Gamida Cell Announces Omidubicel Data To Be Presented as an Oral Presentation at 64th ASH Annual Meeting

November 3, 2022

BOSTON--(BUSINESS WIRE)--Nov. 3, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapy candidates for patients with hematological and solid cancers and other serious diseases, today announced an oral presentation of a real-world analysis comparing the effectiveness of omidubicel to other allo-HCT donor sources from the Center for International Blood and Marrow Transplant Research (CIBMTR) database. These data are being presented at the 64th American Society of Hematology (ASH) Annual Meeting, which is being held in New Orleans from December 10-13, 2022.

“Data from our phase 3 study compared the safety and efficacy of omidubicel to standard cord blood. We are delighted to have the opportunity, in a podium presentation at ASH, to share the work we have done with CIBMTR, exploring their expansive real-world database and performing the first comparative efficacy analyses between omidubicel and other donor sources for patients undergoing allogeneic stem cell transplant,” said Ronit Simantov, M.D., Chief Medical and Scientific Officer of Gamida Cell. “These data reinforce the clinical relevance of the rapid time to neutrophil engraftment observed in patients transplanted with omidubicel, and support the potential use of omidubicel in patients with hematologic malignancies requiring transplant. We are diligently preparing to bring this important therapy to patients upon potential FDA approval.”

Details about the ASH presentation are as follows:

Title: Clinical Outcomes Following Allogeneic Hematopoietic Cell Transplantation with Omidubicel or Other Donor Sources in Patients with Hematologic Malignancies: Comparison of Clinical Trial Results to Center for International Blood and Marrow Transplant Research Database Controls
Session Title: 732. Allogeneic Transplantation: Disease Response and Comparative Treatment Studies: Clinical Outcome: Real World Studies Based on Database Analyses
Lead Author: Smitha Sivaraman, PhD.
Time: Saturday, December 10, 2022, 2:00 p.m. – 3:30 p.m. EST (session time) and 2:30 p.m. EST (presentation time)
Location: Ernest N. Morial Convention Center, 391 – 392

A prospective cohort analysis study to compare the effectiveness of omidubicel versus other allo-HCT donor sources (MUD, MMUD and haploidentical) used in clinical practice is being presented. The study compared data from the omidubicel (n=52) and control arms (n=56) of the phase 3 study with a cohort of similar patients derived from the CIBMTR database (n = 807) who had undergone transplant with matched unrelated donors, mismatched unrelated donors, or haploidentical donors. The analysis showed that omidubicel was associated with more rapid neutrophil recovery (median: 10 days) compared to all other donor sources (median 15-20 days; $p<0.001$). While platelet recovery took longer in the omidubicel cohort, rates of severe acute and chronic graft versus host disease (GVHD) were comparable. Importantly, analyses of non-relapse mortality, disease-free survival, and overall survival showed similar results among all donor sources. While the phase 3 study compared omidubicel to standard cord blood, these real-world data reinforce the clinical utility of omidubicel as a graft source in patients in need of an allogeneic stem cell transplant.

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.

The BLA for omidubicel has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2023. If approved, omidubicel will be the first allogeneic advanced stem cell therapy donor source for patients with blood cancers in need of a stem cell transplant.

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

View source version on businesswire.com: https://www.businesswire.com/news/home/20221102006193/en/

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

For media:
Heather DiVecchia
Director, Investor Relations and Corporate Communications
Heather@gamida-cell.com
1-617-892-9083

Source: Gamida Cell Ltd.