ImmunityBio Achieves Milestone with Large-Scale NK Cell Production and Cryopreservation from Over 60 Healthy and Cancer Donors

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- Methods developed and validated to establish the “World Bank of NK Cells” from healthy donors and cancer patients
- Single apheresis yields up to 5 billion (5×10^9) highly pure activated memory cytokine-enhanced NK cells (M-ceNK), providing up to 8-10 doses of M-ceNK product per patient
- Manufacturing and cryo-banking process established with finished dosage form of M-ceNK cells available within 12 days from apheresis
- M-ceNK cells successfully cryopreserved with demonstration of retained cytotoxicity against multiple tumor cell lines
- Methods now established in readiness for manufacturing in AI-driven automated robotic systems (NANT Leonardo)
- Combination of M-ceNK with ANKTIVA® successfully completed in Phase 1 safety study (QUILT 3.076)

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 13, 2026-- ImmunityBio (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced the successful completion of manufacturing engineering programs, NK2022 and NK2023, establishing a safe, reproducible, and scalable leukapheresis-to-manufacturing pathway for its autologous memory cytokine-enhanced natural killer (M-ceNK) cell therapy platform.

In addition, a Phase I program (QUILT-3.076; NCT04898543) combining M-ceNK with ANKTIVA® (nogapendekin alfa inbakicept-pmln) was completed in patients with relapsed or refractory tumors demonstrating safety following infusion of the M-ceNK drug product. Collectively, these programs enrolled 74 subjects, including both healthy donors and patients with cancer, and generated the foundational process development and robotic automation datasets required to support first-in-human clinical translation.

Manufacturing Validation

The NK2022 (Cancer and Healthy Volunteers) and NK2023 (Healthy Volunteers) programs (N=64) evaluated the safety of large-volume, non-mobilized leukapheresis and the reproducibility of downstream NK cell enrichment and cytokine-driven memory programming across two distinct donor populations.

Across both programs, 64 subjects successfully completed apheresis collection across healthy and cancer subjects without procedure-related serious adverse events (SAEs). Collected cells were stored and used for process development and validation.

Among the 64 completed apheresis subjects, 10 cancer subjects received their collected cells following ImmunityBio’s NK cell enrichment process. A total of 23 doses were administered to patients demonstrating successful repeat dosing and cryo-banking of M-ceNK cells. No SAEs were reported in the 10 cancer subjects during their treatment cycles.

Post-collection immune profiling demonstrated preserved NK cell activity and phenotype in healthy donors and in cancer patients, including those with prior exposure to systemic therapy. Critically, NK cells derived from cancer patients demonstrated cytotoxic activity equivalent to that of healthy donor-derived NK cells against NK-resistant cell lines representing multiple histologies, including breast, Merkel cell, ovarian, chordoma, medulloblastoma, glioblastoma, adenocarcinoma, and lymphoma.

“These data demonstrate that potent NK cell therapy can be manufactured at scale and administered safely, potentially offering a reliable autologous source of potent NK cells,” said Patrick Soon-Shiong, MD, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. “The ability to generate up to 5 billion highly pure NK cells from a single apheresis collection, yielding up to 8-10 therapeutic doses within 12 days, opens the possibility of creating the ‘World Bank of Natural Killer Cells’, with NK cells able to be universally donated to any patient without HLA matching.”

QUILT-3.076 Safety Phase I Trial of M-ceNK Cells

Manufacturing feasibility data from NK2022 and NK2023 directly enabled ImmunityBio’s Phase 1 dose-escalation trial (QUILT-3.076; NCT04898543) evaluating autologous M-ceNK cells in combination with nogapendekin alfa inbakicept-pmln (ANKTIVA®) in patients with relapsed or refractory solid tumors. 10 patients were enrolled in the treatment cohort and received weekly intravenous M-ceNK infusions (0.25 to 0.75×10^9 cells per dose, up to 10 doses) combined with subcutaneous ANKTIVA® administered every two weeks.

- Patient infusions to date: N=10. All infusion performed in an outpatient setting
- Cancer types (2nd line & greater): Breast (N=4), Colon (N=1), Duodenum (N=1), Renal (N=1), Pancreatic (N=1), Rectal (N=1), Osteosarcoma (N=1)
- Range of M-ceNK infusions (2 to 5 bags infused) with NAI subcutaneously
- Safety: Zero (0%) TRAE Grade 4 or 5. Zero (0%) cytokine storm

The combination of autologous M-ceNK cells with ANKTIVA® is mechanistically designed to leverage the IL-15 superagonist activity of ANKTIVA® to sustain in vivo M-ceNK proliferation and persistence following adoptive transfer.

M-ceNK Antitumor Activity in Neuroendocrine Tumors: NCI-Led Preclinical and In Vivo Efficacy Data

Additional translational evidence supporting the M-ceNK platform was presented by K Fousek et al., National Cancer Institute (NCI) at the AACR IO Annual Meeting, 2026.

The AACR IO 2026 presentation reported the first in vivo efficacy data for the M-ceNK platform. In two SCLC xenograft models, M-ceNK cells combined with ANKTIVA produced statistically significant tumor volume reductions ($p<0.01$ and $p<0.001$, respectively), with confirmed in vivo persistence of functional M-ceNK cells. M-ceNK treatment also significantly increased MHC-Class I expression on residual tumor cells ($p<0.0001$), suggesting a potential dual mechanism: direct NK cell mediated tumor killing followed by conversion of residual tumors to a state potentially responsive to immune checkpoint inhibitors.

SCLC is an aggressive neuroendocrine carcinoma with limited treatment options. Tissue microarray analysis demonstrated that 62% of neuroendocrine tumors lack MHC-Class I expression, rendering them resistant to T cell-based immunotherapies but vulnerable to NK cell mediated killing, identifying a substantial patient population with unmet therapeutic need. Low MHC class I surface expression limits T cell-mediated and immune checkpoint blockade (ICB)-dependent tumor killing, a contributing mechanism of ICB resistance, while simultaneously creating susceptibility to NK cell-mediated cytotoxicity via the missing-self recognition mechanism. M-ceNK cells generated from healthy donor peripheral blood mononuclear cells expressed high levels of activating receptors, low levels of inhibitory receptors, and produced elevated interferon-gamma (IFN-γ) and granzyme B upon stimulation, consistent with an enhanced cytotoxic effector phenotype. In standardized cytotoxicity assays, M-ceNK cells demonstrated potent killing activity against the majority of tumor cell lines evaluated, with the greatest cytotoxic activity observed against neuroendocrine tumor models, including five SCLC lines, four pulmonary carcinoid lines, and a large cell neuroendocrine carcinoma line, supporting the potential breadth of clinical applicability across neuroendocrine malignancies.

About ANKTIVA® (nogapendekin alfa inbakicept-pmln)

The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells—NK and CD8+ killer T cells—that are involved in killing cancer cells. By activating NK cells, ANKTIVA® overcomes the tumor escape phase of clones resistant to T cells and restores memory T cell activity with resultant prolonged duration of complete response. A key component in the Company's BioShield platform, ANKTIVA is a first-in-class IL-15 agonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA® mimics the natural biological properties of the membrane-bound IL-15 receptor alpha, delivering IL-15 by dendritic cells and driving the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones.

About ImmunityBio

ImmunityBio, Inc. is a biotechnology company focused on innovating, developing, and commercializing next-generation immunotherapies designed to activate the patient's immune system and deliver durable protection against cancer and infectious diseases. Our approach harnesses both the adaptive and innate immune systems with the goal of restoring immune function and generating lasting immunological memory in patients. At the core of our strategy is the Cancer BioShield ™ platform, which is designed to stimulate critical lymphocytes, including natural killer (NK) cells, cytotoxic T cells, and memory T cells via our proprietary IL-15 superagonist, ANKTIVA® (nogapendekin alfa inbakicept). Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by a portfolio that includes adenovirus-vectored vaccines, allogeneic (off-the-shelf) and autologous NK-cell therapies, and additional immunomodulators intended to promote immunogenic cell death and support durable immune responses while potentially reducing reliance on high-dose chemo-radiation therapy. For more information, visit ImmunityBio.com and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this press release that are not historical facts are forward-looking statements, including, without limitation, statements regarding: the potential clinical utility, safety, and therapeutic benefit of memory cytokine-enhanced natural killer (M-ceNK) cell therapies; the potential of ImmunityBio's NK cell manufacturing and cryopreservation processes to enable scalable, reproducible, and rapid production of NK cell therapies; the ability to generate multiple therapeutic doses from a single leukapheresis collection; the potential to establish a "world bank" of NK cells or otherwise enable broad patient access to NK cell therapies; the readiness and potential advantages of automated or AI-driven robotic manufacturing systems; the expected development pathway, clinical evaluation, and future studies of the M-ceNK platform; the potential clinical benefits of combining M-ceNK cells with ANKTIVA® (nogapendekin alfa inbakicept-pmln); the potential mechanisms of action of M-ceNK cells and ANKTIVA®, including NK cell activation, proliferation, and persistence; the potential applicability of the platform across multiple tumor types; the significance of preclinical or early clinical findings; and ImmunityBio's plans to advance clinical development, present additional data, pursue regulatory discussions, and explore future regulatory approvals.

Forward-looking statements are based on current expectations, estimates, projections, and assumptions of management and involve known and unknown risks, uncertainties, and other factors that may cause actual results, performance, or achievements to differ materially from those expressed or implied by these forward-looking statements. Such risks and uncertainties include, but are not limited to: uncertainties regarding the translation of preclinical findings or early clinical observations into meaningful clinical outcomes; risks related to the development, manufacture, and scale-up of cell therapy products; the possibility that manufacturing processes may not perform as expected at larger scale or in commercial settings; the ability to successfully automate or implement AI-driven manufacturing systems; the ability to establish or maintain reliable supply, cryopreservation, and distribution capabilities for cellular therapies; risks associated with clinical trial design, enrollment, conduct, and outcomes; the possibility that additional data may not confirm initial safety or activity observations; the risk that regulatory authorities may require additional studies, data, or manufacturing validation; uncertainties regarding regulatory review, approvals, timelines, and inspections of the relevant manufacturing facilities; ImmunityBio's ability to successfully advance clinical programs and obtain regulatory approvals in the United States or other jurisdictions; competition from other therapeutic approaches; changes in regulatory requirements or standards; and ImmunityBio's ability to obtain sufficient funding and resources to support its development programs and manufacturing efforts.

More details about these and other risks that may impact ImmunityBio's business are described under the heading "Risk Factors" in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 23, 2026 and in subsequent filings made by ImmunityBio with

the SEC, which are available on the SEC's website at www.sec.gov.

ImmunityBio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. ImmunityBio does not undertake any duty to update any forward-looking statement or other information in this press release, except to the extent required by law.

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ImmunityBio Contacts:
Investors
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1 858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Sarah Singleton
ImmunityBio, Inc.
+1 415-290-8045
Sarah.Singleton@ImmunityBio.com

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