



Gamida Cell to Present Full Data from Phase 3 Study of Omidubichel at TCT, the Combined Transplantation and Cellular Therapy Meetings of ASTCT and CIBMTR

January 11, 2021

BOSTON--(BUSINESS WIRE)--Jan. 11, 2021-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases, today announced that the full results of the Phase 3 clinical trial of omidubichel will be presented for the first time at the TCT Meetings, the Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy (ASTCT) and Center for International Blood & Marrow Transplant Research (CIBMTR), which is being held virtually from February 8–12, 2021.

The international, multi-center, randomized Phase 3 study for omidubichel evaluated the safety and efficacy of omidubichel in patients with hematologic malignancies undergoing allogeneic bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant.

This will be the first presentation of the full efficacy and safety results of this study. Gamida Cell previously reported in 2020 top-line data for omidubichel, an advanced cell therapy under development as a potentially life-saving allogeneic hematopoietic stem cell transplant solution for patients with hematologic malignancies. Last May, Gamida Cell reported that the study [achieved its primary endpoint](#), demonstrating a highly statistically significant reduction in time to neutrophil engraftment, a key milestone in a patient's recovery from a bone marrow transplant. Last October, the company reported that the omidubichel phase 3 study [achieved its secondary endpoints](#) of platelet engraftment, infections, and hospitalizations.

Details about the presentation are as follows:

Title: Improved Clinical Outcomes with Omidubichel Versus Standard Myeloablative Umbilical Cord Blood Transplantation: Results of a Phase III Randomized, Multicenter Study

Lead Author: Mitchell E. Horwitz, M.D.

Time: Tuesday, February 9, 2021, 4:45-5:00 p.m. EST

About Omidubichel

Omidubichel 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), omidubichel demonstrated rapid and durable time to engraftment and was generally well tolerated. The company expects to submit a full biologics licensing application to the U.S. FDA in the second half of 2021. Omidubichel 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 omidubichel. For more information on clinical trials of omidubichel, please visit www.clinicaltrials.gov.

Omidubichel is an investigational therapy, and its safety and efficacy have not been established 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 timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, anticipated regulatory filings, launch readiness and FDA approval, commercialization efforts and Gamida Cell's expectations regarding its projected ongoing operating activities, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; 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 February 26, 2020 and its Report on Form 6-K furnished to the SEC on August 12, 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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