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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 announcement of GenScript Biotech Corporation (the “**Company**”) dated 8 December 2019 and 30 April 2021.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company announces that Legend Biotech Corporation (“**Legend Biotech**”), a non-wholly owned subsidiary of the Company, whose shares are listed by way of American Depositary Shares on the Nasdaq Global Select Market in the United States (the “**U.S.**”), announced that, the U.S. Food and Drug Administration (the “**FDA**”) has approved its first product, CARVYKTI™ (ciltacabtagene autoleucel), for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Legend Biotech entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc., or Janssen, to develop and commercialize CARVYKTI™ in December 2017.

CARVYKTI™ is a chimeric antigen receptor T-cell (CAR-T) therapy with two B-cell maturation antigen (BCMA)-targeting single domain antibodies and given as a one-time infusion with a recommended dose range of 0.5 to 1.0 x 10<sup>6</sup> CARpositive viable T cells per kg of body weight. In the pivotal CARTITUDE-1 study, deep and durable responses were seen in patients with RRMM, with a high overall response rate (ORR) of 98 percent (95 percent confidence interval [CI]: 92.7-99.7), including 78 percent of patients achieved a stringent complete response (sCR, 95 percent CI: 68.8-86.1). At a median of 18 months follow-up, median duration of response (DOR) was 21.8 months (95 CI, 21.8-not estimable).

CARVYKTI™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI™ REMS Program. The Safety Information for CARVYKTI™ includes a Boxed Warning regarding Cytokine Release Syndrome (CRS), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), Parkinsonism and Guillain-Barré syndrome, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLM/MAS), and prolonged and/or recurrent cytopenia. Warnings and Precautions include prolonged and recurrent cytopenias, infections, hypogammaglobulinemia, hypersensitivity reactions, secondary

malignancies and effects on ability to drive and use machines. The most common adverse reactions ( $\geq 20$  percent) are pyrexia, CRS, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogen unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting.

Multiple myeloma affects a type of white blood cell called plasma cells, which are found in the bone marrow. The majority of patients relapse after undergoing initial treatment and face poor prognoses after treatment with three major drug classes, including immunomodulatory agent, a proteasome inhibitor and anti-CD38 monoclonal antibody.

As a personalized medicine, CARVYKTI™'s administration requires extensive training, preparation, and certification to ensure a seamless experience for patients. Through a phased approach, Legend Biotech and Janssen will activate a limited network of certified treatment centers as they work to scale production capacity and increase the availability of CARVYKTI™ throughout the U.S. in 2022 and beyond, ensuring that the CARVYKTI™ treatment can be provided to oncologists and their patients in a reliable and timely manner.

## **About CARVYKTI™ (Ciltacabtagene autoleucel; cilta-cel)**

CARVYKTI™ is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells. The CARVYKTI™ CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.

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In April 2021, Legend Biotech announced the submission of a Marketing Authorisation Application to the European Medicines Agency seeking approval of cilta-cel for the treatment of patients with relapsed and/or refractory multiple myeloma. In addition to U.S. Breakthrough Therapy Designation granted in December 2019, cilta-cel received a Breakthrough Therapy Designation in China in August 2020. cilta-cel also received Orphan Drug Designation from the U.S. FDA in February 2019, and from the European Commission in February 2020.

## **Cautionary Note Regarding Forward-Looking Statements**

Statements in this announcement about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Legend Biotech's strategies and objectives and statements relating to CARVYKTI™, including Legend Biotech's expectations for CARVYKTI™, Legend Biotech's manufacturing and commercialization expectations for CARVYKTI™ and the potential effect of treatment with CARVYKTI™, submissions for cilta-cel

to the European Medicines Agency (EMA) and the Chinese Center for Drug Evaluation of National Medical Products Administration (CDE), and the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech’s expectations could be affected by, among other things, uncertainties involved in the development, manufacturing and commercialization of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech’s patent or other proprietary intellectual property protection, including the uncertainties involved in the U.S. litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the “Risk Factors” section of Legend Biotech’s Annual Report on Form 20-F filed with the Securities and Exchange Commission on 2 April 2021. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this announcement as anticipated, believed, estimated or expected. The Group and Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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

By Order of the Board  
**Genscript Biotech Corporation**  
**MENG Jiange**  
*Chairman and Executive Director*

Hong Kong, 1 March 2022

*As at the date of this announcement, the executive Directors are Mr. Meng Jiange, Ms. Wang Ye and Dr. Zhu Li; 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, Mr. Pan Jiuan and Dr. Wang Xuehai.*

\* *For identification purposes only*