



Gamida Cell Announces Results from Phase 3 Study of Omidubichel to be Presented at the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT)

March 1, 2021

BOSTON--(BUSINESS WIRE)--Mar. 1, 2021-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases, today announced that results from the Phase 3 clinical trial of omidubichel will be 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), which is being held virtually March 14–17, 2021.

Details about the presentation are as follows:

Time: Monday, March 15, 2021, at 3:24 p.m. CET (10:24 a.m. EST)

Abstract Number: GS2-7

Title: Results of a Phase III Randomized, Multicenter Study Comparing Omidubichel with Standard Umbilical Cord Blood Transplantation (UCBT) in Patients with High-Risk Hematologic Malignancies Following Myeloablation

Lead Author: Professor Guillermo F. Sanz, M.D., Ph.D.

The abstract will also be featured in a live panel discussion, "EBMT Talks: Live with Best Abstracts," on March 15 at 6:10 p.m. CET (1:10 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), 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), omidubichel 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 omidubichel 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 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 the anticipated submission of a BLA for omidubichel, 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 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.

¹ Gamida Cell press release, "Gamida Cell Announces Positive Topline Data from Phase 3 Clinical Study of Omidubichel 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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