Gamida Cell Data Presented at the 2024 Tandem Meetings of ASTCT® and CIBMTR®

February 23, 2024

Expanded access program (EAP) data for omidubicel are consistent with Phase 3 trial results on rates of hematopoietic recovery and infections following stem cell transplant with Omisirge® (omidubicel-onlv)

Preliminary data presented on GDA-201, Gamida Cell's natural killer (NK) cell therapy candidate in ongoing Phase 1 study for non-Hodgkin lymphoma, show promising early evidence of anti-tumor activity

BOSTON, Feb. 23, 2024 (GLOBE NEWSWIRE) -- Gamida Cell Ltd. (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today presented data highlighting its expanded access program (EAP) for FDA-approved allogeneic stem cell therapy Omisirge® (omidubicel-onlv) and Phase 1 data for its 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 take place February 21-24 virtually and in person in San Antonio, Texas.

"The data presented at Tandem provide further evidence of the potential of Gamida Cell's nicotinamide (NAM) technology to develop potentially curative therapies by expanding and enhancing cells," said Ronit Simantov, MD, Chief Medical and Scientific Officer of Gamida Cell. "The EAP study provided the opportunity to treat patients after completion of enrollment of the Phase 3 trial and prior to the approval of Omisirge. It allowed for institutional variability in conditioning regimens and supportive care, more closely reflecting the real-world environment. Data were consistent with previous studies, showing that patients transplanted with omidubicel had rapid hematopoietic recovery and a low rate of serious infections post-transplant."

"The Phase 1 data on our natural killer (NK) cell candidate GDA-201 further support the anti-tumor activity of our NAM-enhanced cellular therapy, and today marked the first presentation of study results using our cryopreserved, readily available formulation," Simantov added.

Reporting on omidubicel's EAP data, principal investigator Mitchell E. Horwitz, MD, Stem Cell Transplant Specialist and Professor of Medicine at Duke Cancer Institute, said, "I am highly encouraged by the results in the omidubicel expanded access program. The potential for rapid hematopoietic recovery post-transplant observed with omidubicel could make a meaningful impact on patient health. I am pleased to see that the EAP results are consistent with data from the Phase 3 study."

Additional details on the presentations are as follows:

Title: Omidubicel-onlv 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. CT

- **Presentation highlights**: In this expanded access program (EAP) evaluating outcomes in 29 patients with hematologic malignancies following allogeneic hematopoietic stem cell transplant with omidubicel, outcomes were overall consistent with those from omidubicel's Phase 3 study. Eligible patients ≥12 years of age received myeloablative conditioning, prophylactic medications and supportive care per individual institutional standards. Median time to neutrophil and platelet engraftment were 12 and 34 days, respectively. Results were also similar to the Phase 3 study for infection (first grade 2-3 bacterial / invasive fungal infections at 100 days posttransplant: 18%), graft-versus-host-disease (grades 3-4: 19%), disease-free survival (79%) and overall survival (87%). Demographics of transplanted patients were 55% White, 21% Asian, 17% Black, and 7% other, consistent with the Phase 3 trial, in which >40% of the study participants were racially or ethnically diverse. Omidubicel was approved under the brand name Omisirge® (omidubicel-onlv) 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. CT

- **Presentation highlights**: In this 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 first 12 patients were presented. Patients were heavily pretreated with a median of six prior lines of therapy including CAR-T cell therapy and hematopoietic stem cell transplant. Patients were treated with doses up to $2x10^8$ cells/kg GDA-201 in combination with rituximab. There were no infusion reactions, dose-limiting toxicities or related serious adverse events.

Seven patients exhibited a decrease in tumor burden. Efficacy evaluation using Lugano criteria showed three patients with complete response, two with partial response and two with stable disease. Cytokine release syndrome was reported in two patients (grade 1 and grade 2, respectively). There were no cases of immune effector cell associated neurotoxicity syndrome or graft versus host disease reported. Treatment and evaluation of patients in the fourth cohort of the study at the highest dose level of $2x10^8$ cells/kg is ongoing. Full results are expected in Q1 2024.

Posters are available at: https://www.gamida-cell.com/our-rd/

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-onlv), 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.

About GDA-201
GDA-201 is an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. NAM-modified NK cells have previously been shown to have enhanced metabolic fitness, resistance to oxidative stress and potent cytotoxicity. 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-onlv) 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 Prescribing Information, including Boxed Warning.

About Gamida Cell
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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-onlv), 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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Source: Gamida Cell, Ltd