

CARsgen Therapeutics receives IND clearance for GPC3-CAR-T Cells from NMPA

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CARsgen Therapeutics is a clinical-stage immune-oncology company committed to the development and commercialization of CAR-T therapeutics for unmet medical need.



CARsgen Therapeutics, a clinical-stage company committed to developing Chimeric Antigen Receptor T cell therapies for cancer has announced that one of its leading drug candidates, humanized GPC3-CAR-T cell for the treatment of patients suffering from GPC3-positive solid tumors, has received Investigational New Drug (IND) clearance from the National Medical Products Administration (NMPA). This marks China's first IND clearance for CAR-T cells against solid tumors.

"The IND clearance of GPC3-CAR-T cells by China's NMPA is of great significance to CARsgen," said Dr. Zonghai Li, founder, CEO and CSO of CARsgen. "Solid tumors, particularly hepatocellular carcinoma, represent major health challenges due to increasing incidence and limited available therapeutic solutions. In China, the estimated annual incidence of HCC has already reached 467,000. While in the U.S., HCC is also a leading cause of death with 37,948 new cases every year. To cope with the situation, we plan to submit IND Application for GPC3-CAR-T cells to FDA by the end of 2019. Our goal is to continue the development of novel, safe and effective immunotherapies. This is our long-standing commitment to cancer patients worldwide."

CARsgen Therapeutics is a clinical-stage immune-oncology company committed to the development and commercialization of CAR-T therapeutics for unmet medical need. The company has launched several First-in-Human CAR-T clinical trials to treat relapsed/refractory tumors, including CAR-GPC3-T for hepatocellular carcinoma and squamous lung cancer, CAR-EGFR/EGFRvIII-T for glioblastoma multiforme and CAR-Claudin18.2-T for gastric and pancreatic cancer. CARsgen also has ongoing clinical programs of humanized CAR-CD19-T for acute lymphocyte leukemia and fully humanized CAR-BCMA-T program for multiple myeloma.