Legend Biotech Reports Full-Year 2022 Results and Recent Highlights

March 30, 2023

- *CARTITUDE-4, a Phase 3 study of CARVYKTI® (ciltacabtagene autoleucel) meets primary endpoint at the study's first pre-specified interim analysis*
- *FDA clearance of IND application for LB2102 in Extensive Stage Small Cell Lung Cancer (SCLC)*
- *CARVYKTI® (ciltacabtagene autoleucel) receives approval from Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with relapsed or refractory multiple myeloma*
- *China's National Medical Products Administration (NMPA) has formally accepted the New Drug Application (NDA) for ciltacabtagene autoleucel (cilta-cel)*

SOMERSET, N.J.--(BUSINESS WIRE)--Mar. 30, 2023-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies to treat life-threatening diseases, today reported its full year 2022 audited financial results.

"2022 was a year of significant milestones for Legend Biotech, marked by the regulatory approvals of CARVYKTI® in the U.S., Europe, and Japan. In addition to launching our first commercial product, we advanced our clinical development program for cilta-cel, obtained FDA clearances on two investigational new drug applications targeting solid tumors, and critically, expanded our commercial infrastructure and manufacturing capabilities to support future growth" said Ying Huang, Chief Executive Officer of Legend Biotech.

"Our teams across the entire business delivered exceptionally during an incredibly busy year. Looking forward, we remain focused on the continued expansion of our manufacturing footprint and advancing our clinical program in order to bring CARVYKTI® to more eligible patients."

Second Half 2022 Highlights and Recent Events

- On January 27, 2023, Legend Biotech announced that CARTITUDE-4, the Phase 3 study evaluating CARVYKTI® (ciltacabtagene autoleucel) for the treatment of adult patients with relapsed and lenalidomide-refractory multiple myeloma, met its primary endpoint of showing a statistically significant improvement in progression-free survival (PFS) compared to standard therapy at the study's first pre-specified interim analysis

- On January 2, 2023, Legend Biotech announced that China's National Medical Products Administration (NMPA) has formally accepted the New Drug Application (NDA) for ciltacabtagene autoleucel (cilta-cel)

- On November 21, 2022, Legend Biotech announced that the U.S. Food and Drug Administration (FDA) cleared Legend Biotech's Investigational New Drug (IND) application to proceed with the clinical development of LB2102, an investigational, autologous chimeric antigen receptor T-cell (CAR-T) therapy for the treatment of adult patients with extensive stage small cell lung cancer (SCLC)

- On September 27, 2022, Legend Biotech announced that Japan's Ministry of Health, Labour and Welfare (MHLW) approved CARVYKTI® (ciltacabtagene autoleucel) for the treatment of adults with relapsed or refractory multiple myeloma, limited to cases meeting both of the following conditions: patients have no history of CAR-positive T cell infusion therapy targeting BCMA; and patients have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy

Financial Results for Year Ended December 31, 2022

Cash and Cash Equivalents, Time Deposits, and Short-Term Investments

As of December 31, 2022, Legend Biotech had approximately $1.0 billion of cash and cash equivalents, time deposits, and short-term investments.

Revenue

Revenue for the year ended December 31, 2022 was $117.0 million compared to $68.8 million for the year ended December 31, 2021. The increase of $48.2 million was due to product sales for the commercial launch of CARVYKTI® in the U.S. in connection with Legend Biotech's collaboration agreement with Janssen Biotech, Inc. (the "Janssen Agreement").

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 were $335.6 million compared to $313.3 million for the year ended December 31, 2021. This increase of $22.3 million was primarily due to continued investment in cilta-cel for earlier lines of therapies and increase in Legend Biotech's pipeline expenditures as it filed two Investigational New Drug applications and began preparation for Phase 1 clinical development in the U.S. in the year ended December 31, 2022.

Administrative Expenses

Administrative expenses for the year ended December 31, 2022 were $80.6 million compared to $47.0 million for the year ended December 31, 2021. The increase of $33.7 million was primarily due to the final phase of separation of certain information technology services from GenScript Biotech Corporation, required enhancements for cybersecurity and privacy, along with the required information technology infrastructure build to support manufacturing facilities.

Selling and Distribution Expenses

Selling and distribution expenses for the year ended December 31, 2022 were $93.4 million compared to $102.5 million for the year ended December 31, 2021. This increase of $9.1 million was primarily due to costs associated with the commercialization of CARVYKTI®.

Other Income and Gains

Other income and gains for the year ended December 31, 2022 were $12.0 million compared to $3.1 million for the year ended December 31, 2021. The increase of $8.9 million was primarily due to increase in interest income, government grants and fair value gain from financial assets.

Other Expenses

Other expenses for the year ended December 31, 2022 were $9.8 million compared to $9.1 million for the year ended December 31, 2021. The increase was primarily due to foreign currency exchange loss in the year.

Finance Costs

Finance costs for the year ended December 31, 2022 were $10.8 million compared to $0.9 million for the year ended December 31, 2021. The increase was primarily due to interest on advance funding, which is interest-bearing borrowings funded by Janssen under the Janssen Agreement and constituted by principal and applicable interests upon such principal. Legend Biotech elected to borrow an incremental $130.3 million as of December 31, 2022 in accordance with the terms of the Janssen Agreement.

Fair Value Gain of Warrant Liability

Fair value gain of warrant liability for the year ended December 31, 2022 was $20.9 million caused by changes in the fair value of a warrant that Legend Biotech issued to an institutional investor through a private placement transaction in May 2021 with an initial fair value of $81.7 million at the issuance date. The warrant was assessed as a financial liability with a fair value of $67.0 million as of December 31, 2022.

Loss for the Period

For the year ended December 31, 2022, net loss was $446.3 million, or $1.40 per share, compared to a net loss of $403.6 million, or $1.43 per share, for the year ended December 31, 2021.

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 allogeneic chimeric antigen receptor T-cell 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 cutting-edge therapeutics for patients worldwide.

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

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; statements relating to CARVYKTI ® and other product candidates, including Legend Biotech's expectations for CARVYKTI ® and other product candidates, such as Legend Biotech's manufacturing and commercialization expectations for CARVYKTI® and the potential effect of treatment with CARVYKTI® and other product candidates; statements about submissions for CARVYKTI® and other product candidates to, and the progress of such submissions with, the U.S. Food and Drug Administration (FDA) and other regulatory authorities; the anticipated timing of, and ability to progress, clinical trials; and the ability to generate, analyze and present data from clinical trials. 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 product 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 March 30, 2023. 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

	Twelve months ended December 31		
(in thousands, US$, except share and per share data)	**2022**	**2021**	**2020**
REVENUE			
License revenue	50,000	65,402	75,000
Collaboration revenue	66,677	-	-
Other revenue	328	3,424	0
Total revenue	**117,005**	**68,826**	**75,000**
Collaboration cost of revenue	(65,363)	-	-
Other income and gains	12,049	3,059	6,119
Research and development expenses	(335,648)	(313,346)	(232,160)
Administrative expenses	(80,631)	(46,961)	(23,134)
Selling and distribution expenses	(93,417)	(102,542)	(49,571)
Other expenses	(9,823)	(9,132)	(346)
Fair value gain/(loss) of warrant liability	20,900	(6,200)	-
Fair value loss of convertible redeemable preferred shares	-	-	(79,984)
Finance costs	(10,796)	(900)	(4,209)
LOSS BEFORE TAX	(445,724)	(407,196)	(308,285)
Income tax (expense)/credit	(625)	3,614	41,912
LOSS FOR THE YEAR	(446,349)	(403,582)	(266,373)
Attributable to:			
Ordinary equity holders of the parent	**(446,349)**	**(403,582)**	**(266,373)**
Loss per share attributable to ordinary equity holders of the parent:			
Ordinary shares - basic	(1.40)	(1.43)	(1.13)
Ordinary shares - diluted	(1.40)	(1.43)	(1.13)
Shares used in loss per share computation:			
Weighted average number of ordinary shares	318,083,913	281,703,291	236,305,234

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(in thousands, US$)	**December 31, 2022**	**December 31, 2021**
NON-CURRENT ASSETS		
Property, plant and equipment	105,168	102,506
Advance payments for property, plant and equipment	914	2,168
Right-of-use assets	55,590	38,283
Time deposits	-	4,705
Intangible assets	3,409	4,684
Collaboration prepaid leases	65,276	12,121
Other non-current assets	1,487	5,148
Total non-current assets	**231,844**	**169,615**
CURRENT ASSETS		
Collaboration inventories	10,354	1,749
Trade receivables	90	50,410
Prepayments, other receivables and other assets	61,755	13,852
Financial assets at fair value through profit or loss	185,603	-
Financial assets measured at amortized cost	-	29,937
Pledged deposits	1,270	1,444
Time deposits	54,016	163,520
Cash and cash equivalents	786,031	688,938
Total current assets	1,099,119	949,850
Total assets	1,330,963	1,119,465

CURRENT LIABILITIES		
Trade payables	32,893	7,043
Other payables and accruals	184,109	123,558
Government grants	451	304
Lease liabilities	3,563	911
Tax payable	9,772	9,488
Warrant liability	67,000	87,900
Total current liabilities	297,788	229,204
NON-CURRENT LIABILITIES		
Collaboration interest-bearing advanced funding	260,932	120,462
Lease liabilities long term	20,039	1,593
Government grants	7,659	1,866
Other non-current liabilities	233	396
Total non-current liabilities	288,863	124,317
Total liabilities	586,651	353,521
EQUITY		
Share capital	33	31
Reserves	744,279	765,913
Total ordinary shareholders' equity	744,312	765,944
Total equity	744,312	765,944
Total liabilities and equity	1,330,963	1,119,465

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands, US$)	**2022**	**2021**	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax	(445,724)	(407,196)	(308,285)
Adjustments for:			
Finance income	(8,182)	(971)	(2,930)
Finance costs	10,796	900	4,209
Depreciation of property, plant and equipment	10,173	8,139	6,234
Loss on disposal of property, plant and equipment	481	974	55
Amortization of intangible assets	2,476	1,379	192
Depreciation of right-of-use assets	5,743	4,399	3,507
Fair value (gain)/ loss of warrant liability	(20,900)	6,200	-
Fair value loss of convertible redeemable preferred shares	-	-	79,984
Fair value gains on financial assets measured at fair value change through profit or loss	(593)	-	(47)
Foreign currency exchange loss/(gain), net	9,159	4,867	(66)
Equity-settled share-based compensation expense	34,338	20,158	4,760
Deferred government grant	(307)	(295)	(114)
	(402,540)	**(361,446)**	**(212,501)**
Decrease/(increase) in trade receivables	50,320	24,590	(45,000)
(Increase)/decrease in prepayments, other receivables and other assets	(50,614)	(2,966)	3,366
Decrease/(increase) in other non-current assets	3,661	(1,175)	(3,973)
(Increase)/decrease in collaboration inventories	(8,605)	51	(643)
Government grant received	6,180	80	2,452
Increase/(decrease) in trade payables	25,850	1,805	(4,348)
Increase in other payables and accruals	165,883	140,747	26,932
Increase/(decrease) in other non-current liabilities	(163)	(158)	554
Increase in pledged deposits, net	(15)	(1,060)	(128)
Cash used in operations	**(210,043)**	**(199,532)**	**(233,289)**
Income tax paid	-	-	(278)
Finance income received	6,832	652	3,366
Income tax received	3,709	557	7,391
Interest on lease payments	(527)	(142)	(195)
Net cash used in operating activities	**(200,029)**	**(198,465)**	**(223,005)**

	2022	2021	2020
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment	(20,927)	(42,197)	(26,254)
Purchase of intangible assets	(1,348)	(3,207)	(4,029)
Prepayment to collaborator for collaboration assets	(14,810)	(1,708)	(19,493)
Purchase of financial assets measured at fair value through profit or loss	(285,000)	(50,000)	(22,682)
Cash received from withdrawal of financial assets measured at fair value through profit or loss	99,990	50,081	22,682
Cash received from withdrawal of financial assets measured at amortized cost	30,000	-	-
Cash receipts of investment income	-	-	47
Proceeds from disposal of property, plant and equipment	-	4	1
Addition in time deposits	(369,971)	(298,107)	(50,000)
Decrease in time deposits	483,617	180,000	75,559
Decrease in pledged deposits	105	-	-
Purchase of financial assets measured at amortized cost	-	(29,849)	-
Net cash used in investing activities	**(78,344)**	**(194,983)**	**(24,169)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of cash advances from related parties	-	-	(4)
Proceeds from convertible redeemable preferred shares	-	-	160,450
Proceeds from issuance of ordinary shares for initial public offering, net of issuance costs	-	-	450,085
Proceeds from issuance of ordinary shares relating to private placement by GenScript	-	-	12,000
Proceeds from issuance of ordinary shares for follow on public offering, net of issuance costs	377,643	323,440	-
Proceeds from issuance of ordinary shares and warrant relating to private placement for an institutional investor	-	300,000	-
Proceeds from exercise of share options	2,929	4,642	1,464
Payments of expenses for issuance of convertible redeemable preferred shares	-	-	(2,514)
Principal portion of lease payments	(2,596)	(1,419)	(2,602)
Net cash provided by financing activities	**377,976**	**626,663**	**618,879**

	2022	2021	2020
NET INCREASE IN CASH AND CASH EQUIVALENTS	99,603	233,215	371,705
Effect of foreign exchange rate changes, net	(2,510)	34	620
Cash and cash equivalents at beginning of year	688,938	455,689	83,364
CASH AND CASH EQUIVALENTS AT END OF YEAR	**786,031**	**688,938**	**455,689**

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Investor Contacts:
Joanne Choi, Senior Manager, Investor Relations, Legend Biotech
Joanne.choi@legendbiotech.com

Crystal Chen, Manager, Investor Relations, Legend Biotech
crystal.chen@legendbiotech.com

Press Contact:
Tina Carter, Corporate Communications Lead, Legend Biotech
tina.carter@legendbiotech.com
(908) 331-5025

Source: Legend Biotech