Memorandum

DATE: April 5, 2023

TO: Cara Pardon, MS, RPM, CBER/OTAT/DRPM
Elizabeth Lessey-Morillon, Ph.D., Committee Chair, CBER/OTAT/DCGT
Najat Bouchkouj, M.D., Clinical Reviewer, CBER/OTAT/DCEPT

FROM: Benjamin S. Cyge, Ph.D.
Consumer Safety Officer
APLB/DCM/OCBQ

THROUGH: Lisa L. Stockbridge, Ph.D.
Branch Chief
APLB/DCM/OCBQ

SUBJECT: OMISIRGE (omidubicel-onlv)
BLA: 125738/0
Sponsor: Gamida Cell Ltd.

Background

The sponsor submitted:
_x_ New Approval
_____ Changes Being Effected (CBE) supplement
_____ Prior Approval Supplement (PAS)
_____ Major Amendment

Submission contains:
_x_ Prescribing Information (PI)
_____ Patient Package Insert (PPI)
_x_ Package and/or container labels
_____ Other

Submission Date: June 1, 2022

PDUFA Action Date: May 1, 2023

APLB Comments/Recommendations

This is a labeling review for BLA 125738, submitted by Gamida Cell Ltd. for OMISIRGE (omidubicel-onlv) on June 1, 2022. OMISIRGE is a nicotinamide modified allogeneic cord blood hematopoietic progenitor cell therapy (tentative) indicated to reduce the time to neutrophil recovery and the incidence of infection in adults and pediatric patients 12 years and older with hematologic malignancies undergoing myeloablative conditioning followed by umbilical cord blood transplantation.

APLB reviewed the draft package, and container labels dated June 1, 2022, and the revised draft prescribing information (PI) dated April 5, 2023. The following comments are from a promotional and comprehension perspective.

GENERAL

- Ensure that the use of bullets and numbering is consistent throughout the PI. Do not bullet when there only is one concept.

- There are numerous abbreviations throughout the PI. Please ensure that each abbreviation is spelled out the first time it is used.

HIGHLIGHTS

DOSAGE AND ADMINISTRATION

Consider adding the infusion time to this section. For example,

> "The CF (cultured fraction) bag must be administered FIRST, and infusion should not exceed 2 hours from the end of dilution. Infusion of the NF (non-cultured) bag should not exceed 1 hour from the end of dilution."

DOSAGE FORMS AND STRENGTHS

Remove the bullet on the first sentence: OMISURGE is a cell suspension for intravenous infusion (3).

ADVERSE REACTIONS

Ensure that the statement regarding the common adverse reactions is consistent with the information in the **FULL PRESCRIBING INFORMATION** under **6 ADVERSE REACTIONS**.

USE IN SPECIFIC POPULATIONS

Delete this subsection. The **USE IN SPECIFIC POPULATIONS** subsection in the **HIGHLIGHTS** is limited to clinically important differences in response or use of the drug in specific populations (e.g., differences between adult and pediatric responses, need for specific

monitoring in patients with renal or hepatic impairment, etc.). Do not include absence of information.

FULL PRESCRIBING INFORMATION: CONTENTS

Ensure any changes in the **FULL PRESCRIBING INFORMATION** will also reflect in the **CONTENTS**.

FULL PRESCRIBING INFORMATION

2 DOSAGE AND ADMINISTRATION

- The abbreviations for cultured fraction (CF) and non-cultured fraction (NF) are not directly defined. Ensure these are defined the first time they are used in order to increase comprehension.

- Avoid bolding, unless required by regulation. Subheadings that do not require bolding (e.g., **Receipt of OMISIRGE, Planning prior to OMISIRGE preparation, The CF bag must be administered FIRST., Preparation of OMISIRGE for Infusion,** *et al.***)** should be changed from bold to italic and/or underlined.

- Use of bullets and numbering must be consistent throughout the PI to aid readability. There are several instances where there is an abrupt switch between bullets and numbers. Consider indentation of the numbered items to delineate them more clearly from the bulleted items.

6 ADVERSE REACTIONS

Directly following the section heading, and before subsection **6.1 Clinical Trials Experience**, include a list of the most frequently occurring adverse reactions, along with the criteria used to determine inclusion (e.g., incidence rate greater than x%). This usually is the same statement found in the **ADVERSE REACTIONS** subsection of the **HIGHLIGHTS**.

11 OVERDOSE

Delete this section when there are no data.

14 CLINICAL STUDIES

Do not bold headings unless required by regulation. Use italics or underline instead of bolding.

16 HOW SUPPLIED/STORAGE AND HANDLING

Consider replacing dense paragraphs with tables and bulleting to improve readability.

17 PATIENT COUNSELING INFORMATION

- Directly beneath this section heading, reference any appended FDA-approved product labeling (e.g. MedGuide or PPI) using the following regulatory statement:

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

- Revise to active voice and use bulleting to improve readability. This section is a guide to the provider to use as discussion points with the patient or caregiver.

PACKAGE AND CONTAINER LABELS

APLB has no comments on the package and container labels.

If you have any questions regarding this review, please contact Benjamin S. Cyge, Consumer Safety Officer at (301) 796-4212.