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The EGFR-targeted chimeric antigen receptor-modified T cells immunotherapy for patients with EGFR-expressing advanced or relapsed/refractory solid tumors

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In this phase I/II clinical study (NCT01869166), we have evaluated for the first time the safety and efficacy of EGFR-targeted chimeric antigen receptor-modified T (CAR-T) cells in patients with epidermal growth factor receptor (EGFR) positive (>50% expression), unresectable, and/or relapsed/refractory solid tumors. 24 eligible patients received escalating doses of EGFR-targeted CART cells infusions. The EGFR-targeted CART cells were generated from peripheral blood after a 10 to 13-day in vitro expansion. Serum cytokines and copy numbers of CAR-EGFR transgene in peripheral blood and in tissue biopsy were monitored periodically. The clinical responses were evaluated with RECIST1.1 and immune-related response criteria, and adverse events were graded with CTCAE 4.0. The EGFR-targeted CART cells infusions were well-tolerated. Only 3 out of 24 patients exhibited Grade 2 cytokine release syndrome within one week post infusions. Nineteen of 24 evaluable patients (17 lung cancers, 5 cholangiocarcinomas, 1 pancreatic adenocarcinoma, and 1 renal cell carcinoma) had clinical response (DCR=79%), including 2 ongoing CR achieved by patients with cholangiocarcinoma, 4 PR (1 cholangiocarcinoma, 1 pancreatic carcinoma, and 2 lung cancers), and 13SD. The median dose of transfused CAR+ T cells was 1.18×107 cells/kg (IQR, 0.76 to 1.43×107 cells/kg). Pathological eradication of EGFR positive tumor cells after EGFR-targeted CART cells treatment can be observed in tumor biopsies, along with clear evidence of the CAR-EGFR signal detected in tumor-infiltrating T cells in all 5 biopsied patients. The EGFR-targeted CAR T cells therapy for EGFR-positive, advanced or relapsed/refractory solid tumor patients is safe and effective.

Biography

Professor Weidong Han, M.D. PhD, is the director of Department of Molecular Immunology/Bio-therapeutic, director of Department of Stem Cell and Tissue Regeneration in Chinese PLA General Hospital. He is a pioneer in the field of tumor immunotherapy, initially developed the clinical translation of chimeric antigen receptor T (CART) cells in China. He holds 10 projects of clinical trial, including 8 registered CART-based trials (CART19, CART20, CART30, CART33, CART-EGFR,CART-HER-2, and CART-138). The corresponding patents were also applied or obtained in China. In recent 10 years, he obtained 9 grants in China and published more than 80 papers on International journals.

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