Legend Biotech Reports Fourth Quarter and Full Year 2020 Financial Results and Business Update

March 18, 2021

- Legend received approximately $659.8 million in gross proceeds through share capital increases during 2020, including a successful Nasdaq IPO with aggregate gross proceeds of $487.3 million.
- U.S. FDA clearance for IND application for a Phase 1 clinical trial to evaluate LB1901 in relapsed or refractory T-cell lymphoma (RR TCL).
- Rolling submission of BLA to the FDA initiated for cilta-cel for the treatment of relapsed or refractory multiple myeloma (RRMM).
- Cash and cash equivalents and time deposits of $505.7 million as of December 31, 2020.

SOMERSET, N.J.--(BUSINESS WIRE)--Mar. 18, 2021-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, today reported its unaudited financial results for the three months and year ended December 31, 2020.

“This was a defining year for Legend Biotech, as we achieved important pipeline advancements and completed our initial public offering and Nasdaq listing,” said Ying Huang, PhD, CEO and CFO of Legend Biotech. “Despite the challenges presented by the COVID-19 pandemic, we have achieved a strong 2020 and are continuing this momentum with significant advancements planned for our oncology pipeline during 2021. Through our collaboration with Janssen Biotech, Inc. (Janssen)*, in 2020, we initiated a global Phase 3 study and expanded the multi-cohort Phase 2 study as part of a comprehensive clinical development program for ciltacabtagene autoleucel (cilta-cel), including as an earlier lines of multiple myeloma treatment. In 2021, we expect to achieve important milestones in advancing the regulatory approval process for cilta-cel.”

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

Fourth Quarter 2020 & Recent Highlights

- In February 2021, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) accepted a request from Janssen for the accelerated assessment of the cilta-cel Marketing Authorisation Application (MAA) for the treatment of adults with RRMM.
- In December 2020, Legend Biotech announced that Janssen had initiated a rolling submission to the U.S. Food and Drug Administration (FDA) of a biologics license application (BLA) for cilta-cel for the treatment of adults with RRMM. Pursuant to the terms of Legend Biotech’s agreement with Janssen, Legend received a $75.0 million milestone payment relating to the clinical development of cilta-cel in connection with the initiation of the BLA submission.
- In December 2020, the FDA cleared an investigational new drug (IND) application for Legend Biotech to evaluate LB1901 in a Phase 1 clinical study for the treatment of adults with RR TCL.
- Data from the combined Phase 1b/2 CARTITUDE-1 study of cilta-cel was presented at the 62nd American Society of Hematology (ASH) Annual meeting in December 2020, showing a high overall response rate that deepened over time, with 97% of patients achieving an overall response and 67% of patients achieving a stringent complete response (sCR) at a median follow-up of 12.4 months.

Recent Appointments

- During 2020, Legend Biotech bolstered its leadership team with the appointment of Dr. Ying Huang as Chief Executive Officer, the appointment of Ye (Sally) Wang as Chairwoman of the Board of Directors, and the appointment of two new directors, Dr. Li Zhu and Dr. Patrick Casey.
- In March 2021, Lori Macomber was appointed as Legend Biotech’s Vice President, Finance, in which capacity Ms. Macomber will serve as Legend Biotech’s principal financial officer and principal accounting officer. Ms. Macomber has served as Legend Biotech’s Vice President of Supply Chain Finance and Controller since September 2019. Prior to joining Legend Biotech, Ms. Macomber served as Business Unit Controller at Ametek PDS, a leading supplier of components and systems for the aerospace and defense industries, from April 2018 and as U.S. CFO and Controller of Cello Health from March 2017 until February 2018. Before this Ms. Macomber held various positions, most recently AVP Finance Site Leader, at Eli Lilly & Company where she was employed from May 2010 until March 2017. Ms. Macomber holds a Bachelor of Science in Accounting from Pennsylvania State University and is a Certified Public Accountant.
- In January 2021, Lida Pacaud, M.D., joined Legend Biotech as its Vice President of Clinical Development. Dr. Pacaud, joined Legend Biotech from Novartis International AG, where she held various positions from September 2013 through

January 2021, most recently serving as the Global Clinical Program Head and Executive Medical Director in its Cell & Gene unit. Prior to this, Dr. Pacaud worked at Roche and Wyeth. Dr. Pacaud has been the Medical Lead on several global Phase I, II & III trials and led the clinical development and filling for the first approved CAR T therapy worldwide. Dr. Pacaud holds a Doctor of Medicine degree and certification in Pediatrics from Tbilisi State Medical University and has trained in Pediatric Oncology and hematology in France.

Key Upcoming Milestones

- Legend Biotech's collaborator, Janssen, anticipates submitting a MAA for cilta-cel for the treatment of adults with RRMM to the EMA in the first half of 2021.
- Legend Biotech intends to use the data from the CARTIFAN-1 study in support of a regulatory submission to the China Center for Drug Evaluation (CDE) seeking approval of cilta-cel for the treatment of adults with RRMM. Legend Biotech expects the submission of the application to occur in the second half of 2021.
- Legend Biotech's collaborator, Janssen, anticipates submitting a New Drug Application (NDA) to the Japan Ministry of Health, Labor and Welfare (JMHLW) in the second half of 2021 seeking approval of cilta-cel for the treatment of adults with RRMM.
- Legend Biotech expects to initiate its Phase 1 clinical trial of LB1901 in RR TCL in the United States in 2021.
- Legend Biotech, in collaboration with Janssen, intends to present updated data from the CARTITUDE-1 and data from CARTITUDE-2 studies at major medical conferences in 2021.
- Legend Biotech anticipates supporting investigators with publishing a clinical data update from LEGEND-2 study in 2021.

As the global COVID-19 pandemic continues to evolve, Legend Biotech has continuously monitored the situation in regards to its operations and has put significant measures in place to protect supply chain, operations, employees and the execution of clinical trials. Given the dynamic global situation, Legend Biotech notes that certain clinical trial timelines may be impacted.

Financial Results for the Quarter and Year Ended December 31, 2020

Cash and Cash Equivalents and time deposits:

As of December 31, 2020, Legend Biotech had approximately $455.7 million of cash and cash equivalents and approximately $50.0 million in time deposits.

Revenue

Revenue for the three months ended December 31, 2020 was $40.8 million compared to $19.5 million for the three months ended December 31, 2019. The increase of $21.3 million was primarily due to revenue recognition of additional milestone payment achieved of higher amount pursuant to Legend Biotech's agreement with Janssen and the associated constrained variable consideration is relieved. Revenue for the year ended December 31, 2020 was $75.7 million compared to $57.3 million for the year ended December 31, 2019. Similarly, the increase of $18.4 million for the year ended December 31, 2020 was primarily driven by revenue recognized from an additional milestone achieved of higher amount. Legend Biotech has not generated any revenue from product sales to date.

Research and Development Expenses

Research and development expenses for the three months ended December 31, 2020 were $66.9 million compared to $66.1 million for the three months ended December 31, 2019. This increase of $0.8 million was primarily due to an increase in employee benefit expense and research and development expense, net-off by a decrease in collaborative research and development expenses. Research and development expenses for the year ended December 31, 2020 was $232.2 million compared to $161.9 million for the year ended December 31, 2019 with a $70.3 million increase. The year-over-year increase was primarily due to a higher number of clinical trials, a higher number of patients enrolled in those trials and a higher number of research and development product candidates in the year ended December 31, 2020.

Administrative Expenses

Administrative expenses for the three months ended December 31, 2020 were $9.2 million compared to $2.0 million for the three months ended December 31, 2019. The increase of $7.2 million was primarily due to Legend Biotech's expansion of supporting administrative functions to aid continued research and development activities. Due to the consistent business expansion, administrative expenses for the year ended December 31, 2020 increased by $16.3 million, which was $23.1 million compared to $6.8 million for the year ended December 31, 2019.

Selling and Distribution Expenses

Selling and distribution expenses for the three months ended December 31, 2020 were $24.2 million compared to $13.4 million for the three months ended December 31, 2019. This increase of $10.8 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel. Driven by the same commercial preparation activities, selling and distribution expenses for the year ended December 31, 2020 was $49.6 million compared to $25.6 million for the year ended December 31, 2019.

Other Income and Gains

Other income and gains for the three months ended December 31, 2020 was $2.1 million compared to $0.5 million for the three months ended December 31, 2019. The increase was primarily driven by increase in foreign exchange gain. Other income and gains for the year ended December 31, 2020 was $6.1 million compared to $7.1 million for the year ended December 31, 2019. The decrease of $1.0 million was primarily driven by reduced average interest rate for holding of time deposits that generate interest income.

Finance Costs

Finance costs the year ended December 31, 2020 were $4.2 million compared to $0.2 million for the year ended December 31, 2019. The increase was primarily due to finance costs related to the issuance of convertible redeemable preferred shares, which have been fully converted into ordinary shares upon the completion of Legend Biotech's initial public offering in June 2020.

Loss for the Period

For the three months ended December 31, 2020, net loss was $57.8 million, or $0.22 per share, compared to a net loss of $63.9 million, or $0.32 per share, for the three months ended December 31, 2019. Net loss was $303.5 million, or $1.28 per share, for the year ended December 31, 2020 compared to $133.0 million, or $0.66 per share, for the year ended December 31, 2019.

About Legend Biotech

Legend Biotech is a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 800 employees across the United States, China and Europe, along with our differentiated technology, global development, and manufacturing strategies and expertise, provide us with the strong potential to discover, develop, and manufacture best-in-class cell therapies for patients in need.

We are engaged in a strategic collaboration to develop and commercialize our lead product candidate, cilta-cel, an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. This candidate is currently being studied in registrational clinical trials.

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; the anticipated timing of, and ability to progress, clinical trials, including the initiation of the phase 1 clinical trial of LB1901 in RRTCL; the ability to make, the timing of, and the ultimate success of, regulatory submissions globally, including the rolling BLA for cilta-cel with the U.S. FDA, the MAA for cilta-cel to the EMA, and the submissions for cilta-cell to the CDE and the JMHLW; the ability to generate, analyze and present data from clinical trials; patient enrollment; the potential benefits of our product candidates, and the status and outcome of the investigation being conducted by the Customs Anti-Smuggling Department of Zhenjiang in China and its impact on the Company's operations. 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 US 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 Company's prospectus filed with the Securities and Exchange Commission on June 8, 2020. 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 presentation as anticipated, believed, estimated or expected. 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)	**2020 (Unaudited)**	**2019 (Unaudited)**	**2020 (Unaudited)**	**2019**
REVENUE	40,783	19,450	75,676	57,264
Other income and gains	2,079	476	6,119	7,125
Research and development expenses	(66,934)	(66,097)	(232,160)	(161,943)
Administrative expenses	(9,171)	(2,048)	(23,147)	(6,752)
Selling and distribution expenses	(24,182)	(13,374)	(49,571)	(25,620)
Other expenses	(290)	(5)	(346)	(221)
Fair value loss of convertible redeemable preferred shares	-	-	(79,984)	-
Finance costs	(40)	(84)	(4,209)	(223)
LOSS BEFORE TAX	(57,755)	(61,682)	(307,622)	(130,370)
Income tax (expense)/credit	(72)	(2,261)	4,145	(2,602)
LOSS FOR THE PERIOD	(57,827)	(63,943)	(303,477)	(132,972)
Attributable to:				
Equity holders of the parent	(57,827)	(63,943)	(303,477)	(132,972)
Loss per share attributable to ordinary equity holders of the parent:				
Ordinary shares – basic	(0.22)	(0.32)	(1.28)	(0.66)

Ordinary shares – diluted	(0.22)	(0.32)	(1.28)	(0.66)
Shares used in loss per share computation:				
Ordinary shares – basic	264,720,588	200,000,000	236,305,234	200,000,000
Ordinary shares – diluted	264,720,588	200,000,000	236,305,234	200,000,000

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(in thousands, US$)	**December 31, 2020 (Unaudited)**	**December 31, 2019**
NON-CURRENT ASSETS		
Property, plant and equipment	113,091	70,079
Other non-current assets	3,973	-
Advance payments for property, plant and equipment	224	665
Right-of-use assets	8,009	9,348
Intangible assets	2,852	519
Total non-current assets	**128,149**	**80,611**
CURRENT ASSETS		
Inventories	1,800	1,157
Trade receivables	74,978	29,991
Prepayments, other receivables and other assets	10,007	16,777
Pledged short-term deposits	384	256
Time deposits	50,000	75,559
Cash and cash equivalents	455,689	83,364
Total current assets	**592,858**	**207,104**
Total assets	**721,007**	**287,715**
CURRENT LIABILITIES		
Trade and notes payables	5,238	9,586
Other payables and accruals	99,168	70,854
Government grants	283	-
Lease liabilities	1,464	1,027
Contract liabilities	55,014	46,294
Total current liabilities	**161,167**	**127,761**
NON-CURRENT LIABILITIES		
Contract liabilities	275,071	277,765
Lease liabilities	1,909	5,058
Other non-current liabilities	554	-
Government grants	2,051	-
Total non-current liabilities	**279,585**	**282,823**
Total liabilities	**440,752**	**410,584**
EQUITY		
Share capital	27	20
Reserves/(deficits)	280,228	(122,889)
Total ordinary shareholders' equity/(deficit)	**280,255**	**(122,869)**
Total equity/(deficit)	**280,255**	**(122,869)**

Total liabilities and equity/(deficit)	**721,007**	**287,715**

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands, US$)	**Three months ended December 31**		**Year ended December 31**	
	2020 (Unaudited)	**2019 (Unaudited)**	**2020 (Unaudited)**	**2019**
LOSS BEFORE TAX	(57,755)	(61,682)	(307,622)	(130,370)
CASH FLOWS USED IN OPERATING ACTIVITIES	(55,952)	(59,987)	(223,005)	(83,065)
CASH FLOWS from/(USED IN) INVESTING ACTIVITIES	61,165	113,451	(24,169)	(58,652)
CASH FLOWS FROM/(USED IN) FINANCING ACTIVITIES	661	(6,680)	618,879	14,666
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	5,874	46,784	371,705	(127,051)
Effect of foreign exchange rate changes, net	434	304	620	249
Cash and cash equivalents at beginning of the period	449,381	36,276	83,364	210,166
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	455,689	83,364	455,689	83,364
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	506,073	159,179	506,073	159,179
Less: Pledged short-term deposits	384	256	384	256
Time deposits	50,000	75,559	50,000	75,559
Cash and cash equivalents as stated in the statement of financial position	455,689	83,364	455,689	83,364
Cash and cash equivalents as stated in the statement of cash flows	455,689	83,364	455,689	83,364

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