

Legend Biotech Announces Data Presentations at ASH 2019 for JNJ-68284528 (JNJ-4528)/LCAR-B38M, an Investigational B-Cell Maturation Antigen (BCMA) Chimeric Antigen Receptor (CAR)-T Cell Therapy being Studied in Patients with Relapsed and/or Refractory Multiple Myeloma (RRMM)

CARTITUDE-1 (MMY2001, NCT03548207), United States (US)

- Initial Results from CARTITUDE-1: A Phase 1b/2 Study of JNJ-4528*, a CAR-T Cell Therapy Directed Against BCMA, in Patients with RRMM (Abstract #577)
- Initial Translational Analysis from CARTITUDE-1, an Ongoing Phase 1b/2 Study of JNJ-4528 BCMA-targeted CAR-T Cell Therapy in RRMM, Indicates Preferential Expansion of CD8+ T Cell Central Memory Cell Subset (Abstract #928)

LEGEND-2 (NCT03090659), China

- Long-term Follow-up of a Phase 1, First-in-Human Open-label Study of LCAR-B38M*, a Structurally Differentiated CAR-T Cell Therapy Targeting BCMA, in Patients with RRMM (Abstract #579)
- Updated Phase 1 Results of a First-in-Human Open-label Study of LCAR-B38M, a Structurally Differentiated CAR-T Cell Therapy Targeting BCMA (Abstract #1858)

*JNJ-4528 identifies the investigational product being studied in the US/EU and LCAR-B38M identifies the investigational product in China, both of which are representative of the same CAR-T cell therapy.

Piscataway, NJ, November 6, 2019 – Legend Biotech today announced data from the Janssen Research & Development, LLC (Janssen) CARTITUDE-1 study (US) and the LEGEND-2 study (China) will be presented during the 61st American Society of Hematology (ASH) Annual meeting in Orlando, Florida taking place December 7-10, 2019.

"The data presentations at ASH 2019 represent two key milestones; the initial data from CARTITUDE-1 study in the US and the long term follow-up for the LEGEND-2 study in China," stated Yuan Xu, PhD, CEO of Legend Biotech. "In collaboration with Janssen, we are committed to the clinical development of LCAR-B38M/JNJ-4528 and are working diligently together to bring this investigational therapy to patients with multiple myeloma."

On Monday, December 9th during the Myeloma session titled: *Therapy, excluding Transplantation: Novelty in CAR-T in RRMM,* the first clinical data from the CARTITUDE-1 study will be presented. In the same session, long-term follow-up data from the previously reported LEGEND-2 study in China for the 57 patients enrolled at the Second Affiliated Hospital of Xi'an Jiaotong University will be presented, with updated data.

Additionally, updated results for the 17 patients enrolled in the LEGEND-2 study at the Shanghai Ruijin Hospital, Shanghai Changzheng Hospital, and Jiangsu Province People's Hospital will be presented by the investigators.

Abstracts will be presented during the following dates and times:

Abstract#/Title	Presenting Author	Date and Time
ABSTRACT #577: Results from	D Madduri	Oral Presentation
CARTITUDE-1: a Phase 1b/2 study		Monday, December 9, 7:00 am
of JNJ-4528, a CAR-T cell therapy		Hall D
directed against BCMA, in patients with		
RRMM		
ABSTRACT #579: Long-term follow-up of	BY Wang	Oral Presentation
a Phase 1, first-in-human		Monday, December 9, 7:30 am
open-label study of LCAR-B38M, a		Hall D
structurally differentiated CAR-T cell		
therapy targeting BCMA, in patients		
with RRMM		
ABSTRACT #928: Translational analysis	E Zudaire	Oral Presentation
from CARTITUDE-1, an ongoing Phase		Monday, December 9, 7:00 pm
1b/2 study of JNJ-4528 BCMA-targeted		Valencia A (W415A)
CAR-T cell therapy in RRMM, indicates		
preferential expansion of CD8+ T Cell		
central memory cell subset		
ABSTRACT #1858: Updated Phase 1	LJ Chen	Poster Presentation
results of a first-in-human open-label		Saturday, December 7, 5:30 pm
study of LCAR-B38M, a structurally		Hall B
differentiated CAR-T cell therapy		
targeting BCMA		

In February 2019, the US Food and Drug Administration granted Janssen an Orphan Drug Designation for JNJ-4528. On April 3, 2019, Legend <u>announced</u> that the European Medicines Agency (EMA) granted Janssen a PRIME¹ designation for JNJ-4528, which was supported by results from the Phase 1b/2 CARTITUDE-1 study (NCT03548207)² and the Phase 1/2 LEGEND-2 study (NCT03090659)³ evaluating LCAR-B38M in RRMM.

About LEGEND-2

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 refractory multiple myeloma.

About CARTIFAN-1

In China, the Phase 2 CARTIFAN-1 (MMY2002, NCT03758417)⁴ confirmatory trial registered with the Center for Drug Evaluation (CTR20181007), is actively recruiting to further evaluate LCAR-B38M in patients with advanced relapsed or refractory multiple myeloma.

About 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.

About 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.

About LocoMMotion

In the US and EU, a prospective observational study LocoMMotion (MMY4001, NCT04035226)⁶ is being conducted to evaluate current real-world standards of care in patients with RRMM who received at least 3 prior lines of therapy including a PI, an IMiD, and anti-CD38 antibody. The abstract will be published in *Blood*.

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. Although treatment may result in remission, unfortunately, patients will most likely relapse. Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy. 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. 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. Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options available.

About Legend Biotech

Legend Biotech is a clinical stage biopharmaceutical company engaged in the discovery and development of novel cell therapies in hematology/oncology, infectious diseases and autoimmune disorders. Legend is a subsidiary of GenScript Biotech Corporation (HKEx: 1548), which operates in the US, Hong Kong, mainland China and Ireland.

In December 2017, Legend and Janssen entered into a worldwide collaboration and license agreement to jointly develop and commercialize JNJ-4528/ LCAR-B38M in multiple myeloma.

Learn more at <u>www.LegendBiotech.com</u>.

Cautions Concerning Forward-Looking Statements

This information constitutes forward-looking statements relating to the business of Legend Biotech USA Inc., Nanjing Legend Biotechnology Co. Ltd., and Legend Biotech Ireland Ltd. ("Legend"), including express or implied discussions regarding potential new products, potential new indications, or regarding potential future revenues from any such products. 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.

The safety and efficacy of the agents and/or uses under investigation have not been established. There is no guarantee that the agents will receive health authority approval or become commercially available in any country for the uses being investigated or that such agents as products will achieve any particular revenue levels.

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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, including the uncertainties involved in the U.S. litigation process; 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.

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