**Recent Analysis for FDA-Approved CAR-T Cell Therapies**

Ha Jin Chang, **Chang Soo Lee**, Kwan Hyung Cho

Department of Pharmacy, Inje University, Gimhae, Gyeongsangnam-do, Republic of Korea.

**Background and aims.** CAR-T cell therapy is a treatment that manipulates the immune system to precisely recognize and eliminate cancer cells by expressing chimeric antigen receptors (CARs) specific to the patient's T cells. CAR-T cells selectively target tumor-specific antigens by expressing engineered receptors and show high efficacy in treating relapsed or refractory blood cancers such as ALL and DLBCL. This study aims to comprehensively examine the mechanism of action, clinical application, limitations, side effects, and future development direction of CAR-T cell therapy

**Methods.** This study analyzed six CAR-T cell therapies approved by the FDA from 2017 to 2023, focusing on their clinical indications, response rates, safety profiles, market trends, and positioning within the cellular immunotherapy landscape.

**Results.** Yescarta® has emerged as the market leader with a 54% complete response rate in relapsed/refractory large B-cell lymphoma and a market share of 44%, generating USD 2,472 million in revenue. Breyanzi® gained expanded indications, while Abecma® and Carvykti® advanced to earlier treatment lines. The global CAR-T market reached USD 3.71 billion, led by North America due to strong healthcare infrastructure and reimbursement policies. Despite progress, challenges such as high costs, complex manufacturing, cytokine release syndrome (CRS), and neurotoxicity persist. Notably, CRS was observed in up to 95% of patients treated with Carvykti® and 93% with Abecma®, underscoring the urgent need for safer and more scalable CAR-T therapies.

**Conclusion/Discussion.** CAR-T cell therapy has revolutionized the treatment of certain hematologic cancers, providing new hope for patients with relapsed or refractory diseases. However, issues such as severe adverse effects, high costs, manufacturing complexity, and limited effectiveness in solid tumors continue to pose major challenges. Ongoing research into next-generation CAR designs and improved delivery platforms is essential to address these limitations and broaden the clinical impact of CAR-T therapy.

**Acknowledgements**: This research was supported by the Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT & Future Planning (Grant number: NRF-2022R1A2C1003070).

**References**

(1) Bhaskar, S. et al (2024) Clinical Hematology International 6(4):93

(2) Zhang, Y. et al (2023) Journal of clinical medicine 12(19):6124