Legend Biotech Reports Third Quarter 2021 Financial Results and Recent Highlights

November 16, 2021

- Enrollment of the Phase 3 CARTITUDE-4 study evaluating ciltacabtagene autoleucel (cilta-cel) for multiple myeloma patients with 1-3 prior lines of therapy was completed by Janssen Biotech, Inc.
- U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) target date for cilta-cel by three months to February 28, 2022
- Legend Biotech initiated the Phase 1 clinical trial in the US for LB1901, an investigational autologous CD4-targeted chimeric antigen receptor T-cell (CAR-T) therapy for relapsed or refractory peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma (CTCL)
- New and updated data will be presented at the upcoming 63rd American Society of Hematology (ASH) Annual Meeting and Exposition

SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 16, 2021-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global, clinical-stage biotechnology company developing and manufacturing novel therapies, today reported its 2021 third quarter unaudited financial results.

“It continues to be a banner year for us, as we launch our clinical trial in the US for the T cell lymphoma program and see promising developments in our pipeline,” said Ying Huang, PhD, CEO and CFO of Legend Biotech. “We intend to close the year on a strong note by presenting new and updated results from our CARTITUDE Clinical Development Program at the 63rd American Society of Hematology Annual Meeting next month and work to bring cilta-cel to more patients.”

Recent Highlights

- In October 2021, Legend Biotech and its collaboration partner Janssen Biotech, Inc. (Janssen) completed the enrollment of the Phase 3 CARTITUDE-4 study, evaluating cilta-cel in patients with multiple myeloma who have received 1-3 prior lines of therapy including a proteasome inhibitor and immunomodulatory agent and are refractory to lenalidomide. The purpose of this study is to compare the efficacy of cilta-cel with standard therapy – either pomalidomide, bortezomib and dexamethasone (PVd) or daratumumab, pomalidomide and dexamethasone (DPd).
- The U.S. FDA has extended the PDUFA target date for cilta-cel by three months to February 28, 2022. The extension allows the FDA sufficient time to review information recently submitted pertaining to an updated analytical method following an FDA information request.
- On October 18, 2021, Legend Biotech hosted its first Research & Development (R&D) Day in New York, sharing updates on Legend Biotech’s pipeline advancements, including expanded capabilities in cell therapy, and milestones in the cilta-cel clinical development program. The Legend Biotech pipeline has been updated to reflect the disclosures made at this event, including the targets for two of the company’s investigational autologous CAR-T therapies, LB2101 and LB2102. Additionally, the investigator-initiated clinical trial in China evaluating an investigational autologous CAR-T targeting CD33 and CLL-1 for the treatment of acute myeloid leukemia has been removed. The Phase I dose escalation study showed a lack of CAR-T expansion and efficacy.
- In September 2021, the Phase 1, open-label, multicenter clinical trial began in the United States for LB1901, an investigational autologous CD4-targeted CAR-T therapy for the treatment of adults with relapsed or refractory peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma (CTCL). The primary objectives of the trial are to characterize the safety and tolerability of LB1901 and determine the optimal dose.

Key Upcoming Milestones

- New and updated data from the CARTITUDE Clinical Development Program will be presented at the 63rd ASH Annual Meeting and Exposition taking place from December 11-14, 2021. Highlights include:
    - CARTITUDE-1 updated results from the Phase 1b/2 study of cilta-cel in patients with relapsed or refractory multiple myeloma (RRMM)
    - Adjusted indirect comparisons of patient outcomes in CARTITUDE-1 versus therapies from real-world clinical practice from the prospective LocoMMotion study
    - CARTITUDE-1 subgroup analysis data
    - CARTITUDE-2 first data in patients with multiple myeloma and early relapse after initial therapy (Cohort B) and updated data in lenalidomide-refractory patients with progressive multiple myeloma after 1-3 prior lines of therapy (Cohort A)

    - First preclinical *in vivo* data for novel tri-specific single-domain antibody (VHH) CAR-T cells (LCAR-AIO)
- Legend Biotech's collaboration partner, Janssen, anticipates submitting a New Drug Application (NDA) to the Japan Pharmaceuticals and Medical Devices Agency in Q4 2021, seeking approval of cilta-cel for the treatment of adults with RRMM.

Financial Results for the Three-month and Nine-month Periods Ended September 30, 2021

Cash and Cash Equivalents and Time Deposits

As of September 30, 2021, Legend Biotech had approximately $636.0 million of cash and cash equivalents, interest yielding securities and time deposits.

Revenue

Revenue for the three months ended September 30, 2021 was $16.9 million compared to $11.7 million for the three months ended September 30, 2020. $2.2 million out of the increase of $5.2 million was 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. The remaining $3.0 million increase in revenue was consideration for the exclusive licensing of patents to Nanjing Probio Biotech Co., Ltd (Probio), a related party controlled by Legend Biotech's majority shareholder, Genscript Corporation, and affiliates of Probio in September 2021.

Revenue for the nine months ended September 30, 2021 was $50.8 million compared to $34.9 million for the nine months ended September 30, 2020.

Milestone payments are constrained and only included as customer consideration for revenue recognition when it is highly probable that the associated milestone will be achieved, typically when the triggering event occurs. This resulted in an increase in revenue recognized in 2021.

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 September 30, 2021 were $72.3 million compared to $63.7 million for the three months ended September 30, 2020. This increase of $8.6 million was primarily due to continuous research and development activities in cilta-cel and toward other pipeline advancements. Consistently, research and development expenses for the nine months ended September 30, 2021 was $226.8 million compared to $165.2 million for the nine months ended September 30, 2020, an increase of $61.6 million.

Administrative Expenses

Administrative expenses for the three months ended September 30, 2021 were $11.8 million compared to $6.0 million for the three months ended September 30, 2020. The increase of $5.8 million was primarily due to Legend Biotech's expansion of supporting administrative functions to facilitate continuous research and development activities as well as activities to establish elements of a commercialization infrastructure. Due to the consistent business expansion, administrative expenses for the nine months ended September 30, 2021 increased by $15.8 million, which was $29.8 million for the nine months ended September 30, 2021 compared to $14.0 million for the nine months ended September 30, 2020.

Selling and Distribution Expenses

Selling and distribution expenses for the three months ended September 30, 2021 were $19.5 million compared to $9.3 million for the three months ended September 30, 2020. This increase of $10.2 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel. Driven by the same cause, selling and distribution expenses for the nine months ended September 30, 2021 was $49.7 million compared to $25.4 million for the nine months ended September 30, 2020, an increase of $24.3 million.

Other Income and Gains

Other income and gains for the three months ended September 30, 2021 was $0.6 million compared to $1.5 million for the three months ended September 30, 2020. Other income and gains for the nine months ended September 30, 2021 was $2.3 million compared to $5.3 million for the nine months ended September 30, 2020. The decrease of $0.9 million and $3.0 million, respectively, primarily resulted from lower government grant and interest income earned during the three- and nine-month periods ended September 30, 2021, as compared to the corresponding prior year periods.

Other Expenses

Other expenses for the three months ended September 30, 2021 was $2.5 million compared to $1.2 million for the three months ended September 30, 2020. The increase of $1.3 million was primarily due to higher foreign currency exchange loss. Other expenses for the nine months ended September 30, 2021 was $6.9 million compared to $1.3 million for the nine months ended September 30, 2020. The increase of $5.6 million was primarily due to higher foreign currency exchange loss, loss from disposal of assets and other expenses during the nine months ended September 30, 2021.

Finance Costs

Finance costs for the nine months ended September 30, 2021 was $0.3 million compared to $4.2 million for the nine months ended September 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 nine months ended September 30, 2021 was $37.4 million caused by changes in fair value of a warrant, which was issued to an institutional investor through a private placement transaction in May 2021. Concurrently, ordinary shares were sold to the same institutional investor in a private placement transaction. The warrant was assessed as a financial liability with a fair value of $119.1 million as of September 30, 2021 and a fair value loss of $35.8 million was recorded for the three months ended of September 30, 2021.

Fair Value Loss of Convertible Redeemable Preferred Shares

For the nine months ended September 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 consummation of Legend Biotech's U.S. initial public offering, all outstanding Series 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

Net loss for the three months ended September 30, 2021 was $124.8 million, or $0.43 per share, compared to $66.5 million, or $0.25 per share, for the three months ended September 30, 2020. Net loss for the nine months ended September 30, 2021 was $297.9 million, or $1.07 per share, compared to $245.7 million, or $1.08 per share, for the nine months ended September 30, 2020.

About Legend Biotech

Legend Biotech is a global, clinical-stage cell therapy company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing a diverse array of technology platforms, including autologous and allogenic chimeric antigen receptor T-cell, T-cell receptor (TCR-T), and natural killer (NK) cell-based immunotherapy. From our three R&D sites around the world, we apply these innovative technologies to pursue the discovery of safe, efficacious and cutting-edge options for patients worldwide.

We are currently engaged in a strategic collaboration to develop and commercialize our lead product candidate, ciltacabtagene autoleucel, an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. This candidate is being studied in registrational clinical trials and has received priority review from the U.S. Food and Drug Administration for the first indication.

Learn more at www.legendbiotech.com and follow us on Twitter and LinkedIn.

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 relapsed and/or refractory multiple myeloma (RRMM). 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 RRMM are currently under regulatory review by several health authorities around the world including the U.S. FDA and the European Medicines Agency (EMA).

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. 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. Cohort A included patients who had progressive multiple myeloma after 1–3 prior lines of therapy, including PI and IMiD, were lenalidomide refractory, and had no prior exposure to BCMA-targeting agents. Cohort B included patients with early relapse after initial therapy that included a PI and IMiD. Cohort C included patients with RRMM who had been previously treated with a PI, an IMiD, an anti-CD38 monoclonal antibody and B-cell maturation antigen (BCMA)-directed therapy and had no prior treatment with chimeric antigen receptor T (CAR-T) therapy directed at any target. Cohort D included patients with NDMM per IMWG with a history of 4 to 8 total cycles of initial therapy, including induction, high-dose therapy, and ASCT with or without consolidation, and had no prior exposure to BCMA-targeting agents. Cohort E included patients who had NDMM without prior therapy and classified as high risk. Cohort F included patients with a documented efficacy response of very good partial response (VGPR) or better, without progressive disease prior to enrollment, as assessed per IMWG 2016 criteria, and had no prior exposure to BCMA-targeting agents. 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. 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. 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.

About the LB1901 Clinical Development Program

LB1901-TCL-001 (NCT04712864) is a Phase 1 open-label, multicenter study of LB1901 in patients with histologically confirmed CD4+ RR PTCL (PTCL not otherwise specified, or PTCLNOS, and angioimmunoblastic T cell lymphoma, or AITL) or RR CTCL (mycosis fungoides and Sézary syndrome). The primary objectives are to characterize the safety and tolerability of LB1901 and determine the optimal dose.

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 advancement of Legend Biotech's cilta-cel clinical development program, and the advancement of other product candidates in Legend Biotech's development pipeline; 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 September 30**		**Nine months ended September 30**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
REVENUE	16,882	11,747	50,797	34,893
Other income and gains	567	1,519	2,316	5,315
Research and development expenses	(72,314)	(63,656)	(226,843)	(165,226)
Administrative expenses	(11,806)	(6,038)	(29,797)	(13,976)
Selling and distribution expenses	(19,532)	(9,287)	(49,731)	(25,389)
Other expenses	(2,540)	(1,249)	(6,918)	(1,331)
Fair value loss of warrant liability	(35,800)	-	(37,400)	-
Fair value loss of convertible redeemable preferred shares	-	-	-	(79,984)
Finance costs	(208)	(90)	(298)	(4,169)
LOSS BEFORE TAX	(124,751)	(67,054)	(297,874)	(249,867)
Income tax credit/(expense)	-	508	(1)	4,217
LOSS FOR THE PERIOD	(124,751)	(66,546)	(297,875)	(245,650)
Attributable to:				
Equity holders of the parent	(124,751)	(66,546)	(297,875)	(245,650)
Loss per share attributable to ordinary equity holders of the parent:				
Ordinary shares – basic	(0.43)	(0.25)	(1.07)	(1.08)
Ordinary shares – diluted	(0.43)	(0.25)	(1.07)	(1.08)
Shares used in loss per share computation:				
Ordinary shares – basic	289,917,492	264,328,630	277,829,268	226,764,437
Ordinary shares – diluted	289,917,492	264,328,630	277,829,268	226,764,437

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(in thousands, US$)	**September 30, 2021 (Unaudited)**	**December 31, 2020**
NON-CURRENT ASSETS		

Property, plant and equipment	141,071	113,091
Advance payments for property, plant and equipment	1,766	224
Right-of-use assets	7,561	8,009
Other non-current assets	4,573	3,973
Intangible assets	5,432	2,852
Total non-current assets	**160,403**	**128,149**
CURRENT ASSETS		
Inventories	1,634	1,800
Trade receivables	1,501	74,978
Prepayments, other receivables and other assets	13,838	10,007
Financial assets at fair value through profit and loss	50,040	-
Financial assets measured at amortized cost	29,849	-
Pledged short-term deposits	456	384
Time deposits	217,710	50,000
Cash and cash equivalents	338,334	455,689
Total current assets	**653,362**	**592,858**
Total assets	**813,765**	**721,007**
CURRENT LIABILITIES		
Trade and notes payables	11,593	5,238
Other payables and accruals	87,445	99,168
Government grants	299	283
Warrant liability	119,100	-
Lease liabilities	1,116	1,464
Contract liabilities	55,816	55,014
Total current liabilities	**275,369**	**161,167**
NON-CURRENT LIABILITIES		
Contract liabilities	237,219	275,071
Lease liabilities	1,865	1,909
Interest-bearing loans and borrowings	70,540	-
Other non-current liabilities	991	554
Government grants	1,915	2,051
Total non-current liabilities	**312,530**	**279,585**
Total liabilities	**587,899**	**440,752**
EQUITY		
Share capital	29	27
Reserves	225,837	280,228
Total ordinary shareholders' equity	**225,866**	**280,255**
Total equity	**225,866**	**280,255**
Total liabilities and equity	**813,765**	**721,007**

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands, US$)	**Three months ended September 30**		**Nine months ended September 30**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**

LOSS BEFORE TAX	(124,751)	(67,054)	(297,874)	(249,867)
CASH FLOWS USED IN OPERATING ACTIVITIES	(44,593)	(64,375)	(128,918)	(167,053)
CASH FLOWS USED IN INVESTING ACTIVITIES	(105,672)	(58,623)	(291,495)	(85,334)
CASH FLOWS FROM FINANCING ACTIVITIES	1,143	9,663	303,102	618,218
NET (DECREASE) / INCREASE IN CASH AND CASH EQUIVALENTS	(149,122)	(113,335)	(117,311)	365,831
Effect of foreign exchange rate changes, net	(759)	325	(44)	186
Cash and cash equivalents at beginning of the period	488,215	562,391	455,689	83,364
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	338,334	449,381	338,334	449,381
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	556,500	575,370	556,500	575,370
Less: Pledged short-term deposits	456	430	456	430
Time deposits	217,710	125,559	217,710	125,559
Cash and cash equivalents as stated in the statement of financial position	338,334	449,381	338,334	449,381
Cash and cash equivalents as stated in the statement of cash flows	338,334	449,381	338,334	449,381

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