Gamida Cell Provides Key Program Updates and 2022 Financial Guidance

January 31, 2022

- *Initiating rolling BLA submission for omidubicel in the first quarter of 2022 with full BLA submission on track for first half of 2022*
- *Evaluating strategic alternatives for commercialization of omidubicel, including potential licensing or partnering*
- *Reducing operating expense to extend cash runway to fund activities into mid-2023 in consideration of the timeline for potential FDA approval of omidubicel*

BOSTON--(BUSINESS WIRE)--Jan. 31, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, today provided key program and business updates.

- **Initiating rolling BLA submission for omidubicel.** Following the recent receipt of positive Type B meeting correspondence from the U.S. Food and Drug Administration (FDA), Gamida Cell will initiate a rolling Biologics License Application (BLA) submission for omidubicel, a potentially life-saving treatment for patients with blood cancers in need of a stem cell transplant, in the first quarter of 2022 and plans to complete the full BLA submission in the first half of 2022.

- **Evaluating strategic alternatives for omidubicel**. In parallel with the planned BLA submission, the company will be assessing alternatives for the commercialization of omidubicel, including potential U.S. or global partnerships.

- **Reducing operating expenses.** With the objective of extending its cash runway into mid-2023, consistent with the timeline for potential U.S. approval of omidubicel, the company is reducing operating expenses primarily by implementing a workforce reduction of approximately 10% and delaying other hiring and planned spending in 2022.

- **Readying to advance GDA-201.** The company is addressing comments received from FDA in connection with the clinical hold placed on the IND submission for GDA-201, its lead NAM-enabled innate NK cell immunotherapy. Gamida Cell expects to initiate a company-sponsored Phase 1/2 clinical study in patients with follicular and diffuse large B-cell lymphomas in 2022.

- **Advancing genetically modified NK cell immunotherapy programs**. The company continues to advance itsNAM-enabled genetically modified NK pipeline, which utilizes CAR, membrane bound- and CRISPR-mediated strategies to increase targeting, potency and persistence against hematologic malignancies and solid tumors. The company plans to execute preclinical proof of concept studies for these genetically modified NK therapeutic targets and to select pipeline candidates for IND enabling studies by the end of 2022.

“We are pleased that productive interactions with the FDA enable us to initiate a rolling submission of the BLA for omidubicel this quarter and to complete the full BLA submission during the first half of this year,” said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. “As we advance omidubicel towards potential approval, we will be assessing strategic alternatives for the best way to bring this important therapy to patients, including potential U.S. or global commercialization partnerships. With the strategic steps we are taking, we believe Gamida Cell will be in a stronger position to support omidubicel through the regulatory approval process while we also continue to advance our NK cell pipeline programs, all as intended to serve our goal of providing access to life-saving cell therapies to patients in need.”

2022 Financial Guidance

Gamida Cell ended 2021 with approximately $96.1 million in cash and cash equivalents (unaudited). The company expects cash used for ongoing operating activities in 2022 to range from $60 million to $70 million in cash and cash equivalents based on its current operating plans. The company anticipates that its current cash will support the company’s ongoing operating activities into mid-2023, excluding any additional financing or business development activities that may be undertaken. Gamida Cell plans to report its fourth quarter and full-year 2021 financial results on March 16, 2022, at which time the company will provide an update on its 2022 milestones and more detailed financial guidance.

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. Gamida Cell has completed an international, multi-center, randomized Phase 3 study (NCT0273029) evaluating the safety and efficacy of omidubicel 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. That 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. The Phase 3 study also achieved its secondary endpoints of reduced time to platelet engraftment, reduced infections and shorter days of hospitalization. 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 GDA-201

Gamida Cell applied the capabilities of its nicotinamide (NAM)-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201, the lead candidate in the NAM-enabled NK cell pipeline, has demonstrated promising initial clinical trial results. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs. Furthermore, GDA-201 improves antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells. For more information about GDA-201, please visit https://www.gamida-cell.com.

GDA-201 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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