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CARsgen Therapeutics Receives IND Clearance for BCMA-CAR-T Cells

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CT053 fully human BCMA-CAR-T cell for the treatment of rrMM received IND clearance from the US FDA

CARsgen Therapeutics, a clinical-stage company committed to developing Chimeric Antigen Receptor T cell therapies for cancer, on 19 June 2019, announced that one of its leading drug candidates, CT053 fully human BCMA (B-Cell Maturation Antigen)-CAR-T cell for the treatment of patients suffering from relapsed/refractory multiple myeloma (rrMM), has received Investigational New Drug (IND) clearance from the United States Food and Drug Administration (FDA). CT053 has also received IND clearance from the National Medical Products Administration in China 4 months ago and is the subject of an ongoing phase I clinical trial.

"At the 5th Annual Immunotherapy in Myeloma Scientific Workshop in Denver, Colorado, CARsgen provided an update of the clinical data of CT053 and showed that as of 28 Feb 2019, 87.5% of the patients showed overall response to the treatment. 70.8% of the patients had a complete response and no grade 3 or higher cytokine release syndrome (CRS) was observed in 24 heavily pre-treated patients with rrMM. The IND clearance of CT053 by the U.S. FDA is of great significance to patients" said Dr Zonghai Li, founder, CEO and CSO of CARsgen. "According to JAMA Oncology, in 2016, there were about 130,000 cases of myeloma, which means from 1990 to 2016, incident cases of myeloma increased by 126% globally and despite the development of novel therapies, multiple myeloma remains incurable and new treatment options are needed. Our goal is to continue the development of novel, safe and effective immunotherapies. This is our long-standing commitment to cancer patients worldwide."