Gamida Cell Announces Appointment of Senior Vice President, Global Operations and Manufacturing and Provides Commercial Manufacturing Update

June 7, 2021

BOSTON--(BUSINESS WIRE)--Jun. 7, 2021-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious blood diseases, today announced the appointment of Vladimir Melnikov as senior vice president, global operations and manufacturing. Mr. Melnikov brings over 25 years of experience in the biopharmaceutical industry, particularly in biologics manufacturing, operations, engineering and technology transfer. He will be based in the company's wholly owned commercial manufacturing facility in Israel.

Prior to joining Gamida Cell, Mr. Melnikov served as general manager at Omrix Biopharmaceuticals and biologic technical operations lead at Ethicon Biosurgery, both part of a Johnson & Johnson Company. In those roles he supervised three Israeli biotech manufacturing sites and technology transfer to external partners. In positions of increasing responsibility at Omrix, he played a pivotal role in new product development and launch, process scale-up, development of new facilities and equipment and obtaining regulatory approvals. Mr. Melnikov has proven success in production, supply chain, engineering and leading multifunctional teams. Mr. Melnikov will have responsibility for the Gamida Cell global operations and manufacturing, which will include the company's Israeli manufacturing site and oversight of the company's contract manufacturing partnership with Lonza. The scope will focus on both omidubicel and readiness for Gamida Cell's natural killer cell platform, including GDA-201. Mr. Melnikov holds a M.Sc. in life sciences from Hebrew University of Jerusalem, an MBA in biopharma from the College of Management, and he completed the Course of Directors and Senior Executives at Tel Aviv University.

"With Vladimir on board, we feel even more confident that we are making positive steps toward bringing omidubicel, our proprietary advanced cell therapy, to patients in need of an allogeneic hematopoietic stem cell transplant," said Julian Adams, Ph.D., chief executive officer of Gamida Cell. "In December 2020, the U.S. Food and Drug Administration provided clear feedback on what will be required for our commercial manufacturing facilities to be ready to submit a Biologics License Application for omidubicel, and we remain on track to submit our BLA in the fourth quarter of this year."

In addition to the appointment of Mr. Melnikov, Gamida Cell has made important progress in its strategy to have two commercial manufacturing facilities ready and available at the time of omidubicel's potential approval. One of these manufacturing plants is wholly owned by Gamida Cell and located in Israel. The other site is a commercial manufacturing facility for which the company has a contractual relationship with Lonza. Construction of Gamida Cell's Israel facility has been completed, and the initial production team has been hired, trained and qualified. In Q1 2021, the company successfully completed the required engineering runs and aseptic simulations for process qualification. Methods validations are underway, with planned completion in Q2 2021. Gamida Cell anticipates finalizing analytical comparability runs and process performance qualification by Q3 2021.

The company's additional commercial facility, in partnership with Lonza, is currently manufacturing clinical batches for Gamida Cell's expanded access program and is also progressing on the requirements.

"We are encouraged by the progress we are making to fulfill the FDA CMC requirements for our omidubicel BLA submission and are also diligently working on launch readiness," said Michele Korfin, chief operating officer and chief commercial officer of Gamida Cell. "The key focus of our omidubicel launch is to assure a positive patient and transplant center experience, including the best possible product. Manufacturing is a critical part of this, and we are also progressing well on our timeline to assure readiness for commercial manufacturing."

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 hematologic malignancies (blood cancers). In both Phase 1/2 and Phase 3 clinical studies (NCT01816230, NCT02730299), omidubicel demonstrated rapid and durable time to engraftment and was generally well tolerated.[1,2] 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.

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 an advanced cell therapy company committed to cures for patients with blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit **www.gamida-cell.com** or follow Gamida Cell on **LinkedIn** or Twitter 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 anticipated regulatory filings and approvals, manufacturing capabilities and commercialization efforts, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. 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. Any forward-looking statements speak only as of

the date of this press release and are based on information available to Gamida Cell as of the date of this release.

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[1] Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. J Clin Oncol. 2019 Feb 10;37(5):367-374.

[2] Gamida Cell press release, “Gamida Cell Announces Positive Topline Data from Phase 3 Clinical Study of Omidubicel in Patients with High-Risk Hematologic Malignancies,” issued May 12, 2020. Last accessed August 31, 2020.

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