Gamida Cell Announces Opening to Enrollment of Company-Sponsored Phase 1/2 Study of NK Cell Therapy Candidate GDA-201

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BOSTON--(BUSINESS WIRE)--Jun. 1, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapy candidates for patients with hematologic and solid cancers and other serious diseases, today announced the activation of the initial clinical sites to screen and enroll patients in the company-sponsored Phase 1/2 study evaluating a cryopreserved formulation of GDA-201, a readily available cell therapy candidate for the treatment of follicular and diffuse large B cell lymphomas (NCT05296525). On April 26, 2022, Gamida had announced that the U.S. Food and Drug Administration (FDA) cleared its investigational new drug (IND) application and removed the clinical hold for a cryopreserved formulation of GDA-201.

“We are excited to be screening patients for enrollment in our company-sponsored Phase 1/2 clinical study of our novel, cryopreserved formulation of GDA-201, which has the potential to address the significant unmet need that exists for patients with follicular and diffuse large B cell lymphomas having relapsed or refractory disease,” said Ronit Simantov, M.D., chief medical and scientific officer of Gamida Cell. “As described in previously announced clinical data, an investigator-sponsored (IS) study evaluating the fresh formulation of GDA-201 demonstrated encouraging results in heavily pretreated patients with lymphoma. With the initiation of enrollment, we look forward to dosing the first patient in our clinical study of the novel cryopreserved formulation of GDA-201.”

GDA-201 leverages Gamida Cell’s proprietary NAM technology platform to expand the number and functionality of NK cells to direct tumor cell killing properties and antibody-dependent cellular cytotoxicity (ADCC). In an investigator-sponsored Phase 1/2 study in patients with relapsed or refractory lymphoma, treatment with the fresh formulation of GDA-201 with rituximab demonstrated significant clinical activity. Of the 19 patients with non-Hodgkin lymphoma (NHL), 13 complete responses and one partial response were observed, with an overall response rate of 74% and a complete response rate of 68%. The most common Grade 3/4 adverse events were thrombocytopenia, hypertension, neutropenia, febrile neutropenia, and anemia. At the December 2021 Annual Meeting of American Society of Hematology, two-year follow-up data were reported on outcomes and cytokine biomarkers associated with survival. The data demonstrated a median duration of response of 16 months (range 5-36 months) and an overall survival at two years of 78% (95% CI, 51%–91%). In the IS study, GDA-201 was well-tolerated and no dose-limiting toxicities were observed in 19 patients with NHL and 16 patients with multiple myeloma.

The study of the cryopreserved formulation of GDA-201 is currently open to enrollment at Henry Ford Health (Detroit, MI) and the Masonic Cancer Center at the University of Minnesota; additional sites will be added in the coming months and updated in Clinicaltrials.gov (NCT05296525). The Phase 1 portion of the study is designed to evaluate the safety of GDA-201 in patients with follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL)/high grade B-cell lymphoma (HGBCL), marginal zone lymphoma or mantle cell lymphoma. The Phase 2 expansion phase is designed to evaluate the safety and efficacy of GDA-201 in two patient cohorts, FL and DLBCL/HGBCL. The study will include patients who have relapsed or refractory lymphoma after at least two prior treatments, which may include CAR-T or stem cell transplant.

About NAM Technology

Our NAM-enabling technology, supported by positive Phase 3 data, 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-201

Gamida Cell applied the capabilities of its nicotinamide (NAM)-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy candidate 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. There are approximately 40,000 patients with relapsed/refractory lymphoma in the US and EU, which is the patient population that will be studied in the GDA-201 Phase 1/2 clinical trial.

For more information about GDA-201, please visit https://www.gamida-cell.com. For more information on the Phase 1/2 clinical trial of GDA-201, please visit www.clinicaltrials.gov.

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 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 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 omidubicel), 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 Gamida Cell's product candidates (including 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 10-K, filed with the Securities and Exchange Commission (SEC) on March 24, 2022, 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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