**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 6-K

**Report of Foreign Private Issuer**
**Pursuant to Rule 13a-16 or 15d-16**
**Under the Securities Exchange Act of 1934**

**For the month of October 2020**

**Commission File Number 001-38716**

**GAMIDA CELL LTD.**
**(Translation of registrant's name into English)**

**5 Nahum Heftsadie Street**
**Givaat Shaul, Jerusalem 91340 Israel**
**(Address of principal executive offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On October 6, 2020, Gamida Cell Ltd. issued a press release, a copy of which is furnished as Exhibit 99.1 to this Report on Form 6-K, announcing positive topline data on secondary endpoints from the company's Phase 3 clinical study of omidubicel in patients with hematologic malignancies.

This Report on Form 6-K is hereby incorporated by reference into the Company's Registration Statement on Form F-3 (File No. 333-234701).

**Exhibit**

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|---|---|
| 99.1 | Press Release, dated October 6, 2020, Gamida Cell Announces Positive Topline Data on Secondary Endpoints from Phase 3 Clinical Study of Omidubicel in Patients with Hematologic Malignancies |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**GAMIDA CELL LTD.**

October 6, 2020

By: /s/ Shai Lankry
Shai Lankry
Chief Financial Officer

**FOR RELEASE ON TUESDAY, OCTOBER 6, 2020, AT 6:45 A.M. ET**

# Gamida Cell Announces Positive Topline Data on Secondary Endpoints from Phase 3 Clinical Study of Omidubicel in Patients with Hematologic Malignancies

*— Study met secondary endpoints related to platelet engraftment, infections and hospitalizations, key clinical measures in bone marrow transplant —*

*— Omidubicel represents potential transformative treatment option for patients in need of a bone marrow transplant —*

*— Company anticipates initiating BLA submission in fourth quarter of 2020 —*

**Boston, Mass. – Tuesday, October 6, 2020 –** Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious blood diseases, today announced that the Phase 3 study of omidubicel, an investigational advanced cell therapy in development as a potential life-saving treatment option for patients in need of bone marrow transplant, met all three of its secondary endpoints. Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration and has the potential to be the first FDA-approved engineered bone marrow transplant graft.

The international, multi-center, randomized Phase 3 study was designed to evaluate the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing a bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. In May, Gamida Cell reported that omidubicel achieved its primary endpoint, demonstrating a highly statistically significant reduction in time to neutrophil engraftment, a key milestone in recovery from a bone marrow transplant. The prespecified secondary endpoints of the study, analyzed in all randomized patients (intent-to-treat), were the proportion of patients who achieved platelet engraftment by day 42, the proportion of patients with Grade 2 or Grade 3 bacterial or invasive fungal infections in the first 100 days following transplant, and the number of days alive and out of the hospital in the first 100 days following transplant. All three secondary endpoints demonstrated a statistically significant improvement among patients who received omidubicel compared to the comparator group. The company anticipates reporting the full data set at a medical meeting in the fourth quarter of 2020.

“These data, obtained in a global, randomized, multi-institutional setting could represent an important step forward in the field. In addition to more rapid platelet engraftment, a key step toward recovery, reducing infections and hospitalizations are considered meaningful patient outcomes and have the potential to provide substantial value for patients, their families and the healthcare system,” said Mitchell Horwitz, M.D., principal investigator and professor of medicine at the Duke Cancer Institute. “The totality of these data strengthen my belief that omidubicel has the potential to be a graft source for any patient who does not have access to a matched related donor and could help make stem cell transplantation more accessible and more successful for patients with lethal blood cancers.”

“These additional data reinforce the potential of omidubicel and move us another step closer toward bringing potentially curative therapies to patients. We look forward to presenting data at a future medical meeting, and we are continuing our work to enable the submission of our biologics license application for omidubicel to the FDA on a rolling basis, both expected in the fourth quarter,” stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. “We deeply appreciate the patients who participated in this study, the incredible encouragement from their caregivers and the support we have received from investigators and their teams.”

Despite the curative potential of bone marrow transplant, it is estimated that more than 40 percent of eligible patients in the United States do not receive a transplant for various reasons, including the lack of a matched donor.[1] Even for patients who do receive a transplant, treatment is not always effective and can lead to serious complications that can dramatically affect their quality of life.[2] Omidubicel is intended to address the current limitations of bone marrow transplant by providing a therapeutic dose of stem cells while preserving the cells’ functional therapeutic characteristics.

**About Omidubicel**

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with hematologic malignancies (blood cancers). In both Phase 1/2 and Phase 3 clinical studies (NCT01816230, NCT02730299), omidubicel demonstrated rapid and durable time to engraftment and was generally well tolerated.[3,4] Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn®, which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

*Omidubicel is an investigational therapy, and its safety and efficacy have not been evaluated by the U.S. Food and Drug Administration or any other health authority.*

**About Gamida Cell**

Gamida Cell is an advanced cell therapy company committed to cures for patients with blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit **www.gamida-cell.com** or follow Gamida Cell on **LinkedIn** or Twitter at **@GamidaCellTx**.

1 U.S. Department of Health and Human Services: Health Resources and Services Administration. Bone Marrow and Cord Blood Donation and Transplantation.

2 Carreras et al. The EBMT Handbook. Springer 2019.

3 Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. *J Clin Oncol.* 2019 Feb 10;37(5):367-374.

4 Gamida Cell press release, “Gamida Cell Announces Positive Topline Data from Phase 3 Clinical Study of Omidubicel in Patients with High-Risk Hematologic Malignancies,” issued May 12, 2020. Last accessed August 31, 2020.

**Cautionary Note Regarding Forward Looking Statements**

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to the anticipated timing of the presentation of clinical data and regulatory filing submissions for omidubicel, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the ongoing global COVID-19 pandemic and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section and other sections of Gamida Cell's Annual Report on Form 20-F, filed with the Securities and Exchange Commission (SEC) on February 26, 2020, and other filings that Gamida Cell makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

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