Legend Biotech Reports Fourth Quarter and Full Year 2023 Results and Recent Highlights

March 11, 2024

- *CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) net trade sales of approximately $159 million and $500 million for the fourth quarter and full year 2023, respectively*
- *CHMP recommended CARVYKTI® label expansion in earlier lines of treatment for adult patients with relapsed and lenalidomide-refractory multiple myeloma. FDA ODAC to meet on March 15 to review data from the CARTITUDE-4 study supporting the use of cilta-cel in earlier lines of treatment for adult patients with relapsed and lenalidomide-refractory multiple myeloma*
- *On January 3, 2024, Legend received a $100 million upfront payment in connection with its global license agreement with Novartis Pharma AG to develop, manufacture, and commercialize LB2102 and other potential CAR-T therapies selectively targeting DLL-3*
- *Cash and cash equivalents, deposits, and short-term investments of $1.3 billion, as of December 31, 2023, which Legend Biotech believes will provide financial runway through the end of 2025.*

SOMERSET, N.J.--(BUSINESS WIRE)--Mar. 11, 2024-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global leader in cell therapy, today reported its fourth quarter and full year 2023 unaudited financial results and key corporate highlights.

“With worldwide sales of half a billion dollars in its first full year of commercialization, our rapid, successful launch of CARVYKTI ® reinforces its position as a leading CAR-T therapy for patients with relapsed and refractory multiple myeloma,” said Ying Huang, Ph.D., Chief Executive Officer of Legend Biotech. “Our accomplishments in 2023, through our strategic partnership with Johnson & Johnson*, created the foundation for strong growth and uptake of CARVYKTI®, positioning us to bring CARVYKTI® to more patients in need of treatment going forward.”

Regulatory Updates

- The Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending label expansion for CARVYKTI® to include the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide. The U.S. Food and Drug Administration’s (FDA) Oncologic Drugs Advisory Committee (ODAC) intends to meet on March 15 to review data from the CARTITU-cel in earlier lines of treatment for adult patients with relapsed and lenalidomide-refractory multiple myeloma.DE-4 study supporting the use of cilta

Key Business Developments

- On January 3, 2024, Legend received a $100 million upfront payment in connection with its global license agreement with Novartis Pharma AG to develop, manufacture, and commercialize LB2102 and other potential chimeric antigen receptor T-cell (CAR-T) therapies selectively targeting Delta-like Ligand 3 (DLL-3)
- Promoted Birk Vanderweeën to Senior Vice President of Global Manufacturing & Supply responsible for overseeing the production and delivery of CARVYKTI® for patients across the globe. Previously he was General Manager, Europe. Mr. Vanderweeën brings over 25 years of experience in Operations, Quality, Supply Chain, and Manufacturing at industry leading companies
- Expanded manufacturing capacity by 100% since the beginning of 2023, including starting clinical production at the new Obelisc site in Ghent
- Plans to deliver production capacity of 10,000 annual doses by year-end 2025
- CARVYKTI® is now available in Germany and Austria, as commercial demand continues with over 2,500 patients treated across 80+ authorized treatment centers globally
- Presented patient-reported outcome data at the 2023 American Society of Hematology Annual Meeting from the Phase 3 CARTITUDE-4 study demonstrating clinically meaningful improvements in health-related quality of life and reductions in multiple myeloma symptoms following treatment with CARVYKTI® compared to standard of care[1]

* In December 2017, Legend Biotech entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc., a Johnson & Johnson company, to develop and commercialize cilta-cel (the Janssen Agreement).

Financial Results for Quarter and Year Ended December 31, 2023

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

As of December 31, 2023, Legend Biotech had approximately $1.3 billion of cash and cash equivalents, time deposits, and short-term investments.

Revenue

License Revenue

There was no license revenue for the three months ended December 31, 2023, and December 31, 2022. License revenue for the year ended December 31, 2023, was $35.2 million, compared to $50.0 million for the year ended December 31, 2022. This decrease of $14.8 million was primarily driven by the nature and timing of milestones achieved as outlined in the Global Development Plan under the Janssen Agreement for cilta-cel.

Collaboration Revenue

Collaboration revenue for the three months and year ended December 31, 2023, was $79.4 million and $249.8 million, respectively, compared to $27.4 million and $66.7 million for the three months and year ended December 31, 2022. The increase of $52.0 million and $183.1 million for the three months and year ended, respectively, were due to an increase in revenue generated from sales of CARVYKTI® in connection with the Janssen Agreement.

Other Revenue

Other revenue for the three months and year ended December 31, 2023, was $0.03 million and $0.2 million, respectively, compared to $0.2 million and $0.3 million for the three months and year ended December 31, 2022. Other revenue relates to the licensing of certain patents to Nanjing Probio Biotech Co., Ltd., and its affiliates.

Operating Expenses

Collaboration Cost of Revenue

Collaboration cost of revenue for the three months and year ended December 31, 2023, was $32.5 million and $144.2 million, respectively, compared to $23.0 million and $65.4 million for the three months and year ended December 31, 2022. The increase of $9.5 million and $78.8 million for the three months and year ended, respectively, were due to a combination of Legend Biotech's share of the cost of sales in connection with CARVYKTI ® sales under the Janssen Agreement and expenditures to support expansion in manufacturing capacity.

Research and Development Expenses

Research and development expenses for the three months and year ended December 31, 2023, were $105.7 million and $382.2 million, respectively, compared to $80.8 million and $335.6 million for the three months and year ended December 31, 2022. The increase of $24.9 million and $46.6 million for the three months and year ended, respectively, were primarily due to continuous research and development activities in cilta-cel, including higher patient enrollment for Phase 3 clinical trials, and an increase in research and development activities for other pipeline items. Also, the increase in research and development expenses is due to personnel and startup costs to establish the manufacturing facility in Belgium for initial clinical production. The other pipeline expenses include continued investment in Legend Biotech's solid tumor programs, which include two Investigational New Drug approvals that advanced into Phase 1 development.

Administrative Expenses

Administrative expenses for the three months and year ended December 31, 2023, were $28.7 million and $106.8 million, respectively, compared to $26.7 million and $80.6 million for the three months and year ended December 31, 2022. The increase of $2.0 million and $26.2 million for the three months and year ended, respectively, were primarily due to the expansion of administrative functions to facilitate continuous business growth and continued investment in building Legend Biotech's global information technology infrastructure.

Selling and Distribution Expenses

Selling and distribution expenses for the three months and year ended December 31, 2023, were $33.7 million and $94.2 million, respectively, compared to $25.8 million and $93.4 million for the three months and year ended December 31, 2022. The increase of $7.9 million and $0.8 million for the three months and year ended, respectively were due to costs associated with commercial activities for cilta-cel.

Other Income and Gains

Other income and gains for the three months and year ended December 31, 2023, were $18.5 million and $58.1 million, respectively, compared to $7.4 million and $12.0 million for the three months and year ended December 31, 2022. The increase of $11.1 million and $46.1 million for the three months and year ended, respectively, were primarily attributable to an increase in interest income and gain on investments.

Other Expenses

Other expenses for the three months and year ended December 31, 2023, were $38.4 million and $28.5 million, respectively, compared to $0.3 million and $9.8 million for the three months and year ended December 31, 2022. The increase of $38.1 million and $18.7 million for the three months and year ended, respectively, were primarily due to unrealized foreign currency exchange loss.

Finance Costs

Finance costs for the three months and year ended December 31, 2023, were $5.8 million and $21.8 million, respectively, compared to $4.9 million and $10.8 million for the three months and year ended December 31, 2022. The increase of $0.9 million and $11.0 million for the three months and year ended, respectively, were primarily due to interest on advance funding, which is interest-bearing borrowings funded by Janssen under the Janssen Agreement and constituted of principal and applicable interests upon such principal.

Fair Value (Loss)/Gain of Warrant Liability

There was no fair value (loss)/gain of warrant liability for the three months ended December 31, 2023, compared to a loss of $9.3 million for the three months ended December 31, 2022. Fair value loss of warrant liability for the year ended December 31, 2023, was $85.8 million, compared to a fair value gain of $20.9 million for the year ended December 31, 2022. The decrease of $9.3 million for the three months ended, was because the warrant was exercised on May 11, 2023. The increase of $106.7 million for the year ended, was due to the fair value loss recorded on the full exercise of the warrant we issued to an institutional investor in May 2021, which took place on May 11, 2023.

Loss for the Period

For the three months ended December 31, 2023, net loss was $144.8 million, or $0.40 per share, compared to net loss of $135.9 million, or $0.41 per share, for the three months ended December 31, 2022. For the year ended December 31, 2023, net loss was $518.3 million, or $1.47 per share, compared to a net loss of $446.3 million, or $1.40 per share, for the year ended December 31, 2022.

Webcast/Conference Call Details:

Legend Biotech will host its quarterly earnings call and webcast today at 8:00am ET. To access the webcast, please visit this weblink.

A replay of the webcast will be available on Legend Biotech's website at https://investors.legendbiotech.com/events-and-presentations.

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, gamma-delta 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 https://legendbiotech.com and follow us on X (formerly 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 ®, including patient population for CARVYKTI®, Legend Biotech's expectations for CARVYKTI ®, including manufacturing expectations for CARVYKTI®; expected results and timing of clinical trials; Legend Biotech's expectations for LB2102 and its potential benefits; the potential benefits of licensing transactions; Legend Biotech's expectations on advancing their pipeline and product portfolio; 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 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 for the year ended December 31, 2022 filed with the Securities and Exchange Commission (SEC) on March 30, 2023 and Legend Biotech's other filings with the SEC, as well as Legend Biotech's Annual Report on Form 20-F for the year ended December 31, 2023 to be filed with the SEC. 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,	
US$'000, except share and per share data	**2023 (unaudited)**	**2022 (unaudited)**	**2023 (unaudited)**	**2022 (audited)**
REVENUE				
License revenue	—	—	35,160	50,000
Collaboration revenue	79,435	27,441	249,804	66,677
Other revenue	29	192	179	328
Total revenue	79,464	27,633	285,143	117,005
Collaboration cost of revenue	(32,450)	(22,964)	(144,214)	(65,363)
Other income and gains	18,450	7,356	58,126	12,049
Research and development expenses	(105,683)	(80,756)	(382,218)	(335,648)
Administrative expenses	(28,707)	(26,681)	(106,769)	(80,631)
Selling and distribution expenses	(33,677)	(25,823)	(94,158)	(93,417)

Other expenses	(38,389)	(327)	(28,484)	(9,823)
Fair value (loss)/gain of warrant liability	—	(9,300)	(85,750)	20,900
Finance costs	(5,820)	(4,861)	(21,794)	(10,796)
LOSS BEFORE TAX	(146,812)	(135,723)	(520,118)	(445,724)
Income tax benefit/(expense)	1,994	(153)	1,864	(625)
LOSS FOR THE PERIOD	(144,818)	(135,876)	(518,254)	(446,349)
Attributable to:				
Ordinary equity holders of the parent	(144,818)	(135,876)	(518,254)	(446,349)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT				
Basic	(0.40)	(0.41)	(1.47)	(1.40)
Diluted	(0.40)	(0.41)	(1.47)	(1.40)
ORDINARY SHARES USED IN LOSS PER SHARE COMPUTATION				
Basic	363,655,317	329,923,489	352,165,418	318,083,913
Diluted	363,655,317	329,923,489	352,165,418	318,083,913

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31, 2023	December 31, 2022
	US$'000 (unaudited)	US$'000 (audited)
NON-CURRENT ASSETS		
Property, plant and equipment	108,725	105,168
Advance payments for property, plant and equipment	451	914
Right-of-use assets	80,502	55,590
Time deposits	4,362	—
Intangible assets	4,061	3,409
Collaboration prepaid leases	151,216	65,276
Other non-current assets	1,493	1,487
Total non-current assets	350,810	231,844
CURRENT ASSETS		
Collaboration inventories	19,433	10,354
Trade receivables	100,041	90
Prepayments, other receivables and other assets	69,251	61,755
Financial assets at fair value through profit or loss	663	185,603
Pledged deposits	357	1,270
Time deposits	30,341	54,016
Cash and cash equivalents	1,277,713	786,031
Total current assets	1,497,799	1,099,119
Total assets	1,848,609	1,330,963
CURRENT LIABILITIES		
Trade payables	20,160	32,893
Other payables and accruals	132,802	184,109
Government grants	68	451
Lease liabilities	3,175	3,563
Tax payable	7,203	9,772
Contract liabilities	53,010	—
Warrant liability	—	67,000
Total current liabilities	216,418	297,788
NON-CURRENT LIABILITIES		
Collaboration interest-bearing advanced funding	281,328	260,932
Lease liabilities long term	44,169	20,039
Government grants	7,305	7,659
Contract liabilities	47,962	—
Other non-current liabilities	56	233

Total non-current liabilities	380,820	288,863
Total liabilities	597,238	586,651
EQUITY		
Share capital	36	33
Reserves	1,251,335	744,279
Total ordinary shareholders' equity	1,251,371	744,312
Total equity	1,251,371	744,312
Total liabilities and equity	1,848,609	1,330,963

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

	Three Months Ended December 31,		Year Ended December 31,	
US$'000	**2023**	**2022**	**2023**	**2022**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(audited)**
LOSS BEFORE TAX	(146,812)	(135,723)	(520,118)	(445,724)
CASH FLOWS USED IN OPERATING ACTIVITIES	(95,645)	(49,742)	(393,276)	(201,281)
CASH FLOWS FROM/(USED IN) INVESTING ACTIVITIES	407,509	24,932	92,786	(77,092)
CASH FLOWS FROM/(USED IN) FINANCING ACTIVITIES	925	(783)	791,490	377,976
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	312,789	(25,593)	491,000	99,603
Effect of foreign exchange rate changes, net	1,454	(1,109)	682	(2,510)
Cash and cash equivalents at beginning of the period	963,470	812,733	786,031	688,938
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	1,277,713	786,031	1,277,713	786,031
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	1,312,773	841,317	1,312,773	841,317
Less: Pledged deposits	357	1,270	357	1,270
Time deposits	34,703	54,016	34,703	54,016
Cash and cash equivalents as stated in the statement of financial position	1,277,713	786,031	1,277,713	786,031
Cash and cash equivalents as stated in the statement of cash flows	1,277,713	786,031	1,277,713	786,031

[1] Mina, R. Patient-Reported Outcomes in the Phase 3 CARTITUDE-4 Study of Ciltacabtagene Autoleucel Vs Standard of Care in Patients with Lenalidomide-Refractory Multiple Myeloma after 1-3 Lines of Therapy. Abstract #1063 [Oral Presentation]. Presented at the 2023 American Society of Hematology Annual Meeting.

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