Legend Biotech Reports Third Quarter 2023 Results and Recent Highlights

November 20, 2023

- Legend Biotech Corporation (the “Company” or Legend Biotech), through its wholly owned subsidiary, Legend Biotech Ireland Limited, entered into an exclusive, global license agreement with Novartis Pharma AG. The Company granted Novartis the rights to develop, manufacture and commercialize LB2102 (NCT05680922) and other potential chimeric antigen receptor T-cell (CAR-T) therapies selectively targeting Delta-like ligand 3 (DLL3).[1] Subject to closing, Novartis has agreed to pay the Company an upfront payment of $100 million after closing the transaction and up to $1.01 billion in milestone payments, as well as tiered royalties on net sales
- CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) generated approximately $152 million in net trade sales during the quarter, an increase of 30 percent over the previous quarter, driven by ongoing market launches, expanding market share and capacity improvements
- The first patient was randomized in the Phase 3 CARTITUDE-6 (NCT05257083) clinical trial evaluating daratumumab, bortezomib, lenalidomide and dexamethasone (DVRd) followed by cilta-cel versus DVRd followed by autologous stem cell transplant in participants with newly diagnosed multiple myeloma (sponsored by the European Myeloma Network)[2]
- CARVYKTI® is now available in Germany, as commercial demand continues
- The state-of-the-art facility that will manufacture cilta-cel in Ghent has received a license from the Federal Agency for Medicines and Health Products in Belgium to begin clinical supply manufacturing
- In September 2023, Legend Biotech received payment for a milestone under the Janssen Agreement in the amount of $20.0 million
- In November 2023, Legend Biotech appointed Jim Pepin as General Counsel. Mr. Pepin has been practicing law for over two decades. Prior to joining the Company, Mr. Pepin was Senior Vice President, General Counsel and Corporate Secretary of Aimmune Therapeutics. Prior to that, he also served as Vice President and General Counsel of Nestle HealthCare Nutrition for ten years. Mr. Pepin holds a Bachelor of Arts in Foreign Affairs from the University of Virginia and a Juris Doctor from the University of Virginia School of Law
- Cash and cash equivalents, deposits and short-term investments of $1.4 billion, as of September 30, 2023, which Legend Biotech believes will fund operating and capital expenditures through 2025

SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 20, 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 unaudited financial results for the three and nine months ended September 30, 2023 and key corporate highlights.

Legend Biotech shared the latest updates from its portfolio and pipeline, alongside its financial performance, including detailing Legend Biotech’s license agreement with Novartis. The license agreement grants Novartis the exclusive, worldwide rights to certain potential CAR-T therapies selectively targeting DLL3.

“We continuously explore the full potential of our products and technologies. The out-license agreement with Novartis affirms that our next-generation therapy, LB2102, has the potential to be a differentiated treatment for eligible patients with small cell lung cancer,” said Ying Huang, Chief Executive Officer of Legend Biotech. “We also remain committed to meeting the demand for CARVYKTI®, in collaboration with Janssen, and have progressively increased manufacturing capacity, which has led to an incremental increase in sales.”

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[1] ClinicalTrials.gov. DLL3-Directed Chimeric Antigen Receptor T-cells in Subjects With Extensive Stage Small Cell Lung Cancer. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT05680922. Last accessed Aug 2023.

[2] ClinicalTrials.gov. A Study of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma (CARTITUDE-6). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT05257083

Financial Results for Quarter Ended September 30, 2023

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

As of September 30, 2023, Legend Biotech had approximately $1.4 billion of cash and cash equivalents, time deposits, and short-term investments.

Revenue

License Revenue

License revenue for the three months ended September 30, 2023 was $20.1 million compared to no license revenue for the three months ended

September 30, 2022. The increase was due to the achievement of a milestone under our collaboration and license agreement (Janssen Agreement) with Janssen Biotech, Inc. (Janssen) during the three months ended September 30, 2023. License revenue for the nine months ended September 30, 2023 was $35.2 million, compared to $50.0 million for the nine months ended September 30, 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 and nine months ended September 30, 2023 was $75.9 million and $170.4 million, respectively, compared to $27.3 million and $39.2 million for the three and nine months ended September 30, 2022. The increases of $48.6 million and $131.2 million for the three and nine month periods, respectively, were due to an increase in revenue generated from sales of CARVYKTI® in connection with the Janssen Agreement.

Operating Expenses

Collaboration Cost of Revenue

Collaboration cost of revenue for the three and nine months ended September 30, 2023 was $43.5 million and $111.8 million, respectively, compared to $25.5 million and $42.4 million for the three and nine months ended September 30, 2022. The increases of $18.0 million and $69.4 million for the three and nine months periods, respectively, were 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 that could not be capitalized.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2023 were $95.9 million and $276.5 million, respectively, compared to $104.5 million and $254.9 million for the three and nine months ended September 30, 2022, respectively. The decrease of $8.6 million for the three months ended September 30, 2023 compared to three months ended September 30, 2022 was due to timing of expenses incurred in connection with the Global Development Plan under the Janssen Agreement. The increase of $21.6 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to continuous research and development activities in cilta-cel, including higher patient enrollment for Phase 3 clinical trials for cilta-cel, and an increase in research and development activities for other pipeline items. 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 and nine months ended September 30, 2023 were $28.1 million and $78.1 million, respectively, compared to $23.2 million and $54.0 million for the three and nine months ended September 30, 2022, respectively. The increases of $4.9 million and $24.1 million for the three and nine month periods, 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 and nine months ended September 30, 2023 were $21.1 million and $60.5 million, respectively, compared to $18.9 million and $67.6 million for the three and nine months ended September 30, 2022. The increase of $2.2 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was due to costs associated with the commercialization of CARVYKTI®. The decrease of $7.1 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to non-recurring launch expenses incurred during the nine months ended September 30, 2022 to support the commercial launch of CARVYKTI® in the U.S market.

Other Income and Gains

Other income and gains for the three and nine months ended September 30, 2023 were $35.8 million and $49.8 million, respectively, compared to $3.9 million and $4.7 million for the three and nine months ended September 30, 2022, respectively. The increases of $31.9 million and $45.1 million for the three and nine month periods, respectively, were primarily attributable to an increase in interest income, fair value gain on financial assets and foreign currency exchange gain.

Other Expenses

Other expenses for the three and nine months ended September 30, 2023 were $0.1 million and $0.2 million, respectively, compared to $2.0 million and $9.5 million for the three and nine months ended September 30, 2022. The decrease in both comparative periods was primarily due to an unrealized foreign currency exchange gain in 2023 and an unrealized foreign currency exchange loss in 2022.

Finance Costs

Finance costs for the three and nine months ended September 30, 2023 were $5.7 million and $16.0 million, respectively, compared to $3.2 million and $5.9 million for the three and nine months ended September 30, 2022. The increase in both comparative periods was 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 September 30, 2023 compared to a gain of $61.2 million for the three months ended September 30, 2022, because the warrant was exercised on May 11, 2023. Fair value loss of warrant liability for the nine months ended September 30, 2023 was $85.8 million, compared to a fair value gain of $30.2 million for the nine months ended September 30, 2022. The increase was due to the fair value loss recorded on the full exercise of the warrant, which took place on May 11, 2023.

Loss for the Period

For the three months ended September 30, 2023, net loss was $62.2 million, or $0.17 per share, compared to net loss of $85.0 million, or $0.26 per share, for the three months ended September 30, 2022. For the nine months ended September 30, 2023, net loss was $373.4 million, or $1.07 per share, compared to a net loss of $310.5 million, or $0.99 per share, for the nine months ended September 30, 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 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®, including manufacturing expectations for CARVYKTI®; expected results and timing of clinical trials; Legend Biotech's expectations for LB2102 and its potential benefits; Legend Biotech's ability to close the licensing transaction with Novartis and potential benefits of the transaction; 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 filed with the Securities and Exchange Commission (SEC) on March 30, 2023 and Legend Biotech's other filings 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 September 30,		Nine months ended September 30,	
US$'000, except per share data	**2023 (Unaudited)**	**2022 (Unaudited)**	**2023 (Unaudited)**	**2022 (Unaudited)**
REVENUE				
License revenue	20,057	—	35,172	50,000
Collaboration revenue	75,937	27,299	170,369	39,236
Other revenue	19	62	138	136
Total revenue	96,013	27,361	205,679	89,372
Collaboration cost of revenue	(43,479)	(25,460)	(111,764)	(42,399)
Other income and gains	35,838	3,924	49,812	4,693
Research and development expenses	(95,855)	(104,517)	(276,535)	(254,892)
Administrative expenses	(28,104)	(23,243)	(78,062)	(53,950)
Selling and distribution expenses	(21,098)	(18,852)	(60,481)	(67,594)
Other expenses	(134)	(1,969)	(231)	(9,496)
Fair value gain/(loss) of warrant liability	—	61,200	(85,750)	30,200
Finance costs	(5,676)	(3,248)	(15,974)	(5,935)
LOSS BEFORE TAX	(62,495)	(84,804)	(373,306)	(310,001)
Income tax benefit/(expense)	288	(152)	(130)	(472)
LOSS FOR THE PERIOD	(62,207)	(84,956)	(373,436)	(310,473)
Attributable to:				
Ordinary equity holders of the parent	(62,207)	(84,956)	(373,436)	(310,473)

LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT				
Basic	(0.17)	(0.26)	(1.07)	(0.99)
Diluted	(0.17)	(0.26)	(1.07)	(0.99)
ORDINARY SHARES USED IN LOSS PER SHARE COMPUTATION				
Basic	363,075,209	323,641,010	348,293,363	314,094,019
Diluted	363,075,209	323,641,010	348,293,363	314,094,019

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	September 30, 2023	December 31, 2022
	US$'000 (Unaudited)	US$'000 (Audited)
NON-CURRENT ASSETS		
Property, plant and equipment	109,503	105,168
Advance payments for property, plant and equipment	419	914
Right-of-use assets	74,811	55,590
Time deposits	4,268	—
Intangible assets	4,009	3,409
Collaboration prepaid leases	135,997	65,276
Other non-current assets	1,531	1,487
Total non-current assets	330,538	231,844
CURRENT ASSETS		
Collaboration inventories	18,014	10,354
Trade receivables	20	90
Prepayments, other receivables and other assets	66,569	61,755
Financial assets at fair value through profit or loss	185,792	185,603
Pledged deposits	356	1,270
Time deposits	274,575	54,016
Cash and cash equivalents	963,470	786,031
Total current assets	1,508,796	1,099,119
Total assets	1,839,334	1,330,963
CURRENT LIABILITIES		
Trade payables	17,173	32,893
Other payables and accruals	144,651	184,109
Government grants	630	451
Lease liabilities	2,915	3,563
Tax payable	9,853	9,772
Warrant liability	—	67,000
Total current liabilities	175,222	297,788
NON-CURRENT LIABILITIES		
Collaboration interest-bearing advanced funding	275,906	260,932
Lease liabilities long term	41,687	20,039
Government grants	6,764	7,659
Other non-current liabilities	119	233
Total non-current liabilities	324,476	288,863
Total liabilities	499,698	586,651
EQUITY		
Share capital	36	33
Reserves	1,339,600	744,279
Total ordinary shareholders' equity	1,339,636	744,312
Total equity	1,339,636	744,312
Total liabilities and equity	1,839,334	1,330,963

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

US$'000	Three Months Ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
LOSS BEFORE TAX	(62,495)	(84,804)	(373,306)	(310,001)
CASH FLOWS USED IN OPERATING ACTIVITIES	(60,848)	(72,112)	(297,631)	(151,539)
CASH FLOWS (USED IN)/FROM INVESTING ACTIVITIES	(209,072)	127,891	(314,723)	(102,024)
CASH FLOWS FROM FINANCING ACTIVITIES	961	377,725	790,565	378,759
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(268,959)	433,504	178,211	125,196
Effect of foreign exchange rate changes, net	(784)	(547)	(772)	(1,401)
Cash and cash equivalents at beginning of the period	1,233,213	379,776	786,031	688,938
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	963,470	812,733	963,470	812,733
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	1,242,669	1,031,334	1,242,669	1,031,334
Less: Pledged deposits	356	1,851	356	1,851
Time deposits	278,843	216,750	278,843	216,750
Cash and cash equivalents as stated in the statement of financial position	963,470	812,733	963,470	812,733
Cash and cash equivalents as stated in the statement of cash flows	963,470	812,733	963,470	812,733

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