Gamida Cell Presents Updated One-Year Post-Transplant Follow Up Data from Phase 3 Study of Omidubicel at 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings

April 27, 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*
- *Updated data from oral presentation demonstrates overall survival trend due to early engraftment and lower infections with omidubicel*
- *Concludes that HSCT with omidubicel results in rapid hematopoietic recovery, reduced rates of infections and no increase in GvHD rates compared with standard UCB*

BOSTON--(BUSINESS WIRE)--Apr. 27, 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 updated one-year post-transplant data presented on omidubicel 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.

In an oral presentation titled **"**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," Mitchell Horwitz, M.D., Professor of Medicine, Duke Cancer Institute, shared one-year post-transplant follow up data from the omidubicel Phase 3 trial. The data showed sustained clinical benefits in the first-year post-transplant with omidubicel, as demonstrated by significant reduction in infectious complications. Results also showed reduction in non-relapse mortality and no significant increase in relapse rates with omidubicel, compared to UCBT (23% vs. 18%). It was concluded that HSCT with omidubicel results in rapid hematopoietic recovery, reduced rates of infections and no increase in GvHD rates compared with standard UCB. 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.

"In allo-HSCT, early engraftment and lower infections are the key predictors of long-term success for patients," said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell, "We are encouraged by the continuous positive and sustained results from patients involved in the Phase 3 trial of omidubicel, now one-year out from treatment. These results provide promising rationale that omidubicel could become a compelling treatment option for patients in need of an allo-HSCT transplant."

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 total, Gamida Cell is presenting two oral and six poster presentations at TCT 2022, including an oral presentation that was selected as a TCT Best Abstract. All poster presentations are publicly available at www.ASTCT.org.

About Omidubicel

Omidubicel 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. Omidubicel 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 omidubicel, please visit the Gamida Cell website.

Omidubicel 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 omidubicel, 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 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 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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