**U.S. Food and Drug Administration Grants Breakthrough Therapy Designation for JNJ-68284528, an Investigational BCMA CAR-T Cell Therapy**

*Designation based on the ongoing U.S. Phase 1b/2 CARTITIUDE-1 (MMY2001, NCT03548207) study in advanced relapsed or refractory multiple myeloma*

**Piscataway, NJ, December 6, 2019** – Legend Biotech USA Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted a Breakthrough Therapy Designation (BTD) to Janssen Research & Development, LLC (Janssen) for JNJ-68284528 (JNJ-4528), an investigational B-cell maturation antigen (BCMA) targeted chimeric antigen receptor (CAR) T-cell therapy in previously treated patients with multiple myeloma.

Initial results for JNJ-4528 from the U.S. Phase 1b/2 CARTITUDE-1 (MMY2001, NCT03548207) study will be presented at the 61st American Society of Hematology Annual Meeting in Orlando, Florida, taking place December 7-10th. The BTD for JNJ-4528 is based on the Phase 1b CARTITUDE-1 study.[1]

The BTD process is designed to expedite the development and review of therapies that are intended to treat a serious condition, where preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over available therapies on a clinically significant endpoint(s).[2]

In December 2017, Legend Biotech, USA Inc., and Legend Biotech Ireland Limited ("Legend"), subsidiaries of GenScript Biotech Corporation entered into a worldwide collaboration and license agreement with Janssen, to jointly develop and commercialize LCAR-B38M/JNJ-4828 in multiple myeloma. (JNJ-4528 identifies the investigational product being studied in the US and Europe, and LCAR-B38M identifies the investigational product in China which are representative of the same CAR-T cell therapy.) LCAR-B38M/JNJ-4528 is a structurally differentiated CAR-T cell therapy containing a 4-1BB co-stimulatory domain and two BCMA-targeting single domain antibodies designed to confer avidity.[3]

"This marks an important regulatory milestone, as Legend, together with Janssen, continues the quest to provide a new therapy for patients with multiple myeloma, an incurable disease," said Yuan Xu, PhD, CEO of Legend Biotech. "We are encouraged that the FDA has granted JNJ-4528 Breakthrough Therapy Designation, recognizing the unmet need and expediting the development of the therapy."

In February 2019, the FDA granted Janssen an Orphan Drug Designation for JNJ-4528. On April 3, 2019, Legend announced that the European Medicines Agency (EMA) granted Janssen a PRIME designation for JNJ-4528 which was mainly supported by results from the U.S. Phase 1b/2 CARTITUDE-1 study (NCT03548207) and the Phase 1/2 LEGEND-2 study (NCT03090659)[4] evaluating LCAR-B38M in relapsed refractory multiple myeloma (RRMM).

**About the Clinical Development Program**

**CARTITUDE-1**

In the US, JNJ-4528 is currently being investigated in the Phase 1b/2 CARTITUDE-1 (MMY2001, NCT03548207) registration study for the treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy or are double refractory to a PI and IMiD ®; received a PI, an IMiD; and anti-CD38 antibody and documented disease progression within 12 months of starting the most recent therapy.

**CARTITUDE-2**

In the global, multi-cohort Phase 2 CARTITUDE-2 (MMY2003, NCT04133636)[5] study, JNJ-4528 will be investigated in patients with multiple myeloma in various clinical settings. This study is being conducted to evaluate the overall minimal residual disease (MRD) negative rate of participants who receive JNJ-4528.

**CARTITUDE-4**

In the global, Phase 3 CARTITUDE-4 (MMY3002, NCT04181827)[6]study, JNJ-4528 will be investigated in patients with multiple myeloma who have received 1-3 prior lines of therapy including a PI and IMiD and are refractory to lenalidomide. The study is being conducted to evaluate the efficacy of JNJ-4528 compared to standard therapies[7] including daratumumab, pomalidomide and low-dose dexamethasone (DPd) or pomalidomide, bortezomib and low-dose dexamethasone (PVd).

**LEGEND-2 and CARTIFAN-1**

LEGEND-2 (NCT03090659) is an ongoing single-arm, open-label Phase 1/2 study of 74 patients being conducted at four participating hospitals in China evaluating the efficacy and safety of LCAR-B38M for the treatment of relapsed or RRMM.

The Phase 2 CARTIFAN-1 confirmatory trial (MMY2002, NCT03758417)[8] registered with the China Center for Drug Evaluation (CTR20181007), is actively recruiting to further evaluate LCAR-B38M in patients with advanced RRMM.

**About Multiple Myeloma**

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excessive proliferation of plasma cells.[9]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[10] Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy.[11,12] Relapsed myeloma is when the disease has returned after a period of initial, partial or complete remission and does not meet the definition of being refractory.[13] While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[14] Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options available.[15] In 2019, the American Cancer Society projects that there will be 32,110 new cases of multiple myeloma and 12,960 deaths attributed to the disease in the US.[16]

**About Legend Biotech**

Legend Biotech ("Legend") is a clinical stage biopharmaceutical company engaged in the discovery and development of novel cell therapies in hematology/oncology, infectious diseases and auto-immune disorders. Legend is a subsidiary of GenScript Biotech Corporation (HKEx: 1548), and operates in the United States, Hong Kong, mainland China and Ireland. Learn more at www.LegendBiotech.com.

**Cautions Concerning Forward-Looking Statements**

*This information constitutes forward-looking statements relating to the business of Legend Biotech, including express or implied discussions regarding the clinical development of its product candidates and potential attributes and benefits of such product candidates. Such forward-looking statements reflect the current views of Legend's management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, Legend's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; Legend's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing and other political pressures. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.*

*The safety and efficacy of the product candidates and/or uses under investigation have not been established. There is no guarantee that the product candidates will receive health authority approval or become commercially available in any country for the uses being investigated.*

*The information in this press release speaks only as of the date hereof. Legend assumes no duty to update the information to reflect subsequent developments. Readers should not rely upon the information on this page as current or accurate after its publication date.*

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