Ceria Therapeutics, Inc. Awarded a $2,000,000 SBIR Grant to Advance Development of a Novel Treatment for Non-healing Diabetic Foot Ulcers

The award will go towards the development of CTX-001 in preparation for clinical studies

Tucson, AZ – January 20, 2024 – Ceria Therapeutics, Inc. (Ceria), an Arizona-based biotech startup focusing on the development of novel therapeutics to address several inflammatory diseases, announced today that the company has received a fourth Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH). This award is directed to the development of CTX-001 for the treatment of non-healing diabetic foot ulcers (DFU).

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.

DFU result from impaired circulation and neuropathy due to diabetes presenting a significant clinical problem for diabetic patients because of poor wound healing. Progression of these wounds can result in localized infection and necrosis requiring amputation of digits, portions of the foot, and even large portionsof the affected lower limb.

The standards of care for DFU include limb unweighting and wound care protocols including debridement, dressing, and excision of necrotic tissue. While, topical antibiotics and one product labeled for the treatment of DFU may be used, the latter has demonstrated only modest efficacy and is not widely prescribed. The intention of these efforts is to prevent further progression requiring more aggressive measures but are of limited efficacy.

While the majority of DFU initially present as Stages 1 or 2, a significant proportion progress to Stages 3 or 4. In the U.S. >25 million persons have diabetes, of which >25% will suffer a DFU in their lifetime resulting in >2 million new DFU cases each year. DFU is the #1 cause of emergency room visits for diabetics and progressive disease results in >72,000 amputations each year. The 5-year mortality rate for amputations from DFU is >50%. The costs of care for DFU are estimated to exceed $65B annually in the US. With limited treatment options and efficacy, DFU is considered a major unmet medical need.

This grant was awarded as a result of collaborative research between Ceria, University of Colorado Denver-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 Geoff Gurtner MD, a surgeon and professor 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. Gurtner, and Dr. Zgheib are well published in this field, and Dr. Jackson has led multiple development programs for regulated products for patients.

"This SBIR award to continue the development of CTX-001 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-001 will be a first-in-class therapeutic option to treat non-healing DFU by blocking hyperactivated inflammation."

The award will support the development and manufacturing of CTX-001 in preparation for clinical trials. The program is funded through the National Institute of Diabetes and Digestive and Kidney Diseases of the NIH under Award Number 1R44DK136463-01A1.

The goal of the program is to prepare CTX-001 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 The University of Colorado Denver - 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 products that attack these diseases at the root cause to bring substantial benefit to patients, healthcare providers and other stakeholders.