



Gamida Cell Presents Updated Omidubichel Data During Best Abstract Award Session at 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings

April 26, 2022

- *Omidubichel 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*
- *Oral presentation includes updated analysis demonstrating enhanced circulatory pDC, NK cell and CD4+ T cell recovery with omidubichel*
- *Rapid immune cell recovery results in reduced rates of infection; no increase in GvHD rates compared with standard umbilical cord transplantation*
- *Omidubichel BLA submission is on track to be completed in the 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 that updated infection data on omidubichel in comparison to umbilical cord blood transplantation (UCB), was shared in an oral 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 presentation, which received a TCT Best Abstract Award, titled “Hematopoietic Stem Cell Transplantation (HSCT) with Omidubichel 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,” was presented by Paul Szabolcs, M.D., Division of Blood and Marrow Transplantation and Cellular Therapy, UPMC Children's Hospital of Pittsburgh, Pittsburgh, PA. The data from a sub-study of the Phase 3 randomized trial of omidubichel showed early and enhanced recovery of variety of immune cells, including circulatory dendritic cell subtypes, NK cells and CD4+ T cells within the first 28 days and sustained B-cell recovery from Day 28 onwards, and such immune recovery was associated with lower rates of severe infection. The data from an additional analyses of CD4+ subsets, T-cell receptor repertoire diversity and recent thymic emigrants support the long-term durability and functionality of the omidubichel graft.

“These data provide mechanistic support for the reduced infection rates seen with omidubichel-treated patients in the Phase 3 study, and clear demonstration of the benefits of omidubichel over standard cord blood transplantation, which can be associated with immune and hematopoietic recovery challenges that are devastating to patients,” said Ronit Simantov, M.D., Chief Medical Officer of Gamida Cell. “As we advance omidubichel through the FDA review process, these data demonstrate that the therapy has the potential to change the outlook for patients suffering from blood cancer, who all too often struggle with post-transplant recovery complications.”

Gamida Cell initiated a rolling Biologics License Application (BLA) submission for omidubichel 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. All poster presentations are publicly available at www.ASTCT.org.

About Omidubichel

Omidubichel 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. Omidubichel 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 omidubichel, please visit [the Gamida Cell website](#).

Omidubichel 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 omidubichel, 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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