ImmunityBio Presents Favorable Comparative Effectiveness Data in Complete Response Rates of NAI + BCG Versus Nadofaragene and TAR-200 at AUA 2026

May 19, 2026

NAI+BCG versus Nadofaragene Results:

- NAI+BCG treated patients were twice as likely to achieve a complete response (CR) at any point of the study versus nadofaragene firadenovec-vncg in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* with or without papillary disease
- Median duration of CR with NAI+BCG was more than twice that observed with nadofaragene firadenovec-vncg (22.1 versus 9.7 months)
- NAI+BCG reduced cystectomy risk by 60% versus nadofaragene

NAI+BCG versus TAR-200 Results:

- NAI+BCG demonstrated numerically higher 12-month CR rates and fewer treatment-related adverse events of any grade than TAR-200 (61.7% versus 83.5%)

CULVER CITY, Calif.--(BUSINESS WIRE)--May 19, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a vertically integrated commercial-stage immunotherapy company, today announced results from two indirect treatment comparison (ITC) analyses presented at the 2026 American Urological Association (AUA) Annual Meeting evaluating nogapendekin alfa inbakicept-pmln (NAI, ANKTIVA®) plus Bacillus Calmette–Guérin (BCG) against two other U.S. Food and Drug Administration (FDA) approved therapies for patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS) with or without papillary disease.

The AUA 2026 ITC presentations were:

- Podium presentation - PD25-15 (Edwards et al.): NAI+BCG versus nadofaragene firadenovec-vncg in BCG-unresponsive NMIBC CIS with or without papillary disease
- Interactive poster - IP50-12 (Jayram et al.): NAI+BCG versus TAR-200 in BCG-unresponsive NMIBC CIS with or without papillary disease

Comparative Effectiveness Versus Nadofaragene Firadenovec-vncg

In the absence of head-to-head randomized trials, ImmunityBio conducted a matching-adjusted indirect comparison (MAIC) using individual patient data from QUILT-3.032 (Cohort A, NAI+BCG, n=100) weighted against aggregate data from NCT02773849 (CIS Cohort, nadofaragene firadenovec-vncg, n=103). Baseline matching variables included age (≥65 years), sex, Eastern Cooperative Oncology Group (ECOG) performance status, race, and tumor stage. Effective sample sizes after weighting ranged from 71.7% to 84.2% across endpoints.

After matching, NAI+BCG demonstrated:

- Anytime CR rate of 69.7% (weighted) versus 53.4% for nadofaragene firadenovec-vncg; OR 2.01 (95% CI: 1.08, 3.72); E-value 3.43
- Median duration of complete response of 22.1 months versus 9.7 months, a difference of 12.45 months (95% CI: 8.17, 17.09); HR for end of response 0.57 (95% CI: 0.34, 0.95)
- Cystectomy-free survival HR 0.40 (95% CI: 0.21, 0.75)
- Overall survival HR 0.85 (95% CI: 0.22, 3.31), not statistically different between treatments

Kaplan-Meier curves for duration of response and cystectomy-free survival remained consistently above the nadofaragene firadenovec-vncg comparator throughout the follow-up period. Sensitivity analyses using simulated treatment comparison (STC) methodology produced consistent results.

“The magnitude and durability of complete response observed with NAI+BCG, combined with a meaningful reduction in the risk of cystectomy, are clinically relevant for patients with BCG-unresponsive NMIBC for whom bladder preservation is the priority,” said Dr. Brooke B. Edwards, the Urology Group, Cincinnati, OH. “These comparative data, while subject to the inherent limitations of unanchored indirect comparisons, provide context that can support shared decision making with patients considering bladder-sparing therapy.”

Comparative Effectiveness Versus TAR-200

A separate MAIC was conducted comparing individual patient data from QUILT-3.032 (Cohort A, NAI+BCG, n=100) with aggregate data from SunRISe-1 (Cohort 2, TAR-200, n=85). Matching variables included age, sex, ECOG performance status, race, prior BCG instillations, and tumor stage. Outcomes of interest were complete response rate at 12 months and treatment-related adverse events of any grade.

Key findings from the base-case adjusted MAIC:

- At 12 months, NAI+BCG achieved a higher complete response rate than TAR-200 (49.2% versus 45.9%; OR 1.14; 95% CI: 0.61, 2.15); the difference did not reach statistical significance
- Patients treated with NAI+BCG experienced substantially fewer treatment-related adverse events of any grade than patients treated with TAR-200 (61.7% versus 83.5%), a statistically significant 68% reduction in adverse event odds (OR 0.32; 95% CI: 0.15, 0.67); E-value 5.70
- Sensitivity analyses using both MAIC and STC methodologies produced consistent safety findings, with E-values exceeding 5 across analyses, indicating that any unmeasured confounder capable of negating the safety finding would need to be approximately 5 times stronger than the measured baseline risk factors

"The comparative effectiveness data presented at AUA 2026 reinforce what we have observed across the ANKTIVA development program: that IL-15, working through the trifecta of NK cells, CD8+ T cells, and memory T cells, can produce complete responses that are not only more frequent but materially more durable than other approved therapies for BCG-unresponsive non-muscle invasive bladder cancer," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio. "A duration of complete response more than twice as long as with nadofaragene speaks directly to the central question patients ask: ‘how long will my response last?' These ITC analyses, while subject to the limitations of unanchored comparisons, add to the growing body of evidence that ANKTIVA plus BCG can serve as the immunological backbone of bladder cancer treatments. Beyond the data, the enthusiasm we heard directly from urologists at AUA about our continued advancement of recombinant BCG, and our parallel progress in developing an additional source of conventional BCG with the Tokyo strain, was a welcome confirmation that the field shares our urgency. It is exciting to be in a position to offer urologists and their patients additional sources of intravesical immunotherapy at a moment when the persistent U.S. TICE BCG shortage has made access the binding constraint on care in the urology setting."

Limitations

The QUILT-3.032 versus NCT02773849 and QUILT-3.032 versus SunRISe-1 analyses are unanchored, population-adjusted indirect treatment comparisons and should be interpreted with caution. Some baseline variables were not mutually reported across trials, including tumor grade, size, number of tumors, recurrence classification (relapse versus refractory), and timing of recurrence, limiting the ability to fully verify comparability across all clinically meaningful dimensions. Residual confounding was mitigated by including all reported prognostic variables and treatment effect modifiers in the adjustment process, and stability of results was assessed through sensitivity analyses and E-value tipping-point analyses.

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

U.S. 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. Please see the complete Indication and Important Safety Information and Prescribing Information for ANKTIVA® at Anktiva.com.

Investigational Use Notice: The Tokyo strain of BCG (manufactured by Japan BCG Laboratory) and recombinant BCG or rBCG (manufactured by Serum Institute of India under ongoing partnership with ImmunityBio) are investigational in the United States and have not been approved by the FDA. The safety and effectiveness of these investigational products have not been established. Availability of rBCG is limited to ImmunityBio's FDA Expanded Access Program for eligible patients. To enroll in the Expanded Access Program for recombinant BCG, please visit https://immunitybio.com/rbcg/.

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. Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by an investigational 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, without limitation, statements regarding the potential clinical and commercial implications of the comparative effectiveness data presented at AUA 2026; future regulatory interactions and potential label expansions; the continued development and potential approval of the Tokyo strain of BCG and recombinant BCG (rBCG); the scope and duration of ImmunityBio's Expanded Access Program for rBCG; and statements regarding ImmunityBio's broader pipeline, strategy, and future growth.

These forward-looking statements are based on ImmunityBio's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: the inherent limitations of indirect treatment comparisons and the possibility that head-to-head clinical trials may yield different results; the FDA's review and acceptance of any future regulatory submissions; ImmunityBio's ability to manufacture, supply, and commercialize ANKTIVA® and BCG products at sufficient scale; competition from other NMIBC therapies; the continued availability of BCG and ANKTIVA®; reimbursement and market adoption of NAI+BCG; clinical, regulatory, and commercial risks associated with ANKTIVA® and the Company's broader pipeline; intellectual property risks; macroeconomic and geopolitical conditions; manufacturing and supply chain challenges; and the additional risks and uncertainties identified in ImmunityBio's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K filed on February 23, 2026 and subsequent Quarterly Report on Form 10-Q filed on March 7, 2026, available at www.sec.gov.

The forward-looking statements in this press release speak only as of the date hereof, and ImmunityBio undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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