Neximmune Receives IND Clearance for Phase 1/2 Trial in Relapsed / Refractory Multiple Myeloma

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- *IND clearance enables commencement of clinical trial to evaluate NEXI-002 in Multiple Myeloma patients who have failed >3 previous lines of therapy*
- *FDA action represents the Company's second IND clearance in 4Q2019 for its pipeline of novel cellular therapy products*

GAITHERSBURG, MD -- December 19, 2019 – NexImmune, a clinical-stage biopharmaceutical company developing novel immune-therapeutics based on a proprietary Artificial Immune Modulation (AIM) nanotechnology platform, has received IND clearance for the Company's second cellular therapy product. NEXI-002 is being developed for the treatment of Multiple Myeloma patients that have failed at least three prior lines of therapy. Scott P. Carmer, NexImmune's President and CEO, commented "FDA clearance of our second IND this quarter marks another significant milestone for Neximmune and demonstrates our team's focus and commitment to bringing novel therapies to patients with significant unmet need. NEXI-002 is a T cell therapy that consists of T cell populations directed against multiple tumor-relevant antigen targets. In addition, the T cells expanded by our proprietary E+E system consist of T cell subtypes critical to both potent anti-tumor activity and generation of the long-term immunologic memory required for durable responses. Because of this, we are hopeful NEXI-002 will address key limitations observed with other cellular immunotherapies."

The Phase 1/2 trial of NEXI-002 will begin enrolling patients at clinical sites across the United States. Key sites planning to enroll patients include The Dana Farber Cancer Institute, Memorial Sloan Kettering, MD Anderson, and The Karmanos Cancer Institute. The trial is a multi-center, open-label, single-arm study evaluating the safety, tolerability and initial efficacy of adoptively-transferred patient-derived T-cells as a treatment for Multiple Myeloma patients that have failed >3 previous lines of therapy. The trial will evaluate a single dose of NEXI-002, with three patients enrolled in an initial safety cohort, followed by an expansion phase which will enroll up to 20 additional patients. All patients will be followed for at least one year.

Paul Richardson, MD, the RJ Corman Professor of Medicine at Harvard Medical School, Clinical Program Leader and Director of Clinical Research at Dana Farber's Jerome Lipper Multiple Myeloma Center and the clinical trial's lead investigator, stated "although we have made significant progress in treating patients diagnosed with Mulitple Myeloma, we continue to need novel treatment strategies and, in particular, effective immune therapy. For that reason, a significant unmet need remains for the vast majority of our patients. Novel immune-based therapies like NEXI-002 may represent a promising and practical option for those patients that have either relapsed after, or are refractory to, currently available treatment. We are excited to be a lead site for this trial and look forward to dosing our first patients."

About Multiple Myeloma

According the 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. The hallmark characteristic of multiple myeloma is a high level of M protein in the blood. Multiple myeloma typically displays the most activity in bone marrow, which includes the marrow in the spine, pelvic bones, ribs, shoulders, and hips.

Though it is rarely curable, multiple myeloma is a manageable disease that has seen rapid medical advancement over the past decade. Unfortuntaley, 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 NEXI-002

NEXI-002 is an endogenous (non-genetically engineered) cellular therapy and includes populations of primed antigen specific CD8+ cells directed at five specific multiple myeloma antigen targets. Generating T cells against multiple tumor targets minimizes the potential for tumor escape. In addition, NEXI-002 contains T cell subtypes that are predominantly memory phenotypes, with the majority being characterized as stem cell memory and central memory T cells. T cell products that contain high proportions of memory cells, particularly central memory and stem cell memory, have been associated with potent anti-tumor activity, long-term T cell persistence and durable anti-tumor response.

About NexImmune

NexImmune is a clinical-stage biopharmaceutical company developing novel immune-therapeutics based on the proprietary Artificial Immune Modulation (AIM) nanotechnology platform. The AIM platform enables the ability to expand multi-antigen specific T cells with enhanced anti-tumor properties without the need for genetic manipulation. NexImmune is using the AIM technology platform to develop a pipeline of products to treat cancer and auto-immune diseases.

The AIM platform is comprised of two core components: (1) a synthetic nanoparticle that functions as an artificial antigen presenting cell (aAPC) to prime and activate T cells directed at multiple tumor antigen targets across a broad range of both solid and hematologic malignancies; and (2) a proprietary T cell enrichment and expansion (E&E) process that controls ex vivo T cell proliferation and subtype differentiation. In preclinical experiments, the AIM system has demonstrated the ability to enhance naturally occuring tumor cell recognition, engagement and signaling mechanisms that increased the anti-tumor potency, target specific killing and long-term durability of endogenous cytolytic T-cells. Utilizing natural target recognition and killing mechanisms may also reduce the potential for alloreactive toxicities observed with genetically engineered T cell therapies. The Company's aAPCs have also demonstrated potential utility as both injectable and cellular therapeutic agents.

For more information visit: www.neximmune.com

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