Gamida Cell Announces Data to Be Presented at 62nd ASH Annual Virtual Meeting

November 4, 2020

– Updated data from Phase 1 Study of GDA-201 to be presented during an oral session –

– New data on omidubicel in patients with severe aplastic anemia will also be presented –

BOSTON--(BUSINESS WIRE)--Nov. 4, 2020-- Gamida Cell Ltd. (Nasdaq: GMDA), a leading cellular and immune therapeutics company, today announced that updated data from the ongoing Phase 1 clinical study of GDA-201, an investigational, natural killer (NK) cell-based cancer immunotherapy for the treatment of patients with non-Hodgkin lymphoma, will be presented in an oral presentation at the American Society of Hematology (ASH) 62nd Annual Meeting, which is being held virtually from December 5-8, 2020. NK cell immunotherapies are thought to offer tremendous potential for transforming the care of hematologic malignancies. Gamida Cell is pioneering a novel approach that harnesses the power of its cell expansion technology, which uniquely improves antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells.

Additionally, new data from the ongoing Phase 1/2 study of omidubicel in patients with severe aplastic anemia will be shared in a poster presentation during the meeting. Omidubicel is an investigational advanced cell therapy in development as a potential life-saving treatment option for patients in need of a bone marrow transplant.

Omidubicel is also being evaluated in a Phase 3 study in patients with hematologic malignancies. Earlier this year, Gamida Cell reported that its Phase 3 study of omidubicel met its primary endpoint, demonstrating a highly statistically significant reduction in time to neutrophil engraftment, a key milestone in recovery from a stem cell transplant. Last month, Gamida Cell also reported that all three secondary endpoints for the study demonstrated statistical significance. The secondary endpoints in the study include outcomes for: platelet engraftment, infections and hospitalizations.

Details about the ASH presentations are as follows:

Title: Results of a Phase 1 Trial of GDA-201, Nicotinamide-Expanded Allogeneic Natural Killer (NK) Cells in Patients with Refractory Non-Hodgkin Lymphoma (NHL) and Multiple Myeloma
Abstract Number: 63
Lead Author: Veronika Bachanova, M.D., Ph.D., Division of Hematology, Oncology and Transplantation, University of Minnesota, Minneapolis, MN
Time: Saturday, December 5, 2020, 7:30 a.m. – 9:00 a.m. PT (session time) and 7:30 a.m. PT (presentation)

Title: Rapid Engraftment, Immune Recovery, and Resolution of Transfusion Dependence in Treatment-Refractory Severe Aplastic Anemia Following Transplantation with Ex Vivo Expanded Umbilical Cord Blood (Omidubicel)
Abstract Number: 1531
Lead Author: Mohamed Samour, M.D., Hematology Branch, National Heart, Lung, and Blood Institute, Bethesda, MD
Time: Saturday, December 5, 2020, 7:00 a.m. – 3:30 p.m. PT

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 hematologic malignancies (blood cancers). In both Phase 1/2 and Phase 3 clinical studies (NCT01816230, NCT02730299), omidubicel demonstrated rapid and durable time to engraftment and was generally well tolerated. Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn®, which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

Omidubicel is an investigational therapy, and its safety and efficacy have not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About GDA-201

Gamida Cell applied the capabilities of its NAM-based cell expansion technology to develop GDA-201, an innate natural killer (NK) cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs of NK cells expanded in culture. GDA-201 is in Phase 1 development through an investigator-sponsored study in patients with refractory non-Hodgkin lymphoma and multiple myeloma.[1]

GDA-201 is an investigational therapy, and its safety and efficacy has not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About Gamida Cell

Gamida Cell is an advanced cell therapy company committed to cures for patients with blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn or Twitter 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 the potential of NK cell immunotherapies and the continuation of Gamida Cell's clinical programs, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope and progress of Gamida Cell's clinical trials and other clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of Gamida Cell's public filing on Form 20-F, filed with the SEC on February 26, 2020, 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. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

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