Gamida Cell Presents Data Demonstrating the Impact of Transplantation with Omidubicel for Patients with Hematologic Malignancies at 2022 Cord Blood Connect Meeting

September 12, 2022

- Patients treated with omidubicel reported higher health-related quality of life scores during first-year post-transplant as compared to transplantation with umbilical cord blood (UCB)

- If approved, Omidubicel is projected to have meaningful improvement in patient outcomes among racial and ethnic minorities by potentially extending access to allogeneic hematopoietic cell transplant (allo-HCT) and reducing time to transplant

- Data highlights robust and diverse T cell reconstitution, with significantly higher recent thymic emigrant (RTE) T cells at 1 year, no loss of TCR repertoire diversity, providing mechanistic rationale for lower viral and overall infection rates observed in patients transplanted with omidubicel

BOSTON--(BUSINESS WIRE)--Sep. 12, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapies for patients with hematologic and solid cancers and other serious diseases, today announced the presentation of data supporting the potential of omidubicel for the treatment of patients with blood cancers in need of an allogeneic hematopoietic stem cell transplant at the 2022 Cord Blood Connect Meeting, being held in South Beach, Florida. “We continue to be encouraged by the growing body of evidence supporting the improved outcomes and lower infection rates seen in patients treated with omidubicel as well as the superior health-related quality of life scores compared to transplantation with UCB. We also demonstrated the potential role for omidubicel to address the unmet need for patients who are currently eligible for transplant, but cannot find a match,” said Julian Adams, chief executive officer of Gamida Cell. “Our omidubicel BLA was accepted by the FDA and granted priority review with a PDUFA date of January 30, 2023, which we believe further underscores the unmet need for patients with blood cancers in need of a stem cell transplant.”

Gamida Cell presented a poster titled “Health-Related Quality of Life (HRQL) Following Transplantation with Omidubicel Versus Umbilical Cord Blood (UCB) in Patients with Hematological Malignancies: Results from a Phase III Randomized, Multicenter Study,” which included an analysis of 75 patients to evaluate changes in HRQL measures between the two study arms. Outcomes evaluated included Functional Assessment of Cancer Therapy General (FACT-G) domain scores for physical, social/family, functional and emotional well-being, and EQ-5D-3L index scores at days 42, 100, 180 and 365 post-transplant. During the first-year post-transplant, patients receiving omidubicel had numerically superior average FACT-G domain and EQ-5D-3L index scores compared to UCB, with mean differences across time points ranging from 1.4-3.1 for physical well-being, 0-1.3 for social/family well-being, 0.5-1.4 for emotional well-being, 1.6-3.2 for functional well-being, and 0.03-0.09 for the EQ-5D-3L index score. The data suggest meaningfully greater preservation or improvement of important HRQL domains in patients treated with omidubicel compared to UCB. Learn more

Gamida Cell also presented a poster 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,” which featured an analysis of projected impact of allogeneic hematopoietic cell transplant (allo-HCT) access and clinical outcomes in a hypothetical population of 10,000 allo-HCT-eligible patients with hematologic malignancies lacking an HLA-matched related donor. Assuming 20% omidubicel use, the proportion of patients receiving allo-HCT increased by 71% in Black, 43% in Asian, 30% in Hispanic, and 5% in white patients. The model suggests that access to omidubicel, upon approval, is projected to decrease time to allo-HCT and improve patient outcomes, with the greatest improvements among the racial and ethnic groups underserved by the current standard of care. Learn more

In a poster titled “Hematopoietic Stem Cell Transplantation (HSCT) with Omidubicel Leads to Robust Recovery and Diversity of T cells” patients treated with omidubicel were found to have robust and diverse T cell constitution. In an analysis of the T-cell development of 37 patients, patients transplanted with omidubicel demonstrated higher numbers of Recent Thymic Emigrants (RTEs) in peripheral blood at one year post transplant compared to transplantation with UCB, which suggest faster thymopoiesis and provide mechanistic rational for the lower infection rates and improved outcomes in these patients. Learn more

All three posters were made available beginning Saturday, September 10, 2022, 6:15-7:45 p.m. ET, during the 2022 Cord Blood Connect Meeting.

About Omidubicel

Omidubicel is an advanced cell therapy candidate developed as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant for patients with blood cancers. Omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment in comparison to standard umbilical cord blood in an international, multi-center, randomized Phase 3 study (NCT0273029) in patients with hematologic malignancies undergoing allogeneic bone marrow transplant. The Phase 3 study also showed reduced time to platelet engraftment, reduced infections and fewer days of hospitalization. One-year post-transplant data showed sustained clinical benefits with omidubicel as demonstrated by significant reduction in infectious complications as well as reduced non-relapse mortality and no significant increase in relapse rates nor increases in graft-versus-host-disease (GvHD) rates. Omidubicel is the first stem cell transplant donor source to receive Breakthrough Therapy Designation from the FDA and has also received Orphan Drug Designation in the US and EU.

Omidubicel is an investigational stem cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority. For more information about omidubicel, please visit https://www.gamida-cell.com.

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 can 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. Additionally, our NAM technology improves the metabolic fitness of cells, allowing for continued activity throughout the expansion process.

About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapy candidates 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 therapy candidates 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 omidubicel), regulatory filings submitted to the FDA (including the potential timing of the FDA's review of the BLA for omidubicel), commercialization planning efforts, and the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including 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 Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (SEC) on August 15, 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.

[1]CIBMTR 2019 – allogeneic transplants in patients 12+ years with hematological malignancies.
[2]Gamida Cell market research

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