a novel immune therapy that was developed by New Jersey-based Celularity Inc. as part of a national clinical trial. The first patient has been administered CYNK-001, Celularity’s investigational placenta-derived immunotherapy containing Natural Killer (NK) cells. Participating sites include Hackensack University Medical Center and Atlantic Health in New Jersey, MultiCare Health System in Washington State, Banner University Medical Center Phoenix in Arizona, the University of Arkansas in Arkansas, and UC Davis and UC Irvine in California, with the first patient receiving treatment at UC Irvine in California. While there have been numerous treatments for COVID-19 that have been studied, to date all available treatments are modestly effective and there is a urgent need for new approaches to COVID-19 as the pandemic continues across the world.

The treatment is driven by an infusion of CYNK-001 immune cells known as Natural Killer or “NK cells” which have been safely given to patients in Celularity’s studies for treatment of leukemia and multiple myeloma. Low NK cell counts have been associated with severe cases of COVID-19, so the study investigators theorize that delivering NK cells will encourage the body to mount an immune response that safely destroys the virus and controls infection. Celularity’s CYNK-001 is the only cryopreserved allogeneic, off-the-shelf NK cell therapy derived from human placental CD34+ cells.

“This pivotal clinical trial takes a unique and novel approach to the treatment of COVID-19. By providing a critical type of immune cell, known as a natural killer cell, to patients ill with COVID-19, we hope this treatment will both kill the SARS-CoV-2 virus and also coordinate a more effective immune response to control the infection and prevent damage to the vital organs,” said Corey Casper, M.D., MPH, the Principal Investigator on the study.

The first phase of the trial will evaluate the safety and efficacy of multiple doses of CYNK-001 and will be administered to up to 14 patients in three doses over the course of seven days. Physicians at the participating sites will identify patients for enrollment based on Celularity’s specific eligibility criteria, and the first infusions took place on Thursday, September 3. The second phase of the trial will measure multiple doses of CYNK-001 against a control group receiving only best supportive care for a similar degree of infection.

The study seeks to determine whether treatment with CYNK-001 controls the viral infection, improves symptoms, and reduces the progression to severe outcomes such as the need for intensive care support or death. Researchers anticipate the study will conclude in the Fourth Quarter 2021, but preliminary data may be available in advance. To date, four patients have received CYNK-001 for treatment of COVID-19 as part of an expanded access program under the permission of the Food and Drug Administration. All patients were critically ill and had failed all available treatments for COVID-19. Two of the four patients had improvements in their respiratory status and all four patients tolerated the treatment without any negative effects. Investigators are therefore encouraged and are looking to quickly enroll participants in the trial to formally and rigorously test the effectiveness of this treatment regimen.

Casper, who is also a Clinical Professor of Global Health and Medicine (Infectious Disease) at the University of Washington and an Affiliate Professor at the Fred Hutch Cancer Research Center in Seattle, also noted that “of the other therapies currently available, antiviral medications have been shown to be modestly effective, while anti-inflammatory approaches
help patients with advanced disease. The use of immunotherapy could help patients in the critical period after they are hospitalized and before they are critically ill and could therefore be an enormous asset to providers on the front lines.”

“We are pleased to have IDRI as our collaborator on what we believe is the first NK cell-based immunotherapy trial targeting COVID-19,” said Robert J. Hariri, M.D., Ph.D., Celularity’s founder, Chairman and CEO. Hariri added, “The collaboration enabled a very rapid scale up, allowing us to administer CYNK-001 to COVID-19 to the first patients within five weeks of obtaining Investigational New Drug clearance from the FDA.”

Patients who are interested in this clinical trial should discuss their interest and eligibility with their treating clinician(s) who will determine if participation is appropriate. For more information on this clinical trial, please visit https://clinicaltrials.gov/ct2/show/NCT04365101?term=CYNK001&draw=2&rank=2.

About IDRI
As a nonprofit global health organization, IDRI (Infectious Disease Research Institute) takes a comprehensive approach to combat infectious diseases, combining the high-quality science of a research organization with the product development capabilities of a biotech company to create vaccines and therapeutics. IDRI combines passion for improving human health with the understanding that it is not just what our scientists know about disease, but what we do to change its course that will have the greatest impact. Founded in 1993, IDRI has 55 employees headquartered in Seattle with more than 100 partners/collaborators around the world. For more information, visit www.idri.org.

About Celularity
Celularity, headquartered in Florham Park, N.J., is a clinical-stage biotechnology company leading the next evolution in cellular medicine with the development of off-the-shelf allogeneic cellular therapies derived from the postpartum human placenta. Celularity’s innovative approach harnesses the unique therapeutic potential of cells derived from the postpartum placenta therapeutics, including investigational CAR-T, genetically-modified and unmodified NK cells, and pluripotent stem cell therapies to target unmet and underserved clinical needs in cancer, and infectious and degenerative diseases. To learn more, please visit www.celularity.com.