Gamida Cell Provides Update on Omidubicel BLA Submission

January 19, 2022

- *Planning to initiate rolling BLA submission for omidubicel following positive Type B meeting with FDA*
- *Full BLA submission on track for first half of 2022*

BOSTON--(BUSINESS WIRE)--Jan. 19, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, announced that following receipt of positive Type B meeting correspondence from the U.S. Food and Drug Administration (FDA) yesterday, the company plans to initiate a rolling Biologics License Application (BLA) submission for omidubicel, a potentially life-saving treatment for patients with blood cancers in need of stem cell transplant. As previously disclosed, in late 2021 the FDA requested a revised analysis of the manufacturing data generated at Gamida Cell's wholly owned commercial manufacturing facility to demonstrate the analytical comparability to the Lonza clinical manufacturing site that produced omidubicel for the Phase 3 study. Gamida Cell and the FDA have now reached alignment that analytical comparability has been established between the commercial manufacturing facility and the product that was manufactured for the Phase 3 study. Based on this demonstration of comparability, along with the positive clinical results of the Phase 3 study, the FDA has agreed that the initiation of a rolling BLA submission is appropriate. Additional clinical data will not be required to initiate the BLA submission.

"We are very pleased that our productive interactions with the FDA have resulted in alignment on the omidubicel manufacturing comparability analysis and agreement to initiate a rolling submission of our BLA application," said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. "Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the FDA and has the potential to be the first FDA-approved advanced cell therapy for allogeneic bone marrow transplant. Initiating the BLA submission will move us one step closer toward bringing potentially curative therapies to patients. We plan to complete the full BLA submission in the first half of this year, which will be an important achievement for Gamida Cell and the bone marrow transplant community."

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 blood cancers. Omidubicel is the first bone marrow transplant graft to receive Breakthrough Therapy Designation from the U.S. FDA and has also received Orphan Drug Designation in the U.S. and EU. For more information about omidubicel, please visit https://www.gamida-cell.com.

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 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.

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 (including GDA-201), 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, and Gamida Cell's expectations for the expected clinical development milestones set forth herein.. 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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