Our STN: BLA 125738/0

MID-CYCLE COMMUNICATION SUMMARY
November 2, 2022

Gamida Cell Ltd.
Attention: Priyanka Desai
116 Huntington Ave., 7th floor
Boston, MA 02116

Dear Ms. Desai:

Attached is a copy of the summary of your October 3, 2022 Mid-Cycle Communication Teleconference with CBER. This memorandum constitutes the official record of the Teleconference. If your understanding of the Teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

Please include a reference to STN 125738/0 in your future submissions related to omidubicel.

If you have any questions, please contact Cara Pardon at cara.pardon@fda.hhs.gov.

Sincerely,

Steven S. Oh, PhD
Acting Director
Division of Cellular and Gene Therapies
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Summary

Application Type and Number:	BLA 125738/0
Product Name:	omidubicel
Proposed Indication for Use:	(b) (4)
Applicant:	Gamida Cell Ltd.
Meeting Date & Time:	October 3, 2022 at 9:30 AM, ET
Committee Chair:	Elizabeth Lessey-Morillon, PhD
RPM:	Cara Pardon, MS

FDA Attendees:
Meghna Alimchandani, MD, CBER/OBPV/DPV
Rachael Anatol, PhD, CBER/OTAT
Rabia Ballica, PhD, CBER/OCBQ/DMPQ
Kimberly Benton, PhD, CBER/OTAT
Najat Bouchkouj, MD, CBER/OTAT/DCEPT
Danielle Brooks, PhD, CBER/OTAT/DCEPT
Wilson W. Bryan, MD, CBER/OTAT
Juliane Carvalho, MS, RAC, CBER/OTAT/DRPM
Heba Degheidy, MD, PhD, CBER/OTAT/DCGT
Melanie Eacho, PhD, CBER/OTAT/DCGT
Christine Harman, PhD, OCBQ/DMPQ
Ping He, CBER/OTAT/DHT
Adnan Jaigirdar, MD, FACS, CBER/OTAT/DCEPT
Sukhanya Jayachandra, PhD, CBER/OTAT/DCGT
Safa Karandish, BS, MT, CBER/OTAT/DHT
Simleen Kaur, MSc, CBER/OCBQ/DBSQC
Peter Lenahan, DC, PhD, MPH, CBER/OCBQ/DIS/BMB
Elizabeth Lessey-Morillon, PhD, CBER/OTAT/DCGT
Nicole Li, CBER/OCBQ/DMPQ
Wei Liang, PhD, CBER/OTAT
Miriam Ngundi, PhD, CBER/OCBQ/DMPQ
Manette Niu, MD, CBER/OBPV
Steven Oh, PhD, CBER/OTAT/DCGT
Tao Pan, PhD, CBER/OCBQ/DBSQC
Cara Pardon, MS, CBER/OTAT/DRPM
Helkha Peredo-Pinto, MD, CBER/OTAT/DCEPT
Lori Peters, CBER/OCBQ/DMPQ
Tejashri Purohit-Sheth, MD, CBER/OTAT/DCEPT
Julia Russell, MS, CBER/OTAT/DRPM
Wen (Aaron) Seeto, PhD, CBER/OTAT/DCGT
Archana Siddam, PhD, CBER/OTAT/DCGT
Ramani Sista, PhD, CBER/OTAT/DRPM
Million Tegenge, PhD, CBER/OTAT/DCEPT

Irina Tiper, PhD, CBER/OTAT/DCGT
Ramjay Vatsan, PhD, CBER/OTAT/DCGT
Shaokui Wei, MD, MPH, CBER/OBPV/DE
Thomas Zhou, PhD, CBER/OBPV/DB
Tingting Zhou, PhD, CBER/OBPV/DB

Applicant Attendees:
Priyanka Desai, Senior Director Regulatory CMC
(b) (6) Senior Associate Regulatory
Yona Geffen, VP R&D
Dorit Jacob, Senior Manager Regulatory CMC
Abbigail Jenkins, President and CEO
Efrat Landau, Senior Director R&D
Vladimir Melnikov, Senior VP Global Operations and Manufacturing
Yossi Ohana, Director Quality
Nelly Sebban, Senior Director Regulatory
Eyal Shoshani, VP Clinical Operations
Ronit Simantov, Chief Medical and Chief Scientific Officer
Jas Uppal, Chief Regulatory Officer
Elizabeth Whitworth, Director Documentation Training and Systems

Discussion Summary:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.

   Meeting Discussion
   FDA reiterated the CMC concerns communicated in CMC information request (IR) #3:
   a. The process performance qualification (PPQ) manufacturing runs had deviations that resulted in higher residual (b) (4) and (b) (4) concentrations in the final product. This is a potential safety concern.
   b. The proposed change in the number of product bags washed per (b) (4) will require additional data, including revised manufacturing documents and data to support the change in the number of product bags washed per (b) (4) (b) (4) does not impact product quality.
   c. There are concerns the PPQ batches do not represent the proposed manufacturing process when a second (b) (4) is required.
   d. Additional information is required to review the (b) (4) validation.

   The Applicant confirmed they are putting steps in place to ensure the manufacturing process and impurities are controlled as defined. As communicated to FDA, the Applicant changed the number cell culture bags washed per (b) (4) to no more than (b) (4) rather than up to (b) (4) Beyond this defined change, no other manufacturing process or testing changes have been

made. The Applicant is planning to submit the additional data and (b) (4) confirmatory runs prior to the late cycle meeting. The (b) (4) information was recently submitted for review.

FDA reiterated the clinical concerns and requests for information as communicated in clinical IR #4:

a. The clinical data submitted in this BLA are insufficient for the review team to independently confirm the efficacy and safety results to support labeling claims.
b. Responses to Clinical IR #4, which should contain the complete and updated laboratory data files and requested information for all chimerism assays used in Study P0501, are expected to be received on November 8, 2022.

The Applicant confirmed they are gathering the requested information for submission by November 8, 2022.

In response to the Applicant's query regarding the status of the clinical review, FDA confirmed that the data submitted with the BLA are still under review, and there may be additional Clinical IRs sent before receipt of the requested datasets on November 8, 2022.

2. Information regarding major safety concerns.

Meeting Discussion
No major safety concerns were communicated. However, the review team is awaiting the response to Clinical IR #4, and the 120-day safety update received September 29, 2022 is under review.

3. Preliminary Review Committee thinking regarding risk management.

Meeting Discussion
FDA communicated that at this time, no Risk Evaluation Mitigation Strategy (REMS) is anticipated.

4. Any information requests sent, and responses not received.

Meeting Discussion
A number of pending IRs were communicated:

a. CMC IR #3 was sent on September 14th. Response to the IR received September 26, 2022 was incomplete and the full response is expected prior to late cycle meeting, recommended by November 8th, 2022.

The Applicant stated they are actively working on this request, but the sterility data may not be available by November 8, 2022. The Applicant asked if the FDA would like submission of partial data when available (e.g., submitting product testing data while the (b) (4)-day sterility tests are still pending).

FDA confirmed the Applicant may submit partial data as available, provided the submitted data is sufficient to review without the pending data. If the Applicant could provide an outline of what is pending with their submission, that would be helpful for review. FDA confirmed any partial data should still be submitted to the BLA and not sent via email.

The Applicant confirmed their openness to informal telecons, as warranted.

b. Clinical IR #4 responses are expected by November 8, 2022.

There were no additional comments regarding the clinical IR #4.

c. DBSQC IR as communicated during the September 21, 2022 informal telecon is due by the end of November.

The Applicant confirmed they are working to provide the requested information by this date.

d. DMPQ IR sent on September 22, 2022 is due October 7, 2022.

There were no additional questions or comments for DMPQ IR.

5. Any new information requests to be communicated.

Meeting Discussion
As review continues, any new IRs will be communicated as warranted, including any Clinical IRs required following receipt of Clinical IR #4 responses. No additional discussion.

6. Proposed date(s) for the Late-Cycle meeting (LCM).

Meeting Discussion
The Applicant was informed of the scheduled late-cycle meeting on December 5, 2022 from 9:30-11 AM, ET. The late cycle materials will be provided at least ten days beforehand, by November 25, 2022. There were no questions or concerns about this scheduled meeting.

7. Updates regarding plans for the advisory committee (AC) meeting.

Meeting Discussion
The Applicant was informed that at this time, no AC meeting is anticipated.

The Applicant asked if an AC meeting was still possible, though not currently expected.

FDA communicated it was unlikely but cannot confirm until receipt of Clinical IR #4 responses. FDA will confirm with the Applicant within a few weeks following receipt of the clinical IR responses.

The Applicant asked about timing regarding the new proprietary name request and labeling as the PDUFA date approaches.

FDA will work with the Applicant to meet the timelines. There is a possibility of designating the amendment containing the response to the IR expected to be submitted on November 8, 2022 as a major amendment, depending on the information submitted. FDA will communicate any changes to the timeline. FDA recognizes changes to labeling may be required and can work with the Applicant on labeling negotiations prior to formal communication of the first round of labeling negotiations. The Applicant may expect the label after the late cycle meeting.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

Meeting Discussion

There were no changes to previously communicated dates for the remainder of the review cycle. Any changes will be communicated as warranted.