



Gamida Cell Presents New Omidubicel Data at 63rd ASH Annual Meeting

December 11, 2021

- *Oral presentation demonstrated rapid and sustained T cell and B cell recovery following transplantation with omidubicel in a subset of patients in Phase 3 study, providing mechanistic support for reducing viral infections*
- *Additional poster presentation highlighting long-term data from single-center study with 10-year follow-up after omidubicel transplantation showing omidubicel continues to be safe and effective with no unexpected long-term complications*

BOSTON--(BUSINESS WIRE)--Dec. 11, 2021-- [Gamida Cell Ltd.](#) (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, presented clinical updates on omidubicel in two presentations on the first day of the 63rd American Society of Hematology (ASH) Annual Meeting being held in Atlanta, Georgia and virtually December 11-14, 2021.

In an oral presentation titled "Hematopoietic Stem Cell Transplantation (HSCT) with Omidubicel is Associated with Robust Immune Reconstitution and Lower Rates of Severe Infection Compared to Standard Umbilical Cord Blood Transplantation," Gamida Cell shared data from an analysis of a subset of 37 patients from the Phase 3 randomized trial of omidubicel. The analysis was aimed at investigating the reduced infection rates observed in the study and showed that the omidubicel-treated patients had more rapid recovery of a wide variety of immune cells including CD4+ T cells, B cells, NK cells and dendritic cell subtypes. The robust recovery of the immune system provides rationale for fewer severe bacterial, fungal and viral infections in patients treated with omidubicel. Further analyses are ongoing to further characterize the immune recovery following omidubicel transplantation.

"These results demonstrating rapid and functional reconstitution of the immune cells - particularly the T cell recovery which is known to lag in cord blood transplants - provides mechanistic support for the lower rates of severe infection observed in the omidubicel-treated patients," said Paul Szabolcs, M.D., Division of Blood and Marrow Transplantation and Cellular Therapy, UPMC Children's Hospital of Pittsburgh. "These data provide encouraging support for patients suffering from blood cancers who are particularly vulnerable to devastating infections following transplant."

An additional poster presentation unveiled today, "Allogeneic Stem Cell Transplantation with Omidubicel: Long-Term Follow-up from a Single Center," includes outcomes of 22 patients in the Phase 1 and 2 studies of omidubicel at Duke University over a 10-year period and shows long-term sustained bone marrow function and immune recovery. With a median follow-up of 2.3 years the estimated 10-year overall survival (OS) is 48.5% and disease-free survival (DFS) is 43.6%, with no major and or unexpected long-term complications. Durable hematopoiesis was observed at up to 10 years with one case of secondary graft failure and no secondary malignancies.

"Following our positive Phase 3 study results that showed enhanced hematopoietic recovery with omidubicel, it is extremely encouraging to see these additional data that demonstrate the durability of the graft, providing long-term recovery of the hematopoietic system," said Ronit Simantov, M.D., Chief Medical Officer of Gamida Cell. "The analyses presented at ASH build on our understanding of the clinical benefits of omidubicel and provide compelling evidence of its potential to change the outlook for a patient population in dire need of enhanced treatment options."

Gamida Cell will present additional clinical updates at ASH including two-year survival data for GDA-201, the company's lead NAM-enabled NK cell therapy, and an analysis of hospital and healthcare resource use for patients treated with omidubicel compared to cord blood transplantation. Both poster presentations will be publicly available on Monday, Dec. 13.

About Omidubicel

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with blood cancers. Omidubicel is the first bone marrow transplant graft to receive Breakthrough Therapy Designation from the U.S. FDA and has also received Orphan Drug Designation in the U.S. and EU. For more information about omidubicel, please visit <https://www.gamida-cell.com>.

Omidubicel 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 (including the timing of submission of the BLA for omidubicel to the FDA), commercialization planning efforts, and the potentially life-saving or curative therapeutic and commercial potential of omidubicel, and Gamida Cell's expectations for the expected clinical development milestones set forth herein.. 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.

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