New Data from LEGEND-2 Study of LCAR-B38M BCMA CAR-T Therapy Show High Overall Response in Patients with Advanced Relapsed or Refractory Multiple Myeloma

- *National Academy of Sciences publishes update from three LEGEND-2 study sites*
- *Results support findings from fourth study site previously presented at ASH 2018*

Piscataway, NJ, April 15, 2019 – New data from three sites involved in the LEGEND-2 Phase 1/2 open-label study showed that treatment with the investigational anti-B-cell maturation antigen (BCMA) chimeric antigen receptor T-cell (CAR-T) therapy LCAR-B38M resulted in deep and durable responses, with a manageable and tolerable safety profile, in patients with advanced relapsed or refractory (R/R) multiple myeloma. A total of 74 patients were enrolled in the LEGEND-2 study. The data from 17 patients studied at Shanghai Ruijin Hospital, Shanghai Changzheng Hospital, and Jiangsu Province People's Hospital are now published in the *Proceedings of the National Academy of Sciences of the United States of America*. Data from the first 11 patients enrolled at these sites were presented at the 2017 American Society of Hematology (ASH) annual meeting. Results from 57 patients enrolled at the fourth site, The Second Affiliated Hospital of Xi'an Jiaotong University, were previously published in the *Journal of Hematology & Oncology* and presented at the 2018 ASH annual meeting.[1]

"Patients with multiple myeloma continue to need better treatment options because their disease is incurable and becomes more difficult to treat with each relapse," said study investigator Jian-Qing Mi, MD, PhD, Deputy Chief of Hematology at Ruijin Hospital, an Affiliated Hospital of Shanghai Jiaotong University in Shanghai, China. "As a result of continued research, the multiple myeloma treatment landscape is constantly evolving to meet the unmet needs of patients. LCAR-B38M is an investigational CAR-T cell therapy that targets B-cell maturation antigen and could provide a potential meaningful therapeutic option that may achieve and maintain deep and durable responses with a generally tolerable safety profile."

Patients in this study received LCAR-B38M intravenously after lymphodepleting chemotherapy. As of October 20, 2018, of the 17 evaluable patients, the overall response rate was 88.2%, with 13 patients achieving stringent complete response (sCR), 2 achieving very good partial response (VGPR), and 1 non-responder. At median follow-up of 14.0 months, 8 patients (47.1%) remained in sCR or VGPR. Progression-free survival was 82.4% at 6 months

and 52.9% at 12 months, and 12-month overall survival was 82.3%. Adverse events included cytokine release syndrome (CRS) (100%), cytopenia (82.4%), infections (52.9%), and Grade 2 or 3 liver dysfunction (52.9%). Six patients (35.3%) experienced Grade 3 CRS, and 1 died due to severe CRS and tumor lysis syndrome.[2]

"We are very encouraged to see additional data that further strengthen our confidence in LCAR-B38M," said Yuan Xu, PhD, CEO of Legend Biotech. "Data from this study and future clinical trials will continue to shape our understanding of the evolving treatment landscape in R/R multiple myeloma globally."

In China, a Phase 2 confirmatory trial (CARTIFAN-1) registered with the Center for Drug Evaluation (CTR20181007, NCT03758417) is currently enrolling patients to further evaluate LCAR-B38M in patients with advanced R/R multiple myeloma. Globally, Legend, together with Janssen Biotech, Inc., is advancing the Phase 1b/2 trial (CARTITUDE-1, NCT03548207) with JNJ-68284528 (LCAR-B38M) to evaluate its efficacy and safety in adults with R/R multiple myeloma. The study is currently enrolling patients following U.S. Food and Drug Administration clearance of an Investigational New Drug application as announced in May 2018.

About LEGEND-2
LEGEND-2 (NCT03090659) is an ongoing Phase 1/2, single-arm, open-label study of 74 patients being conducted at four participating hospitals in China evaluating the efficacy and safety of LCAR-B38M for the treatment of patients with R/R multiple myeloma who have failed a median of three prior therapies.

About CAR-T and BCMA
CAR-T cells are an innovative approach to eradicating cancer cells by harnessing the power of a patient's own immune system. BCMA is a protein that is highly expressed on myeloma cells. By targeting BCMA, CAR-T therapies may have the potential to redefine the treatment paradigm for multiple myeloma.

About Multiple Myeloma
Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.[3,4] Refractory cancer occurs when a patient's disease is resistant to treatment or, in the case of multiple myeloma, patients progress within 60 days of their last therapy.[5,6] Relapsed cancer means the disease has returned after a period of initial, partial, or complete remission.[7] In 2019, it is estimated that more than 32,000 people will be diagnosed and nearly 13,000 will die from the disease in the United States.[8] Most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood counts, fatigue, calcium elevation, kidney problems, or infections.[9]

About Legend Biotech

Legend Biotech is a clinical stage biopharmaceutical company engaged in the discovery and development of novel cell therapies targeting various oncology indications. Legend is a subsidary of GenScript Biotech Corporation (HKEx: 1548), which operates in the USA, Hong Kong, mainland China, and Ireland. Learn more at www.LegendBiotech.com.

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