

Ceria Therapeutics, Inc. Awarded a \$2,100,000 SBIR Grant to Advance Development of a Novel Treatment for Acute Lung Injuries, Acute Lung Failure, and Acute Respiratory Distress Syndrome

The award will go towards the development of CTX-002 in preparation for clinical studies

Tucson, AZ – September 19, 2023 – <u>Ceria Therapeutics, Inc. (Ceria)</u>, an Arizona-based biotech startup focusing on the development of novel therapeutics to address several inflammatory diseases, today announced the company has received a third Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH). This award is directed to the development of CTX-002 for the treatment of progressive inflammatory lung disorders, including Acute Lung Injuries (ALI), Acute Lung Failure (ARF), and Acute Respiratory Distress Syndrome (ARDS).

Ceria's pipeline of therapeutic products addresses inflammatory conditions at the root cause with a suite of novel drug products that block the inflammatory signaling pathway and restore natural healing. ALI can be caused by infections, inhaled chemicals, or chest trauma, which all result in lung inflammation. Inflamed lung tissue leads to fluid accumulation (edema), which can impair gas exchange. Significant pulmonary edema is a key clinical component of ARF, and when severe, is a hallmark of ARDS. Patients with ARF require supplemental oxygen, and patients who progress to ARDS require aggressive countermeasures, including mechanical ventilation. The mortality rate from ARDS is >40%.

Prior to the SARS-CoV-2 viral pandemic, there were >1.5 million annual cases of ALI from all causes, 210,000 cases of ARDS, and 82,000 resulting deaths in the U.S. More than 4.2 million persons have died in the U.S. during the pandemic with the vast majority dying from complications due to ARDS. There are no labeled drugs for ALI, ARF, or ARDS, and the spectrum of these inflammatory lung disorders is considered a major unmet medical need.

This grant was awarded as a result of collaborative research between Ceria, Colorado University, Anschutz Medical Campus, and the University of Arizona Medical Center. David Jackson PhD, chief executive officer of Ceria, will serve as the principal investigator (PI). He is joined by Carlos Zgheib PhD, chief scientific officer of Ceria and co-PI of the program, Ken Liechty MD, inventor of the company's core technology, and Christian Bime MD, a pulmonologist and researcher at the University of Arizona Medical Center. This team has extensive experience with the design and management of directed research and development programs. Dr. Liechty, Dr. Bime, and Dr. Zgheib are well published in this field, and Dr. Jackson has led multiple development programs for regulated products for patients.

"This follow-on SBIR award to continue the development of CTX-002 reflects recognition of the potential of this drug to change the practice of medicine. This product shares core technology with our entire pipeline, which has the potential to improve the lives of millions of patients," said Dr. David Jackson, CEO of Ceria. "If successful in clinical trials, CTX-002 will be a first-in-class therapeutic option to treat ALI, ARF, and ARDS by blocking pulmonary inflammation and edema."

The award will support development and manufacturing of CTX-002 in preparation for clinical trials. The program is funded through the National Heart, Lung & Blood Institute of the NIH under Award Number 5R44HL162137-03.

The goal of the program is to prepare CTX-002 for submission of an Investigational New Drug (IND) to the Food & Drug Administration (FDA) to advance clinical studies of the drug. The work will support drug product manufacturing and analyses, as well as confirmatory efficacy and GLP IND-enabling studies. "Ceria is dedicated to bringing novel, game-changing products to market." Added Ken Liechty, MD, FACS, FAAP, and Founder of Ceria. "The company is looking forward to continuing our fruitful collaborations with Colorado University Anschutz Medical Campus and the University of Arizona Medical Center."

About Ceria Therapeutics, Inc.

Ceria Therapeutics, Inc. is a preclinical-stage biotech company dedicated to improving the lives of patients suffering from unregulated inflammatory conditions. Ceria is headquartered in Tucson, Arizona with research and development facilities in Tucson and Aurora, Colorado. Founded in 2019, the company, along with collaborators and partners, is focused on developing and commercializing products derived from a core technology platform using nanoparticles to deliver microRNA therapeutics. Ceria's mission is to deliver therapies that attack these diseases at the root cause to bring substantial benefit to patients, healthcare providers, and other stakeholders.

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