

China approves phase II trial of Akeso's cancer drug

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Akeso announces IND approval from China NMPA for phase II clinical trial of Cadonilimab in combination with docetaxel to treat NSCLC



Akeso, Inc., a biopharmaceutical company dedicated to the development of innovative antibody drugs, has announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has approved the IND application for the initiation of the open-label, multicenter phase II trial in China using Cadonilimab (PD-1/CTLA-4 bispecific antibody, AK104) in combination with Docetaxel in patients with advanced NSCLC which progressed on combination therapy of PD-1/L1 inhibitor and platinum-based doublet chemotherapy.

PD-1/L1 inhibitor plus chemotherapy serves as the first-line treatment for patients with advanced NSCLC. However, more than 70% of patients have progressed one year following the therapy. The current standard treatment for progressive advanced NSCLC is Docetaxel, which the reported progression-free survival (PFS) was approximately 4 months, and overall survival (OS) was approximately 10 months. A new therapeutic approach is needed to improve the prognosis of patients.

Cadonilimab is a bi-specific antibody with dual blockade of both PD-1 and CTLA-4. By combining with Docetaxel, this combo strategy may reduce the risk of delayed efficacy and pseudoprogression and may benefit patients with advanced NSCLC following PD-1/L1 inhibitor and platinum-based doublet chemotherapy.