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Legend Announces FDA clearance of IND application on CAR-T immuno-cell therapy for the Treatment of Multiple Myeloma

LCAR-B38M CAR-T therapy (JNJ-68284528) to be developed as part of strategic partnership between Legend and Janssen

Piscataway, NJ (May 30, 2018) – Legend Biotech, a subsidiary of GenScript Biotech Corporation (HKEx: 1548), announced today that the U.S. Food and Drug Administration (FDA) has authorized its development partner, Janssen Biotech, Inc. (“Janssen”), to commence a Phase 1b/2 clinical trial in patients with relapsed or refractory Multiple Myeloma (MM) to evaluate the safety and efficacy of LCAR-B38M (JNJ-68284528), a Chimeric Antigen Receptor T cell (CAR-T) therapy. Scheduled to begin enrollment in the second half of 2018, the Phase 1b/2 study (68284528MMY2001) is part of a collaboration between Legend Biotech and Janssen that was formed in December 2017 to develop CAR-T therapy for MM globally.

LCAR-B38M (JNJ-68284528) is an autologous CAR-T therapy that targets B cell Maturation Antigen (BCMA), a molecule expressed on the surface of mature B lymphocytes and malignant plasma cells. The investigational therapy expresses an identical CAR protein as Legend’s LCAR-B38M CAR-T product, which was evaluated in a first-in-human clinical study (Legend-2) conducted in multiple sites by Legend Biotech in China.

The Phase 1b/2, open-label, multicenter study will evaluate the safety and efficacy of JNJ-68284528 in adults with relapsed or refractory multiple myeloma. The primary objective of the Phase 1b portion of the study is to characterize the safety and establish the dose of JNJ-68284528, which was informed by the Legend-2 first-in-human study. The primary objective for the Phase 2 portion of the study is to evaluate the efficacy of JNJ-68284528 (primary endpoint: overall response rate [partial response or better] as defined by the International Myeloma Working Group response criteria).

“This is a very exciting moment, as we celebrate the achievement of this critical milestone with our strategic partner Janssen,” said Dr. Frank Zhang, Chairman and Chief Executive Officer of GenScript Biotech Corporation. “We are very pleased with the pace of progress already achieved through the diligent efforts of the Janssen and Legend teams, reflecting our goal of bringing this important therapeutic option to patients as soon as possible.”

“This milestone demonstrates tremendous progress, achieved within six months of establishing our development partnership with Janssen, and reflects the productive and collaborative relationship

formed between the teams at both organizations that are working to bring this program forward swiftly,” said Dr. Yuan Xu, Chief Executive Officer of Legend Biotech.

About LCAR-B38M

LCAR-B38M is a dual epitope Chimeric Antigen Receptor T cell (CAR-T) immunotherapy product developed by Legend Biotech. Autologous T cells isolated from patients are genetically modified to express the chimeric antigen receptors on the cell surface, allowing the CAR-T cells to specifically recognize and bind the Multiple Myeloma (MM) biomarker protein BCMA and kill MM cancer cells.

About Legend Biotech

Legend Biotech is a subsidiary of GenScript Biotech Corporation (HKEx: 1548), with its global presence in the United States, Hong Kong, Ireland and Nanjing China. Legend Biotech engages and concentrates on the construction of CAR-T cell therapy platform, and it has built up its own proprietary intellectual property position. Its LCAR-B38M based products have demonstrated outstanding overall response rate (ORR) in a series of pre-clinical studies treating refractory Multiple Myeloma. At present, around 200+ employees globally located have been committing in continuous research and development process aiming to provide revolutionary CAR-T and other forms of cell therapies to cancer patients. Learn more at www.LegendBiotech.com

About GenScript Biotech Corporation

GenScript Biotech Corporation (HKEx: 1548) provides reagents services for researchers in basic life sciences, translational and biomedical fields, as well as pre-clinical antibody drug development, through its global operating entities located in the United States, Hong Kong, Ireland, the Netherlands, Japan and China. The diverse portfolio of GenScript encompasses extensive services in gene synthesis and molecular biology, peptide synthesis, protein expression and engineering, custom antibody development and engineering, in vitro/in vivo pharmacology as well as variety of catalogue products for research. Two subsidiaries of GenScript, under the brand name of Bestzyme Biotech and Legend Biotech engaged in Industrial Enzymes and CAR-T as well as other forms of specific cell Immunotherapies respectively, have both made rapid progress and breakthrough in their business development. Learn more at www.GenScript.com