FDA Grants NKore BioTherapeutics, Inc. a Type B Pre-IND Meeting for Lead Supercharged NK Cell Therapy Candidate NK101

The scheduled meeting marks the Company's first formal regulatory interaction with the FDA in support of a planned U.S. IND filing

NKore

LOS ANGELES, CA, UNITED STATES, July 29, 2026 /EINPresswire.com/ -- Los Angeles, Calif. — July 29, 2026 — NKore BioTherapeutics, Inc. ("NKore" or the "Company"), a biotechnology company developing next-generation Supercharged Natural Killer (sNK™) cell therapies for cancer, announced that the U.S. Food and Drug Administration (FDA) has granted the Company's request for a Type B pre-Investigational New Drug (pre-IND) meeting for its lead product candidate, NK101.

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>
> *Dr. Aneel Paulus*

The Company submitted its meeting request on June 24, 2026, received a pre-IND number, has been granted a formal meeting with the FDA and also completed and submitted its pre-IND briefing package, marking the Company's first formal regulatory interaction with the agency and an important milestone toward a planned U.S. IND submission for NK101.

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

"Reaching this milestone reflects the coordinated efforts of our clinical, regulatory, manufacturing, quality, product development, and executive teams. It demonstrates that NKore has established the strategic infrastructure necessary to advance a complex cellular immunotherapy program through the U.S. regulatory pathway," stated Dr. Aaron U. Levy, Chairman and Chief Executive Officer of NKore BioTherapeutics, Inc.

The FDA's pre-IND process enables sponsors to obtain regulatory feedback before submitting an IND application. The Company's briefing package requests FDA input on key aspects of the NK101 development program, including manufacturing and product characterization, nonclinical pharmacology and safety, available human clinical experience, planned IND-enabling toxicology studies, dose selection, and the proposed design of NKore's first U.S. clinical trial.

Dr. Aneel Paulus, Medical Advisor to NKore and a member of the Company's Board of Directors, commented, "This meeting represents the beginning of an important regulatory dialogue with the FDA rather than an endpoint. Under Dr. Levy's leadership, NKore has strengthened its regulatory, manufacturing, and operational capabilities while consolidating manufacturing, nonclinical, and clinical information into a comprehensive submission. We believe this disciplined approach positions the Company well as it advances toward an IND filing."

The Company believes the pre-IND process provides an important opportunity to identify and address regulatory considerations early in development. NKore intends to incorporate the FDA's feedback into its ongoing development plans and wishes to acknowledge the contributions of its scientific advisors, employees, consultants, Board of Directors, shareholders, and research collaborators whose efforts supported this milestone.

Disclaimer: NK101 is an investigational product and has not 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 submission of a pre-IND briefing package and the granting of a pre-IND meeting do not constitute FDA review, acceptance, or endorsement of NK101 or of any clinical data generated to date.

About NKore BioTherapeutics, Inc.

NKore BioTherapeutics, Inc. is a biotechnology company developing proprietary Supercharged Natural Killer (sNK™) 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 submission or receipt of FDA feedback does not guarantee acceptance of an IND application, initiation of clinical trials, regulatory approval, or commercial success. FDA feedback is advisory and non-binding, and the Company cannot predict when or whether it will submit an IND application. NKore undertakes no obligation to update these forward-looking statements except as required by applicable law.

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