ImmunityBio Announces NCCN® Clinical Practice Guidelines in Oncology Have Been Updated to Include ANKTIVA® Plus BCG for Patients With BCG-Unresponsive NMIBC With Papillary-Only Disease

March 17, 2026

Recommendation is based on peer-reviewed clinical data supporting long-term effectiveness and safety durability in patients with papillary-only disease treated with ANKTIVA plus BCG[1].

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 17, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the National Comprehensive Cancer Network (NCCN®) has updated its 2026 NCCN Clinical Practice Guidelines in Oncology for Bladder Cancer to include ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary-only disease.

This update expands previous NCCN clinical guideline recommendations, which included patients with BCG-unresponsive NMIBC with carcinoma in situ (CIS) with or without papillary disease, to now also recognize patients with BCG-unresponsive NMIBC with papillary-only disease as candidates for treatment with ANKTIVA plus BCG. Both recommendations are Category 2A. The immunotherapy regimen is designed to activate natural killer (NK) cells and T cells and has demonstrated durable responses in clinical studies. The NCCN guideline reference to ANKTIVA® for patients with BCG-unresponsive NMIBC with papillary-only disease reflects a use that is not included in the current U.S. Food and Drug Administration approved indication for ANKTIVA.

“These updated NCCN guideline recommendations in bladder cancer represent an important milestone for patients with BCG-unresponsive NMIBC papillary-only disease who have exhausted standard BCG therapy,” said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. “The addition of ANKTIVA plus BCG for papillary-only disease in the NCCN guidelines reflects the growing body of clinical data evaluating ANKTIVA in this patient population and reinforces our commitment to developing comprehensive treatment solutions that address the full spectrum of patients living with BCG-unresponsive NMIBC. We welcome these updated guideline recommendations and await the FDA’s review of ANKTIVA plus BCG for this indication.”

The NCCN Clinical Practice Guidelines in Oncology for Bladder Cancer are developed by multidisciplinary expert panels and are updated regularly as new clinical evidence becomes available. The guidelines are intended to support clinical decision-making and policy in cancer management, and are widely used by physicians, patients, and payers to inform treatment decisions.

“This update is an important step in the continued evolution of clinical guidance for patients with BCG-unresponsive NMIBC and validates the growing role of immune-based therapies in the treatment landscape,” said Richard Adcock, President and CEO of ImmunityBio.

Clinical Background

The NCCN Clinical Practice Guideline in Oncology for Bladder Cancer Version 1.2026 update reflects clinical data generated from ImmunityBio's comprehensive bladder cancer development program, including updated findings from the QUILT-3.032 study evaluating ANKTIVA plus BCG in patients with papillary-only NMIBC (Cohort B). These data contribute to the overall body of evidence informing treatment considerations in the BCG-unresponsive setting.

Commercial and Access Implications

Coverage and reimbursement decisions are made independently by payers and may vary based on plan design and medical policy. ImmunityBio continues to engage with payers and healthcare institutions to support education and appropriate access consistent with approved labeling and applicable regulations.

ANKTIVA received U.S. Food and Drug Administration approval in April 2024 for use in combination with BCG in BCG-unresponsive NMIBC CIS with or without papillary tumors and was assigned a permanent J-code (J9028) by the Centers for Medicare & Medicaid Services in January 2025. ANKTIVA plus BCG is currently covered by insurance plans representing more than 100 million insured patients in the United States.

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. 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.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (BCG) for the treatment of

adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

WARNINGS AND PRECAUTIONS: Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the development of muscle-invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA® with BCG, reconsider cystectomy.

DOSAGE AND ADMINISTRATION: For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS

The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

Please see the complete Prescribing Information for ANKTIVA® at Anktiva.com.

References:

1 Chang SS et al. *Journal of Urology.* 2026;215:44-56. doi:10.1097/JU.0000000000004782.

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. Forward-looking statements include statements regarding the potential clinical impact of the updated NCCN Clinical Practice Guidelines in Oncology for Bladder Cancer, including the guideline reference to ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) for patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary-only disease, which represents an off-label use of ANKTIVA; the potential for the guideline update to improve awareness or access for patients with BCG-unresponsive NMIBC; the clinical potential and therapeutic benefits of ANKTIVA in combination with BCG; the continued development of ImmunityBio's bladder cancer program; the anticipated role of immune-based therapies in the treatment landscape; and ImmunityBio's plans to engage with payers and healthcare institutions to support education and appropriate patient access. These forward-looking statements are based on current expectations and assumptions regarding future events and are subject to risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied by such statements.

Factors that could cause actual results to differ materially include, among others: uncertainties regarding the interpretation and application of NCCN guideline updates by physicians, payers, and healthcare systems; the fact that the NCCN guideline reference includes an off-label use of ANKTIVA and that such references do not establish regulatory approval for that use; the timing and extent of coverage and reimbursement decisions by third-party payers; the ability of ImmunityBio's to successfully commercialize ANKTIVA; the availability and supply of BCG; the results of ongoing or future clinical studies; regulatory developments; the ability of ImmunityBio to maintain regulatory approvals; and market acceptance of ANKTIVA; competition from other therapies.

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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