Korean CAR T-Cell Registry: Inauguration and the Current Status of CAR T-Cell Therapy in Korea

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Chimeric antigen receptor (CAR) T-cell therapy has emerged as a transformative treatment modality for patients with relapsed or refractory hematologic malignancies, including B-cell non-Hodgkin lymphoma and multiple myeloma. With the increasing clinical adoption of CAR T-cell products in Korea, attention has shifted beyond short-term efficacy toward long-term safety, durability of response, and real-world treatment outcomes. In particular, CAR T-cell therapy is classified as an advanced biopharmaceutical containing genetically modified cells, for which long-term follow-up (LTFU) is mandated under the Act on the Safety and Support of Advanced Regenerative Medicine and Advanced Biopharmaceuticals, implemented in Korea in 2020.

Currently, several CAR T-cell therapies have been approved or reimbursed in Korea, with additional indications and products expected to enter clinical practice. However, systematic long-term data collection has largely relied on sponsor-specific post-marketing surveillance or fragmented institutional efforts, limiting the comprehensive evaluation of delayed toxicities such as secondary malignancies, prolonged cytopenia, immune reconstitution failure, and persistent B-cell aplasia. Moreover, the absence of a unified national registry has posed challenges in generating real-world evidence (RWD) to support regulatory requirements, health technology assessment, and future clinical research.

To address these unmet needs, the Korean CAR T-Cell Registry (Ko-CARTR) has been established under the leadership of the Korean Society of Hematology (KSH). Ko-CARTR is designed as an academic, society-led, multicenter registry aimed at prospectively and retrospectively collecting standardized data from all patients receiving CAR T-cell therapy in Korea. The registry captures key domains including baseline patient characteristics, disease status, CAR T-cell product information, treatment outcomes, acute and long-term adverse events, secondary malignancies, and special safety considerations such as pregnancy outcomes. Importantly, Ko-CARTR is structured to enable up to 15 years of follow-up after CAR T-cell infusion, in alignment with national regulatory LTFU requirements.

A central objective of Ko-CARTR is to serve as an integrated data platform that can simultaneously fulfill academic research goals and regulatory obligations. By harmonizing registry variables with requirements from the Ministry of Food and Drug Safety, the Korea Disease Control and Prevention Agency, and international registries such as CIBMTR, Ko-CARTR aims to minimize redundant reporting and reduce the administrative burden on participating centers. The registry also emphasizes transparent data governance, with data ownership retained by the academic community rather than individual pharmaceutical sponsors, thereby promoting investigator-initiated research and collaborative studies.

The official inauguration of Ko-CARTR, scheduled for April 2026, represents a critical milestone in the maturation of CAR T-cell therapy in Korea. Through comprehensive long-term outcome assessment, Ko-CARTR is expected to enhance patient safety, inform evidence-based clinical decision-making, support regulatory science, and facilitate the development and global integration of domestically developed CAR T-cell therapies. Ultimately, this national registry provides a foundation

for sustainable, high-quality CAR T-cell care and positions Korea as an active contributor to the global CAR T-cell research community.