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ASIA EDITION

JW Therapeutics announces IND approval of Carteyva

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Carteyva is an anti-CD19 autologous chimeric antigen receptor T (CAR-T) cell immunotherapy product

China's JW Therapeutics has received the Investigational New Drug (IND) clearance from the National Medical Products Administration (NMPA) of China for a pivotal clinical trial of its anti-CD19 autologous chimeric antigen receptor T (CAR-T) cell immunotherapy product Carteyva (relmacabtagene autoleucel injection) in the treatment of second-line large B-Cell lymphoma.

B-cell lymphoma is a group of malignant B-cell monoclonal amplified heterogeneous malignancies, accounting for approximately 85% of non-Hodgkin lymphoma (NHL). Large B-cell lymphoma (LBCL) is the most common subtype of NHL world-wide, accounting for 35% to 50% of all newly diagnosed cases in China. 50% of patients could be cured by current standard of care (R-CHOP) chemotherapy. Nevertheless, R-CHOP was found to be inadequate in 30% to 40% patients. R-CHOP failures were principally due to either primary refractoriness or relapse after reaching a complete response (CR), resulting in little benefit for those failure patients from conventional chemotherapy. Previous study demonstrate that for patients who could not achieve CR or maintain CR less than one year, overall response rate (ORR) of received second-line treatment was about 29%, median progression-free survival (PFS) was about 3 months, and median overall survival (OS) was about 10 months. High unmet medical needs are to be addressed for those patients with relapsed or refractory large B-cell lymphoma (r/r LBCL) from first-line treatment.

This is a multi-centre, randomized, open label phase 3 study to compare the efficacy and safety of Carteyva to standard second-line therapy in adult subjects with relapse/refractory large B-cell lymphoma (r/r LBCL), not reaching CR after first-line therapies (including anthracyclines and rituximab or other CD20-targeted agents) or relapsed within 12 months of CR. Eligible adults will be randomized at the 1:1 ratio to control group and Carteyva group.