

## **Cellatoz Therapeutics, Inc. initiates Phase 1 Clinical Trial of Cell Therapy for Charcot-Marie-Tooth Disease**

Cellatoz Therapeutics, Inc., a South Korean biotech venture company specializing in cell therapy drug development, has commenced the first patient enrollment in the Phase 1 clinical trial of their peripheral neuropathy treatment (code name: CLZ-2002) at Samsung Seoul Hospital on July 10th. The trial aims to evaluate the safety, maximum tolerated dose, and potential therapeutic effects of CLZ-2002 in patients with Charcot-Marie-Tooth Type 1 (CMT1). It marks the world's first-in-human trial utilizing Neuronal Regeneration Promoting Cells (Schwann cell-like cells), which play a significant role in the peripheral nervous system and represents a pioneering attempt in the field of genetic disease area using functional somatic cells. Recently, Vertex Pharmaceuticals in the United States obtained BLA approval for a diabetes type 1 (genetic disease) treatment utilizing encapsulated pancreatic cells for administration, which indicates that functional cell technology begins to be spotlighted in cell therapy area.

CMT is a genetic disorder resulting from gene duplications and other chromosomal abnormalities, which leads to abnormalities resembling a reversed champagne bottle in the development of peripheral nerves in the hands and feet. As one of significant neurological disorders, it is a relatively rare condition with an incidence rate of 1 case per 2,500 individuals. CMT patients experience progressive muscle weakness and deformities in the hands and feet.

Cellatoz Therapeutics, Inc. has completed preclinical and clinical trial preparations in phases, including the establishment of Schwann cell differentiation technology, mechanism of action studies, evaluation of clinical efficacy using animal models, and Chemistry, Manufacturing, and Controls (CMC) to produce nerve regeneration-promoting cells (Schwann cell-like cells) derived from stem cells through a project supported by the Korean Ministry of Health and Welfare. In February 2023, the company obtained IND approval from the Ministry of Food and Drug Safety (MFDS) for the Phase 1 clinical trial.

According to Cellatoz Therapeutics, Inc., after the initiation of the Phase 1 trial, they plan to expand the clinical study of CMT to other regions such as Australia and the United States. They also aim to broaden the indications to include peripheral nerve injuries (PNI), diabetic neuropathy (DN), chemotherapy-induced peripheral neuropathy (CIPN), amyotrophic lateral sclerosis (ALS), and multiple sclerosis (MS).

In addition to the ongoing clinical trial of the peripheral neuropathy treatment CLZ-2002, Cellatoz Therapeutics, Inc. is also conducting research and development on musculoskeletal disorder treatment CLZ-1001, immune oncology therapy CLZ-300X, and other pipeline products. The company's technology demonstrates high scalability and growth potential, not only in the field of rare diseases but also in the

areas of common neurological disorders and musculoskeletal disorders where effective treatments are currently lacking. Furthermore, with internationally accredited Good Manufacturing Practice (GMP) facilities in place, the company is well-prepared for the production of investigational products and commercialization of therapeutics.

Cellatoz Therapeutics, Inc. envisions becoming a leading bio-tech company that enhances the advantages of cell therapy, overcomes its limitations, fosters trust in the field, and promotes cutting-edge science. Founded in 2017 by CEO Jaeseung Lim, the company consists of leaders with extensive expertise and specialization in the field of cell and gene therapies from major domestic biotechnology companies.

To date, Cellatoz Therapeutics, Inc. has secured a cumulative investment of KRW 38 billion (approximately USD 32 million) from domestic venture capitalists, with a goal to be listed within two years.