ANKTIVA® with BCG Demonstrates 96% Survival from Bladder Cancer at Three Years with Median Survival Not Yet Reached in BCG-Unresponsive High-Grade Papillary-Only Non-Muscle Invasive Bladder Cancer

December 16, 2025

- Results from the QUILT-3.032 study of 80 subjects, published in *The Journal of Urology,* showed 96% disease-specific survival and 83% progression-free survival at 36 months, demonstrating the long-term duration of effect of ANKTIVA® in patients with high-grade papillary NMIBC without CIS[1]
- High cystectomy avoidance rates of 92% and 82% were seen at 12 months and 36 months[1], validating the durable response and bladder sparing effect of ANKTIVA plus BCG in this indication
- ANKTIVA plus BCG demonstrated a tolerable safety profile consistent with BCG alone, with 3% of grade 3 and no grade 4 or 5 treatment-related adverse events[1]
- There are currently no approved therapies for BCG-unresponsive papillary-only NMIBC, leaving patients with total radical cystectomy as the alternative despite its high mortality and morbidity

CULVER CITY, Calif.--(BUSINESS WIRE)--Dec. 16, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced treatment with ANKTIVA® (nogapendekin alfa inbakicept-pmln) plus Bacillus Calmette-Guérin (BCG) demonstrates efficacy at 12 and 36 months, including disease-free survival (DFS), disease-specific survival (DSS), long-term progression-free survival (PFS), and high cystectomy avoidance in patients with BCG-unresponsive high-grade papillary-only non-muscle invasive bladder cancer (NMIBC). Published in *The Journal of Urology's* current January 2026 print edition, the findings also show tolerable safety that was consistent with BCG treatment alone, with 3% of grade 3 and no grade 4 or 5 treatment-related adverse events (TRAEs).[1]

Specific key efficacy findings from cohort B (N=80) of the Phase 2/3 open-label, single-arm multi-center QUILT-3.032 study include:[1]

- The DFS rate at 12 months (primary endpoint) was 58.2% (95% CI 46.6, 68.2); corresponding rates at 24 and 36 months were 52.1% (95% CI 40.3, 62.7) and 38.2% (95% CI 25.6, 50.6).
- DSS rates were 98.7% (95% CI 91.4, 99.8) at 12 months and 96.0% (95% CI 88.2, 98.7) at 36 months; the median DSS has not been reached.
- PFS rates were 94.9% (95% CI 86.9, 98.0) at 12 months and 83.1% (95% CI 69.5, 91.0) at 36 months.
- Cystectomy avoidance rates at 12 and 36 months were 92.2% (95% CI 83.4, 96.4) and 81.8% (95% CI 68.1, 90.1).

The safety profile of ANKTIVA plus BCG, which was assessed for study cohorts A and B (N=180), was tolerable and consistent with BCG alone.[1] Grade 1 or 2 TRAEs were seen in 61% of patients, with grade 3 events observed in 3% and no grade 4 or 5 events.[1] The most frequently reported TRAEs (incidence ≥ 3%) for participants who received ANKTIVA plus BCG (cohorts A and B, N=180) were those expected for intravesical instillation of BCG and included dysuria, pollakiuria, and hematuria.[1]

“Patients with BCG-unresponsive papillary-only non-muscle invasive bladder cancer have few treatment options, with cystectomy being considered the definitive treatment,” said lead author Sam S. Chang, M.D., Professor of Urology and Chief Surgical Officer of the Vanderbilt Ingram Cancer Center. “Prolongation of progression-free survival, disease-specific free survival and avoidance of bladder removal are clinically meaningful goals of next-generation chemotherapy-free immunotherapy. Our findings provide evidence that ANKTIVA plus BCG would offer a novel and efficacious treatment option for these patients.”

NMIBC comprises the subtypes of papillary (Ta, T1) and carcinoma in situ (CIS) disease, and while papillary disease is more common, the subtypes frequently occur together.[2-4] Importantly, from a pathological standpoint, papillary tumors and carcinoma in situ (CIS) in non-muscle invasive bladder cancer are closely linked by both clonality and histology. Molecular sequencing studies show that papillary lesions and CIS frequently arise from the same clonal urothelial precursor, sharing common genetic alterations and evolutionary lineage, rather than representing separate diseases. Histologically, both originate from malignant transformation of the urothelium and reflect disordered growth of the same epithelial cell layer, differing primarily in architectural pattern rather than biological origin. Papillary tumors grow outward into the bladder lumen, while CIS spreads flat along the bladder lining, but both represent manifestations of the same clonal cancer process within the bladder epithelium.

Standard initial treatment for intermediate- or high-risk NMIBC of either subtype consists of transurethral resection of the bladder tumor, followed by intravesical instillation of BCG.[3] While effective in many patients, approximately 40% will not respond to BCG, and for those who respond, about 50% will relapse and receive a diagnosis of BCG-unresponsive NMIBC.[5] Currently, there are no approved therapies for the treatment of these patients.

“The 12- and 36-month rates for disease-free, progression-free, and disease-specific survival seen in this study are higher than those reported for other investigational therapies in this patient population,” added Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. “Together with the high rates of cystectomy avoidance, with the median to cystectomy not yet reached, and the 96% bladder cancer-specific survival at three years, also with median not yet reached, demonstrates the effectiveness of ANKTIVA in enhancing the

immune response. These finding point to a potential paradigm change in the treatment of BCG-unresponsive high-grade papillary-only NMIBC."

ANKTIVA is currently approved by the U.S. Food and Drug Administration, United Kingdom and Conditional Marketing Authorization by the European Union with Bacillus Calmette-Guérin (BCG) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.

"The evidence that CIS and papillary disease are clonally linked, combined with the QUILT-3.032 findings showing long-term cystectomy avoidance, sustained avoidance of progression to muscle-invasive disease, and 96% bladder cancer-specific survival at three years, supports the consideration that ANKTIVA plus BCG addresses the unmet need for patients with papillary disease alone who face the prospect of total radical cystectomy following failure of BCG therapy," said Dr. Soon-Shiong.

QUILT-3.032 (NCT03022825) is a registrational, open-label, single-arm multicenter phase 2/3 trial of ANKTIVA plus BCG in patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). Cohort B (N=80) enrolled participants with histologically confirmed BCG-unresponsive high-grade Ta/T1 papillary NMIBC. During induction, participants in cohort B received ANKTIVA plus BCG intravesically through a urinary catheter to the bladder weekly for 6 consecutive weeks. The primary endpoint was DFS at 12 months. Secondary efficacy endpoints included PFS, DSS and cystectomy avoidance. Efficacy was assessed at 12, 24 and 36 months. Treatment-related adverse events (TRAEs) were evaluated for study cohorts A and B (N=180) and monitored throughout the study.

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.

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.

References:

1. Chang SS, Chamie K, Kramolowsky E, Gonzalgo ML, Agarwal PK, Bassett JC, et al. Prolonged Progression-Free Survival, Disease-Free Survival, and Cystectomy Avoidance With IL-15 Receptor Lymphocyte-Stimulating Agent NAI Plus Bacillus Calmette-Guérin in Bacillus Calmette-Guérin-Unresponsive Papillary-Only Nonmuscle-Invasive Bladder Cancer. *J Urol*. 2026 Jan;215(1):44-56. doi: 10.1097/JU.0000000000004782. Epub 2025 Sep 16. PMID: 40956664.
2. Llano A, Chan A, Kuk C, Kassouf W, Zlotta AR. Carcinoma In Situ (CIS): Is There a Difference in Efficacy between Various BCG Strains? A Comprehensive Review of the Literature. *Cancers* (Basel). 2024;16(2).
3. Holzbeierlein J, Bixler BR, Buckley DI, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. J Urol. 2024;10.1097/ JU.0000000000003846.
4. Anastasiadis A, de Reijke TM. Best practice in the treatment of nonmuscle invasive bladder cancer. *Ther Adv Urol*. 2012;4(1):13-32.
5. Filon M, Schmidt B. New Treatment Options for Non–Muscle-Invasive Bladder Cancer. American Society of Clinical Oncology Educational Book. 2025;45(2):e471942.

About ImmunityBio

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies that bolster the natural immune system to defeat cancers and infectious diseases. The Company's range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. Designated an FDA Breakthrough Therapy, ANKTIVA is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer CIS that activates NK cells, T cells, and memory T cells for a long-duration response. The Company is applying its science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases. For more information, visit **ImmunityBio.com** (Founder's Vision) 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, but are not limited to, statements regarding the significance of the data from the Company's QUILT-3.032 study published in the

Journal of Urology, the potential clinical relevance of such data, the potential impact of the publication on future research, clinical practice, regulatory interactions, commercialization strategies, and the Company's expectations regarding the development, approval, or potential expanded use of its products, the potential benefits to patients, the potential treatment outcomes for patients, the application of the Company's science and platforms to treat cancers or develop cancer vaccines, immunotherapies and cell therapies that has the potential to change the paradigm in cancer care, the Company's ability to distribute treatment broadly to patients. These statements are based on current expectations, assumptions, and information available to the Company as of the date of this press release and are subject to a number of risks and uncertainties, including, but not limited to, uncertainties inherent in clinical research and data interpretation, the fact that off-label uses have not been approved by the U.S. Food and Drug Administration or other regulatory authorities, the outcome of future studies, regulatory review and approval processes, changes in medical practice standards, market acceptance, competition, or intellectual property protection. 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 March 3, 2025, and the Company's Form 10-Q filed with the SEC on November 5, 2025 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.

The publication of off-label data does not imply regulatory approval or an intention to promote any product for an unapproved use.

View source version on businesswire.com: https://www.businesswire.com/news/home/20251216185945/en/

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

Source: ImmunityBio, Inc.