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Genscript Biotech Corporation
金斯瑞生物科技股份有限公司*
(Incorporated in the Cayman Islands with limited liability)
(Stock code: 1548)

VOLUNTARY ANNOUNCEMENT
RESEARCH AND DEVELOPMENT UPDATE

Reference is made to the voluntary announcements of Genscript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) dated 28 October 2016, 14 May 2017, 6 June 2017, 19 September 2017, 1 November 2018, 4 December 2018, 16 April 2019 and 7 November 2019. The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that updated data on the LEGEND-2 (NCT03090659) was reported during an oral presentation (Abstract #579) and a poster presentation (Abstract #1858) at the 2019 American Society of Hematology (“**ASH**”) annual meeting held in Orlando, Florida, the United States on 7 December 2019 and 9 December 2019, which revealed that LCAR-B38M responses in patients with advanced relapsed and/or refractory multiple myeloma (“**RRMM**”) who failed a median of three prior therapies.

LCAR-B38M is a structurally differentiated CAR-T cell therapy containing a 4-1BB co-stimulatory domain and two B-cell maturation antigen (“**BCMA**”)–targeting single-domain antibodies designed to confer avidity. The study findings build upon previously reported data from the four clinical study sites: The Second Affiliated Hospital of Xi’an Jiaotong University, Shanghai Ruijin Hospital, Shanghai Changzheng Hospital, and Jiangsu Province People’s Hospital. A total of 74 patients were enrolled in the LEGEND-2 study.

In the study update (data cut-off 31 July 2019) presented by The Second Affiliated Hospital of Xi’an Jiaotong University, 57 patients with RRMM received LCAR-B38M CAR-T cell therapy (median administered dose 0.5×10^6 cells/kg; range, 0.07 – 2.1×10^6 CAR+T cells/kg) at The Second Affiliated Hospital of Xi’an Jiaotong University clinical study site. The median age of the patients was 54 years (range, 27–72 years). A median number of prior therapies was three (range, 1–9). 74% of patients had stage 3 disease by Durie-Salmon staging and 37% of patients had stage 3 disease by ISS staging.

According to study findings, there was an 88% overall response rate (ORR). Complete response (CR) was achieved by 74% of patients; very good partial response (VGPR) was achieved by 4% of patients; and partial response was achieved by 11% of patients. With a median follow-up of 25 months, the median duration of response (DOR) was 27 months (95% CI, 14.3–not evaluable NE) for all patients. The median progression-free survival (PFS) of 19.9 months and the median overall survival (OS) of 36.1 months was observed for all patients.

The most common adverse events (AEs) were pyrexia (91%), cytokine release syndrome (CRS) (90%), thrombocytopenia (49%), and leukopenia (47%). In patients who experienced grade 3/4 AEs (65%), the most common were leukopenia (30%), thrombocytopenia (23%), and increased aspartate aminotransferase (21%). CRS was mostly low grade, which included grade 1 (47%), grade 2 (35%), and grade 3 (7%). The median time to onset of CRS was nine days (range, 1-19 days), with a median duration of nine days (range, 3-57 days). Neurotoxicity was observed in one patient who had grade 1 aphasia, agitation, and seizure-like activity.

Additionally, Ruijin Hospital affiliated with Shanghai Jiao Tong University School of Medicine, presented a study update (data cut-off October 31, 2019) for 17 patients with RRMM who were enrolled at the Shanghai Ruijin Hospital, Shanghai Changzheng Hospital, and Jiangsu Province People's Hospital and received LCAR-B38M CAR-T cell therapy (mean administered dose 0.7×10^6 ; range, $0.2-1.5 \times 10^6$ CAR+ T cells/kg). The median age of the patients was 56 years (range, 35-73 years). The median number of prior therapies was 4 (range, 3-11). According to study findings, there was an 88% ORR. CR was achieved by 82% percent of patients and VGPR was achieved by 6% of patients. The median time to first response was approximately 1 month. With a median follow-up of 26 months (0.4-30), a median PFS of 18 months (95% CI: 9-NE) was observed for all patients. The median OS has not been reached (95% CI: 12-NE).

The most common AEs were CRS (100%), cytopenia (82%), and increased aspartate aminotransferase (94%). There was one grade 5 AE of CRS using CAR-T cell therapy-associated toxicity (CARTOX) criteria.

As the results for the CARTITUDE-1 study in the United States emerge, the Company observes the initial safety and efficacy data are consistent with the LEGEND-2 study. In collaboration with Janssen Biotech, Inc., Legend Biotech Corporation is dedicated to advancing the clinical development program of LCAR-B38M/JNJ-4528 for patients with RRMM.

For details in relation to LEGEND-2 and CARTITUDE-1, please refer to the voluntary announcement of the Company dated 7 November 2019.

Shareholders and potential investors of the Company are advised to pay attention to investment risks and exercise in caution when they deal or contemplate dealing in the securities of the Company.

By order of the Board
Genscript Biotech Corporation
Zhang Fangliang
Chairman and Chief Executive Officer

Hong Kong, 9 December 2019

As at the date of this announcement, the executive Directors are Dr. Zhang Fangliang, Ms. Wang Ye and Mr. Meng Jiange; the non-executive Directors are Dr. Wang Luquan, Mr. Pan Yuexin and Ms. Wang Jiafen; and the independent non-executive Directors are Mr. Guo Hongxin, Mr. Dai Zumian and Mr. Pan Jiuan.

* For identification purposes only