Legend Biotech Reports Second Quarter 2021 Financial Results and Recent Highlights

August 23, 2021

- *Investigational BCMA CAR-T therapy ciltacabtagene autoleucel (cilta-cel) granted priority review by the U.S. Food and Drug Administration for the treatment of relapsed or refractory multiple myeloma (RRMM)*
- *A Marketing Authorisation Application (MAA) was accepted by the European Medicines Agency (EMA) for cilta-cel for the treatment of RRMM*
- *New and updated cilta-cel data presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) Virtual Congress*
- *New investment announced for facility in Belgium, expanding global presence for cell therapy manufacturing*

SOMERSET, N.J.--(BUSINESS WIRE)--Aug. 23, 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 2021 second quarter unaudited financial results.

“We have made exciting progress in advancing our first investigational CAR-T therapy cilta-cel in the past few months, with key regulatory, data and manufacturing updates. This includes the acceptance of our applications for cilta-cel by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) and the presentation of additional efficacy and safety data from the CARTITUDE cilta-cel clinical development program at ASCO and EHA Annual meetings,” said Ying Huang, PhD, CEO and CFO of Legend Biotech. “We look forward to a momentous second half of the year as we work towards bringing cilta-cel to patients living with multiple myeloma and providing their healthcare providers a new therapeutic option, in collaboration with Janssen.”

Second Quarter 2021 Highlights

- In May 2021, the rolling submission of the Biologics License Application (BLA) was accepted by the U.S. FDA for cilta-cel for the treatment of adults with relapsed or refractory multiple myeloma (RRMM), following the submission by Legend Biotech’s collaborator, Janssen Biotech, Inc. (Janssen). As part of the BLA acceptance, the FDA granted cilta-cel priority review and set the Prescription Drug User Fee Act (PDUFA) target action date for November 29, 2021.
- In May 2021, the Marketing Authorisation Application (MAA) submitted by Janssen was accepted by the European Medicines Agency (EMA) for cilta-cel for the treatment of adults with RRMM.
- In addition, a submission for cilta-cel was made to the Brazilian Health Regulatory Agency by Janssen in April 2021.
- Longer term data from the CARTITUDE-1 trial of cilta-cel in 97 heavily pretreated patients with RRMM, which was presented at the 2021 ASCO and EHA Annual meetings, showed 98 percent overall response rate, 80 percent stringent complete response rate (sCR), progression free survival rate of 66 percent and an overall survival (OS) rate of 81 percent at the 18-month follow-up. A full manuscript containing earlier data from the CARTITUDE-1 trial at 12.4-months of follow up was published in *The Lancet* in June 2021.
- First results from Cohort A of the CARTITUDE-2 study of cilta-cel, which was featured at the 2021 ASCO and EHA Annual meetings, showed early and deep responses in the cohort of 20 patients with progressive MM after 1-3 prior lines of therapy, and who were lenalidomide refractory, with a safety profile consistent with what has been observed in the CARTITUDE clinical development program.
- On June 22, 2021, Legend Biotech announced the establishment of a state-of-the-art manufacturing facility in Belgium as part of a joint investment with Janssen, to expand global manufacturing capacity of innovative cellular therapies.
- On May 21, 2021, Legend Biotech completed the 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), in each case, pursuant to a subscription agreement dated May 13, 2021, with an institutional investor.
- In June 2021, the CARTITUDE clinical program expanded to include the initiation of the CARTITUDE-5 study (NCT04923893), a Phase 3 randomized study evaluating cilta-cel in patients with newly diagnosed MM (NDMM) for whom autologous stem cell transplant (ASCT) is not planned as initial therapy. The CARTITUDE-5 study will evaluate bortezomib, lenalidomide and dexamethasone, known as VRd, followed by cilta-cel versus VRd, followed by lenalidomide and dexamethasone, or Rd, maintenance therapy.
- The ongoing Phase 2 CARTITUDE-2 study (NCT04133636) was expanded with the addition of two cohorts: Cohort E (high-risk NDMM, transplant not planned) and Cohort F (standard-risk NDMM).
- In May 2021, Legend Biotech achieved a $15 million milestone payment related to a cilta-cel development milestone,

according to the terms and conditions of an agreement with Janssen.

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

Key Upcoming Milestones

- As part of the acceptance of the BLA for cilta-cel for the treatment of adults with RRMM, the FDA has set the PDUFA target action date for November 29, 2021.
- In collaboration with Janssen, Legend Biotech intends to present updated data from the CARTITUDE-1 and the CARTITUDE-2 studies at major medical conferences in 2021.
- Legend Biotech anticipates supporting investigators to submit a manuscript on the clinical data update from LEGEND-2 study in 2021.
- 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 Pharmaceuticals and Medical Devices Agency 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.

Financial Results for Three Months and Six Months Ended June 30, 2021

Cash and Cash Equivalents and Time Deposits

As of June 30, 2021, Legend Biotech had approximately $488.2 million of cash and cash equivalents and approximately $174.6 million in time deposits.

Revenue

Revenue for the three months ended June 30, 2021 was $20.2 million compared to $11.6 million for the three months ended June 30, 2020. The increase of $8.6 million was primarily due to two additional milestones achieved pursuant to Legend Biotech's agreement with Janssen in the fourth quarter of 2020 and in the second quarter of 2021, respectively. Revenue for the six months ended June 30, 2021 was $33.9 million compared to $23.1 million for the six months ended June 30, 2020. The increase of $10.8 million was primarily due to the aforementioned two additional milestones achieved. Milestone payments are constrained as a result of the uncertainty of whether the milestone will be achieved, but included as customer consideration for revenue recognition when the associated milestone is achieved and the uncertainty relieved. In half year 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 June 30, 2021 were $83.5 million compared to $53.6 million for the three months ended June 30, 2020. This increase of $29.9 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. Consistently, research and development expenses for the six months ended June 30, 2021 was $154.5 million compared to $101.6 million for the six months ended June 30, 2020 with an $52.9 million increase.

Administrative Expenses

Administrative expenses for the three months ended June 30, 2021 were $9.2 million compared to $4.5 million for the three months ended June 30, 2020. The increase of $4.7 million was primarily due to Legend Biotech's expansion of supporting administrative functions to aid continued research and development activities. Due to the consistent business expansion, administrative expenses for the six months ended June 30, 2021 increased by $10.1 million, which was $18.0 million for the six months ended June 30, 2021 compared to $7.9 million for the six months ended June 30, 2020.

Selling and Distribution Expenses

Selling and distribution expenses for the three months ended June 30, 2021 were $16.8 million compared to $9.6 million for the three months ended June 30, 2020. This increase of $7.2 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel. Driven by the same commercial preparation activities, selling and distribution expenses for the six months ended June 30, 2021 was $30.2 million compared to $16.1 million for the six months ended June 30, 2020.

Other Income and Gains

Other income and gains for the three months ended June 30, 2021 was $1.7 million compared to $1.3 million for the three months ended June 30, 2020. Other income and gains for the six months ended June 30, 2021 was $2.4 million compared to $3.8 million for the six months ended June 30, 2020. The decrease of $1.4 million was primarily due to larger government grant and interest income received in the first half of the year in 2020.

Other Expenses

Other expenses for the three months ended June 30, 2021 was $2.3 million compared to $0.04 million for the three months ended June 30, 2020. The increase of $2.26 million was primarily due to higher foreign currency exchange loss, loss from disposal of assets and other expenses in the second quarter of 2021. Consistently, other expenses for the six months ended June 30, 2021 was $4.4 million compared to $0.08 million for the six months ended June 30, 2020, with an increase of $4.32 million.

Finance Costs

Finance costs for the six months ended June 30, 2021 was $0.09 million compared to $4.1 million for the six months ended June 30, 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.

Fair Value Loss of Warrant Liability

Fair value loss of warrant liability for the six months ended June 30, 2021 was $1.6 million caused by changes of fair value of a warrant, which was issued to an institutional investor through a private placement in May 2021. Concurrently, 20,809,805 ordinary shares were offered and sold to the institutional investor. The warrant was assessed as a financial liability with a fair value of $83.3 million as of June 30, 2021 and a fair value loss of $1.6 million was recorded for the six months ended June 30, 2021.

Fair Value Loss of Convertible Redeemable Preferred Shares

For the six months ended June 30, 2020, Legend Biotech reported a one-time non-cash charge of $80.0 million caused by changes of fair value of Series A convertible redeemable preferred shares (Series A Preferred Shares). Upon listing on the Nasdaq Global Market, all outstanding Series A Preferred Shares were converted into ordinary shares of Legend Biotech and all accrued but unpaid dividends were settled in the form of ordinary shares of Legend Biotech.

Loss for the Period

For the three months ended June 30, 2021, net loss was $91.6 million, or $0.33 per share, compared to a net loss of $134.9 million, or $0.63 per share, for the three months ended June 30, 2020. Net loss was $172.5 million, or $0.63 per share, for the six months ended June 30, 2021 compared to $179.1 million, or $0.86 per share, for the six months ended June 30, 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 900 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 that is being studied in a comprehensive clinical development program for the treatment of patients with multiple myeloma. Cilta-cel is a differentiated CAR-T therapy with two BCMA-targeting single domain antibodies. In December 2017, Legend Biotech entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. 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. Orphan Drug Designation was granted for cilta-cel by the U.S. FDA in February 2019, and by the European Commission in February 2020. Applications seeking approval of cilta-cel for the treatment of patients with relapsed/refractory multiple myeloma are currently under regulatory review by several health authorities around the world including the United States and Europe.

About the Cilta-cel 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-cel in 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).

CARTITUDE-5 (NCT04923893) is a global, randomized Phase 3 open-label study evaluating cilta-cel in patients with newly diagnosed MM for whom autologous stem cell transplant (ASCT) is not planned as initial therapy.[4] The study is being conducted to evaluate the efficacy of bortezomib, lenalidomide and dexamethasone (VRd) followed by cilta-cel vs. VRd followed by Rd maintenance.

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.[5]

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 RR TCL; the ability to make, the timing of, and the ultimate success of,

regulatory submissions globally, including the applications seeking approval of cilta-cel for the treatment of patients with RRMM submitted to health authorities around the world; 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 Legend Biotech'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

(in thousands, US$, except share and per share data)	**Three months ended June 30**		**Six months ended June 30**	
	2021 (Unaudited)	**2020 (Unaudited)**	**2021 (Unaudited)**	**2020 (Unaudited)**
REVENUE	20,233	11,600	33,915	23,146
Other income and gains	1,668	1,265	2,390	3,796
Research and development expenses	(83,457)	(53,567)	(154,529)	(101,570)
Administrative expenses	(9,249)	(4,508)	(17,991)	(7,938)
Selling and distribution expenses	(16,782)	(9,557)	(30,199)	(16,102)
Other expenses	(2,344)	(37)	(4,378)	(82)
Fair value loss of warrant liability	(1,600)	-	(1,600)	-
Fair value loss of convertible redeemable preferred shares	-	(79,984)	-	(79,984)
Finance costs	(52)	(88)	(90)	(4,079)
LOSS BEFORE TAX	(91,583)	(134,876)	(172,482)	(182,813)
Income tax (expense)/credit	(1)	-	(1)	3,709
LOSS FOR THE PERIOD	(91,584)	(134,876)	(172,483)	(179,104)
Attributable to:				
Equity holders of the parent	(91,584)	(134,876)	(172,483)	(179,104)
Loss per share attributable to ordinary equity holders of the parent:				
Ordinary shares – basic	(0.33)	(0.63)	(0.63)	(0.86)
Ordinary shares – diluted	(0.33)	(0.63)	(0.63)	(0.86)
Shares used in loss per share computation:				
Ordinary shares – basic	277,016,799	215,551,887	271,684,977	207,775,944
Ordinary shares – diluted	277,016,799	215,551,887	271,684,977	207,775,944

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(in thousands, US$)	**June 30, 2021 (Unaudited)**	**December 31, 2020**
NON-CURRENT ASSETS		
Property, plant and equipment	135,216	113,091
Advance payments for property, plant and equipment	2,197	224
Right-of-use assets	7,312	8,009
Other non-current assets	4,885	3,973
Intangible assets	4,681	2,852

Total non-current assets	**154,291**	**128,149**
CURRENT ASSETS		
Inventories	1,700	1,800
Trade receivables	15,000	74,978
Prepayments, other receivables and other assets	11,170	10,007
Financial investment measured at amortized cost	29,849	-
Pledged short-term deposits	256	384
Time deposits	174,644	50,000
Cash and cash equivalents	488,215	455,689
Total current assets	**720,834**	**592,858**
Total assets	**875,125**	**721,007**
CURRENT LIABILITIES		
Trade and notes payables	11,001	5,238
Other payables and accruals	109,183	99,168
Government grants	300	283
Warrant Liability	83,300	-
Lease liabilities	1,178	1,464
Contract liabilities	56,139	55,014
Total current liabilities	**261,101**	**161,167**
NON-CURRENT LIABILITIES		
Contract liabilities	252,628	275,071
Lease liabilities	1,621	1,909
Interest-bearing loans and borrowings	17,310	-
Other non-current liabilities	554	554
Government grants	1,992	2,051
Total non-current liabilities	**274,105**	**279,585**
Total liabilities	**535,206**	**440,752**
EQUITY		
Share capital	29	27
Reserves	339,890	280,228
Total ordinary shareholders' equity	**339,919**	**280,255**
Total equity	**339,919**	**280,255**
Total liabilities and equity	**875,125**	**721,007**

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands, US$)	**Three months ended June 30**		**Six months ended June 30**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
LOSS BEFORE TAX	(91,583)	(134,876)	(172,482)	(182,813)
CASH FLOWS USED IN OPERATING ACTIVITIES	(57,538)	(56,885)	(84,325)	(102,681)
CASH FLOWS USED IN INVESTING ACTIVITIES	(168,673)	(9,212)	(185,823)	(26,711)

CASH FLOWS FROM FINANCING ACTIVITIES	301,752	459,803	301,959	608,558
NET INCREASE IN CASH AND CASH EQUIVALENTS	75,541	393,706	31,811	479,166
Effect of foreign exchange rate changes, net	378	(112)	715	(139)
Cash and cash equivalents at beginning of the period	412,296	168,797	455,689	83,364
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	488,215	562,391	488,215	562,391
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	663,115	638,206	663,115	638,206
Less: Pledged short-term deposits	256	256	256	256
Time deposits	174,644	75,559	174,644	75,559
Cash and cash equivalents as stated in the statement of financial position	488,215	562,391	488,215	562,391
Cash and cash equivalents as stated in the statement of cash flows	488,215	562,391	488,215	562,391

[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 Aug 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 Aug 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). Available at: https://clinicaltrials.gov/ct2/show/NCT04181827. Last accessed Aug 2021.

[4] ClinicalTrials.gov. A Study of Bortezomib, Lenalidomide and Dexamethasone (VRd) Followed by Cilta-cel, a CAR-T Therapy Directed Against BCMA Versus VRd Followed by Lenalidomide and Dexamethasone (Rd) Therapy in Participants With Newly Diagnosed Multiple Myeloma for Whom ASCT is Not Planned as Initial Therapy (CARTITUDE-5) Available at: https://clinicaltrials.gov/ct2/show/NCT04923893. Last accessed Aug 2021.

[5] 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 Aug 2021.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210823005189/en/

Investor Contacts:
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

Press Contact:
Tina Carter, Corporate Communications Lead, Legend Biotech
tina.carter@legendbiotech.com or media@legendbiotech.com

Source: Legend Biotech