Legend Biotech Reports Second Quarter 2024 Results and Recent Highlights

August 9, 2024

- *CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) net trade sales of approximately $186 million*
- *MHRA and Health Canada approved CARVYKTI® in earlier lines of treatment for adult patients with relapsed and lenalidomide-refractory multiple myeloma*
- *CARVYKTI® demonstrates positive overall survival results in second interim analysis of CARTITUDE-4 study*
- *Cash and cash equivalents, deposits and short-term investments of $1.3 billion, as of June 30, 2024, which Legend Biotech believes will provide financial runway into 2026, when Legend Biotech anticipates achieving an operating profit*

SOMERSET, N.J., Aug. 09, 2024 (GLOBE NEWSWIRE) -- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global leader in cell therapy, today reported its second quarter 2024 unaudited financial results and key corporate highlights.

“In the second quarter, approval of CARVYKTI in the second line increased demand and interest from patients and the healthcare community. Momentum for CARVYTKI is growing and we are excited to see it helping not only later line patients, but an increasing number of earlier line patients. I am encouraged by the progress we have been making in both the inpatient and outpatient settings, enabling more patients to receive our transformative one-time treatment,” said Ying Huang, Ph.D., Chief Executive Officer of Legend Biotech. “We look forward to starting commercial production at our Obelisc facility in Belgium later this year in order to meet the growing demand, and we remain laser-focused on increasing our manufacturing capacity.”

Regulatory Updates

- The United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA) approved CARVYKTI ® for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least one prior therapy, including an immunomodulatory agent (IMiD) and a proteasome inhibitor (PI), have demonstrated disease progression on the last therapy and are refractory to lenalidomide.
- Health Canada approved CARVYKTI® for the treatment of adult patients with multiple myeloma, who have received one to three prior lines of therapy including a PI and an IMiD, and who are refractory to lenalidomide.

Key Business Developments

- Novartis Pharmaceuticals Corporation initiated clinical production in July 2024.
- Completed CARTITUDE 5 enrollment in July 2024.
- Announced positive results from a second interim analysis of the Phase 3 CARTITUDE-4 study demonstrating a statistically significant and clinically meaningful improvement in overall survival for multiple myeloma patients treated with CARVYKTI® versus standard-of-care treatment regimens. These new results will be presented at an upcoming medical meeting and shared with regulatory agencies for label updates worldwide.
- New data from the Phase 2 CARTITUDE-2 Cohort D study and new and updated data from the Phase 3 CARTITUDE-4 study of cilta-cel were featured at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstracts #7504 and 7505) and European Hematology Association (EHA) 2024 Hybrid Congress (Abstract #S205).
- On June 28, 2024, Legend Biotech received a milestone payment of $30 million in connection with the Janssen Agreement.
- On August 8, 2024, Peter Salovey, Ph.D., was appointed to the Company's Board of Directors, effective August 9, 2024.

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

Second Quarter 2024 Financial Results

- ***License Revenue***: License revenue was $90.8 million for the three months ended June 30, 2024, compared to $15.1 million for the three months ended June 30, 2023. The increase was primarily driven by a $60.0 million increase in revenue that was recognized due to the nature of, and timing of milestones achieved as outlined in the Global Development Plan under the Janssen Agreement for cilta-cel. Additionally, the increase in license revenue is driven by the recognition of $15.7 million of revenue due to the timing of underlying activities performed in connection with the global license agreement with Novartis Pharma AG (the "Novartis License Agreement") to develop, manufacture, and commercialize LB2102 and other potential CAR-T therapies selectively targeting DLL3. Legend Biotech did not recognize any license

revenue from the Novartis License Agreement for the three months ended June 30, 2023.

- ***Collaboration Revenue***: Collaboration revenue was $93.3 million for the three months ended June 30, 2024, compared to $58.2 million for the three months ended June 30, 2023. The increase was primarily due to an increase in revenue generated from sales of CARVYKTI® in connection with the Janssen Agreement.

- ***Collaboration Cost of Revenue***: Collaboration cost of revenue was $45.4 million for the three months ended June 30, 2024, compared to $32.7 million for the three months ended June 30, 2023. The increase was primarily due to Legend Biotech's share of the cost of sales in connection with CARVYKTI ® sales under the Janssen Agreement.

- ***Cost of License and Other Revenue***: Cost of license and other revenue for the three months ended June 30, 2024, was $5.1 million and consisted of costs in connection with the Novartis License Agreement. The Company did not incur any cost of license and other revenue for the three months ended June 30, 2023.

- ***Research and Development Expenses***: Research and development expenses were $112.6 million for the three months ended June 30, 2024, compared to $95.8 million for the three months ended June 30, 2023. The increase was primarily driven by continuous research and development activities in cilta-cel, including start up costs for clinical production in Belgium and continued investment in Legend Biotech's solid tumor programs.

- ***Administrative Expenses:*** Administrative expenses were $35.4 million for the three months ended June 30, 2024, compared to $27.8 million for the three months ended June 30, 2023. The increase was primarily due to the expansion of administrative functions and infrastructure to increase manufacturing capacity.

- ***Selling and Distribution Expenses***: Selling and distribution expenses were $30.1 million for the three months ended June 30, 2024, compared to $21.4 million for the three months ended June 30, 2023.The increase was primarily driven by costs associated with commercial activities for cilta-cel, including the expansion of the sales force and second line indication launch preparation.

- ***Net Loss***: Net loss was $18.2 million for the three months ended June 30, 2024, compared to a net loss of $199.1 million for the three months ended June 30, 2023.

- ***Cash Position***: Cash and cash equivalents, time deposits, and short-term investments were $1.3 billion as of June 30, 2024.

Webcast/Conference Call Details:
Legend Biotech will host its quarterly earnings call and webcast today at 8:00 a.m. 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 www.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 Legend Biotech's expectations for CARVYKTI ® and its therapeutic potential; statements relating to the potential approval of CARVYKTI® for earlier lines of therapy; statements related to Legend Biotech manufacturing expectations for CARVYKTI®; statements related to Legend Biotech's ability to achieve operating profit; 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; government, industry, and general product pricing and other political pressures; 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 19, 2024. 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.

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LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Three Months Ended June 30, 2024		Six Months Ended June 30, 2024	
	2024	2023	2024	2023
US$'000, except share and per share data	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
REVENUE				
License revenue	90,846	15,115	103,027	15,115
Collaboration revenue	93,254	58,152	171,735	94,432
Other revenue	2,423	63	5,752	119
Total revenue	186,523	73,330	280,514	109,666
Collaboration cost of revenue	(45,355)	(32,672)	(94,456)	(68,285)
Cost of license and other revenue	(5,096)	—	(10,734)	—
Other income and gains	29,484	16,433	93,037	20,994
Research and development expenses	(112,626)	(95,791)	(213,590)	(180,680)
Administrative expenses	(35,353)	(27,753)	(67,282)	(49,958)
Selling and distribution expenses	(30,063)	(21,429)	(54,286)	(39,383)
Other expenses	—	(21)	(2)	(7,117)
Fair value loss of warrant liability	—	(105,750)	—	(85,750)
Finance costs	(5,484)	(5,185)	(10,959)	(10,298)
LOSS BEFORE TAX	(17,970)	(198,838)	(77,758)	(310,811)
Income tax expense	(226)	(290)	(231)	(418)
LOSS FOR THE PERIOD	(18,196)	(199,128)	(77,989)	(311,229)
Attributable to:				
Ordinary equity holders of the parent	(18,196)	(199,128)	(77,989)	(311,229)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT				
Basic	(0.05)	(0.57)	(0.21)	(0.91)
Diluted	(0.05)	(0.57)	(0.21)	(0.91)
ORDINARY SHARES USED IN LOSS PER SHARE COMPUTATION				
Basic	365,204,154	350,517,429	364,610,589	340,779,779
Diluted	365,204,154	350,517,429	364,610,589	340,779,779

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	June 30, 2024	December 31, 2023
	US$'000	US$'000
	(Unaudited)	
NON-CURRENT ASSETS		
Property, plant and equipment	105,018	108,725
Advance payments for property, plant and equipment	295	451
Right-of-use assets	114,718	80,502
Time deposits	4,400	4,362
Intangible assets	2,772	4,061
Collaboration prepaid leases	144,552	151,216
Other non-current assets	1,596	1,493
Total non-current assets	373,351	350,810

CURRENT ASSETS		
Collaboration inventories	18,870	19,433
Trade receivables	13,064	100,041
Prepayments, other receivables and other assets	100,628	69,251
Financial assets at fair value through profit or loss	42,201	663
Pledged deposits	431	357
Time deposits	1,048,385	30,341
Cash and cash equivalents	201,253	1,277,713
Total current assets	1,424,832	1,497,799
Total assets	1,798,183	1,848,609
CURRENT LIABILITIES		
Trade payables	39,490	20,160
Other payables and accruals	169,531	132,802
Government grants	545	68
Lease liabilities	3,325	3,175
Tax payable	6,566	7,203
Contract liabilities	74,845	53,010
Total current liabilities	294,302	216,418
NON-CURRENT LIABILITIES		
Collaboration interest-bearing advanced funding	291,559	281,328
Lease liabilities long term	44,042	44,169
Government grants	6,574	7,305
Contract liabilities	2,704	47,962
Other non-current liabilities	—	56
Total non-current liabilities	344,879	380,820
Total liabilities	639,181	597,238
EQUITY		
Share capital	37	36
Reserves	1,158,965	1,251,335
Total ordinary shareholders' equity	1,159,002	1,251,371
Total equity	1,159,002	1,251,371
Total liabilities and equity	1,798,183	1,848,609

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

	Three Months Ended June 30,		Six Months Ended June 30,	
US$'000	**2024**	**2023**	**2024**	**2023**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
LOSS BEFORE TAX	(17,970)	(198,838)	(77,758)	(310,811)
CASH FLOWS (USED IN)/PROVIDED BY OPERATING ACTIVITIES	(1,651)	(95,730)	13,867	(236,783)
CASH FLOWS USED IN INVESTING ACTIVITIES	(695,631)	(123,581)	(1,091,779)	(105,651)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES	955	789,890	1,786	789,604
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(696,327)	570,579	(1,076,126)	447,170
Effect of foreign exchange rate changes, net	9	2,584	(334)	12
Cash and cash equivalents at beginning of the period	897,571	660,050	1,277,713	786,031
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	201,253	1,233,213	201,253	1,233,213
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	1,254,469	1,334,482	1,254,469	1,334,482
Less: Pledged deposits	431	1,246	431	1,246
Time deposits	1,052,785	100,023	1,052,785	100,023
Cash and cash equivalents as stated in the statement of financial position	201,253	1,233,213	201,253	1,233,213
Cash and cash equivalents as stated in the statement of cash flows	201,253	1,233,213	201,253	1,233,213



Source: Legend Biotech USA Inc.