Preliminary Results from NexImmune's Phase 1/2 Trial of NEXI-001 in AML Presented at 62nd ASH Annual Meeting and Exposition

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Initial data demonstrate early signs of safety, tolerability and robust immune responses in acute myeloid leukemia (AML) patients with relapsed disease after allogeneic hematopoietic cell transplantation (allo-HSCT)

GAITHERSBURG, MD - December 7, 2020 – NexImmune, a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to employ the body's own T cells to generate a specific, potent and durable immune response that mimics natural biology, today announced that City of Hope's Monzr Al Malki, M.D., delivered an oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition featuring initial data from the Phase 1/2 trial of NEXI-001 in AML. Entitled "Preliminary Results of the First-in-Human Study of NEXI-001, a Multi-Antigen Specific CD8+ T Cell Product, in Acute Myeloid Leukemia (AML) Patients with Relapsed Disease after Allogeneic Hematopoietic Cell Transplantation (Allo-HSCT) Demonstrate Early Signs of Safety, Tolerability and Robust Immune Responses," the presentation included responses following a single infusion of the experimental therapy.

These data represent safety and tolerability results from the first five patients treated and reflect a median of four months of follow-up with infusion doses ranging from 50-200 million total T cells. As noted by Dr. Al Malki in his presentation, there have been no cases of acute Graft versus Host Disease (aGvHD), Cytokine Release Syndrome (CRS), immune cells-associated neurological syndromes (ICANs), or infusion related reactions (IRRs) reported to-date, nor have there been any treatment-related adverse events (AEs) observed.

Biomarker data characterizing initial immunologic responses for the first three patients analyzed were also shared. Absolute lymphocyte counts, or ALC, were followed over time after the administration of lymphodepleting therapy, and showed a rapid return to baseline levels for each patient assessed (range 3 to 35 days). In addition, data on T cell reconstitution after lymphodepletion demonstrated that a single infusion of NEXI-001 T cells triggered a broad, rapid and robust immune response, inclusive of both CD8+ and CD4+ T cell types. TCR analysis showed the presence, persistence, expansion and migration of individual NEXI-001 T cell clones from the peripheral blood to the bone marrow of each patient. Finally, the immune phenotype of individual T cell subtypes in each NEXI-001 product were maintained in the peripheral blood of each patient at all time points measured, up to two months. These included sustained populations of T stem-cell-like memory and T central memory subtypes.

"Early results from this Phase 1/2 trial suggest that infusion of the NEXI-001 product is well-tolerated and capable of triggering early, robust and persistent cell-mediated immune responses," said Dr. Al Malki, the trial's lead investigator and associate clinical professor in City of Hope's Department of Hematology & Hematopoietic Cell Transplantation. "The initial data are encouraging, and we look forward to dosing more patients with longer follow-up in order to more fully characterize the clinical potential of this exciting new cell therapy."

Relapse after allo-HSCT is the leading cause of death in patients with AML and represents a significant challenge for treating physicians. There are no approved therapies, and current treatment options are limited. Donor lymphocyte infusions (DLIs) represent the current standard of care but are associated with modest Graft versus Leukemia (GvL) responses and high rates of life-threatening GvHD-associated toxicities. There is significant need for new cellular therapies with potential to enhance the benefits of GvL while decreasing the incidence of GvHD-related toxicities.

Han Myint, M.D., Chief Medical Officer at NexImmune added, "While still early in this trial, we believe the initial data reported, combined with the unique and consistent composition of each NEXI-001 product, may offer a cell therapy with potential to decouple the benefits of GvL from the toxicities associated with GvHD, which would be transformative for both allogeneic stem cell transplant patients and the physicians that provide care for them."

About the Phase 1/2 NEXI-001 Clinical Trial

The first clinical trial with NEXI-001 is a prospective, multi-center, open-label, single-arm, dose-escalating Phase 1/2 study that aims to enroll between 22 to 28 patients. The primary objective is to assess the safety and tolerability of a single infusion of NEXI-001 T cells in patients with AML who have either minimum residual disease (MRD) or relapsed disease after a human leukocyte antigen (HLA)-matched allo-HSCT. Secondary objectives include signals of immunologic responses and preliminary anti-tumor activity. Additional analysis will assess the in vivo persistence, proliferation, functionality and TCR repertoire of NEXI-001 T cells as measured in blood and bone marrow samples.

This study includes two phases. The initial "Safety Evaluation Phase" determines the safety and tolerability of a single infusion of NEXI-001 at escalating dose levels. In the second part of the study, the "Dose Expansion Phase," investigators further define safety and will also evaluate the initial efficacy of NEXI-001 T cells at the dose established in the Safety Evaluation Phase. Once a Recommended Phase II Dose has been determined, safety, tolerability and initial clinical response will become the objectives of the expansion phase of the trial, which is expected to begin in [the first quarter] of 2021.

NEXI-001 products contain populations of CD8+ T cells directed against HLA 02.01-restricted peptides from the WT1, PRAME and Cyclin A1 antigens, each of which is commonly over-expressed on AML blasts and leukemic stem cells. Each NEXI-001 product is composed of T cell memory subtypes that combine anti-tumor potency with long-term persistence. Of significance to this Phase 1/2 trial, each patient-specific experimental cell therapy product also contains very low proportions of T cell subtypes with potential to cause GvHD-related toxicities.

About NexImmune

NexImmune is a clinical-stage biotechnology company developing unique approaches to T cell immunotherapies based on its proprietary Artificial Immune Modulation (AIM) technology. The AIM technology is designed to generate a targeted T cell-mediated immune response and is initially being developed as a cell therapy for the treatment of hematologic malignancies. AIM nanoparticles act as synthetic dendritic cells to deliver immune-

specific signals to targeted T cells and can direct the activation or suppression of cell-mediated immunity. In cancer, AIM-expanded T cells have demonstrated best-in-class anti-tumor properties as characterized by in vitro analysis, including a unique combination of anti-tumor potency, antigen target-specific killing, and long-term T cell persistence. The modular design of the AIM platform enables rapid expansion across multiple therapeutic areas, with both cell therapy and injectable products.

NexImmune's two lead T cell therapy programs, NEXI-001 and NEXI-002, are in Phase 1/2 clinical trials for the treatment of relapsed AML after allo-HSCT and multiple myeloma refractory to at least three prior lines of therapy, respectively. The Company's pipeline also has additional preclinical programs, including cell therapy and injectable product candidates for the treatment of solid tumors, autoimmune disorders and infectious diseases.

For more information visit: www.neximmune.com

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