First Patient Dosed in NexImmune Phase 1/2 Clinical Trial of NEXI-002 in Multiple Myeloma

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With the start of its second clinical trial, NexImmune expands development of its unique non-genetically engineered T cell immunotherapies across a range of hematologic malignancies

GAITHERSBURG, MD -- October 6, 2020 – NexImmune, a clinical-stage biotechnology company developing a portfolio of unique non-genetically-engineered T cell immunotherapies, announced today that it has dosed the first patient in its Phase 1/2 clinical trial for NEXI-002. NEXI-002 is a patient-derived cellular product that contains populations of naturally-occurring CD8+ T cells directed against several multiple myeloma (MM)-specific antigen targets. It is the second clinical product NexImmune has generated with its AIM nanoparticle technology.

"While the primary objective in this trial with NEXI-002 is to demonstrate safety and tolerability, we also hope to see initial signs of immunological and clinical activity," said Han Myint, MD, Chief Medical Officer at NexImmune. "The AIM technology gives us the unique ability to direct populations of natural T cells against a powerful combination of cell surface and endogenous anti-tumor targets specific to multiple myeloma. We believe this approach has potential to address primary tumor escape mechanisms, and provide deep and durable clinical responses."

Investigators will enroll between 22 to 28 patients in the prospective, multi-center, open-label, single-arm Phase 1/2 study. The trial's primary objective is to assess the safety and tolerability of a single infusion of NEXI-002 T cells in patients with MM who have failed at least three prior lines of therapy. 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-002 T cells as measured in blood and bone marrow samples. Clinical sites participating in this trial include Dana Farber Cancer Institute, Karmanos Cancer Institute, MD Anderson Cancer Center, City of Hope Comprehensive Cancer Center and Memorial Sloan Kettering Cancer Center.

Despite recent advances in the treatment of multiple myeloma, there remains no cure for the disease. Virally-transduced CAR-T products that target the BCMA protein represent a new and promising form of genetically-engineered T cell therapy for multiple myeloma patients who have failed >3 lines of prior therapy, but unfortunately, a majority of patients who initially respond to these therapies relapse within one year of treatment. Because the T cells in NEXI-002 products can attack several multiple myeloma tumor-specific targets simultaneously and are comprised of T cell subtypes that can survive for years in patients, they have potential to address the limitations of current single-target genetically-engineered T cell therapies.

"With the initiation of NexImmune's second clinical trial, we are bringing our transformational technology to another group of patients with a high unmet medical need," said Scott Carmer, Chief Executive Officer at NexImmune. "We believe T cell immunotherapies based on the AIM nanoparticle technology represent a highly differentiated and clinically meaningful option for many patients facing life-threatening conditions across the spectrum of cancer, auto-immune and infectious diseases."

About Multiple Myeloma

According to the Multiple Myeloma Research Foundation, multiple myeloma is a type of blood cancer that affects plasma cells. In multiple myeloma, malignant plasma cells accumulate in the bone marrow, crowding out the normal plasma cells that help fight infection. These malignant plasma cells then produce an abnormal antibody called M protein, which offers no benefit to the body and may cause tumors, kidney damage, bone destruction, and impaired immune function. Unfortunately, despite the introduction of novel therapies that offer many multiple myeloma patients temporary remission from their cancer, all patients will ultimately experience disease relapse.

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 as determined by in vitro analysis, 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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