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Infected hepatocyte clearance and sustained tumor regression by first-in-Class HBsAg-Specific TCR-T (SCG101) therapy for HBV-Related HCC**Shunda Du***Peking Union Medical College Hospital, China*

Hepatitis B virus (HBV) infections account for 75 to 80% of virus-associated Hepatocellular carcinoma (HCC). HBV-DNA integration into the host cell genome leads to production of viral antigens and tumorigenesis, which can be effectively targeted by HBsAg-specific TCR-T cells. A first-in-class autologous HBsAg-specific TCR-T cell therapy (SCG101) demonstrated high affinity/avidity and profound antiviral and antitumor functionalities in preclinical studies, and is further evaluated in patients with HBV-related HCC to assess its safety, efficacy and mechanism of action. HBsAg clearance and sustained tumor regression were observed in the patient after single dose of SCG101 monotherapy treatment. The treatment was well-tolerated. On Day 7 after SGG101 infusion, serum HBsAg significantly decreased from baseline 558 IU/mL to 1.3 IU/mL, and further reduced to 0.08 IU/ml on Day 28, which was maintained for 6 months as of data cutoff. Pre- and post-treatment biopsies indicated the expression of HBsAg in hepatocyte reduced from 10% at baseline to undetectable. The patient achieved a partial response (PR, mRECIST) on Day 28, with more than 50% decrease in the sum of diameters of target lesions. The tumor response has maintained for 6 months as of data cutoff. SCG101 persistence were detected for at least 6 months as of data cutoff and majority of the T cells acquired memory stem cell phenotype. The clinical data demonstrated encouraging clinical proof-of-mechanism of HBsAg-specific TCR-T cell therapy in treatment of HBV-related HCC. A phase I/II clinical trial to further evaluate the safety and efficacy of SCG101 is ongoing.

Biography

Shunda Du graduated from Peking Union Medical College with a doctorate degree in 2002. After that, he worked in the Department of Surgery of Peking Union Medical College Hospital. In 2009, he was qualified as the Deputy Chief Physician of the Ministry of Health and was hired as an Associate Professor of Liver Surgery. He has won the National Natural Science Foundation of China, Peking Union Medical College Hospital Excellent Youth Fund and other funds, and has one patent. He has more than ten articles published in reputed journals.