NexImmune Announces IND Clearance by the US FDA for NEXI-003 for the Treatment of HPV-Related Cancers

July 14, 2022

- *First IND for NexImmune's AIM nanoparticle platform in solid tumors*
- *IND clearance enables commencement of a clinical trial to evaluate NEXI-003, an autologous antigen-specific T cell product (CD3+/CD4-), in patients with relapsed or refractory human papillomavirus (HPV)-related cancers*

GAITHERSBURG, Md., July 14, 2022 (GLOBE NEWSWIRE) -- NexImmune, Inc. (Nasdaq: NEXI), a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to orchestrate a targeted immune response by directing the function of antigen-specific T cells, has received IND clearance for the Company's first cellular therapy product candidate addressing solid tumors. NEXI-003, an autologous antigen-specific T cell product (CD3+/CD4-), is being developed for patients with relapsed or refractory human papillomavirus (HPV)-related cancers.

Kristi Jones, NexImmune's CEO, commented, "The FDA clearance of our third IND marks another significant milestone for NexImmune and demonstrates our team's continued focus and commitment to bringing novel therapies to patients with significant unmet need. NEXI-003 is our third T cell therapy and first candidate to address solid tumors. NEXI-003 consists of T cell populations simultaneously directed against multiple HPV tumor-relevant antigen targets. The T cells in our product candidate will consist of T cell subtypes critical to both potential anti-tumor activity and a phenotype intended to produce long-term immunologic memory required for durable responses."

The Phase 1 trial will enroll patients at multiple clinical sites across the United States. The proposed study is a two-part, multicenter, open-label, dose-finding, first-in-human (FIH) study to characterize the safety and clinical activity of NexImmune's HPV tumor-relevant antigen-specific CD8+ T cell product candidate (NEXI-003) in patients with relapsed or refractory locally advanced or metastatic HPV-related oropharyngeal cancers (with confirmed histopathology detection of HPV-16 and/or HPV-18 expression), who have received at least 1 prior regimen of standard therapy according to local standard of care guidance(s). The dose escalation phase will consist of multiple safety cohorts investigating increasing doses of NEXI-003 followed by an expansion phase that will enroll 24 to 36 patients overall, depending on the number of dose escalations. All patients will be followed for at least one year. Following initial data and after the recommended Phase 2 dose has been confirmed, NexImmune plans to expand the NEXI-003 development program to include other HPV related malignancies and evaluate potential SOC combination options across the patient populations.

About HPV-Related Cancers

Human papillomavirus (HPV)-related cancers are common epithelial malignancies that account for approximately 5% of all cancers globally. These cancers cause an estimated 12,500 deaths each year in the United States and more than 300,000 deaths each year throughout the world. Histologically, this family of cancers consists of squamous cell carcinomas and adenocarcinomas that occur in various anatomical sites including the oropharynx, uterine cervix, anus, vagina, vulva and penis. The high-risk HPV subtypes are most commonly HPV-16 and HPV-18. Malignant transformation results through the activation of the expression of the E6 and E7 HPV oncogenes, which inhibit the tumor suppressors p53 and Rb. These oncoproteins also inhibit apoptosis of tumor cells, deregulate the cell cycle, result in the accumulation of genetic instability, promote angiogenesis and facilitate the invasiveness and metastatic spread of cancerous cells.

About NexImmune

NexImmune is 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. The backbone of NexImmune's approach is a proprietary Artificial Immune Modulation (AIM™) nanoparticle technology platform. The AIM technology enables NexImmune to construct nanoparticles that function as synthetic dendritic cells capable of directing a specific T cell-mediated immune response. AIM constructed nanoparticles employ natural biology to engage, activate and expand endogenous T cells in ways that combine anti-tumor attributes of antigen-specific precision, potency and long-term persistence with reduced potential for off-target toxicities.

NexImmune's two lead 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 at least three prior lines of therapy, respectively. NexImmune is also developing new AIM nanoparticle constructs and modalities for potential clinical evaluation in oncology and in disease areas outside of oncology, including autoimmune disorders and infectious disease.

For more information, visit www.neximmune.com.

Forward Looking Statements

This press release may contain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the beliefs and assumptions and on information currently available to management of NexImmune, Inc. (the "Company"). All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements concerning our planned and ongoing clinical studies for the Company's product candidates, including NEXI-001, NEXI-002 and NEXI-003; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical studies; and the utility of prior preclinical and clinical data in determining future clinical results. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (“SEC”) on March 9, 2022, and subsequent reports that we file with the SEC. Forward-looking statements represent the Company’s beliefs and assumptions only as of the date of this press release. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this press release to conform any of the forward-looking statements to actual results or to changes in its expectations.

Contacts:

NexImmune:
Chad Rubin, SVP Corporate Affairs
NexImmune, Inc.
646.319.3261
crubin@neximmune.com