Gamida Cell Provides Update on Pre-BLA Meeting With FDA for Omidubicel

November 11, 2021

- Gamida Cell conducted pre-BLA meeting for omidubicel with FDA

- FDA requested revised analysis of manufacturing data generated at Gamida Cell's commercial manufacturing facility

- BLA submission expected in the first half of 2022

BOSTON--(BUSINESS WIRE)--Nov. 11, 2021-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, completed a Type B Pre-Biologics License Application (BLA) meeting with the U.S. Food and Drug Administration (FDA) for omidubicel, a potentially life-saving treatment for patients with blood cancers in need of stem cell transplant. The FDA requested that Gamida Cell provide revised analysis of the manufacturing data generated at Gamida Cell's wholly-owned commercial manufacturing facility to demonstrate the comparability to the omidubicel that was produced at the clinical manufacturing sites for the Phase 3 study. The FDA did not request additional clinical data to initiate the BLA submission once analytical comparability is demonstrated. The company will continue to work collaboratively with the FDA and anticipates submitting the BLA in the first half of 2022 in lieu of the company's previous plan to submit the BLA by the end of 2021.

"Despite the delay in timing to bring omidubicel to patients after a potential FDA approval, we are encouraged by the FDA's reaction to our Phase 3 data as the pivotal trial of omidubicel. We have gained further clarity with the FDA on the requirements for demonstrating comparability for our commercial manufacturing facility," said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. "With the FDA's feedback in hand, we believe that we are one step closer for omidubicel to be made available to patients in need."

Omidubicel, an investigational advanced cell therapy for allogeneic bone marrow transplant

Omidubicel is the foundational product based on Gamida Cell's proprietary NAM-enabled cell expansion technology. It is the first cell therapy for bone marrow transplant to receive Breakthrough Therapy Designation from the FDA. The BLA submission will be based on the results of an international, randomized Phase 3 study of omidubicel that was designed to evaluate the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing a bone marrow transplant compared to patients who received a standard umbilical cord blood transplant. The study achieved its primary endpoint, a statistically significant reduction in time to neutrophil engraftment, as well as all key secondary endpoints. A key milestone in a patient's recovery, neutrophil engraftment is a measure of how quickly the stem cells a patient receives in a bone marrow transplant are established and begin to make healthy new cells. In the Phase 3 study, the median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group ($p < 0.001$). Additionally, the study met key secondary endpoints related to the speed of platelet engraftment, decrease in infections and reduction in hospitalizations, all significant clinical measures in bone marrow transplant.

About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapies 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 therapies 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.

About Omidubicel

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant for patients with hematologic malignancies (blood cancers), for which it has been granted Breakthrough Status by the FDA. 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**.

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 (including the timing of submission of the BLA for omidubicel to the FDA), commercialization planning efforts and the potentially life-saving or curative therapeutic and commercial potential of omidubicel. 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 Annual Report on Form 20-F, filed with the Securities and Exchange Commission (SEC) on March 9, 2021, 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.

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