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Dystrogen Therapeutics Announces Approval of Clinical Trial Application (CTA) to Initiate a Phase 1/2 Clinical Trial of DT-DEC01 for the Treatment of Duchenne Muscular Dystrophy

Chicago, Illinois, December 20, 2023 – Dystrogen Therapeutics Corp,
A privately held clinical-stage chimeric cell therapy company focused on neuromuscular diseases, announced today that it has received a positive decision from the Polish Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) to initiate a clinical trial in Poland. The trial, titled "A PHASE 1/2, OPEN-LABEL, EXPLORATORY CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF DT-DEC01 THERAPY IN PATIENTS WITH DUCHENNE MUSCULAR DYSTROPHY".

Duchenne Muscular Dystrophy is a rare genetic disease that leads to progressive muscle weakness. It is the most common cause of death in children and teenagers with muscular diseases. DT-DEC01 therapy is an innovative cell therapy that uses chimeric cells. DT-DEC01 was previously administered to 7 patients in a proof-of-concept clinical experiment. DT-DEC01 therapy demonstrated both safety and efficacy on a number of subjective and objective parameters and resulted in improved muscle function and slowed the progression of the disease. Average follow-up was 16.4 months with maximum follow up of 26 months. There were no Adverse Events (AE) or Severe Adverse Events (SAE) observed at any point in time in any patient.
"Receiving permission from the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is an important milestone in the development of DT-DEC01 therapy," said Kris Siemionow, MD, PhD CEO of Dystrogen Therapeutics.

The clinical trial will be the first Phase 1/2 clinical trial of DT-DEC01 therapy planned in the European Union. "We are excited about the possibility of initiating this trial in Poland. Duchenne muscular dystrophy is a serious disease that can have a significant impact on patients' lives. DT-DEC-01 therapy does not require any genetic manipulation, it does not use viral vectors, and it is not restricted to any specific gene mutation, and as such represents a universal therapy for all Duchenne patients. We hope that DT-DEC01 therapy will halt progression of the disease and will improve the quality of life of DMD patients ." said Maria Siemionow, MD, PhD CMO of Dystrogen Therapeutics.

About DT-DEC01

DT-DEC01 is a chimeric cell therapy. The advanced therapeutic medicinal product (ATMP) is made using Dystrogen's proprietary cell engineering technology which creates a Dystrophin Expressing Chimeric (DEC) cell. Clinically, DEC cells have been shown to express CD56 at significantly higher levels than myoblasts from Duchenne patients. DEC cells express favorable HLA characteristics and contain healthy cell organelles (eg. mitochondria) from donor cells, both of which carry multiple advantages. In preclinical studies, DEC cells have also been shown to express clinically significant levels of dystrophin when compared to controls. DEC cell therapy demonstrated significant functional improvement in cardiac, diaphragm, and other skeletal muscle strength and associated function in preclinical trials. Because DEC therapy is designed to prevent triggering an immune system response, a major advantage of DEC therapy is that it does not require immunosuppression. The therapy is not associated with any genetic manipulation and therefore involves no risk of off-target mutations, does not use viral vectors, and its use is not dependent on the genetic mutation of the DMD patient, thus making DEC a universal therapy for all DMD patients.

About Dystrogen Therapeutics Corp

Dystrogen Therapeutics is a privately held, clinical-stage life sciences company committed to developing therapies for rare genetic diseases. Dystrogen has developed a patented cell engineering technology platform, which has been shown to improve function in both preclinical and clinical trials.

SOURCE Dystrogen Therapeutics Corporation