



Gamida Cell Announces Data to be Presented at 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings

January 7, 2022

BOSTON--(BUSINESS WIRE)--Jan. 7, 2022-- [Gamida Cell Ltd.](#) (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, today announced eight presentations at the 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings (TCT) being held in Salt Lake City, UT, from February 2-6, 2022.

New data and analyses on omidubicel will be presented including an oral presentation by Dr. Mitchell Horwitz of Duke Cancer Institute detailing one-year post-transplant follow up from the phase 3 study; a poster by Dr. Horwitz presenting health-related quality of life data; a new analysis of the projected impact of omidubicel on racial and ethnic disparities in allogeneic hematopoietic cell transplant to be presented by Dr. Usama Gergis of Jefferson University; and an abstract which has received TCT's Best Abstract Award to be presented by Dr. Paul Szabolcs from the Children's Hospital of Pittsburgh providing updated analyses of immune reconstitution data in patients transplanted with omidubicel during the phase 3 study.

Details about the TCT presentations are as follows:

Title: Allogeneic Hematopoietic Stem Cell (Allo-HSCT) Transplant with Omidubicel Demonstrates Sustained Clinical Improvement Versus Standard Myeloablative Umbilical Cord Blood Transplantation (UCBT): Final Results of a Phase III Randomized, Multicenter Study (oral presentation)

Abstract Number: 86

Lead Author: Mitchell Horwitz, M.D., Professor of Medicine, Duke Cancer Institute

Time: Sunday, February 6, 2022, 12:50-1:10 p.m.

- **Abstract highlights:** One-year post-transplant follow up from the omidubicel Phase 3 trial showed that the advantages of early engraftment and lower infections with omidubicel translated into long term benefits in the first year post-transplant, as demonstrated by reduction in non-relapse mortality and no increase in relapse rates compared to UCBT. There was a continued trend toward improved OS in favor of the omidubicel arm over time (73% vs 60%). The overall and sustained clinical benefit of omidubicel makes it an important addition to the options for allogeneic HSCT.

Title: Health-Related Quality of Life (HRQL) Following Transplantation with Omidubicel Versus UCB In Patients with Hematologic Malignancies: Results from a Phase III Randomized, Multicenter Study (poster)

Abstract Number: 509

Lead Author: Mitchell Horwitz M.D., Professor of Medicine, Duke Cancer Institute

Time: February 2-5, 2022

- **Abstract highlights:** This study compared changes in HRQL measures (FACT-G and EQ-5D) that were assessed in the Phase III study of omidubicel. Along with statistically significantly faster time to engraftment, shorter hospitalizations and lower infection risk, omidubicel was associated with meaningfully greater preservation or improvement of important HRQL domains compared to UCB.

Title: Projected Impact of Omidubicel on Racial and Ethnic Disparities in Allogeneic Hematopoietic Cell Transplant (allo-HCT) Access and Outcomes for Patients with Hematologic Malignancies in the US (poster)

Abstract Number: 325

Lead Author: Usama Gergis, M.D., MBA, Director, Stem Cell Transplant and Cellular Therapy Program, Jefferson University

Time: February 2-5, 2022

- **Abstract highlights:** The under-representation of racial and ethnic minorities in donor registries is well-established and a source of inequity in access to care. Over 40% of patients enrolled in the omidubicel Phase III study were racial and ethnic minorities. The study assessed the projected impact of omidubicel access on racial and ethnic health disparities in a projection model. Broad access to omidubicel was projected to decrease time to allo-HCT and improve allo-HCT outcomes overall, with the greatest improvements among racial and ethnic groups least served by current graft sources, thus helping to reduce racial disparities and improving health equity in allo-HCT care.

Title: Total Costs of Care and Complication Rates Among Patients with Hematologic Malignancies Who Receive Allogeneic Hematopoietic Cell Transplants (allo-HCT) in the US (poster)

Abstract Number: 334

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

Time: February 2-5, 2022

- **Abstract highlights:** A commercial claims and encounters database was utilized to quantify the total cost of care associated with allo-HCT and real-world complication rates after allo-HCT among US commercially insured patients. The

study concluded that patients with hematologic malignancies undergoing allo-HCT experienced significant health resource use and costs post-HCT. Hospitalizations accounted for 80% of the total costs. Complications, especially acute GVHD and infections, were commonly observed in post-transplant medical billings, which may still underestimate the full clinical incidence. Reducing need for in-patient care can significantly reduce total cost of care in this population.

Title: 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 (winner of TCT's Best Abstract Award; oral presentation; initial data presented at the American Society of Hematology Annual Meeting 2021 to be updated for TCT)

Abstract Number: 5

Lead Author: Paul Szabolcs, M.D., Division of Blood and Marrow Transplantation and Cellular Therapy, UPMC Children's Hospital of Pittsburgh, Pittsburgh, PA

Time: Friday, February 4, 2022, 6:20-6:35 p.m.

Title: Transcriptional and Metabolic Profiling of Nicotinamide-Enhanced Natural Killer (NAM-NK) Cells (GDA-201) (poster; initial data presented at Society for Immunotherapy of Cancer Annual Meeting 2021 to be updated for TCT)

Abstract Number: 266

Lead Author: Dima Yackoubov, Scientist, Gamida Cell

Time: February 2-5, 2022

Title: Hospitalization and Healthcare Resource Use of Omidubicel vs Umbilical Cord Blood (UCB) for Hematological Malignancies in a Global Randomized Phase III Clinical Trial Setting (poster, encore presentation from American Society of Hematology Annual Meeting 2021)

Abstract Number: 419

Lead Author: Navneet Majhail, M.D., Taussig Cancer Institute, Department of Hematology and Oncology, Cleveland Clinic, Cleveland, OH

Time: February 2-5, 2022

Title: Allogeneic Hematopoietic Stem Cell Transplantation (Allo-HSCT) with Omidubicel: Long-Term Follow-Up from a Single Center (poster; encore presentation from American Society of Hematology Annual Meeting 2021)

Abstract Number: 322

Lead Author: Chenyu Lin, M.D., Department of Medicine, Division of Hematologic Malignancies and Cellular Therapy, Duke University Medical Center, Durham, NC

Time: February 2-5, 2022

About Omidubicel

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant for patients with hematologic malignancies (blood cancers), for which it has been granted Breakthrough Status by the FDA. Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn[®], which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

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

About GDA-201

Gamida Cell applied the capabilities of its nicotinamide (NAM)-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201, the lead candidate in the NAM-enabled NK cell pipeline, has demonstrated promising initial clinical trial results, as reported at the 2020 American Society of Hematology (ASH) Annual Meeting & Exposition¹. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and *in vivo* retention and proliferation in the bone marrow and lymphoid organs. Furthermore, GDA-201 improves antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells. For more information about GDA-201, please visit <https://www.gamida-cell.com>.

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

About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapies for patients with solid tumor and blood cancers and other serious blood diseases. 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 therapies with potential to redefine standards of care. These include omidubicel, an investigational product with potential as a life-saving alternative for patients in need of bone marrow transplant, and a line of modified and unmodified NAM-enabled NK cells targeted at solid tumor and hematological 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 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 omidubicel. 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 20-F, filed with the Securities and Exchange Commission (SEC) on March 9, 2021, 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.

¹ Bachanova, et al. ASH 2020. Abstract #63.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220107005455/en/): <https://www.businesswire.com/news/home/20220107005455/en/>

For investors:

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

For media:

Rhiannon Jeselonis
Ten Bridge Communications
rhiannon@tenbridgecommunications.com
1-978-417-1946

Source: Gamida Cell Ltd.