Our STN: BL 125738/0

LATE-CYCLE
MEETING MEMORANDUM
March 24, 2023

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

Dear Ms. Desai:

Attached is a copy of the memorandum summarizing your February 23, 2023 Late-Cycle teleconference with CBER. This memorandum constitutes the official record of teleconference. If your understanding of the teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER in writing as soon as possible.

Please include a reference to the appropriate Submission Tracking Number (STN) in future submissions related to the subject product.

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

Sincerely,

Ramani Sista, PhD
Director
Division of Review Management and Regulatory Review 1
Office of Review Management and Regulatory Review
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Late-Cycle Meeting Summary

Meeting Date and Time:	February 23, 2023 from 9:30 AM – 11 AM, EST
Meeting Location:	via Zoom
Application Number:	BLA 125738/0
Product Name:	omidubicel-onlv
Proposed Indication:	(b) (4)
Applicant Name:	Gamida Cell Ltd.
Meeting Chair:	Elizabeth Lessey-Morillon, PhD
Meeting Recorder:	Cara Pardon, MS

FDA ATTENDEES

Marie Anderson, PhD, CBER/OCBQ/DBSQC
Rabia Ballica, PhD, CBER/OCBQ/DMPQ
Najat Bouchkouj, MD, CBER/OTP/OCE
Juliane Carvalho, MS, RAC, CBER/OTP/ORMRR
Dennis Cato, CBER/OCBQ/DIS/BMB
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Archana Siddam, PhD, CBER/OTP/OCTHT
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Irina Tiper, PhD, CBER/OTP/OCTHT
Nicole Trudel, CBER/OCBQ/DMPQ
Kerry Welsh, MD, CBER/OBPV/DPV
Boguang Zhen, PhD, CBER/OBPV/DB
Thomas Zhou, PhD, CBER/OBPV/DB
Tingting Zhou, PhD, CBER/OBPV/DB

APPLICANT ATTENDEES
Nurit Birenboim, Associate Director Regulatory
Priyanka Desai, Senior Director Regulatory CMC
(b) (6) Senior Associate Regulatory
Yona Geffen, VP R&D
Tami Greenberg, VP QA
Dorit Jacob, Manager Regulatory CMC
Abbigail Jenkins, President and CEO
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Efrat Landau, Senior Director R&D
Roei Mazor, Medical Director Clinical
Vladimir Melnikov, Senior VP Global Operations and Manufacturing
(b) (6) Clinical Project Manager
Eyal Shoshani, VP Clinical Operations
Ronit Simantov, Chief Medical and Chief Scientific Officer
Smitha Sivaraman, VP Medical Affairs

BACKGROUND

BLA 125738/0 was submitted on June 1, 2022, for omidubicel-onlv [OMISIRGE].

Proposed indication: (b) (4)

PDUFA goal date: May 1, 2023

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on February 13, 2023.

DISCUSSION

1. Discussion of established Pharmacologic Class (EPC)

   The Agency disagreed with the Applicant's proposed EPC and proposed the following EPC, "Processed allogeneic cord blood hematopoietic progenitor cell therapy." The Applicant disagreed that the word "processed" reflects the final product and noted cord blood, even unmanipulated, is processed. The Applicant asked if the word "processed" could be replaced with wording such as "advanced

culturing," "enhanced," "expansion," or "manipulation" to describe what is happening to the product.

The Agency explained that the proposed EPC reflects the distinction between this new class of product and minimally manipulated cord blood. However, the Agency acknowledged the Applicant's viewpoint and noted this will be discussed internally and any revisions will be communicated during labeling negotiations. The Agency noted that the EPC will not be finalized until after approval.

2. Current assessment of risk management activities, e.g., REMS, the ability of adverse event reporting and CBER's Sentinel Program to provide sufficient information about product risk:

   The Agency confirmed that there is no anticipation for a REMS at this time.

3. Postmarketing Requirements (PMR)/Postmarketing Commitments (PMCs)

   Three anticipated Chemistry, Manufacturing, and Controls (CMC) PMCs were discussed. The first information request (IR) for the PMCs was sent February 22, 2023.

   a. Regarding a postmarketing confirmatory study to determine the concentration of (b) (4) and to provide assurance that the residual (b) (4) levels in OMISIRGE are within the established manufacturing range, the Agency reiterated that the study should be designed to include a sampling of clinical batches over the course of a year and cover the range in the number of cell culture bags per batch (e.g., (b) (4) cell culture bags per batch).

      The Applicant asked for clarity on the study design and sampling of clinical batches over a year. The Agency confirmed that they would like to see a sampling over the course of the full year, rather than, for example, the first (b) (4) batches, to obtain a representative overview of manufacturing consistency for the full manufacturing year.

      The Applicant also asked if representative non-clinical batches could be used. The Agency said that this approach could be considered and the Applicant should include that in their response along with the justification for the approach.

      The Applicant expressed concern about the range of cell culture bags per batch, specifically if (b) (4) and (b) (4) number of bags must be included, as it is difficult to predict the starting material volume and if including the full range in (b) (4) processing runs was acceptable. The Agency confirmed they do not need to have exactly (b) (and (b) (4) bags represented, but the sampling strategy will need to be representative of the range in number of bags per batch.

The Applicant also asked if the proposed protocol is expected by March 8, 2023, and if (b) (4) representative batches sampled over a full year would suffice. The Agency clarified the protocol is not expected March 8, 2023, rather the Applicant's proposal and justifications in the response for how the protocol proposal will represent a full year of manufacturing is expected by this date.

The Applicant asked if including (b) (4) would address the concerns regarding the range in manufacturing. The Agency said that is something that they would consider if it addressed the full range observed in manufacturing to determine product quality and constancy.

b. The Agency stated that the assessment of elemental and organic leachables submitted on January 31, 2023, is under review. Thus far, the elemental leachables assessment remains insufficient and a real process study is required, which can be addressed under a PMC.

   The Applicant asked if the elemental leachables real process study would be considered a PMC and not a PMR. The Agency confirmed this study will be considered a PMC.

c. The Applicant cross-references master file (MF) (b) (4) for information regarding the (b) (4) reagent. The Agency stated that the cross-referenced MF contains insufficient information. However, the concerns identified for the MF are being addressed by the MF Holder, (b) (4) (b) (4) is making commitments to resolve remaining concerns. The Agency asked the Applicant to communicate with the MF Holder for notification of when the commitments are resolved and update the BLA.

   The Applicant confirmed they will reach out to the MF holder and provide response by March 8, 2023.

   The Agency confirmed the response should include how the concerns will be addressed with the MF holder.

4. Major labeling issues

   The Agency noted that labeling issues will be discussed during the labeling negotiations.

   The Applicant asked about the status of their Drug Supply Chain Security Act (DSCSA) serialization exemption request.

   The Agency confirmed this request is under review and a decision letter will be sent following an approval.

5. Review Plans

The Agency confirmed the label is currently under review and will be sent to the Applicant for negotiations no later than March 31, 2023.

The Applicant asked if IRs would continue to be sent up until the action due date. The Agency confirmed IRs could be sent up until the action due date, especially regarding labeling negotiations.

6. Applicant Questions

   The Applicant had no additional questions.

7. Wrap-up and Action Items

   There were no additional action items discussed.

This application has not yet been fully reviewed by the signatory authorities, Division Directors and Review Committee Chair and therefore, this meeting did not address the final regulatory decision for the application.