

Center for Gene & Cell Therapy

遺伝子・細胞治療センター

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To improve the safety and effectiveness of gene and cell therapies, we are developing Good Manufacturing Practices (GMP)-based production systems for high-quality viral vectors and cell products. Our main focus is on oncolytic virotherapy, gene therapy and vaccine development with Adeno-associated virus vectors, genetically modified T cell therapy, T cell therapy for viral infections after hematopoietic stem cell transplantation, and mesenchymal stromal cell (MSC) therapy.

Construction of large-scale viral vector purification systems

Large-scale purification systems for viral vectors, such as adeno-associated virus and lentivirus, typically require multiple steps to ensure the high purity and yield of functional viral particles that are crucial for gene therapy applications. Advances in these purification systems are crucial to meet the increasing demand for gene therapies, enabling more efficient and cost-effective production of high-quality viral vectors for clinical applications. Of particular importance is the scalability and efficiency of large-scale viral vector purification systems. This demand-supply gap necessitates the development of more efficient and scalable purification processes. Thus, selecting the proper manufacturing platform is crucial to ensure consistent quality and compliance with GMP standards.

Development of an oncolytic virus therapy using third-generation herpesvirus G47D

G47 Δ is a third-generation oncolytic herpes simplex virus type 1 (HSV-1) that has been developed for cancer therapy. It is a triple-mutant virus with enhanced replication capability and highly selective to

tumor cells. The development of G47 Δ represents a significant advancement in oncolytic virus therapy. G47 Δ has three genetically engineered mutations in the HSV-1 genome, that significantly improve its safety profile compared to existing cancer treatment viruses. These modifications allow G47 Δ to selectively replicate in cancer cells while leaving healthy cells unharmed, and to induce both innate and adaptive immune responses against the tumor. In addition, G47 Δ has shown promising results in various cancer types, such as glioblastoma, esophageal cancer, and gastric cancer. In a Phase II trial, G47 Δ demonstrated a 1-year survival rate of 84.2% and a median overall survival of 20.2 months in patients with residual or recurrent glioblastoma. Preclinical studies have shown significant inhibition of tumor growth in both subcutaneous and orthotopic models. G47 Δ exhibited efficacy in advanced gastric cancer models, including scirrhous gastric cancer with peritoneal dissemination. In addition, research has shown that combining G47 Δ with other cancer treatments can enhance its efficacy. When used in combination with checkpoint inhibitors, G47 Δ led to tumor disappearance in more than two-thirds of mice in a melanoma model. The development of G47 Δ represents a successful academic-led approach to creating a novel cancer therapy, from invention to practical application. The effica-

cy and safety of this oncolytic virus were confirmed in an investigator-initiated clinical trial conducted at IMSUT Hospital for malignant glioma patients. An application for manufacturing and marketing approval was submitted in 2020, and it was approved in 2021 as a regenerative medical product (teselpatulev, Delytact) for the treatment of malignant glioma. As research continues, G47 Δ and other oncolytic viruses may become integral components of multimodal cancer treatment strategies, potentially revolutionizing cancer therapy.

Development of a treatment for Duchenne muscular dystrophy (DMD) using MSCs

Another promising new therapy method for Duchenne muscular dystrophy (DMD) involves cell therapy using mesenchymal stromal cells (MSCs), which can improve pulmonary and cardiac functions, thereby enhancing survival in DMD patients. MSCs have several advantages, including immunomodulatory properties, non-tumorigenicity, enhanced regeneration capabilities, in vitro expansion ability, and anti-senescence properties. While MSC therapy shows promise for the treatment of DMD, further research is needed to fully understand its characteristics and potential long-term effects. As the field of re-

generative medicine advances, MSC therapy may offer new hope for improving the quality of life and extending the lifespan of DMD patients.

Improvement of CAR-T cell therapy for solid cancers by using interleukin (IL)-7 and chemokine (C-C motif) ligand 19 (CCL19) production

IL7/CCL19-expressing CAR-T cells (7 \times 19 CAR-T) have shown promising therapeutic efficacy in intractable solid tumor models of glioblastoma and pancreatic cancer. These next-generation CAR-T cells have demonstrated superior antitumor activity compared to conventional CAR-T cells in preclinical studies. This study is the first to demonstrate the therapeutic efficacy of next-generation CAR-T cells in an autologous model using patient-derived tumor organoids and CAR-T cells generated from the same patient's PBMCs. This approach eliminates unwanted allogeneic immune responses, providing a more accurate representation of potential clinical outcomes. The promising results of 7 \times 19 CAR-T cells in these intractable solid tumor models suggest that this technology could become a viable therapeutic option for glioblastoma and pancreatic cancer, which have shown resistance to conventional immunotherapies and have poor prognoses.

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