



Gamida Cell to Present at the 2024 Tandem Meetings of ASTCT® and CIBMTR®

January 17, 2024

BOSTON, Jan. 17, 2024 (GLOBE NEWSWIRE) -- [Gamida Cell Ltd.](#) (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today announced it will present new data on its FDA approved allogeneic stem cell therapy Omisirge® (omidubicel-only) and allogeneic cryopreserved natural killer (NK) cell therapy candidate GDA-201 at the 2024 Tandem Meetings, Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The hybrid meetings will take place virtually and in person at the Henry B. González Convention Center in San Antonio, Texas, February 21-24.

Additional details about the poster presentations are as follows:

Title: [Omidubicel-only for Allogeneic Transplantation \(allo-HCT\) in Patients with Hematologic Malignancies: Results of a Multicenter Open-Label Expanded Access Program \(EAP\)](#)

Abstract Number: 313

Lead Author: Mitchell E. Horwitz, MD, Stem Cell Transplant Specialist and Professor of Medicine at Duke Cancer Institute

Time: February 22, 6:45-7:45 p.m. ET

- **Abstract highlights:** An Expanded Access Program (EAP) evaluated outcomes in 29 patients with hematologic malignancies following allo-HCT with omidubicel. Eligible patients ≥ 12 years of age received myeloablative conditioning, prophylactic medications and supportive care per individual institutional standards. Results demonstrated rapid hematopoietic recovery and low rate of infections. Safety and efficacy, including relapse, disease-free survival and overall survival, were similar to those observed in the Phase 3 study of omidubicel. Omidubicel was approved under the brand name Omisirge® (omidubicel-only) by the U.S. FDA in April 2023 for allogeneic stem cell transplant.

Title: [A Phase I/II Study of GDA-201. Cryopreserved Nicotinamide-Enhanced Allogeneic Natural Killer Cells in Patients with Relapsed/Refractory B-cell Lymphoma](#)

Abstract Number: 255

Lead Author: Brian C. Shaffer, Associate Professor of Medicine and Head of the Adult Mismatched Donor Sub-Program at Memorial Sloan Kettering Cancer Center in New York

Date and Time: February 22, 6:45-7:45 p.m. ET

- **Abstract highlights:** This is an ongoing multicenter Phase 1 study of allogeneic cryopreserved NK cell therapy candidate GDA-201 in patients with relapsed/refractory B-cell CD20 positive non-Hodgkin lymphoma. Preliminary data for the 10 patients enrolled in the first three of four total cohorts, who were heavily pretreated with a median of six prior lines of therapy including CAR-T cell therapy and hematopoietic stem cell transplant, showed no infusion reactions, dose limiting toxicities or related serious adverse events reported in patients treated with doses up to 1×10^8 cells/kg GDA-201 in combination with rituximab. Marked shrinkage of target lesions was observed in five patients and efficacy evaluation showed two patients with complete response, two with partial response and one with stable disease. Two patients treated had cytokine release syndrome. There were no reported cases of immune effector cell associated neurotoxicity syndrome or graft versus host disease.

About GDA-201

GDA-201 is an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. A multicenter Phase 1 study of GDA-201 for the treatment of non-Hodgkin lymphoma is ongoing (NCT05296525). Results are expected in Q1 2024.

GDA-201 is an investigational cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

Omisirge® (omidubicel-only) 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.

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. PTLT manifests as a lymphoma-like disease favoring non-nodal sites. PTLT 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® (omidubicel-only), 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](#), [Facebook](#), [X](#) and [Instagram](#).

Cautionary Note Regarding Forward-Looking Statements

This press release may contain 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 Omisirge® (omidubicel-only), and the Company's cell therapy candidate, GDA-201. 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 14, 2023, and other filings that Gamida Cell makes with the SEC from time to time (which are available at 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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