



Gamida Cell Presents New Data on Allogeneic Stem Cell Therapy Omidubicel and Natural Killer (NK) Cell Therapy Candidate GDA-201 at Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 4, 2023

Data further characterize the mechanism for Gamida Cell's proprietary nicotinamide (NAM) technology's expansion and enhancement of cells

BOSTON, Nov. 04, 2023 (GLOBE NEWSWIRE) -- [Gamida Cell Ltd.](#) (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today shared new data on the impact of the company's proprietary nicotinamide (NAM) technology on its allogeneic stem cell therapy omidubicel and investigational natural killer (NK) cell therapy candidate GDA-201 at the Society for Immunotherapy of Cancer's (SITC) Annual Meeting in San Diego, CA.

Both omidubicel and GDA-201 are powered by Gamida Cell's proprietary NAM technology, which enhances and expands cells to create potentially curative cell therapies for patients with cancer. Omidubicel was approved under the brand name Omisirge™ (omidubicel-only) by the U.S. FDA in April 2023 for allogeneic stem cell transplant; GDA-201 is in Phase 1 study for the treatment of non-Hodgkin lymphoma (NCT05296525). Data on the first three cohorts of the Phase 1 study of GDA-201 were recently [reported](#).

"The data presented at SITC further our understanding of the effect of NAM in enhancing and expanding cells," said Ronit Simantov, MD, Chief Medical and Scientific Officer of Gamida Cell. "Our data characterize the unique cellular composition of omidubicel, which is enriched in myeloid populations and dendritic cells, providing a potential mechanism for rapid engraftment and immune reconstitution, and is associated with lower infection rates observed in patients transplanted with omidubicel. Similarly, our data on GDA-201 demonstrate the unique, active phenotype of our NK cells expanded in the presence of NAM."

Additional details are as follows:

Title: Significant myeloid and dendritic cellular enrichment of omidubicel graft suggests fast homeostatic proliferation of lymphoid populations

Abstract number: 336

Presenting author: Dima Yackoubov

Time: Saturday, November 4, 2023, 9:00 a.m. – 8:30 p.m. PDT

Location: Exhibit Halls A and B1

- **Highlights:** In this study, immunophenotyping was used to evaluate and characterize the cellular populations in the cultured fraction (CF) and non-cultured fraction (NF) of omidubicel (manufactured with Gamida Cell's proprietary NAM technology) compared to standard umbilical cord blood (UCB). Manufacturing significantly increased the total nucleated cells (1.2-1.6-fold) and myeloid cells (2.2-3.6-fold) in the omidubicel CF compared to UCB. In addition, high resolution analysis of the CF showed a 25-62-fold increase in myeloid populations and dendritic cells and an absence of mature lymphoid cell populations. The NF was found to contain 50-70% fewer total with a comparable percentage of T cells, B cells, NK cells and NK-T cells to UCB. The results of this phenotypic characterization of omidubicel provide a potential mechanism for the rapid engraftment and immune reconstitution observed in transplanted patients.

Title: GDA-201, nicotinamide (NAM) expanded NK cells derived from peripheral apheresis, show unique culture kinetics and increased expansion

Abstract number: 401

Presenting author: Avner Yeffet, Ph.D.

Time: Friday, November 3, 2023, 9:00 a.m. – 7:00 p.m. PDT

Location: Exhibit Halls A and B1

- **Highlights:** This study evaluated the impact of Gamida Cell's NAM technology on NK cell kinetics. During the first days of expansion, NAM increased the survival of the feeder cells (45% on day 2-3 vs 13% on day 2-3) and prolonged their support in NK cell expansion, resulting in higher fold expansion persisting up to 21 days. In addition, NK cells expanded using NAM showed significantly higher cytotoxicity against leukemia cells (from a killing cytotoxicity function of 62.54% without NAM to 81.84% with NAM), and preservation of the NK cells in a partially mature state with low expression of CD57. These data provide further evidence for the unique cell culture kinetics of NAM-NK cells, GDA-201, which is currently being evaluated in a Phase 1 clinical trial in patients with non-Hodgkin lymphoma.

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. 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 , 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](#), [X](#), [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 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 August 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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