



Gamida Cell Announces Results of New Health Economic and Outcome Study Reporting Improved Health Equity and Health Outcomes With Omidubicel at 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings

April 25, 2022

- *Omidubicel is a first-in-class, advanced NAM-enabled stem cell therapy candidate with breakthrough and orphan drug designations being evaluated as the first potential allogeneic advanced cell therapy donor source for patients with blood cancers in need of a transplant*
- *Study highlights increases in omidubicel use in eligible patients were associated with higher proportions of patients undergoing allo-HCT and overall improved outcomes, with improvements being greater among racial minorities*
- *Only 20% of Black cancer patients can find a matched unrelated donor through donor registries, limiting access to disease-altering allogeneic hematopoietic stem cell transplants*
- *Omidubicel BLA submission on track to be completed in second quarter of 2022*

BOSTON--(BUSINESS WIRE)--Apr. 25, 2022-- [Gamida Cell Ltd.](#) (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapies for patients with solid and hematological cancers and other serious diseases, today announced the results of a new study demonstrating the potential impact of access to omidubicel on health disparities in allogeneic hematopoietic stem cell transplant in a poster presentation at the 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings (TCT), being held in Salt Lake City, UT, April 23-26, 2022.

The study, titled “Projected Impact of Omidubicel on Racial and Ethnic Disparities in Allogeneic Hematopoietic Cell Transplant Access and Outcomes for Patients with Hematologic Malignancies in the US,” leveraged a decision-tree model to project allo-HCT access and clinical outcomes in a hypothetical population of 10,000 allo-HCT-eligible patients in the U.S. with hematologic malignancies without an available match-related donor. The study concluded that broad use of omidubicel will extend access for allo-HCT-eligible patients, decrease time to transplant and improve clinical outcomes, notably among racial and ethnic groups with worse status quo outcomes. Projected increases in one-year overall survival ranged (with 20% omidubicel use among allo-HCT-eligible patients) from 2.5% for whites patients to 6.3% for Black patients. The study also concluded that higher levels of modeled omidubicel uptake were associated with greater improvements in clinical outcomes and greater reductions in racial disparities.

Previous studies indicate that non-white patients have a lower likelihood of finding an appropriate match in the U.S. public donor registries, with Black patients have a 16-20% chance of finding an appropriate match. Given that an allogeneic stem cell transplant is intended as a curative option, if patients cannot find an appropriate match they will not have access to allogeneic stem cell transplant, a potentially curative treatment. The Phase 3 study of omidubicel demonstrated the ability of the therapy to be used as a donor source for racially and ethnically diverse patients with 40% of patients enrolled in the study being non-white.

“Today, minority groups comprise only about 30% of all allogeneic hematopoietic stem cell transplant transplants, indicating that lack of access to a matched donor is a significant barrier to treatment in the current landscape,” said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. “This study is encouraging in that it projects that broad access to omidubicel has the potential to open up allo-HSCT as an effective treatment for more patients and address the barriers that have contributed to this alarming health disparity. These data are particularly encouraging as we continue to advance our rolling BLA submission to the FDA and move closer to bringing the therapy to more patients in need.”

Gamida Cell initiated a rolling Biologics License Application (BLA) submission for omidubicel in the first quarter of 2022 and is on-track to complete submission of all modules of the BLA in the second quarter of 2022.

In addition to this poster, two oral presentations and four additional poster presentations on omidubicel and a poster presentation on GDA-201, the company’s leading NK cell therapy program, will be shared during the conference. All poster presentations will be publicly available at www.ASTCT.org. Details below:

- **Title (Oral Presentation):** Hematopoietic Stem Cell Transplantation (HSCT) with Omidubicel is Associated with Enhanced Circulatory Plasmacytoid Dendritic Cells (pDC), NK Cells and CD4+ T Cells with Lower Rates of Severe Infections Compared to Standard Umbilical Cord Blood Transplantation (Part of Best Abstract Award Session)
 - **Presenting Author:** Paul Szabolcs, M.D., Division of Blood and Marrow Transplantation and Cellular Therapy, UPMC Children’s Hospital of Pittsburgh, Pittsburgh, PA
 - **Session Title:** Tandem Meetings Best Abstracts Session in the Scientific Track
 - **Session Date / Time:** Monday, April 25, 2022, 6:00 PM - 6:15 PM MT, SPCC, Ballroom D
- **Title (Oral Presentation):** Allogeneic HSCT with Omidubicel demonstrates sustained clinical improvement versus standard myeloablative UCBT: Final results of a Phase III randomized multicenter study
 - **Presenting Author:** Mitchell Horwitz, M.D., Professor of Medicine, Duke Cancer Institute
 - **Session Title:** Oral Abstract - Session L - Consider the Source: Stem Cell Grafts and Donors
 - **Session Date / Time:** Tuesday, April 26, 2022, 3:15 PM – 3:30 PM MT

- **Title (Poster):** Allogeneic Hematopoietic Stem Cell Transplantation (Allo-HSCT) With Omidubice1: Long-Term Follow-Up From A Single Center (ASH Encore)
 - **Lead Author:** Chenyu Lin, M.D., Department of Medicine, Division of Hematologic Malignancies and Cellular Therapy, Duke University Medical Center, Durham, NC
- **Title (Poster):** Total Costs of Care and Complication Rates Among Patients with Hematologic Malignancies Who Receive Allogeneic Hematopoietic Cell Transplants in the US
 - **Lead Author:** Richard Maziarz, M.D., Professor of Medicine, Medical Director Adult Blood and Marrow Stem Cell Transplant Program, Oregon Health and Science University, Portland, OR
- **Title (Poster):** Hospitalization and Healthcare Resource Use of Omidubice1 Vs Umbilical Cord Blood (UCB) for Hematological Malignancies in a Global Randomized Phase III Clinical Trial Setting
 - **Lead Author:** Navneet Majhail, M.D., Taussig Cancer Institute, Department of Hematology and Oncology, Cleveland Clinic, Cleveland, OH
- **Title (Poster):** HRQOL following transplantation with omidubice1 versus UCB in patients with hematologic malignancies: Results from a Phase III randomized , multicenter study
 - **Lead Author:** Mitchell Horwitz, M.D., Professor of Medicine, Duke Cancer Institute
- **Title (Poster):** Transcriptional and Metabolic Profiling of Nicotinamide-Enhanced Natural Killer (NAM-NK) Cells (GDA-201)
 - **Lead Author:** Dima Yackoubov, Scientist, Gamida Cell

About Omidubice1

Omidubice1 is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell transplant for patients with hematologic malignancies (blood cancers), for which it has been granted Breakthrough Status and orphan drug designation by the FDA. Omidubice1 is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). For more information on clinical trials of omidubice1, please visit [the Gamida Cell website](#).

Omidubice1 is an investigational therapy, and its safety and efficacy have not been established by the FDA or any other health authority.

About NAM Technology

Our NAM-enabling technology is designed to enhance the number and functionality of targeted cells, enabling us to pursue a curative approach that moves beyond what is possible with existing therapies. Leveraging the unique properties of NAM (nicotinamide), we are able to enhance, expand and metabolically modulate multiple cell types — including stem cells and natural killer cells — with appropriate growth factors to maintain the cells' active phenotype and enhance potency. This allows us to administer a therapeutic dose of cells that may help cancer patients live longer better lives.

About Gamida Cell

Gamida Cell is pioneering a proprietary NAM-enabled immunotherapy pipeline of diverse potentially curative cell therapies for patients with solid tumor and blood cancers and other serious blood diseases. We apply a proprietary platform leveraging the properties of NAM to allogeneic cell sources including umbilical cord blood-derived cells and NK cells to create therapies with potential to redefine standards of care. These include omidubice1, an investigational product with potential as a life-saving alternative for patients in need of transplant, and a line of modified and unmodified NAM-enabled NK cells targeted at solid tumor and hematological malignancies. For additional information on Gamida Cell, 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 initiation and progress of, and data reported from, the clinical trials of Gamida Cell's product candidates (including GDA-201), anticipated regulatory filings and the potentially life-saving or curative therapeutic and commercial potential of omidubice1. 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, and including the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; 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, and in the endeavor of building a business around such product candidates. 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 24, 2022, as amended, 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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