NexImmune Announces Preliminary Phase 1/2 NEXI-002 Results in Patients with Multiple Myeloma

December 12, 2021

- *Initial Phase 1/2 data presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition*
- *Phase 1/2 study of NEXI-002 as a monotherapy in patients with relapsed/refractory multiple myeloma patients who have failed ≥3 prior lines of therapy is ongoing*

GAITHERSBURG, Md., Dec. 12, 2021 (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, today announced preliminary Phase 1/2 results from an ongoing study of NEXI-002, a patient-derived multi-antigen-specific CD8+ T cell treatment for patients with relapsed/refractory multiple myeloma who have failed ≥3 prior lines of therapy. The data on low doses of NEXI-002, presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition, showed a promising safety and tolerability profile and evidence of immunologic and clinical activity.

Poster Presentation:

Title: Preliminary Analysis of a Phase 1/2 Study of NEXI-002 Autologous Multi-Antigen-Specific CD8+ T cells for the Treatment of Relapsed or Refractory Multiple Myeloma (RRMM)
Abstract Number: 2824
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Date & Time: Sunday, December 12, 2021; Poster Hall Hours 6-8 pm EST

In this heavily pre-treated patient group (n=6 with an average of 7.6 lines of prior therapy), the clinical data suggests that NEXI-002 is well-tolerated without dose-limiting toxicities (no grade ≥3 CRS or any grade of ICANS). Biomarker data show that the NEXI-002 product candidate contains CD8+ antigen-specific T cells with key memory phenotypes which, after administration, are detected in peripheral blood and bone marrow of treated individuals and proliferate and persist over time. Furthermore, TCR sequencing shows that the NEXI-002 product candidate contains CD8+ T cell clones that were undetectable in the peripheral blood of the patients at baseline and which expand in both blood and bone marrow over time. After receiving lymphodepleting therapy followed by NEXI-002 infusion, patients experienced rapid lymphocyte recovery with reconstitution of both CD4+ and CD8+ T cell subtypes. Despite the infusion of very low numbers of NEXI-002 T cells (4-10x10e6 total T cells), these heavily pre-treated patients achieved stable disease for 2 to 3.5 months of duration. Importantly, despite receiving an average of 7.6 previous lines of therapy, the quality, functionality and *in vivo* persistence of all patient-derived NEXI-002 T cell products were comparable to those expanded from healthy donors. Strategies to yield higher product doses are underway, including evaluating patients with lower disease burden plasma cell dyscrasias.

"We are very encouraged by the initial Phase 1/2 results observed to-date with NEXI-002," said Scott Carmer, CEO of NexImmune. "We have now shown, in two separate clinical trials using apheresis material from either healthy donors or heavily pre-treated patients, that we can manufacture CD8+ T cell products with high target antigen specificity and with T cell phenotypes that promote *in vivo* proliferation, persistence and anti-tumor activity. Even at the very low doses of NEXI-002 administered in this ongoing trial, we've seen robust biomarker and immunological responses with evidence of clinical activity. These preliminary data provide further evidence of the NEXI-002 mechanism of action, and we are eager to continue assessing NEXI-002's potential in this patient population and in additional patients with lower-disease-burden plasma cell dyscrasias."

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 3 or more 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 trials for the Company's product candidates, including NEXI-001 and NEXI-002; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical trials; the Company's beliefs and expectations regarding the preliminary results from the Phase 1/2 clinical trial of NEXI-002; 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, 2020 filed with the Securities and Exchange Commission (“SEC”) on March 31, 2021, 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.

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