# Legend Biotech Reports First Quarter 2021 Financial Results and Recent Highlights

May 18, 2021

- Rolling submission of BLA to the FDA completed for ciltacabtagene autoleucel (cilta-cel) for the treatment of relapsed or refractory multiple myeloma (RRMM)
- European Marketing Authorisation Application (MAA) submitted for cilta-cel for the treatment of RRMM
- New and updated cilta-cel data to be presented at the upcoming 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) Virtual Congress

SOMERSET, N.J.--(BUSINESS WIRE)--May 18, 2021-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, today reported its unaudited financial results for the first quarter of 2021.

"We built on the momentum of 2020 during the first quarter of this year for our BCMA CAR-T therapy cilta-cel with our collaboration partner, Janssen Biotech, Inc.*(Janssen), completing the Biologics License Application to the U.S. FDA and the Marketing Authorisation Application to the EMA," said Ying Huang, PhD, CEO and CFO of Legend Biotech. "We look forward to an exciting year with new and updated data from the CARTITUDE clinical development program and reaching our goal of bringing a new CAR-T treatment option to patients living with multiple myeloma worldwide pending regulatory approvals."

*In December 2017, Legend Biotech entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. to develop and commercialize cilta-cel.

**First Quarter 2021 & Recent Highlights**

- In the first quarter of 2021, the rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) was completed by Legend Biotech's collaborator, Janssen, for cilta-cel, for the treatment of adults with RRMM.
- On April 30, 2021 the Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) was made by Legend Biotech's collaborator, Janssen, for cilta-cel for the treatment of adults with RRMM. This follows the granting of an accelerated assessment for this MAA by the EMA's Committee for Medicinal Products for Human Use (CHMP) in February 2021.
- On May 13, 2021, Legend Biotech entered into a subscription agreement with an institutional investor for the offer and sale of 20,809,805 ordinary shares in a private placement at a purchase price of $14.41625 per ordinary share (equivalent to $28.8325 per American Depositary Share, or ADS) and the issuance of a warrant exercisable for up to an aggregate of 10,000,000 ordinary shares, exercisable for a two-year period at an exercise price of $20.00 per ordinary share (equivalent to $40.00 per ADS).

**Key Upcoming Milestones**

- Updated clinical data, including longer term follow up results from the CARTITUDE-1 trial, will be presented at the virtual 2021 ASCO Annual Meeting taking place on June 4-8 , 2021 (oral presentation, abstract #8005) along with initial data from the CARTITUDE-2 trial (abstracts #8013, #8028). In addition, there will be three poster presentations featuring real-world data (abstracts #8045, #8030 and #8041).
- Nine abstracts will be presented at the European Hematology Association Virtual Congress taking place virtually on June 9-17, 2021. (abstracts #S190, #EP964, #EP1003, #EP987, #EP990, #EP1049, #EP978, #EP977 and #EP972).
- Legend Biotech intends to use the data from the CARTIFAN-1 study in support of a regulatory submission to the China Center for Drug Evaluation (CDE) in the second half of 2021 seeking approval of cilta-cel for the treatment of adults with RRMM.
- Legend Biotech's collaboration partner, Janssen, anticipates submitting a New Drug Application (NDA) to the Japan Ministry of Health, Labor and Welfare (JMHLW) in the second half of 2021 seeking approval of cilta-cel for the treatment of adults with RRMM.
- Legend Biotech expects to initiate its Phase 1 clinical trial of LB1901 in RR T-cell lymphoma (TCL) in the United States in 2021.
- Legend Biotech anticipates supporting investigators with publishing a clinical data update from LEGEND-2 study in 2021.

**Financial Results for First Quarter Ended March 31, 2021**

*Cash and Cash Equivalents and Time Deposits*

As of March 31, 2021, Legend Biotech had approximately $412.3 million of cash and cash equivalents and approximately $50.0 million in time deposits.

*Revenue*

Revenue for the three months ended March 31, 2021 was $13.7 million compared to $11.5 million for the three months ended March 31, 2020. The increase of $2.2 million was primarily due to revenue recognition of additional milestone payment achieved pursuant to Legend Biotech's agreement with Janssen. Milestone payments are constrained as a result of the uncertainty of whether the milestone will be achieved, but recognized when the associated milestone is achieved and the uncertainty relieved. In the first quarter of 2021, this resulted in a larger amount of revenue recognized from the contract liabilities. Legend Biotech has not generated any revenue from product sales to date.

*Research and Development Expenses*

Research and development expenses for the three months ended March 31, 2021 were $71.1 million compared to $48.0 million for the three months ended March 31, 2020. This increase of $23.1 million was primarily due to a higher number of clinical trials with more patients enrolled and a higher number of research and development product candidates.

*Administrative Expenses*

Administrative expenses for the three months ended March 31, 2021 were $8.7 million compared to $3.4 million for the three months ended March 31, 2020. The increase of $5.3 million was primarily due to Legend Biotech's expansion of supporting administrative functions to aid continued research and development activities.

*Selling and Distribution Expenses*

Selling and distribution expenses for the three months ended March 31, 2021 were $13.4 million compared to $6.5 million for the three months ended March 31, 2020. This increase of $6.9 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel.

*Other Income and Gains*

Other income and gains for the three months ended March 31, 2021 was $0.7 million compared to $2.5 million for the three months ended March 31, 2020. The decrease of $1.8 million was primarily due to lower government grant and interest income received in first quarter of 2021.

Other Expenses

Other expenses for the three months ended March 31, 2021 was $2.0 million compared to $0.05 million for the three months ended March 31, 2020. The increase was primarily due to higher foreign currency exchange loss in first quarter of 2021.

*Finance Costs*

Finance costs for the three months ended March 31, 2021 was $0.04 million compared to $4.0 million for the three months ended March 31, 2020. The decrease was primarily due to finance costs related to the issuance of convertible redeemable preferred shares in 2020, which were fully converted into ordinary shares upon the completion of Legend Biotech's initial public offering in June 2020.

*Loss for the Period*

For the three months ended March 31, 2021, net loss was $80.9 million, or $0.30 per share, compared to a net loss of $44.2 million, or $0.22 per share, for the three months ended March 31, 2020.

**About Legend Biotech**

Legend Biotech is a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 800 employees across the United States, China and Europe, along with our differentiated technology, global development, and manufacturing strategies and expertise, provide us with the strong potential to discover, develop, and manufacture best-in-class cell therapies for patients in need.

We are engaged in a strategic collaboration to develop and commercialize our lead product candidate, cilta-cel, an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. This candidate is currently being studied in registrational clinical trials.

**About Ciltacabtagene autoleucel (cilta-cel)**

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy, formerly identified as JNJ-4528 outside of China and LCAR-B38M CAR-T cells in China, that is being studied in a comprehensive clinical development program for the treatment of patients with relapsed and/or refractory multiple myeloma and in earlier lines of treatment. Cilta-cel is a differentiated CAR-T therapy with two BCMA-targeting single domain antibodies. In December 2017, Legend Biotech, Inc. entered into an exclusive worldwide license and collaboration agreement to develop and commercialize cilta-cel. In addition to a Breakthrough Therapy Designation (BTD) granted in the U.S. in December 2019, cilta-cel received a BTD in China in August 2020. In addition, Orphan Drug Designation was granted for cilta-cel by the U.S. FDA in February 2019, and by the European Commission in February 2020. A Biologics License Application seeking approval of cilta-cel was submitted to the U.S. FDA and a Marketing Authorization Application was submitted to the European Medicines Agency.

**About Clinical Development Program**

**CARTITUDE-1** (NCT03548207) is a Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of cilta-cel in adults with relapsed and/or refractory multiple myeloma who have received at least three prior lines of therapy or are double refractory to an immunomodulatory drug (IMiD) and a proteasome inhibitor (PI), received an IMiD, a PI and an anti-CD38 antibody, and documented disease progression within 12 months of

starting the most recent therapy.[1] The primary objective of the Phase 1b portion of the study was to characterize the safety and confirm the dose of cilta-cel, informed by the first-in-human study with LCAR-B38M CAR-T cells (LEGEND-2). The Phase 2 portion further evaluated the efficacy of cilta-cel with overall response rate as the primary endpoint.

**CARTITUDE-2** (NCT04133636) is a global, multi-cohort Phase 2 study evaluating cilta-cel in patients with multiple myeloma in various clinical settings.[2] This study is being conducted to evaluate the overall minimal residual disease (MRD) negative rate of participants who receive cilta-cel.

**CARTITUDE-4** (NCT04181827) is a global, randomized Phase 3 study, evaluating cilta-celin patients with multiple myeloma who have received 1-3 prior lines of therapy including a PI and IMiD and are refractory to lenalidomide.[3] The study is being conducted to evaluate the efficacy of cilta-cel compared to standard therapies including daratumumab, pomalidomide and low-dose dexamethasone (DPd) or pomalidomide, bortezomib and low-dose dexamethasone (PVd).

**CARTIFAN-1** (NCT03758417) is a Phase 2 confirmatory trial registered with the China Center for Drug Evaluation (CTR20181007) to further evaluate LCAR-B38M CAR-T cells in patients with advanced RRMM.[4]

**Cautionary Note Regarding Forward-Looking Statements**

Statements in this press release 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; the anticipated timing of, and ability to progress, clinical trials, including the initiation of the phase 1 clinical trial of LB1901 in RRTCL; the ability to make, the timing of, and the ultimate success of, regulatory submissions globally, including the BLA for cilta-cel submitted to the U.S. FDA, the MAA for cilta-cel submitted to the EMA, and the submissions for cilta-cell to the CDE and the JMHLW; the ability to generate, analyze and present data from clinical trials; patient enrollment; and the potential benefits of our product candidates. 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 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 US 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 the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 2, 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 presentation as anticipated, believed, estimated or expected. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

**LEGEND BIOTECH CORPORATION**
**CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS**

| | Three months ended March 31 | |
|---|---|---|
| **(in thousands, US$, except share and per share data)** | **2021 (Unaudited)** | **2020 (Unaudited)** |
| **REVENUE** | 13,682 | 11,546 |
| Other income and gains | 722 | 2,531 |
| Research and development expenses | (71,072) | (48,003) |
| Administrative expenses | (8,742) | (3,430) |
| Selling and distribution expenses | (13,417) | (6,545) |
| Other expenses | (2,034) | (45) |
| Finance costs | (38) | (3,991) |
| **LOSS BEFORE TAX** | (80,899) | (47,937) |
| Income tax credit | - | 3,709 |
| **LOSS FOR THE PERIOD** | (80,899) | (44,228) |
| Attributable to: | | |
| Equity holders of the parent | (80,899) | (44,228) |
| Loss per share attributable to ordinary equity holders of the parent: | | |
| Ordinary shares – basic | (0.30) | (0.22) |
| Ordinary shares – diluted | (0.30) | (0.22) |
| Shares used in loss per share computation: | | |

| | | |
|---|---|---|
| Ordinary shares – basic | 266,293,913 | 200,000,000 |
| Ordinary shares – diluted | 266,293,913 | 200,000,000 |

**LEGEND BIOTECH CORPORATION**
**CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

| **(in thousands, US$)** | **March 31, 2021 (Unaudited)** | **December 31, 2020** |
|---|---|---|
| **NON-CURRENT ASSETS** | | |
| Property, plant and equipment | 122,905 | 113,091 |
| Other non-current assets | 3,983 | 3,973 |
| Advance payments for property, plant and equipment | 1,663 | 224 |
| Right-of-use assets | 7,547 | 8,009 |
| Intangible assets | 4,081 | 2,852 |
| Total non-current assets | **140,179** | **128,149** |
| **CURRENT ASSETS** | | |
| Inventories | 2,097 | 1,800 |
| Trade receivables | - | 74,978 |
| Prepayments, other receivables and other assets | 10,425 | 10,007 |
| Pledged short-term deposits | 256 | 384 |
| Time deposits | 50,000 | 50,000 |
| Cash and cash equivalents | 412,296 | 455,689 |
| Total current assets | **475,074** | **592,858** |
| Total assets | **615,253** | **721,007** |
| **CURRENT LIABILITIES** | | |
| Trade and notes payables | 9,649 | 5,238 |
| Other payables and accruals | 80,096 | 99,168 |
| Government grants | 281 | 283 |
| Lease liabilities | 1,460 | 1,464 |
| Contract liabilities | 54,456 | 55,014 |
| Total current liabilities | **145,942** | **161,167** |
| **NON-CURRENT LIABILITIES** | | |
| Contract liabilities | 258,666 | 275,071 |
| Lease liabilities | 1,673 | 1,909 |
| Other non-current liabilities | 554 | 554 |
| Government grants | 1,967 | 2,051 |
| Total non-current liabilities | **262,860** | **279,585** |
| Total liabilities | **408,802** | **440,752** |
| **EQUITY** | | |
| Share capital | 27 | 27 |
| Reserves | 206,424 | 280,228 |
| Total ordinary shareholders' equity | **206,451** | **280,255** |
| Total equity | **206,451** | **280,255** |
| Total liabilities and equity | **615,253** | **721,007** |

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

| (in thousands, US$) | Three months ended March 31 2021 (Unaudited) | 2020 (Unaudited) |
|---|---|---|
| **LOSS BEFORE TAX** | (80,899) | (47,937) |
| **CASH FLOWS USED IN OPERATING ACTIVITIES** | (26,787) | (45,796) |
| **CASH FLOWS USED IN INVESTING ACTIVITIES** | (17,150) | (17,499) |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | 207 | 148,755 |
| **NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS** | (43,730) | 85,460 |
| Effect of foreign exchange rate changes, net | 337 | (27) |
| Cash and cash equivalents at beginning of the period | 455,689 | 83,364 |
| **CASH AND CASH EQUIVALENTS AT END OF THE PERIOD** | 412,296 | 168,797 |
| **ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS** | | |
| Cash and bank balances | 462,552 | 244,612 |
| Less: Pledged short-term deposits | 256 | 256 |
| Time deposits | 50,000 | 75,559 |
| Cash and cash equivalents as stated in the statement of financial position | 412,296 | 168,797 |
| Cash and cash equivalents as stated in the statement of cash flows | 412,296 | 168,797 |

[1] ClinicalTrials.gov. A Study of JNJ-68284528, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against B-Cell Maturation Antigen (BCMA) in Participants With Relapsed or Refractory Multiple Myeloma (CARTITUDE-1). Available at: https://clinicaltrials.gov/ct2/show/NCT03548207. Last accessed May 2021.

[2] ClinicalTrials.gov. A Study of JNJ-68284528, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against B-cell Maturation Antigen (BCMA) in Participants With Multiple Myeloma (CARTITUDE-2). Available at: https://clinicaltrials.gov/ct2/show/NCT04133636. Last accessed May 2021.

[3] ClinicalTrials.gov. A Study Comparing JNJ-68284528, a CAR-T Therapy Directed Against B-cell Maturation Antigen (BCMA), Versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Participants With Relapsed and Lenalidomide-Refractory Multiple Myeloma (CARTITUDE-4). https://clinicaltrials.gov/ct2/show/NCT04181827. Last accessed May 2021.

[4] ClinicalTrials.gov. A Study of LCAR-B38M CAR-T Cells, a Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against B-cell Maturation Antigen (BCMA) in Chinese Participants With Relapsed or Refractory Multiple Myeloma (CARTIFAN-1). https://clinicaltrials.gov/ct2/show/NCT03758417. Last accessed May 2021.

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Media and Investor Relations:
Jessie Yeung, Head of Corporate Finance and Investor Relations, Legend Biotech
jessie.yeung@legendbiotech.com or investor@legendbiotech.com

Crystal Chen, Manager of Investor Relations and Corporate Communications, Legend Biotech
crystal.chen@legendbiotech.com or media@legendbiotech.com

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