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# GDA-501, NAM enabled NK Cell Therapy, Demonstrates Promising Antitumor Activity Against HER2+ Cancers

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Preclinical data presented at Society of Immunotherapy of Cancer's 37 <sup>th</sup> Annual Meeting shows proprietary NAM technology expands NK cells, enhances functionality, increases antitumor activity, and improves homing to targeted cancer cells

Data demonstrates that genetically modified NK cell GDA-501 enhances potency, persistence and cytotoxicity against cancer cells expressing HER2

#### More than 100,000 patients in US have cancers that express HER2

BOSTON--(BUSINESS WIRE)--Nov. 7, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA), the global leader in the development of NAM-enabled cell therapies for patients with solid and hematological cancers and other serious diseases, today announced encouraging preclinical data on GDA-501, a genetically modified NAM (nicotinamide) Natural Killer (NK) pre-clinical cell therapy candidate from Gamida Cell's expanding pipeline of cell therapy candidates. The data will be presented at the Society for Immunotherapy of Cancer's 37 <sup>th</sup> Annual Meeting taking place in Boston, MA from November 10-12, 2022.

NK cells have generated significant interest as potential new treatment options for patients with cancers. In pre-clinical and clinical studies, Gamida Cell's proprietary NAM technology has demonstrated successful expansion of NK cells, enhanced functionality, increased cytotoxic activity as well as creating a protective effect against oxidative stress and improved homing to targeted blood and solid tumor cancers.

"Our proprietary NAM technology enhances desirable cancer fighting qualities across a broad range of innate and adaptive cell types, including NK cells. As shown in our SITC poster, by optimizing downstream signaling we were able to directly enhance NK cell activity resulting in potent cytotoxicity against HER2-expressing cells. These results suggest that GDA-501 represents a unique allogeneic cell therapy candidate potentially targeting HER2+ solid tumors," said Yona Geffen, Ph.D., Vice President, Research and Development at Gamida Cell. "These data further validate our NAM technology and our pipeline of genetically modified NK cell therapy candidates that offer the potential to improve clinical outcomes for patients with cancers, including cancers that express HER2."

The success of immune cell therapies has been limited in solid tumors due to multiple barriers, including immunosuppressive tumor microenvironment, inefficient trafficking, and heterogeneity of tumor antigens. In a poster presentation titled, *"Engineered NAM-NK cells with HER2-CAR expression demonstrate increased cytotoxicity against HER2-expressing solid tumors"*, GDA-501, a genetically modified HER2-CAR NAM-NK cell, displayed significantly enhanced and persistent *in vitro* cytotoxicity and potency when cultured with HER2+ targeted cancer cells. Cryopreserved GDA-501 significantly inhibited tumor growth of a HER2+ solid tumor model *in vivo*. These preclinical data demonstrate potent antitumor activity and suggest that GDA-501 represents a unique potential treatment option using an allogeneic NAM-enabled cell therapy candidate for this poor prognostic group of patients with cancers that express HER2.

The GDA-501 poster (abstract #273) will be presented in Hall C on Thursday, November 10, 2022, from 9:00 AM EST to 9:00 PM EST. The poster presentation is publicly available at <u>www.sitcancer.org</u>.

#### About NAM Technology

Our NAM-enabling technology is designed to enhance the number and functionality of targeted cells, enabling us to pursue a curative approach that moves beyond what is possible with existing therapies. Leveraging the unique properties of NAM (nicotinamide), we can expand and metabolically modulate multiple cell types — including stem cells and natural killer cells — with appropriate growth factors to maintain the cells' active phenotype and enhance potency. Additionally, our NAM technology improves the metabolic fitness of cells, allowing for continued activity throughout the expansion process.

#### About GDA-501

Gamida Cell expanded the use of its NAM-enabled technology to create GDA-501, an allogeneic innate NK cell therapy candidate for the potential treatment of HER2+ solid tumors. Human epidermal growth factor receptor 2 (HER2) is a tyrosine kinase receptor growth-promoting protein expressed on the surface of many types of tumors including breast, gastric, lung and colorectal cancers.<sup>1</sup> **GDA-501** is genetically modified with a chimeric antigen receptor (CAR) to target HER2 by optimizing downstream signaling which directly enhances GDA-501 cytotoxicity. *In vitro* data demonstrated potent cytotoxicity against HER2-expressing cells. As a result, HER2-CAR may be used to target multiple HER2+ solid tumors. For more information about GDA-501, please visit <u>https://www.gamida-cell.com</u>.

#### About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapy candidates 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 therapy candidates with potential to redefine standards of care. These include omidubicel, an investigational product under review with the FDA as a potential 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 non-clinical and clinical trials of Gamida Cell's product candidates (including

GDA-501), and the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including GDA-501). 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 Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (SEC) on August 15, 2022, as amended, and other filings that Gamida Cell makes with the SEC from time to time (which are available at <a href="http://www.sec.gov">http://www.sec.gov</a>), 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.

1. Iqbal N, et al. Human Epidermal Growth Factor Receptor 2 (HER2) in Cancers: Overexpression and Therapeutic Implications. *Mol Biol Int.* 2014;852748.

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