NexImmune Completes Dosing of First Cohort in Phase 1/2 Clinical Trial of NEXI-001 in Relapsed Acute Myelogenous Leukemia (AML)

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Company is using its Artificial Immune Modulation (AIM) nanoparticle technology to develop T cell immunotherapies for patients with relapsed and/or refractory hematologic malignancies

GAITHERSBURG, MD - September 23, 2020 – NexImmune, a clinical-stage biotechnology company developing unique non-genetically-engineered T cell immunotherapies, announced today that it has completed dosing of the first safety cohort (n=3) in its Phase 1/2 clinical trial for NEXI-001, representing a significant milestone for the Company. NEXI-001 is a cellular product that contains populations of naturally-occurring CD8+ T cells directed against multiple AML-specific antigen targets, and it is the first clinical product generated by the Company's AIM nanoparticle technology.

The prospective, multi-center, open-label, single-arm, dose-escalating Phase 1/2 study will 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 allogeneic stem cell transplant (SCT). Secondary objectives include signals of anti-tumor activity, progression-free survival (PFS) and overall survival (OS). Additional analysis will assess the in vivo persistence, proliferation, functionality and T cell receptor (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' will determine the safety and tolerability of a single infusion of NEXI-001 at different dose levels. In the second part of the study, the 'Dose Expansion Phase,' investigators will further define safety and will also evaluate the initial efficacy of NEXI-001 T cells at the dose established from the Safety Evaluation Phase.

"For the first clinical trial with NEXI-001, our primary objective is to demonstrate the safety and tolerability of this novel immunotherapeutic approach. We also hope to see initial signs of immunological and clinical activity across escalating dose levels," said Han Myint, MD, Chief Medical Officer at NexImmune. "With NEXI-001, our hope is to advance a cell therapy with potential to decouple the benefits of graft-versus-leukemia (GvL) from the toxicities of graft-versus-host disease (GvHD). If accomplished, this would truly be transformative for patients and for the transplant physicians that treat them."

Disease relapse after allogeneic SCT remains the major cause of treatment failure in patients with AML, is associated with very poor prognosis, and represents a major therapeutic challenge for physicians. Most commonly, patients with relapsed disease are given a donor lymphocyte infustion (DLI), but only 15%-20% respond to this approach while up to 60% experience life-threatening toxicities associated with GvHD. NEXI-001 products contain high porportions of T cells that are specific to leukemia cells and very low proportions of T cells (<5%) that have alloreactive potential (i.e., those associated with GvHD).

"Ongoing enrollment in this clinical trial marks an important milestone for NexImmune and is a critical step toward validating the clinical promise of our AIM nanoparticle technology," said Scott Carmer, Chief Executive Officer at NexImmune. "Cancer, auto-immune, and infectious diseases continue to represent disease areas with significant unmet need for patients and ongoing challenges for healthcare systems worldwide. We believe that our T cell immunotherapies are meaningfully differentiated and well positioned to meet the gaps in today's treatment landscape."

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 allogeneic stem cell transplantation and multiple myeloma refractory to >3 prior lines of therapy, respectively. The Company expects initial data in the fourth quarter of 2020 for both indications. The Company's pipeline also has additional preclinical programs, including cell therapy and injectable product candidates, for the treatment of oncology, autoimmune diseases, and infectious diseases.

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 cancers. AIM nano-particles (AIM-np) 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, including the ability to address key mechanisms of tumor escape and relapse through a unique combination of anti-tumor potency, multi-antigen target-specific killing, and long-term T cell persistence. The modular design of the AIM platform enables rapid expansion across multiple therapeutic areas (such as autoimmune diseases and infectious diseases), with both cell therapy and injectable products.

For more information visit: www.neximmune.com

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