

## DELTAREX-G GAINS EMERGENCY USE AUTHORIZATION FOR SEVERE COVID-19

A TARGETED GENE THERAPY FOR COVID-19 INDUCED ARDS

LOS ANGELES, CA, USA, December 21, 2020 /EINPresswire.com/ -- The Aveni Foundation (www.avenifoundation.org), in collaboration with Larkin Community Hospital, South Miami FL, Drs. Ellie Soheili and George Yatzkan, is proud to announce that the USFDA has granted Emergency Use Authorization (EUA) for DeltaRex-G, a diseasetargeted gene therapy, for the treatment of a patient with severe COVID-19 infection. According to Dr. Soheili, Principal Investigator at Larkin Community Hospitals (www.larkinhospital.com), "Thousands of patients worldwide still die every day of COVID-19 related ARDS. The Emergency Use Authorization of DeltaRex-G establishes a precedent for many patients with severe COVID-19 who have run out of therapeutic options (Right to Try Law of 2018)".

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 causes life threatening complications including Cytokine Release

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The Aveni Foundation mission is to expedite development of gene-

targeted technologies for cancer and

COVID-19, an unmet medical need.

Syndrome (CRS) or Cytokine Storm and Acute Respiratory Distress Syndrome (ARDS). However, these complications are believed to be caused not just by the virus itself, but by an exaggerated immune reaction to the infection. The overactive (bad) immune cells are thought to make certain proinflammatory chemicals (cytokines) that cause raging fevers and damage to the lungs and other organs.

Over 1000 clinical trials are on-going to diagnose, prevent, treat, and improve the aggressive nature of COVID-19. DeltaRex-G is the first and only disease-targeted gene therapy with the potential of effectively treating cytokine storm and ARDS and increasing survival of COVID-19 patients.

"DeltaRex-G is currently being developed for cancer but there are striking similarities between the pathologic features of ARDS of COVID-19 and lung cancer that has led us to believe that DeltaRex-G could work as a treatment for severe COVID-19 as well", said Dr. Erlinda M. Gordon, President of the Aveni Foundation. Common features include (1) presence of abnormal Signature (SIG) proteins in the damaged lung environment of COVID-19 and the tumor microenvironment of lung cancer, and (2) presence of rapidly dividing cells (overactive immune cells in ARDS and cancer cells in lung cancer).

DeltaRex-G is a disease-targeted gene therapy that (a) displays a SIG-binding peptide on its surface for targeting sites of injury, and (b) encodes a designer killer gene for eradicating rapidly dividing cells. When injected intravenously, the DeltaRex-G nanoparticles seek out and accumulate in areas of pathology where SIG



Dr. Ellie Soheili is Principal Investigator and Internal Medicine Resident at Larkin Community Hospital, South Miami FL

proteins are abnormally found, in the vicinity of overactive immune cells or cancer cells. Mechanistically, DeltaRex-G would then enter the bad immune cells and kill them, hence, reducing cytokine storm and the severity of ARDS.



"Thousands of patients worldwide still die every day of severe COVID-19. The EUA for DeltaRex-G establishes a precedent for patients with severe COVID-19 (Right to Try Law of 2018)."

Ellie Soheili, MD

From our experience in 5 Phase 1 and 2 US-based clinical trials for metastatic cancer, we have shown that intravenous DeltaRex-G has minimal, if any, systemic toxicity. According to Dr. Gordon, Emergency Use Authorization of DeltaRex-G for ARDS opens the door to its potential use in autoimmune disorders wherein a person's own immune cells recognize "self" as foreign, and attack "self" causing debilitating disease. These autoimmune disorders include lupus, rheumatoid arthritis, myasthenia gravis, Parkinson's disease, psoriasis, lichen planus and atopic dermatitis.

For further information, please visit our websites: <a href="www.avenifoundation.org">www.avenifoundation.org</a>, contact Dr. Gordon at egordon@avenifoundation.org

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## A TEACHING HOSPITAL

Larkin Community Hospital is a general medicalsurgical-psychiatric and teaching hospital. This 146acute-care-bed hospital is located in South Miami, Florida. It is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

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