UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 17, 2023

Gamida Cell Ltd.
(Exact name of registrant as specified in its Charter)

Israel	001-38716	Not Applicable
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

116 Huntington Ave., 7th Floor Boston, Massachusetts	02116
(Address of principal executive offices)	(Zip Code)

(713) 400-6400
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, NIS 0.01 par value	**GMDA**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Gamida Cell Ltd. (Nasdaq: GMDA) announced today that the U.S. Food and Drug Administration (FDA) has approved Gamida Cell's allogeneic cell therapy, Omisirge® (omidubicel-onlv), for use in adult and pediatric patients 12 years and older with hematologic malignancies planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated April 17, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Gamida Cell Ltd.

Dated: April 17, 2023

By: /s/ Josh Patterson
Josh Patterson
General Counsel

Exhibit 99.1

Gamida Cell's Allogeneic Cell Therapy Omisirge® (omidubicel-onlv)
Receives FDA Approval

Omisirge is approved by the FDA as a new donor source for allogeneic stem cell transplant

Global, randomized Phase 3 clinical trial showed faster neutrophil recovery and reduced bacterial and fungal infections as compared to standard cord blood

Omisirge may increase access to stem cell transplant, including among patients from diverse backgrounds

Conference call April 18 at 8 am ET

BOSTON – April 17, 2023– Gamida Cell Ltd. (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has approved Gamida Cell's allogeneic cell therapy, Omisirge® (omidubicel-onlv), for use in adult and pediatric patients 12 years and older with hematologic malignancies planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Omisirge received breakthrough therapy designation, priority review and orphan drug designation from the FDA, reflecting the unmet need for additional donor sources for stem cell transplant. It is the first allogeneic stem cell transplant therapy to be approved on the basis of a global, randomized Phase 3 clinical study. Please see the accompanying full Prescribing Information for more information.

"FDA approval of Omisirge is a major advancement in the treatment of patients with hematologic malignancies that we believe may increase access to stem cell transplant and help improve patient outcomes," said Abbey Jenkins, President and Chief Executive Officer of Gamida Cell. "We are grateful to all the clinicians, patients and the entire Gamida Cell team without whom this approval would not have been possible. We also acknowledge the key role the FDA has played in supporting the development of Omisirge and other innovative and potentially life-saving cell therapies for patients with cancer and other serious diseases."

In a global, randomized Phase 3 clinical study, Omisirge demonstrated a median time to neutrophil recovery of 12 days in the intent to treat population, compared to 22 days for standard cord blood ($p<0.001$).[1] Incidence of Grade 2/3 bacterial or Grade 3 fungal infections through 100 days following transplantation occurred in 39% of patients in the Omisirge arm and 60% of patients in the standard cord blood arm.[2] The full Phase 3 clinical study results are available in *Blood,* the official journal of the American Society of Hematology. The safety profile for Omisirge is consistent with the expected adverse events of allogeneic hematopoietic stem cell transplantation following myeloablative conditioning. Among 117 patients who received Omisirge for any disease, infusion reactions occurred in 47% of patients (Grade 3 or 4 in 15%), acute graft-versus-host disease (GvHD) in 58% (Grade III-IV in 17%), chronic GvHD in 35% and graft failure in 3%.[3]

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1 Horwitz, M. E., Stiff, P. J., Cutler, C., Brunstein, C., Hanna, R., Maziarz, R. T., Rezvani, A. R., Karris, N. A., McGuirk, J., Valcarcel, D., Schiller, G. J., Lindemans, C. A., Hwang, W. Y., Koh, L. P., Keating, A., Khaled, Y., Hamerschlak, N., Frankfurt, O., Peled, T., … Sanz, G. (2021). Omidubicel vs standard myeloablative umbilical cord blood transplantation: Results of a phase 3 randomized study. *Blood*, *138*(16), 1429–1440. https://doi.org/10.1182/blood.2021011719

2 Horwitz, M. E., et al. (2021).

3 Omisirge [package insert]. Boston, MA: Gamida Cell; 2023.

More than 40% of the patients in the Omisirge Phase 3 study were racially and ethnically diverse,[4] underscoring the degree to which Omisirge may help address health disparities in stem cell transplantation.

"The approval of Omisirge is a significant development in hematopoietic stem cell transplantation," said Steven M. Devine, M.D., Chief Medical Officer at the National Marrow Donor Program® (NMDP)/Be The Match®. "Patients who are Black or African American have just a 29% chance of finding a match via the donor registry vs. a 79% chance for patients who are White.[5] Adding Omisirge as a new donor source may help increase access to stem cell transplant for patients from racially or ethnically diverse backgrounds who struggle to find a fully matched donor in the registry."

Allogeneic hematopoietic stem cell transplantation offers a potentially curative option for hematologic malignancies including acute myeloid leukemia, acute lymphoblastic leukemia, chronic myeloid leukemia and myelodysplastic syndromes. Allogeneic transplant uses cells from a donor other than the recipient.

Omisirge is manufactured to enhance and expand the number of progenitor cells utilizing proprietary nicotinamide (NAM) technology. This process produces enriched hematopoietic progenitor cells, leading to preservation of their stemness, homing to the bone marrow and retained engraftment capacity.

Omisirge is manufactured in Gamida Cell's state-of-the-art, fully licensed GMP manufacturing facility in Kiryat Gat, Israel. Omisirge is expected to be delivered to transplant centers within 30 days after the start of manufacturing. Gamida Cell Assist, a key resource for scheduling the manufacturing of Omisirge, will provide support to patients, caregivers and the hospital's transplant team at each step of the process.

Omisirge is now available in the United States for transplant centers to order for appropriate patients. Onboarding of transplant centers is underway. As discussed in the company's March 27 earnings call, Gamida Cell is pursuing strategic partnerships to support the launch and commercialization of Omisirge. The company also announced that is has retained Moelis & Company LLC to assist in the exploration of partnerships or broader strategic alternatives that would provide additional resources to support the launch of Omisirge and associated commercial activities in the United States and rest of world.

Conference Call

Gamida Cell will host a conference call to discuss the FDA's approval of Omisirge Tuesday, April 18, at 8 am ET. To access the conference call, please register here and be advised to do so at least 10 minutes prior to joining the call. A live webcast of the conference call can be accessed in the "Investors & Media" section of the Gamida Cell website at www.gamida-cell.com. A replay of the webcast will be available approximately two hours after the event, for approximately 30 days.

Omisirge Indication

Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

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4 Horwitz, M. E., et al. (2021).

5 *Why Ethnicity Matters When Donating Bone Marrow*. Be The Match. (n.d.). Retrieved April 16, 2023, from https://bethematch.org/transplant-basics/how-blood-stem-cell-transplants-work/how-does-a-patients-ethnic-background-affect-matching/

Important Safety Information for Omisirge

BOXED WARNING: INFUSION REACTIONS, GRAFT VERSUS HOST DISEASE, ENGRAFTMENT SYNDROME, AND GRAFT FAILURE

- **Infusion reactions may be fatal. Monitor patients during infusion and discontinue for severe reactions. Use is contraindicated in patients with known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin or bovine material.**
- **Graft-versus-Host Disease may be fatal. Administration of immunosuppressive therapy may decrease the risk of GvHD.**
- **Engraftment syndrome may be fatal. Treat engraftment syndrome promptly with corticosteroids.**
- **Graft failure may be fatal. Monitor patients for laboratory evidence of hematopoietic recovery.**

Contraindications

OMISIRGE is contraindicated in patients with known hypersensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine products.

Warnings and Precautions

Hypersensitivity Reactions

Allergic reactions may occur with the infusion of OMISIRGE. Reactions include bronchospasm, wheezing, angioedema, pruritis and hives. Serious hypersensitivity reactions, including anaphylaxis, may be due to DMSO, residual gentamicin, Dextran 40, human serum albumin (HSA) and bovine material in OMISIRGE. OMISIRGE may contain residual antibiotics if the cord blood donor was exposed to antibiotics in utero. Patients with a history of allergic reactions to antibiotics should be monitored for allergic reactions following OMISIRGE administration.

Infusion Reactions

Infusion reactions occurred following OMISIRGE infusion, including hypertension, mucosal inflammation, dysphagia, dyspnea, vomiting, and gastrointestinal toxicity. Premedication with antipyretics, histamine antagonists, and corticosteroids may reduce the incidence and intensity of infusion reactions. In patients transplanted with OMISIRGE in clinical trials, 47% (55/117) patients had an infusion reaction of any severity. Grade 3-4 infusion reactions were reported in 15% (18/117) patients. Infusion reactions may begin within minutes of the start of infusion of OMISIRGE, although symptoms may continue to intensify and not peak for several hours after the completion of the infusion. Monitor patients for signs and symptoms of infusion reactions during and after OMISIRGE administration. When a reaction occurs, pause the infusion and institute supportive care as needed.

Graft-versus-Host Disease

Acute and chronic GvHD, including life-threatening and fatal cases, occurred following treatment with OMISIRGE. In patients transplanted with OMISIRGE Grade II-IV acute GvHD was reported in 58% (68/117). Grade III- IV acute GvHD was reported in 17% (20/117). Chronic GvHD occurred in 35% (41/117) of patients. Acute GvHD manifests as maculopapular rash, gastrointestinal symptoms, and elevated bilirubin. Patients treated with OMISIRGE should receive immunosuppressive drugs to decrease the risk of GvHD, be monitored for signs and symptoms of GvHD, and treated if GvHD develops.

Engraftment Syndrome

Engraftment syndrome may occur because OMISIRGE is derived from umbilical cord blood. Monitor patients for unexplained fever, rash, hypoxemia, weight gain, and pulmonary infiltrates in the peri-engraftment period. Treat with corticosteroids as soon as engraftment syndrome is recognized to ameliorate symptoms. If untreated, engraftment syndrome may progress to multiorgan failure and death.

Graft Failure

Primary graft failure occurred in 3% (4/117) of patients in OMISIRGE clinical trials. Primary graft failure, which may be fatal, is defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplantation. Immunologic rejection is the primary cause of graft failure. Monitor patients for laboratory evidence of hematopoietic recovery.

Malignancies of Donor Origin

Two patients treated with OMISIRGE developed post-transplant lymphoproliferative disorder (PTLD) in the second-year post-transplant. PTLD manifests as a lymphoma-like disease favoring non-nodal sites. PTLD is usually fatal if not treated. The etiology is thought to be donor lymphoid cells transformed by Epstein-Barr virus (EBV). Serial monitoring of blood for EBV DNA may be warranted in patients with persistent cytopenias. One patient treated with OMISIRGE developed a donor-cell derived myelodysplastic syndrome (MDS) during the fourth-year post-transplant. The natural history is presumed to be the same as that for *de novo* MDS. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Gamida Cell at (844) 477-7478.

Transmission of Serious Infections

Transmission of infectious disease may occur because OMISIRGE is derived from umbilical cord blood. Disease may be caused by known or unknown infectious agents. Donors are screened for increased risk of infection, clinical evidence of sepsis, and communicable disease risks associated with xenotransplantation. Maternal and infant donor blood is tested for evidence of donor infection. See full Prescribing Information, Warnings and Precautions, Transmission of Serious Infections for list of testing performed. OMISIRGE is tested for sterility, endotoxin, and mycoplasma. There may be an effect on the reliability of the sterility test results if the cord blood donor was exposed to antibiotics in utero. Product manufacturing includes bovine-derived reagents. All animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents**. Test results may be found on the container label and/or in accompanying records.** If final sterility results are not available at the time of use, Quality Assurance will communicate any positive results from sterility testing to the physician. Report the occurrence of transmitted infection to Gamida Cell at (844) 477-7478.

Transmission of Rare Genetic Diseases

OMISIRGE may transmit rare genetic diseases involving the hematopoietic system because it is derived from umbilical cord blood. Cord blood donors have been screened to exclude donors with sickle cell anemia, and anemias due to abnormalities in hemoglobins C, D, and E. Because of the age of the donor at the time cord blood collection takes place, the ability to exclude rare genetic diseases is severely limited.

ADVERSE REACTIONS

The most common adverse reactions (incidence > 20%) are infections, GvHD, and infusion reaction.

Please see full Prescribing Information, including Boxed Warning.

About Gamida Cell

Gamida Cell is a cell therapy pioneer working to turn cells into powerful therapeutics. The company's proprietary nicotinamide (NAM) technology leverages the properties of NAM to enhance and expand cells, creating allogeneic cell therapy products and candidates that are potentially curative for patients with hematologic malignancies. These include Omisirge®, an FDA-approved nicotinamide modified allogeneic hematopoietic progenitor cell therapy, and GDA-201, an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, Twitter, Facebook or Instagram.

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 potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product, Omisirge® (omidubicel-onlv) and with respect to potential increased access to stem cell transplant. Any statement describing Gamida Cell's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to a number of risks, uncertainties and assumptions including those related to clinical, scientific, regulatory and technical developments and those inherent in the process of developing and commercializing product candidates that are safe and effective for use as human therapeutics. 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 10-K, filed with the Securities and Exchange Commission (SEC) on March 31, 2023, 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. Although Gamida Cell's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Gamida Cell. As a result, you are cautioned not to rely on these forward-looking statements.

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