Legend Biotech Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Highlights

March 18, 2022

- *U.S. Food Drug Administration approved CARVYKTI ™ (ciltacabtagene autoleucel; cilta-cel), a BCMA-directed CAR T-cell therapy for the treatment of adults with relapsed or refractory multiple myeloma (MM) who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody*
- *The CARTITUDE clinical development program is progressing to evaluate cilta-cel in patients with newly diagnosed MM across two randomized Phase 3 studies (CARTITUDE-5 and CARTITUDE-6)*
- *Longer-term follow-up data for CARTITUDE-1 presented at 63rd American Society of Hematology Annual Meeting continued to show deep and durable responses*
- *Legend Biotech appoints Marc L. Harrison as Vice President and General Counsel*

SOMERSET, N.J.--(BUSINESS WIRE)--Mar. 18, 2022-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies, today reported unaudited financial results for the fourth quarter of 2021.

"Legend Biotech ended the fourth quarter with strong data on our lead product candidate and nearly $900 million in cash," said Ying Huang, PhD, Chief Executive Officer and Chief Financial Officer of Legend Biotech. "Both achievements put us in a strong position to commercialize CARVYKTI in 2022 and advance our pipeline."

Dr. Huang added: "As we close another quarter, I continue to be impressed by our incredible teams around the world. Thanks to their dedication, our pipeline candidates have shown tremendous promise across multiple therapeutic areas, including gastric cancer. As I look to the year ahead, I am confident that Legend will continue its work of realizing the promise of CAR-T."

Recent Highlights

- The U.S. Food and Drug Administration (U.S. FDA) approved CARVYKTI ™ (ciltacabtagene autoleucel) for the treatment of adults with relapsed or refractory multiple myeloma (MM) who have received four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
- Legend Biotech and its collaboration partner Janssen Biotech, Inc. (Janssen) is progressing the CARTITUDE clinical development program in earlier lines across Phase 3 studies, including a collaborative study.
    - CARTITUDE-4 completed enrollment. The Phase 3, open-label study evaluates 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).
    - CARTITUDE-5 initiated enrollment. The Phase 3, randomized, open-label study compares bortezomib, lenalidomide and dexamethasone (VRd) induction followed by cilta-cel vs. VRd induction followed by lenalidomide and dexamethasone (Rd) maintenance in patients with newly diagnosed MM for whom autologous stem cell transplant (ASCT) is not planned as initial therapy (NCT04923893)
    - CARTITUDE-6 (not yet recruiting; sponsored by the European Myeloma Network). The Phase 3, randomized, open-label study compares daratumumab, bortezomib, lenalidomide and dexamethasone (DVRd) followed by cilta-cel vs. DVRd followed by autologous stem cell transplant (ASCT) in newly diagnosed patients with MM who are transplant eligible (NCT05257083)
- New and updated results from the CARTITUDE clinical development program studying cilta-cel in various clinical settings were presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition in 2021. Two-year follow-up data for CARTITUDE-1 were presented showing continued deep and durable responses of cilta-cel in patients with heavily pretreated MM.
- A New Drug Application for cilta-cel was submitted to the Ministry of Health, Labour and Welfare (MHLW) in Japan by Janssen in December 2021.
- New, preclinical *in vivo* data on Legend Biotech's novel tri-specific, single-domain antibody (VHH) CAR-T (LCAR-AIO) were presented at ASH 2021 as a poster (Abstract #1700). LCAR-AIO targets three antigens—CD19, CD20 and CD22.
- Legend Biotech raised approximately $345 million in gross proceeds in a follow-on public offering of its American depositary shares (ADSs).
- Marc L. Harrison was appointed Vice President and General Counsel of Legend Biotech in January 2022. Mr. Harrison brings more than 20 years of experience in healthcare and life sciences to the role. He previously served as Vice

President, General Counsel and Head of Compliance at Breckenridge Pharmaceutical, Inc. and has held senior legal and leadership positions at Ipsen Biopharmaceuticals, Medco Health Solutions and WebMD.

- A clinical hold was placed by the U.S. FDA in February 2022 on the Phase 1, open-label, multicenter clinical trial to evaluate 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) (NCT04712864). Legend Biotech subsequently received an official clinical hold letter from the FDA dated March 1, 2022. In the letter, FDA stated that the reason for the hold is because the related IND does not contain sufficient information required by 21 CFR 312.23 to assess the risks to subjects.
- Legend Biotech achieved two milestone payments amounting to $50 million, under the terms of its collaboration and license agreement with Janssen for the joint development and commercialization of cilta-cel.

Financial Results for the Quarter and Year Ended December 31, 2021

Cash Position

As of December 31, 2021, Legend Biotech had approximately $887.1 million of cash and cash equivalents, deposits and short-term investments.

Revenue

Revenue for the three months ended December 31, 2021 was $39.0 million compared to $40.8 million for the three months ended December 31, 2020. The decrease of $1.8 million was mainly due to the timing of when different milestones were achieved during those quarters.

Revenue for the year ended December 31, 2021 was $89.8 million, compared to $75.7 million for the year ended December 31, 2020. This increase of $14.1 million was primarily driven by revenue recognized from three additional milestones achieved in fiscal year 2021 and an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd and its affiliates during the year ended December 31, 2021. We have not generated any revenue from product sales to date.

Research and Development Expenses

Research and development expenses for the three months ended December 31, 2021 were $86.5 million compared to $66.9 million for the three months ended December 31, 2020. This increase of $19.6 million was primarily due to continuous research and development activities in cilta-cel and for other pipelines in 2021. Research and development expenses in 2021 were $313.3 million, compared to $232.2 million for the year ended December 31, 2020, an increase of $81.1 million.

Administrative Expenses

Administrative expenses for the three months ended December 31, 2021 were $17.1 million compared to $9.2 million for the three months ended December 31, 2020. The increase of $7.9 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 year ended December 31, 2021 increased by $23.8 million, to $46.9 million, compared to $23.1 million for the year ended December 31, 2020.

Selling and Distribution Expenses

Selling and distribution expenses for the three months ended December 31, 2021 were $52.8 million compared to $24.2 million for the three months ended December 31, 2020. This increase of $28.6 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel launch. Due to the consistent business expansion, selling and distribution expenses for the year ended December 31, 2021 increased by $52.9 million, to $102.5 million, compared to $49.6 million for the year ended December 31, 2020.

Other Income and Gains

Other income and gains for the three months ended December 31, 2021 was $0.7 million compared to $2.1 million for the three months ended December 31, 2020. The decrease of $1.4 million was primarily driven by a decrease in foreign exchange gain. Other income and gains for the year ended December 31, 2021 was $3.1 million compared to $6.1 million for the year ended December 31, 2020. The decrease of $3.0 million primarily resulted from less interest income from time deposits of lower average interest rate and less government grants.

Other Expenses

Other expenses for the three months ended December 31, 2021 was $2.2 million compared to $0.3 million for the three months ended December 31, 2020. The increase of $1.9 million was primarily due to higher foreign exchange loss. Other expenses for the year ended December 31, 2021 was $9.1 million compared to $0.3 million for the year ended December 31, 2020. The increase was primarily due to foreign exchange loss and loss from disposal of assets.

Finance Costs

Finance costs for the year ended December 31, 2021 was $0.9 million, mainly composed of interest for advance funding, which is interest-bearing borrowings funded by the collaborator and constituted by a principal and applicable interests upon such principal. Finance costs for the year ended December 31, 2020 was $4.2 million, resulted from the finance costs for the issuance of convertible redeemable preferred shares (Series A Preferred Shares) that 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 year ended December 31, 2021 was $6.2 million caused by changes in the fair value of a warrant that we issued to an institutional investor through a private placement transaction in May 2021 with initial fair value of $81.7 million at the issuance date. The

warrant was assessed as a financial liability with a fair value of $87.9 million as of December 31, 2021.

Fair Value Loss of Convertible Redeemable Preferred Shares

For the year ended December 31, 2020, Legend Biotech reported a one-time non-cash charge of $80.0 million caused by changes of the fair value of its Series A Preferred Shares. Upon Legend Biotech's listing of its ADSs on the Nasdaq Global Market, all outstanding Series A Preferred Shares were automatically converted into ordinary shares of Legend Biotech and all accrued but unpaid dividends were settled in the form of ordinary shares of Legend Biotech. No such fair value loss in 2021 as the Company has no outstanding preferred shares after the listing.

Loss for the Period

Net loss for the three months ended December 31, 2021 was $88.3 million, or $0.30 per share, compared to $57.8 million, or $0.22 per share, for the three months ended December 31, 2020. Net loss for the year ended December 31, 2021 was $386.2 million, or $1.37 per share, compared to $303.5 million, or $1.28 per share, for the year ended December 31, 2020.

About Legend Biotech

Legend Biotech is a global biotechnology company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing advanced cell therapies across 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 therapeutics for patients worldwide.

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

About CARVYKTI™ (Ciltacabtagene autoleucel; cilta-cel)

CARVYKTI™ is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells. The CARVYKTI™ CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.[1]

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

In April 2021, Legend announced the submission of a Marketing Authorisation Application to the European Medicines Agency seeking approval of cilta-cel for the treatment of patients with relapsed and/or refractory multiple myeloma. In addition to U.S. Breakthrough Therapy Designation granted in December 2019, cilta-cel received a Breakthrough Therapy Designation in China in August 2020. Cilta-cel also received Orphan Drug Designation from the U.S. FDA in February 2019, and from the European Commission in February 2020.

About the CARTITUDE-1 Study

CARTITUDE-1 (NCT03548207) is an ongoing Phase 1b/2, open-label, single arm, multi-center trial evaluating cilta-cel for the treatment of adult patients with relapsed or refractory multiple myeloma, who previously received at least three prior lines of therapy including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 monoclonal antibody. Of the 97 patients enrolled in the trial, 99 percent were refractory to the last line of treatment and 88 percent were triple-class refractory, meaning their cancer did not respond, or no longer responds, to an IMiD, a PI and an anti-CD38 monoclonal antibody.[1]

The longer-term efficacy and safety profile of cilta-cel is being assessed in the ongoing CARTITUDE-1 study, with two-year follow-up results recently presented at ASH 2021.[2]

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.[3] In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.[4] 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.[5] Although treatment may result in remission, unfortunately, patients will most likely relapse.[6] Patients who relapse after treatment with standard therapies, including protease inhibitors, immunomodulatory agents, and an anti-CD38 monoclonal antibody, have poor prognoses and few treatment options available.[7,8]

Cautionary Statement:

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; statements relating to CARVYKTI™, including Legend Biotech's expectations for CARVYKTI™, such as Legend Biotech's manufacturing and commercialization expectations for CARVYKTI™ and the potential effect of treatment with CARVYKTI™; statements about submissions for cilta-cel to, and the progress of such submissions with, the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Chinese Center for Drug Evaluation of National Medical Products Administration (CDE) and other regulatory authorities; the anticipated timing of, and ability to progress, clinical trials, including patient enrollment; the submission of Investigational New Drug (IND) applications to, and maintenance of such applications with, regulatory authorities; the ability to generate, analyze and present data from clinical trials; and the potential benefits of Legend Biotech's 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 U.S. 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 Legend Biotech's Annual Report 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 press release as anticipated, believed, estimated or expected. Any forward-looking statements contained in this press release speak only as of the date of this press release.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 December 31		Year ended December 31	
(in thousands, US$, except share and per share data)	**2021**	**2020**	**2021**	**2020**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	
REVENUE	38,995	40,783	89,792	75,676
Other income and gains	743	2,079	3,059	6,119
Research and development expenses	(86,503)	(66,934)	(313,346)	(232,160)
Administrative expenses	(17,142)	(9,171)	(46,939)	(23,147)
Selling and distribution expenses	(52,811)	(24,182)	(102,542)	(49,571)
Other expenses	(2,214)	(290)	(9,132)	(346)
Fair value gain/(loss) of warrant liability..	31,200	-	(6,200)	-
Fair value loss of convertible redeemable preferred shares	-	-	-	(79,984)
Finance costs	(602)	(40)	(900)	(4,209)
LOSS BEFORE TAX	(88,334)	(57,755)	(386,208)	(307,622)
Income tax (expense)/credit	-	(72)	(1)	4,145
LOSS FOR THE PERIOD	(88,334)	(57,827)	(386,209)	(303,477)
Attributable to:				
Equity holders of the parent	(88,334)	(57,827)	(386,209)	(303,477)
Loss per share attributable to ordinary equity holders of the parent:				
Ordinary shares – basic	(0.30)	(0.22)	(1.37)	(1.28)
Ordinary shares – diluted	(0.30)	(0.22)	(1.37)	(1.28)
Shares used in loss per share computation:				
Ordinary shares – basic	293,199,033	264,720,588	281,703,291	236,305,234
Ordinary shares – diluted	293,199,033	264,720,588	281,703,291	236,305,234

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31, 2021	December 31, 2020
(in thousands, US$)	**(Unaudited)**	
NON-CURRENT ASSETS		
Property, plant and equipment	145,724	113,091
Advance payments for property, plant and equipment	2,168	224
Right-of-use assets	7,186	8,009
Other non-current assets	5,148	3,973
Intangible assets	4,684	2,852
Time deposits	4,705	-
Total non-current assets	**169,615**	**128,149**

CURRENT ASSETS		
Inventories	1,749	1,800
Trade receivables	50,410	74,978
Prepayments, other receivables and other assets	12,754	10,007
Financial assets measured at amortized cost	29,937	-
Pledged deposits	1,444	384
Time deposits	163,520	50,000
Cash and cash equivalents	688,938	455,689
Total current assets	**948,752**	**592,858**
Total assets	**1,118,367**	**721,007**
CURRENT LIABILITIES		
Trade and notes payables	7,043	5,238
Other payables and accruals	123,464	99,168
Government grants	304	283
Warrant liability	87,900	-
Lease liabilities	911	1,464
Contract liabilities	60,644	55,014
Total current liabilities	**280,266**	**161,167**
NON-CURRENT LIABILITIES		
Contract liabilities	242,578	275,071
Lease liabilities	1,593	1,909
Interest-bearing loans and borrowings	120,462	-

(in thousands, US$)	**December 31, 2021 (Unaudited)**	**December 31, 2020**
Government grants	1,866	2,051
Other non-current liabilities	396	554
Total non-current liabilities	**366,895**	**279,585**
Total liabilities	**647,161**	**440,752**
EQUITY		
Share capital	31	27
Reserves	471,175	280,228
Total equity	**471,206**	**280,255**
Total liabilities and equity	**1,118,367**	**721,007**

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three months ended December 31		**Year ended December 31**	
(in thousands, US$)	**2021 (Unaudited)**	**2020 (Unaudited)**	**2021 (Unaudited)**	**2020**
LOSS BEFORE TAX	(88,334)	(57,755)	(386,208)	(307,622)
CASH FLOWS USED IN OPERATING ACTIVITIES	(69,547)	(55,952)	(198,465)	(223,005)
CASH FLOWS FROM/(USED IN) INVESTING ACTIVITIES	96,512	61,165	(194,983)	(24,169)

CASH FLOWS FROM FINANCING ACTIVITIES	323,561	661	626,663	618,879
NET INCREASE IN CASH AND CASH EQUIVALENTS	350,526	5,874	233,215	371,705
Effect of foreign exchange rate changes, net	78	434	34	620
Cash and cash equivalents at beginning of the period	338,334	449,381	455,689	83,364
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	688,938	455,689	688,938	455,689
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	858,607	506,073	858,607	506,073
Less: Pledged deposits	1,444	384	1,444	384
Time deposits	168,225	50,000	168,225	50,000
Cash and cash equivalents as stated in the statement of financial position	688,938	455,689	688,938	455,689
Cash and cash equivalents as stated in the statement of cash flows	688,938	455,689	688,938	455,689

[1] CARVYKTI™ Prescribing InformationHorsham, PA: Janssen Biotech, Inc.

[2] Martin, T. Updated Results From CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-cell Maturation Antigen–Directed Chimeric Antigen Receptor T Cell Therapy, in Patients with Relapsed/Refractory Multiple Myeloma. Abstract #549 [Oral]. Presented at the 2021 American Society of Hematology (ASH) Annual Meeting & Exposition.

[3] American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction. Accessed February 2022.

[4] American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed February 2022.

[5] American Cancer Society. Multiple myeloma: early detection, diagnosis and staging. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/8740.00.pdf. Accessed February 2022.

[6] Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. *Am J Hematol*. 2020;95(5),548-567. doi:10.1002/ajh.25791.

[7] Kumar SK, Dimopoulos MA, Kastritis E, et al. Natural history of relapsed myeloma, refractory to immunomodulatory drugs and proteasome inhibitors: a multicenter IMWG study. *Leukemia*. 2017;31(11):2443-2448.

[8] Gandhi UH, Cornell RF, Lakshman A, et al. Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy. *Leukemia*. 2019;33(9):2266-2275.

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