Gamida Cell Presents Efficacy and Safety Results of Phase 3 Study of Omidubicel in Patients with Hematologic Malignancies at the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT)

March 15, 2021

-Abstract will be shared at Presidential Symposium and featured in this year's "Live with Best Abstracts" session-

BOSTON--(BUSINESS WIRE)--Mar. 15, 2021-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases, today announced the results of a Phase 3 clinical study of omidubicel presented in an oral session at the Presidential Symposium of the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2021). In addition to the Presidential Symposium, the session will be featured in a live panel discussion, "EBMT Talks: Live with the Best Abstracts."

"There is an acute need in stem cell transplantation to treat patients who do not have access to a matched donor, and the results of this global Phase 3 study demonstrate that omidubicel has the potential to address this critical gap," said Professor Guillermo F. Sanz, M.D., Ph.D., Head, Hematology Department, Hospital Universitario y Politécnico La Fe in Valencia, Spain. "In the study, treatment with omidubicel showed faster hematopoietic recovery, fewer bacterial and viral infections and fewer days in hospital. These pivotal data create a compelling case that omidubicel could transform outcomes for patients."

This clinical data set, which was also recently presented at the Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy (ASTCT) and Center for International Blood & Marrow Transplant Research (CIBMTR), or the TCT Meetings, was from the international, multi-center, randomized Phase 3 study of omidubicel designed to evaluate the safety and efficacy of omidubicel in patients with high-risk hematologic malignancies undergoing a bone marrow transplant compared to patients who received a standard umbilical cord blood transplant.

"The inclusion of the omidubicel Phase 3 results in these prominent sessions at EBMT 2021 and other recent prestigious peer-reviewed settings reinforce the strength of these data and the potential of omidubicel to make a meaningful impact in the hematopoietic bone marrow transplant treatment landscape," said Julian Adams, Ph.D., chief executive officer of Gamida Cell. "As always, we thank the patients and investigators in this global clinical trial for their contributions as we work to bring this potentially curative cell therapy to those whose future depends on stem cell transplantation but who do not have a matched donor."

The full presentation shared at the Presidential Symposium is available on the Gamida Cell website.

Details of Phase 3 Efficacy and Safety Results Shared at EBMT
Patient demographics including racial and ethnic diversity and baseline characteristics were well-balanced across the two study groups. The study's intent-to-treat analysis included 125 patients aged 13–65 years with a median age of 41. Diseases included acute lymphoblastic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, myelodysplastic syndrome or lymphoma. Patients were enrolled at more than 30 clinical centers in the United States, Europe, Asia, and Latin America.

Gamida Cell previously reported in May 2020 that the study **achieved its primary endpoint,** showing that omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment, a measure of how quickly the stem cells a patient receives in a transplant are established and begin to make healthy new cells, and a key milestone in a patient's recovery from a bone marrow transplant. The median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group ($p < 0.001$).

All three secondary endpoints demonstrated a statistically significant improvement among patients who were randomized to omidubicel in relation to patients randomized to the comparator group (intent-to-treat). Platelet engraftment was significantly accelerated with omidubicel, with 55 percent of patients randomized to omidubicel achieving platelet engraftment at day 42, compared to 35 percent for the comparator ($p = 0.028$). The rate of infection was significantly reduced for patients randomized to omidubicel, with the cumulative incidence of first grade 2 or grade 3 bacterial or invasive fungal infection for patients randomized to omidubicel of 37 percent, compared to 57 percent for the comparator ($p = 0.027$). Hospitalization in the first 100 days after transplant was also reduced in patients randomized to omidubicel, with a median number of days alive and out of hospital for patients randomized to omidubicel of 60.5 days, compared to 48.0 days for the comparator ($p = 0.005$). The details of these **data were first reported** in December 2020.

Data from the study relating to exploratory endpoints also support the clinical benefit demonstrated by the study's primary and secondary endpoints. There was no statistically significant difference between the two patient groups related to grade III/IV acute GvHD (14 percent for omidubicel, 21 percent for the comparator) or all grades chronic GvHD at one year (35 percent for omidubicel, 29 percent for the comparator). Transplants with umbilical cord blood, the comparator, have been historically shown to result in low incidence of GvHD in relation to other graft sources, and in this study, omidubicel demonstrated a similar GvHD profile. Non-relapse mortality was shown to be 11 percent for patients randomized to omidubicel and 24 percent for patients randomized to the comparator ($p = 0.09$).

These clinical data results will form the basis of a Biologics License Application (BLA) that Gamida Cell expects to submit to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2021.

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), for which it has been granted Breakthrough Status by the US Food and Drug

Administration. 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.[1,2] Based on the recently reported Phase 3 clinical study, in which omidubicel achieved statistically significant and clinical meaningful results in the prespecified primary and secondary endpoints, Gamida Cell plans to submit the full Biologics License Application (BLA) to the FDA in the fourth quarter of 2021. 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 established by the FDA 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 anticipated submission of a BLA for omidubicel, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to Gamida Cell's ability to prepare regulatory filings and the review process therefor; complications in Gamida Cell's plans to manufacture its products for commercial distribution; and 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 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, 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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[1] Gamida Cell press release, "Gamida Cell Announces Positive Topline Data from Phase 3 Clinical Study of Omidubicel in Patients with High-Risk Hematologic Malignancies," issued May 12, 2020. Last accessed August 31, 2020.

[2] Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. J Clin Oncol. 2019 Feb 10;37(5):367-374.

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