CARsgen Announces Investigational CAR-T Therapy CT053 Granted PRIME Eligibility by the European Medicines Agency

Shanghai, September 23, 2019 — CARsgen Therapeutics Inc., a clinical-stage biopharmaceutical company today announced the European Medicines Agency (EMA) has granted PRIority MEdicines (PRIME) eligibility to its investigational CAR-T cell therapy fully human anti-BCMA (B Cell Maturation Antigen) autologous chimeric antigen receptor (CAR) T Cells (CT053) for the treatment of relapsed or refractory multiple myeloma.

PRIME eligibility was based on clinical data from an ongoing CT053 BCMA CAR-T phase 1 study in China. The results from the trial were presented at an oral presentation on September 14, 2019 in Boston at the 17th International Myeloma Workshop. As of June 30, 2019, 21 out of 24 myeloma patients (87.5%) who received a median of 4.5 prior lines of myeloma therapy showed objective response. 19 out of 24 patients (79.2%) achieved complete response. There was
no grade 3 or higher cytokine release syndrome. The duration of response data will be reported at a future date.

“PRIME eligibility is an important regulatory milestone in the continued development and commercialization of CT053 anti-BCMA CAR T cells,” said Zonghai Li, M.D., Ph.D., chief executive officer of CARsgen. “CT053 has demonstrated the potential to become the best-in-class BCMA CAR-T therapy. PRIME designation is invaluable to the advancement of this cutting-edge therapeutic to potential market approval and being available to patients as quickly as possible.” The CT053 anti-BCMA CAR-T program has received Investigational New Drug (IND) clearance and Orphan Drug designation from the U.S. Food and Drug Administration and authorization of its Clinical Trial Application (CTA) from Health Canada.

EMA’s voluntary PRIME scheme supports the development of promising medicines that show a high potential to benefit patients and target a significant unmet medical need. The status is granted to medicines that may offer a major therapeutic advantage over existing treatments. The program provides developers with enhanced interaction and early dialogue with the EMA to expedite drug development. Between the launch of PRIME in March 2016 through July 25, 2019, the EMA has received and assessed a total of 246 requests for eligibility. Of these, only 24 out of a total of 76 requests in oncology and hematology have been accepted into the scheme.
About CARsgen Therapeutics

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 collaborated with top hospitals in China to launch several other First-in-Human studies such as anti-GPC3 CAR-T for hepatocellular carcinoma and squamous lung cancer, anti-EGFR/EGFRvIII CAR-T for glioblastoma multiforme and anti-Claudin18.2 CAR-T for gastric and pancreatic cancer.

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