Gamida Cell to Present NAM-Enabled, Genetically Modified NK Cell Therapy Pipeline and Update on GDA-201 at Today's Virtual R&D Day

October 26, 2021

- *Company recently filed an IND application for GDA-201; FDA placed the application on Clinical Hold pending modifications to donor eligibility procedures and sterility assay qualification*
- *Today's presentations to highlight expanded NAM-enabled NK cell therapy platform including a new collaboration with the Dana-Farber Cancer Institute for GDA-601 targeting multiple myeloma*

BOSTON--(BUSINESS WIRE)--Oct. 26, 2021-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for cancer and other serious diseases, will be hosting a virtual R&D Day event detailing the company's proprietary NAM-enabled natural killer (NK) cell therapy pipeline today, Tuesday, October 26, at 8:00 a.m. ET. During the event, the company will highlight Gamida Cell's new programs leveraging next-generation, NAM-enabled, genetically modified NK cells in development for solid tumors and hematological cancers, as well as provide an update on the clinical development of GDA-201, its lead cryopreserved, off-the-shelf cell therapy candidate for the treatment of patients with follicular and diffuse large B cell lymphomas, including an update on the status of its Phase 1/2 Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA).

Update Regarding IND Application for GDA-201:

The company recently submitted an IND application to FDA for a Phase 1/2 trial with a cryopreserved formulation of GDA-201 in patients with diffuse large B cell lymphoma and follicular lymphoma and was notified that the IND application has been placed on Clinical Hold prior to the initiation of patient dosing. The FDA has requested modifications in donor eligibility procedures and sterility assay qualification. Gamida Cell is in active communication with the FDA with the objective to promptly address these requests to potentially enable the requirements for IND acceptance and study initiation. The initiation of the planned Phase 1/2 trial of GDA-201 may be delayed beyond the end of 2021, pending the outcome of FDA interactions.

"While we work to resolve outstanding issues with our IND, we are pleased to be able to share updates regarding our NAM-enabled NK cell programs," said Julian Adams, Ph.D., Chief Executive Officer of Gamida Cell. "We believe that the issues raised by FDA are addressable and can hopefully be resolved in an expeditious manner. In the meantime, we are pleased to elaborate on the power of NAM combined with the genomic tools that we have harnessed to enable us to create potentially transformative immuno-oncological therapies that may move beyond what is currently possible with existing approaches. These advances in our NK cell pipeline will help to further our mission to bring cancer patients potentially curative cell therapies."

Update Regarding NK Cell Therapy Programs:

During today's virtual event, Gamida Cell management and partners will provide an overview of the company's NK cell programs, including:

- Objective to improve treatment of both hematological cancers and solid tumors in which genetic modifications to allogeneic NK cells may overcome immunosuppressive microenvironments.
- Review of Gamida Cell's proprietary NAM expansion process, which enhances the potency, function and persistence of NK cells while improving homing to and retention in lymphoid tissues.
- Descriptions of Gamida Cell's genetically modified NK cell immunotherapy programs (GDA-301, GDA-401, GDA-501 and GDA-601), which utilize CAR- and CRISPR-mediated strategies to increase targeting, potency and persistence against hematologic malignancies and solid-tumors.
- Discuss a research collaboration with the Dana-Farber Cancer Institute studying the *in vitro* natural killer (NK) cell killing activity of GDA-601, Gamida Cell's nicotinamide (NAM)-enabled genetically modified NK cell therapy in multiple myeloma. GDA-601 is a CD38 CRISPR knockout combined with a CD38 CAR NK cell construct that has demonstrated promising preclinical results, including reduced fratricide and increased cytotoxicity against a multiple myeloma cell line.
- Phase 1 data on the safety and efficacy of GDA-201, a NAM-enabled, unmodified allogeneic NK cell therapy that has produced positive clinical results in the treatment of diffuse large B cell lymphoma and follicular lymphoma, both of which have significant unmet need.

"This is an exciting time for Gamida Cell as we have expanded R&D activities to augment our NK cell pipeline," said Ronit Simantov, M.D., Chief Medical Officer of Gamida Cell. "During today's event, we will share our plans to advance the clinical development of GDA-201 based on highly encouraging clinical data in patients with lymphoma that have arisen from a physician sponsored study. We also plan to illustrate how our proprietary NAM expansion process, combined with our advanced genetic modifications, differentiate our NK cell programs as may meaningfully help patients with solid tumors and hematologic malignancies."

A replay of the webcast will be available on the "Investors & Media" section of Gamida Cell's website at **www.gamida-cell.com**, and will be available for at least 14 days following the event.

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, as reported at the 2020 American Society of Hematology (ASH) Annual Meeting & Exposition[1]. 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 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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[1] Bachanova, et al. ASH 2020. Abstract #63.

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