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VIA EDGAR

April 20, 2020

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
100 F Street, N.E.  
Mail Stop 4546  
Washington, D.C. 20549

Attn: Ms. Jenn Do  
Ms. Lisa Vanjoske  
Mr. Jeffrey Gabor  
Ms. Celeste Murphy

Re: **Legend Biotech Corporation**  
**Confidential Draft Registration Statement on Form F-1**  
**Submitted March 9, 2020**  
**CIK No. 0001801198**

Ladies and Gentlemen:

On behalf of our client, Legend Biotech Corporation (the "**Company**"), we are responding to the comments (the "**Comments**") of the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") contained in its letter dated April 2, 2020 (the "**Comment Letter**"), relating to the above referenced Confidential Draft Registration Statement on Form F-1 (the "**DRS**"). In response to the Comments set forth in the Comment Letter, the Company has revised the DRS and is confidentially submitting via EDGAR a revised version (the "**Amended DRS**") with this response letter. For the Staff's reference, we are also delivering both a clean copy of the Amended DRS and a copy marked to show all changes from the DRS confidentially submitted on March 9, 2020.

Set forth below in bold are the Company's responses to the Comments. The numbering of the paragraphs below corresponds to the numbering of the Comments, which for your convenience we have incorporated into this response letter. Page references in the text of this response letter correspond to the page numbers of the Amended DRS. Capitalized terms used but not defined herein are used herein as defined in the Amended DRS.

[Prospectus Summary, page 1](#)

[Overview, page 1](#)

1. Please delete references to your product candidates as potentially "best-in-class." This statement implies an expectation of regulatory approval and is inappropriate given the length of time and uncertainty with respect to securing marketing approval. If your use of this term was intended to convey your belief that the products are based on a novel technology or approach, you may discuss how your technology differs from existing antibodies.

## **Response to Comment 1**

**In response to the Staff's comment, the Company has revised the disclosure throughout the Amended DRS as requested.**

2. We note your use of "manageable safety profile" here and throughout the prospectus. Please revise your disclosure to explain what constitutes a "manageable safety profile." Please also discuss the specific experiences of your subjects which led you to reach this conclusion.

## **Response to Comment 2**

**In response to the Staff's comment, the Company has revised the disclosure throughout the Amended DRS as requested.**

3. We note you describe here in the Summary and elsewhere favorable results observed in LCAR-B38M/JNJ-4528. Please expand to provide fuller context for these statements by providing the specific details and parameters of these trials, including the statistical significance of the observed results.

## **Response to Comment 3**

**The Company respectfully advises the Staff that LEGEND-2 and CARTITUDE-1 are single-arm trials without a control arm. As such, no statistical significance analysis could be conducted to compare LCAR-B38M/JNJ-4528 to another therapy or a placebo. The U.S. Food and Drug Administration ("FDA") agreed with the single-arm design of the trial given the lack of effective treatment options for patients who are refractory to or have relapsed from existing treatment options.**

**As disclosed in the Amended DRS, in the LEGEND-2 trial, patients treated with LCAR-B38M achieved an overall response rate ("ORR") of 88 percent. In the largest site of 57 patients, median overall survival ("mOS") was 36.1 months as of July 31, 2019. In the CARTITUDE-1 trial, 29 patients treated with JNJ-4528 from the Phase 1b portion achieved an ORR of 100 percent. As of November 6, 2019, 27 of the 29 patients were progression free with a median follow-up time of six months.**

**Other approved therapies for the treatment of relapsed or refractory multiple myeloma have reported an ORR of approximately 30 percent or less. Among heavily pre-treated patients who received at least one subsequent treatment after becoming refractory to anti-CD38 therapy, the response rate averaged 31 percent, with mOS of 9.3 months. Accordingly, the Company believes that the results that it has observed to date are favorable.**

4. We note that you anticipate that a BLA will be submitted to the FDA and a MAA will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020. However, we note that CARTITUDE-1/2 are in the midst of Phase II and your Phase III trial, CARTITUDE-4, has not started enrollment. Please supplementally tell us why you believe you will be in a position to submit BLA/MAA for JNJ-4528 in the second half of 2020.

#### **Response to Comment 4**

The Company acknowledges the Staff's comment and respectfully advises the Staff that, while the FDA and European Medicines Agency ("EMA") generally rely on well designed and executed Phase 3 randomized controlled clinical trials that demonstrate positive safety and efficacy for a product candidate to support BLA or MAA approval, both the FDA and EMA acknowledge that there are situations where such clinical trials are not feasible operationally and ethically. Under these circumstances, evidence from early non-randomized clinical trials may be used to support approval when an investigational product candidate is observed to demonstrate substantial benefit over currently available therapies. As indicated in the FDA guidance titled "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics," in "settings where there is no available therapy and where major tumor regressions can be presumed to be attributed to the tested [product candidate], the FDA has sometimes accepted ORR and response duration observed in single-arm clinical trials as substantial evidence supporting accelerated approval[s]." A similar concept is also included in the EMA Guideline on Clinical Trials in Small Populations.

There are numerous examples in oncology where approval of new therapies has been granted based on single-arm clinical trials. Moreover, the only two CAR-T cell therapies that have received approval have been approved based on single-arm clinical trials. The FDA and EMA approved Kymriah for relapse or refractory acute lymphoblastic leukemia based on a single-arm Phase 2 clinical trial with 68 treated patients and for relapse or refractory large B-cell lymphoma based on a single-arm Phase 2 clinical trial with 106 treated patients. The FDA and EMA also approved Yescarta for relapse or refractory large B-cell lymphoma based on a single-arm Phase 2 clinical trial with 101 treated patients. Bristol-Myers Squibb also announced on March 31, 2020 the submission of a BLA for its product candidate, bb2121, based on a single-arm Phase 2 clinical trial in patients with relapsed or refractory multiple myeloma.

JNJ-4528, a CAR-T cell therapy, is being investigated in a Phase 1b/2 clinical trial (CARTITUDE-1) in patients with relapsed or refractory multiple myeloma. These patients typically have a very poor prognosis with no effective available therapies and the unmet medical need is high. In this patient population and with the results from CARTITUDE-1 disclosed in the Amended DRS, the Company intends to pursue approval based on overall response rate and duration of response from a single-arm clinical trial. The planned BLA and MAA for JNJ-4528 will be based on the ongoing CARTITUDE-1 clinical trial after the data from the Phase 2 portion of CARTITUDE-1 is available. The Company believes data from the CARTITUDE-2 or CARTITUDE-4 trials will not be needed for the BLA or MAA submissions.

Our Pipeline, page 2

5. The table of your product candidate pipeline on pages 2 and 111 should reflect the actual, and not the anticipated, status of your pipeline candidates as of the latest practicable date. The table currently suggests that CARTITUDE-4 trial is in the midst of Phase 3 but your disclosure indicates that you have not started enrollment. Please revise to show the actual status.

**Response to Comment 5**

**In response to the Staff's comment, the Company has revised pages 2 and 114 of the Amended DRS as requested. The Company further advises the Staff that the Company has selected active clinical trial sites and begun screening patients for CARTITUDE-4 and therefore considers the clinical trial to have been initiated.**

Risk Factors

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval..., page 24

6. We note the deaths reported in your LEGEND-2 clinical trial. Please revise to clarify whether the deaths were treatment related.

**Response to Comment 6**

**In response to the Staff's comment, the Company has revised page 25 of the Amended DRS as requested.**

Use of Proceeds, page 90

7. We note your statement that the net proceeds from this offering, together with your existing cash and cash equivalents, may be insufficient to fund any of your product candidates through regulatory approval, and you anticipate needing to raise additional capital. Please revise your use of proceeds to clarify how far along in the development process of LCAR-38M/JNJ-4528 you expect the proceeds from this offering, together with your existing cash and cash equivalents, will take you.

**Response to Comment 7**

**The Company acknowledges the Staff's comment and advises the Staff that, upon identifying the estimated net proceeds from the offering, it will include, in a subsequent amendment to the Draft Registration Statement, estimated dollar amounts to quantify the net proceeds the Company expects to use to fund its clinical and pre-clinical programs and an indication of how far the proceeds from the offering will allow the Company to proceed with the continued development of LCAR-38M/JNJ-4528.**

Research and Development Expenses, page 99

8. You state on page 100 “We track outsourced development costs by product candidate or preclinical program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or preclinical programs.” Please disclose costs by product candidate for each period presented or direct us to that disclosure.

**Response to Comment 8**

**In response to the Staff’s comment, the Company has revised page 102 of the Amended DRS to clarify that the Company tracks outsourced development costs by either its BCMA program or to all of its other non-BCMA programs, as opposed to by product candidate or individual program. The Company has supplemented the disclosure on page 102 to present research and development costs for each period presented by BCMA program or non-BCMA programs.**

Critical Accounting Policies, page 105

Shared-Based Compensation, page 107

9. Please revise to disclose the extent to which any stock-based compensation has been awarded during 2019 and provide the fair valuations of each award. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

**Response to Comment 9**

**In response to the Staff’s comment, the Company has revised pages 110 and 111 of the Amended DRS as requested. The Company further advises the Staff that it will provide the Staff under separate cover with the requested analysis for any differences between the recent valuations of its common stock and the estimated offering price once the Company has an estimated offering price or range.**

Our Programs, page 116

10. Please describe the International Myeloma Working Group criteria and explain how it is used to measure patient response.

**Response to Comment 10**

**In response to the Staff’s comment, the Company has revised page 119 of the Amended DRS as requested.**

11. We note that your disclosures throughout this section references “overall response rate,” “partial response,” “very good partial response,” “stable disease,” and “objective response.” For your completed clinical trials, please revise your document to describe the clinical endpoints and clarify what constitutes an overall response rate, objective response, partial response, and very good partial response. Additionally clarify how you have measured or concluded that the disease is stable.

**Response to Comment 11**

**In response to the Staff’s comment, the Company has revised page 119 of the Amended DRS as requested.**

Completed Clinical Results

LEGEND-2 (China), page 123

12. We note use of p-values on page 123. At first use, please explain how “p-value” is used to measure statistical significance and the relevance of statistical significance to the FDA’s evidentiary standards for drug approval.

**Response to Comment 12**

**In response to the Staff’s comment, the Company has revised page 127 of the Amended DRS as requested.**

Company-Owned Intellectual Property, page 136

13. Please disclose the jurisdictions of your most material foreign patent applications.

**Response to Comment 13**

**In response to the Staff’s comment, the Company has revised page 140 of the Amended DRS as requested.**

Competition, page 138

14. Please revise your discussion of competitive conditions by describing the current landscape for patent protections in your industry. In this regard, we note that across several risk factors on pages 53 to 62 you highlight risks stemming from existing third party patents and patent applications. In your discussion of the competitive landscape, identify specific patents and patent applications, if material, as well as their holders/applicants.

**Response to Comment 14**

**In response to the Staff’s comment, the Company has revised pages 56 and 142 of the Amended DRS.**

Jury Trial Waiver, page 198

15. We note your disclosure regarding the waiver of jury trial provision on page 198. Please include a risk factor to highlight the material risks related to this provision, including the possibility of less favorable outcomes, uncertainty regarding its enforceability, the potential for increased costs to bring a claim, whether it may discourage or limit suits against you or the depositary and whether the provision applies to purchasers in secondary transactions. Also disclose whether this provision would apply if the ADS holder were to withdraw the ordinary shares.

**Response to Comment 15**

**In response to the Staff's comment, the Company has revised page 81 of the Amended DRS as requested.**

Financial Statements, page F-1

16. Pleasetell us why you do not include a note to the financial statements regarding the Janssen Agreement that:
- includes disclosure of the significant judgments underlying your conclusion that the license granted to Janssen was distinct and represented a right-to-use license, as addressed in paragraph 123 and 125 of IFRS 15;
  - quantifies the amount allocated to each performance obligation at inception and at each time the transaction price was updated pursuant to paragraph 120 of IFRS 15;
  - describes and quantifies the methods and assumptions used to determine standalone selling price;
  - a rollforward of the contract liability account showing increases and decreases to the balance pursuant to paragraph 118 of IFRS 15;
  - discloses the amount recognized for the license at inception and how that amount was determined;
  - explains how you determined the \$7,570,000 of revenue for the license in 2018 shown in Note 5 to the financial statements;
  - explains how you determined the \$40,534,000 of revenue for joint steering committee in 2018 shown in Note 5;
  - explains why you defer milestone payments received;
  - discloses how you determined that performing research and development services for Janssen was not a performance obligation; and
  - you disclose that you had contracted but not yet recognized revenue of approximately \$322 million as of December 31, 2018 of which you expect to recognize approximately 12.5% over the next twelve months and the remainder thereafter

## Response to Comment 16

In response to the Staff's comment, the Company has revised the F-pages of the Amended DRS. Specifically, with respect to the subparts of the Staff's comment, the Company respectfully advises the Staff as follows:

- *includes disclosure of the significant judgments underlying your conclusion that the license granted to Janssen was distinct and represented a right-to-use license, as addressed in paragraph 123 and 125 of IFRS 15;*

In response to the Staff's comment, the Company has revised the disclosures on page F-26 of the Amended DRS to include the significant judgments underlying the conclusion that the license granted to Janssen was distinct and represented a right-to-use license.

- *quantifies the amount allocated to each performance obligation at inception and at each time the transaction price was updated pursuant to paragraph 120 of IFRS 15;*

In response to the Staff's comment, the Company has revised the disclosures on page F-29 of the Amended DRS to include the amount allocated to each performance obligation at inception and at each time the transaction price was updated.

- *describes and quantifies the methods and assumptions used to determine standalone selling price;*

The Company respectfully advises the Staff that the standalone value of license is determined by using income approach while the standalone value of Joint Steering Committee ("JSC") service is determined by using expected cost plus margin approach, with the assistance of an independent third-party valuer. In response to the Staff's comment, the Company has revised the disclosures on page F-26 of the Amended DRS to include the description of the methods and assumptions.

- *a rollforward of the contract liability account showing increases and decreases to the balance pursuant to paragraph 118 of IFRS 15;*

In response to the Staff's comment, the Company has revised the disclosures on page F-43 of the Amended DRS to include the rollforward of the contract liabilities.

- *discloses the amount recognized for the license at inception and how that amount was determined;*

The Company respectfully advises the Staff that the amount recognized for the license at inception was \$30 million. The amount was determined based on the estimated transaction prices at inception and the allocation to each performance obligation based on the relative standalone selling price. The Company has revised the disclosures on page F-29 of the Amended DRS to include the amount recognized for the license at inception and how that amount was determined.



- *explains how you determined the \$7,570,000 of revenue for the license in 2018 shown in Note 5 to the financial statements;*

In response to the Staff's comment, the Company has revised the disclosures on page F-29 of the Amended DRS to include the determination of the license revenue for 2018 and 2019.

- *explains how you determined the \$40,534,000 of revenue for joint steering committee in 2018 shown in Note 5;*

In response to the Staff's comment, the Company has revised the disclosures on page F-29 of the Amended DRS to include the determination of revenue for JSC service in 2018 and 2019.

- *explains why you defer milestone payments received;*

The Company respectfully advises the Staff that the terms of the agreement include non-refundable upfront fees and milestone payments. The milestone payments were allocated to the license and JSC service which are separate performance obligations based on the Group's best estimate of their relative stand-alone selling prices. As JSC service is satisfied over time, milestone payments allocated to JSC service is deferred and recognized as revenue on straight-line basis over the period when the JSC service is provided. The Company has revised the disclosures on page F-29 of the Amended DRS to include the determination of the license and JSC service revenue.

- *discloses how you determined that performing research and development services for Janssen was not a performance obligation; and*

In response to the Staff's comment, the Company has revised the disclosures on page F-22 of the Amended DRS.

- *you disclose that you had contracted but not yet recognized revenue of approximately \$322 million as of December 31, 2018 of which you expect to recognize approximately 12.5% over the next twelve months and the remainder thereafter through the remaining collaboration period. Please tell us how you considered that these two time bands would be the most appropriate to explain when you expect to recognize the revenue related to your remaining performance obligations given the initial band only represents 11% of a 9 year remaining estimated collaboration period. Refer to paragraph 120(b) of IFRS 15.*

In response to the Staff's comment, the Company has revised the disclosures on page F-30 of the Amended DRS to include the five time bands.

17. With regard to the \$1,115 million in the Janssen agreement that may be received for the achievement of specified future development, regulatory and net trade sales milestones:
- we believe additional disclosure would improve information regarding the nature, amount, timing, and uncertainty of revenue and cash flows arising from your contracts. Refer to IFRS 15 paragraph 110. Provide disclosure that further disaggregates the aggregate amount. Given the differences in the nature, timing, and uncertainty between development, regulatory and net trade sales milestones, we believe that separate amounts should be provided for those categories.
  - also, tell us your consideration of disclosing individually material milestones.
  - finally, disclose the triggering event for receipt of the four milestones that have been received as specified in paragraph 117 of IFRS 15.

#### **Response to Comment 17**

**In response to the Staff's comment, the Company has revised pages 137 and F-22 of the Amended DRS to disclose the aggregate milestone amounts across the development, regulatory and net sales milestones. Although the Company does not consider any particular future milestone to be individually material, the Company has included disclosure in the Amended DRS to disclose the trigger events for the four milestones that have been achieved and for which milestone payments have been received. The achievement of the remaining milestones are still highly uncertain, and the related milestone payments are therefore not included in the transaction price. The milestone payments will be included in the transaction price when the triggering event described in the agreement is expected to be met and it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur.**

#### **24. Reserves, page F-44**

18. We note the risk factor on page 69 related to PRC restrictions that could prevent you from distributing dividends to your foreign subsidiaries and the amount of restricted net assets as of December 31, 2018 quantified herein. Please tell us how you considered the requirements under Item 8 of Form F-1 and Article 5-04 of Regulation S-X to provide condensed financial information of the registrant.

#### **Response to Comment 18**

**The Company acknowledges the Staff's comment and respectfully advises the Staff that, upon re-examination, the Company has determined that this risk factor is not material to the Company as it does not intend to distribute dividends from its PRC subsidiary and has therefore been removed from the Amended DRS. In addition, the Company has revised the disclosures on page F-59 of the Amended DRS in accordance with Article 5-04 of Regulation S-X to include the condensed financial information of the Company.**

#### **General**

19. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

**Response to Comment 19**

**The Company acknowledges the Staff's comment. The Company advises the Staff that it has commenced "testing the waters" meetings with potential investors and the Company will supplementally provide the Staff with a copy of the presentation that the Company has used in these meetings with qualified institutional buyers or institutional accredited investors. The Company further advises the Staff that it will supplementally provide the Staff with copies of any additional written communications of the type referenced in the Staff's comment.**

\* \* \* \*



Please direct any questions or comments concerning the Registration Statement or this response letter to either the undersigned at (212) 479-6474, Robert W. Phillips at (415) 693-2020 or Mark Ballantyne at (703) 456-8084.

Very truly yours,

/s/ Divakar Gupta

Divakar Gupta

cc: Yuan Xu, Ph.D., Legend Biotech Corporation  
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