Data Presented on Gamida Cell's Omidubicel, GDA-201 at the 2023 Tandem Meetings of ASTCT and CIBMTR

February 18, 2023

New data add to the body of evidence supporting efficacy of omidubicel, Gamida Cell's lead product candidate, which has a target PDUFA action date with U.S. Food and Drug Administration (FDA) of May 1, 2023

New data for GDA-201, Gamida Cell's natural killer (NK) cell therapy candidate in ongoing Phase 1/2 study for non-Hodgkin lymphoma, show robust immune system engagement and high cytotoxicity levels

BOSTON--(BUSINESS WIRE)--Feb. 18, 2023-- Gamida Cell Ltd. (Nasdaq: GMDA), a cell therapy pioneer working to turn cells into powerful therapeutics, today announced that two oral presentations and a poster presentation highlighting Gamida Cell's investigational product candidates, omidubicel and GDA-201, were shared at the 2023 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 meetings took place February 15-19 virtually and in person in Orlando, Florida.

"The data presented at Tandem demonstrate Gamida Cell's expertise in developing potent, potentially curative cell therapies for patients with hematologic malignancies," said Ronit Simantov, M.D., chief medical and scientific officer of Gamida Cell. "The translational data from our Phase 3 study of omidubicel, our lead product candidate, show faster, multi-faceted immune response – as quickly as seven days—in omidubicel-treated patients compared to standard cord blood. These data add to the substantial body of knowledge that supports omidubicel's potential, if approved, as a new advanced cell therapy donor source for patients in need of an allogeneic stem cell transplant. The data on GDA-201, our NK cell therapy candidate in Phase 1/2 development for non-Hodgkin lymphoma, provide further characterization of its phenotype and functionality, and demonstrate its activity in triggering an adaptive immune response. These data advance our understanding of GDA-201's potential as a well-differentiated NK cell therapy."

Reporting on translational data from a Phase 1 study of a fresh formulation of GDA-201, external investigator Veronika Bachanova, M.D., Ph.D., professor at the University of Minnesota Medical School, said, "The GDA-201 treatment results in engagement with the adaptive immune system, which is what we would hope for from an NK cell therapy. The high T cell infiltration to the tumor site three to 16 days post GDA-201 administration points to the recruitment of the adaptive immune system, and signals the potential for durable effectiveness. These data elaborate on previous results that show the safety and preliminary evidence of activity of GDA-201 in patients with relapsed refractory non-Hodgkin lymphoma."

Additional details about the presentations are as follows:

Title: GDA-201: A Cryopreserved, Readily Available Formulation of Nicotinamide-Enabled Natural Killer Cells, Shows Increased Potency and Enhanced Cytotoxicity
Abstract Number: 204
Lead Author: Yael Yoffe-Mizrahi, Ph.D.; Associate Director and Head of Natural Killer Pipeline at Gamida Cell

- **Highlights:** GDA-201 cells were tested for viability, phenotyping, function and potency. Previous characterization of GDA-201 showed high levels of CD56, CD16, CD49a and CD62L expression, and low levels of CD57, as well as low levels of immune checkpoints such as LAG3 and CD200R. The new analyses showed that cryopreserved GDA-201 exhibited high viability (>90%), and high purity up to 12 months post-manufacturing, and preserved the ability to proliferate post-thaw. GDA-201 maintained high levels of expression of CD16, which mediates antibody-dependent cellular toxicity, and CD62L, which is a homing and retention marker. GDA-201 also demonstrated high potency, based on intracellular secretion of TNF-alpha & IFN-gamma and extracellular degranulation marker CD107a.

Title: Tumor Microenvironment Spatial Analysis after Adoptive NK Cell Therapy for Lymphoma Revealed Cross-Talk with Adaptive T Cell Immunity
Abstract Number: 81
Lead Author: Veronika Bachanova, M.D., Ph.D.; Professor at the University of Minnesota Medical School

- **Highlights:** This presentation highlights the novel observations of "on treatment" tumor biopsies from eight patients treated with GDA-201 in a Phase 1 study. Spatial analysis demonstrated that NK cells infiltrated the lymph nodes at low frequencies (<1% of all cells in the tumor microenvironment). GDA-201 cells were undetectable after 14 days. Remarkably, T cells were observed in 50-95% of tumor site cellularity. Most biopsies obtained as early as three to seven days post-infusion showed strong indications of widespread tumor death. These observations suggest that GDA-201 infusions trigger profound immune microenvironment changes, supporting the influx of host T cells early post GDA-201 infusion. This further suggests the engagement of the adaptive immune system, and effective tumor elimination.

Title: Longitudinal Immune Reconstitution Profiling Suggests Anti-Viral Protection after Transplantation with Omidubicel: A Phase 3 Substudy
Abstract Number: 84
Lead Author: Roei Mazor, M.D., Ph.D.; Head of the Clinic of Histiocytic Neoplasms at Assuta Medical Center and Medical Director at Gamida Cell

- **Highlights:** New data on peripheral blood lymphocyte counts measured in correlation with time to neutrophil and platelet engraftment in omidubicel transplanted and standard cord blood transplanted patients. Seven days post-transplant, omidubicel transplanted patients showed a statistically significant correlation between CD3+/CD4+ T cell counts and time to neutrophil engraftment. Similar correlations were noted between CD3+/CD8+/CD19+ cell counts and time to platelet engraftment. Patients transplanted with standard cord blood showed no such correlations at Day 7 post-transplant, and only began to show correlations starting at 14 days post-transplant. Data support past findings that omidubicel stimulates a faster immune response than standard cord blood and may also explain the lower incidence of serious bacterial, fungal and viral infections for omidubicel transplanted patients.

Presentations are available at gamida-cell.com/our-rd.

About Omidubicel

Omidubicel is an advanced cell therapy candidate for allogeneic hematopoietic stem cell (bone marrow) transplant that, if approved, has the potential to expand access and improve outcomes for patients with blood cancers. Omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment in comparison to standard umbilical cord blood in an international, multi-center, randomized Phase 3 study (NCT02730299) in patients with hematologic malignancies undergoing allogeneic bone marrow transplant. The Phase 3 study also showed reduced time to platelet engraftment, reduced infections and fewer days of hospitalization. One year post-transplant data showed sustained clinical benefits with omidubicel as demonstrated by significant reduction in infectious complications as well as reduced non-relapse mortality and no significant increase in relapse rates nor increases in graft-versus-host-disease (GvHD) rates. Omidubicel is the first stem cell transplant donor source to receive Breakthrough Therapy Designation from the FDA and has also received Orphan Drug Designation in the US and EU. Omidubicel has a PDUFA target action date of May 1, 2023.

Omidubicel is an investigational stem cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority. For more information about omidubicel, please visit https://www.gamida-cell.com.

About GDA-201

GDA-201 is an intrinsic NK cell therapy candidate being investigated for the treatment of hematologic malignancies. Preclinical studies have shown that GDA-201 may address key limitations of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs. Furthermore, these data suggest GDA-201 may improve antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells. GDA-201 is the lead investigational candidate among a pipeline of enhanced and engineered intrinsic NK cell therapy candidates Gamida Cell is investigating as next-generation cell therapies. A multicenter Phase 1/2 study of GDA-201 for the treatment of non-Hodgkin lymphoma is ongoing.

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.

About NAM Technology

Gamida Cell's NAM based technology is designed to expand the number and increase functionality of targeted cells, enhancing the intrinsic properties of targeted cells as they are developed into cell therapy candidates. In the case of omidubicel, our NAM based technology enhances the inherent 'stemness' of stem cells, expanding the number of cells and enhancing their ability to home to the bone marrow. In the case of NK cells, our proprietary technology reduces oxidative stress and preserves a highly cytotoxic phenotype.

About Gamida Cell

Gamida Cell is a cell therapy pioneer working to turn cells into powerful therapeutics. The company has a diverse pipeline of potentially curative cell therapy candidates for patients with blood cancers and solid tumors. We apply a proprietary expansion platform leveraging the properties of NAM to allogeneic cell sources including umbilical cord blood-derived cells and NK cells to create therapy candidates with the potential to redefine standards of care. These include omidubicel, an advanced cell therapy candidate for allogeneic hematopoietic stem cell transplant that, if approved, has the potential to expand access and improve outcomes for patients with blood cancers, and a line of enhanced and engineered NK cells targeted at solid tumors and hematologic malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, Twitter, Facebook or Instagram at @GamidaCellTx.

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 timing of the FDA's review of the BLA for omidubicel, and the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including omidubicel and 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 the impact that the COVID-19 pandemic could have on our business; 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, 2022, 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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Investor Contact

Courtney Turiano
Stern Investor Relations, Inc.
Courtney.Turiano@sternir.com
1-212-362-1200

Media Contact
Dan Boyle
Orangefiery
dan@orangefiery.com
1-818-209-1692

Source: Gamida Cell Ltd.