NKore BioTherapeutics, Inc. announces the successful completion of its pre-IND meeting with the FDA

FDA feedback provided regulatory direction as NKore advances NK101 toward a U.S. IND submission and future US clinical trials in cancer

LOS ANGELES, CA, UNITED STATES, October 1, 2026 /EINPresswire.com/ -- NKore BioTherapeutics, Inc. ("NKore" or the "Company"), a biotechnology company developing next-generation patented Supercharged Natural Killer (sNK™) cell therapies for cancer, today announced the successful completion of its Type B pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) for NK101, the Company's lead allogeneic cell therapy candidate.

> "This meeting represents an important continuation of NKore's regulatory dialogue with the FDA," said Dr. Aneel Paulus, Medical Advisor to NKore and a member of the Company's Board."
>
> *Dr. Aneel Paulus*

The pre-IND meeting provided an opportunity for NKore to obtain FDA feedback on key elements of the NK101 development program, including chemistry, manufacturing and controls (CMC), nonclinical pharmacology and toxicology and the proposed clinical development program for the Company's planned first U.S. clinical trial. The feedback received from the FDA provides important regulatory direction as NKore continues advancing the manufacturing, nonclinical, and clinical activities necessary to support a future IND submission and future US clinical trials in cancer.

"Completion of our Type B pre-IND meeting represents an important milestone in NKore's evolution and in the development of NK101," said Dr. Aaron U. Levy, Chairman and Chief Executive Officer of NKore BioTherapeutics. "The FDA's feedback provided us gave us clarity on how to advance our clinical development program and important direction to refine our manufacturing, nonclinical, and clinical development strategy. More importantly, this meeting marks a major corporate transition from initially establishing the foundation of the NK101 program to advancing into a robust U.S. clinical development program. We are now focused on translating the work accomplished to date into the studies, data, and regulatory submissions that can position NK101 for its next important milestones in the United States. While there is substantial work ahead, we believe the progress achieved to date establishes an increasingly

strong foundation for what we intend to accomplish next."

NK101 is an allogeneic Supercharged Natural Killer (sNK™) patented cell therapy built upon more than three decades of immunology research led by Dr. Anahid Jewett at UCLA. NKore's proprietary platform is designed to enhance the innate cancer-fighting capabilities of Natural Killer cells while supporting the development of scalable, potentially off-the-shelf cellular immunotherapies across multiple oncology indications.

The Company's pre-IND briefing package included information regarding the intended manufacturing process, nonclinical data, and the proposed initial clinical trial design, including a basket-trial approach intended to evaluate NK101 across multiple cancer indications. NKore intends to incorporate the FDA's feedback into its ongoing development activities while completing the additional studies, analyses, manufacturing activities, and documentation necessary to support a future IND submission.

"This meeting represents an important continuation of NKore's regulatory dialogue with the FDA," said Dr. Aneel Paulus, Medical Advisor to NKore and a member of the Company's Board of Directors. "The feedback provides valuable direction as the Company continues integrating its U.S. regulatory, manufacturing, nonclinical, and clinical development plans. This type of early regulatory engagement is an important part of building a disciplined development strategy for a novel cell therapy program."

NKore acknowledges the contributions of its employees, scientific and medical advisors, consultants, Board of Directors, shareholders, manufacturing partners, and research collaborators whose efforts have contributed to this milestone and to the continued advancement of the NK101 program.

About NKore BioTherapeutics, Inc.

NKore BioTherapeutics, Inc. is a biotechnology company developing proprietary Supercharged Natural Killer (sNK™) patented cell therapies for the treatment of cancer. Built upon more than three decades of immunology research led by Dr. Anahid Jewett at UCLA, the Company's lead product candidate, NK101, is an allogeneic Supercharged NK cell therapy designed to enhance the natural cancer-fighting capabilities of Natural Killer cells. NKore's proprietary platform is designed to amplify NK cell cytotoxic activity while supporting the development of scalable, potentially off-the-shelf cellular immunotherapies across multiple oncology indications.

Forward-Looking Statements

This press release contains forward-looking statements regarding NKore BioTherapeutics' development programs, regulatory activities, clinical plans, and future business objectives. These statements are based on current expectations and involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied. Completion of a pre-

IND meeting and receipt of FDA feedback do not guarantee acceptance of an IND application, authorization to initiate clinical trials, regulatory approval, or commercial success. FDA feedback provided during the pre-IND process is intended to provide regulatory guidance regarding the Company's development program and does not constitute approval or endorsement of NK101. The Company cannot predict whether or when it will submit an IND application or whether any future IND application will be accepted or cleared to proceed. NKore undertakes no obligation to update these forward-looking statements except as required by applicable law.

Important Disclaimer

NK101 is an investigational product and has not yet been approved by the U.S. Food and Drug Administration or any other regulatory authority. The safety and effectiveness of NK101 have not been established. The completion of a pre-IND meeting, submission of a pre-IND briefing package, or receipt of FDA feedback does not constitute FDA approval, acceptance, or endorsement of NK101 or of any clinical or nonclinical data generated to date.

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