ImmunityBio Announces FDA Acceptance of Supplemental BLA for ANKTIVA® Plus BCG in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Papillary Disease; PDUFA Date Set for January 6, 2027

May 19, 2026

- Supplemental BLA seeks to expand the ANKTIVA label to include patients with BCG-unresponsive NMIBC with papillary disease
- FDA noted in its filing communication that the supplemental BLA accepted for review was based on the additional scientific data ImmunityBio provided at the Agency's request, detailing the overlapping features of papillary and CIS disease to determine adequate justification to allow for the expansion of the already approved indication of ANKTIVA with BCG to include the treatment of patients with BCG unresponsive NMIBC with papillary tumors
- During the FDA workshop held on May 18, 2026, panelists stated that CIS and papillary disease arise from the same cancer inducing clone, is therefore the same disease biologically, and that the clinical treatment decision made by the panelists when papillary disease alone is identified, is to treat the patient off-label with an already FDA approved therapy for CIS and papillary disease
- This analysis of the experts at the FDA workshop was consistent with the recent decision (March 2026) by the NCCN panel of experts to designate the treatment of BCG-unresponsive non-muscle invasive bladder cancer papillary disease as a Category 2A guideline for practicing urologists treating such patients with papillary disease alone.
- FDA assigns Prescription Drug User Fee Act (PDUFA) target action date of January 6, 2027
- Approximately 85% of the 64,000 people diagnosed with NMIBC in the U.S. each year present with papillary disease[1]

CULVER CITY, Calif.--(BUSINESS WIRE)--May 19, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the U.S. Food and Drug Administration has accepted for review the supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guerin (BCG) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary disease without carcinoma in situ (CIS). The FDA assigned a PDUFA target action date of January 6, 2027.

In the filing communication, the FDA stated, "*In support of this expansion, you have submitted the results of QUILT-3.032 Cohort B and a literature-based rationale proposing that papillary NMIBC has an overlapping clinical and non-clinical profile with CIS that may allow for extrapolation of results from patients with CIS, as was demonstrated in QUILT-3.032 Cohort A, the basis of the existing indication, to those with papillary-only disease*." The Agency further provided insight as to the focus of the review of this sBLA by stating, " *The scientific data detailing these overlapping features will be the focus of the review of this sBLA to determine if there is adequate justification to allow for such an extrapolation and expansion of the indication of Anktiva with BCG to include the treatment of patients with BCG-unresponsive NMIBC with papillary tumors*," while reiterating their concerns relating to single-arm trials in papillary disease alone (Cohort B) in which the initial indication for CIS and papillary disease (Cohort A) has already been approved in a single-arm trial. If approved, the sBLA would expand the current indication for ANKTIVA plus BCG and further broaden treatment options for patients with BCG-unresponsive NMIBC.

Recently the FDA convened a public workshop on May 18, 2026 titled, "Contemporary Issues in Non-Muscle Invasive Bladder Cancer (NMIBC) Trial Design and Interpretation," which addresses the issues to be reviewed in this sBLA and included discussion among clinicians, scientific experts and thought leaders regarding the biological similarities of CIS and papillary and the treatment decisions for patients with papillary disease alone. The meeting was available to the public in real-time. *At the workshop, panelists stated that CIS and papillary disease arise from the same cancer inducing clone, is therefore the same disease and the clinical decision treatment made when papillary disease alone is identified in the real-world is to treat the patient with already FDA approved therapies for CIS and papillary disease.* These statements made by the expert panel at the FDA workshop on May 18, 2026, are consistent with the decision of the NCCN panel of experts to designate on March 2026, the treatment of BCG unresponsive non-muscle invasive bladder cancer papillary disease as a Category 2A guideline for practicing urologists treating such patients with papillary disease alone.

The FDA workshop meeting goals included the issues directly pertinent to sBLA submission currently under review and, as the Agency stated, the focus of the sBLA review as follows:

"Discuss the similarities and differences between the two types of histology (papillary and CIS) observed in NMIBC and implications for the demonstration of efficacy in clinical trials."

"Patients with BCG-unresponsive NMIBC with papillary disease are faced with the option of a total radical cystectomy and continue to face limited treatment options with no FDA approved therapy to date that strives to preserve the bladder, while reducing the risk of disease progression to muscle-invasive cancer," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "The FDA's acceptance of this supplemental application for review represents an important step toward potentially expanding access to ANKTIVA plus BCG for patients with high-grade BCG unresponsive NMIBC. We were encouraged by the scientific discussion at the recent FDA workshop regarding the biological overlap between CIS and papillary disease and the current real-world treatment approaches for these patients. We look forward to continuing to work with the Agency during its review of the application."

Dr. Soon-Shiong who attended the FDA workshop, further stated, “The feedback from the thought leaders at the FDA workshop meeting relating to the real-world clinical treatment of patients with papillary disease alone was significantly important in informing the Agency of the clinical and scientific views of clinicians treating patients with high-grade non-muscle invasive bladder cancer. Of significance was the statements by the panelists at the FDA workshop, that when patients with this indication of papillary disease alone are identified, the conclusion was that CIS may indeed exist but not identified and furthermore the identification of CIS was irrelevant in their treatment decisions. The panelists stated that in this instance, the treatment for these patients in the real-world was to offer therapies that are already approved by the FDA for BCG unresponsive NMIBC with CIS and papillary disease, emphasizing the real-world need for an approved therapy for patients with papillary disease alone. I was grateful for these insights and the consistency of these statements with the recent designation by the expert panel at NCCN to provide Category 2A inclusion as part of the guidelines for practicing physicians managing patients with BCG unresponsive NMIBC papillary disease alone,” he said.

The supplemental application is supported by data from the QUILT 3.032 Phase 2/3 trial (Cohort B; NCT03022825) in 80 patients with high-grade papillary-only NMIBC. As published in *The Journal of Urology* (Chang *et al.*, 2025), the study met its primary endpoint with a 12-month disease-free survival (DFS) rate of 58.2% (95% confidence interval: 46.6-68.2%)**.**

The ultimate clinical goal of the treatment of patients with high-risk non-muscle invasive bladder cancer is to avoid or delay a life-changing total radical cystectomy, which is fraught with high morbidity and mortality rates, and to prevent progression of the disease from non-muscle invasive to muscle-invasive and metastasis. The secondary endpoints of the chemo-free immunotherapy based treatment of ANKTIVA plus BCG in Cohort B that identifies the results addressing this goal of delaying progression into muscle-invasiveness and accomplishing bladder sparing are:

- Progression Free Survival (PFS)
- Cystectomy Free Survival
- Disease Specific Survival (DSS)

The data submitted to the Agency regarding these secondary endpoints for consideration and published in peer reviewed journals (New England Journal of Medicine and Journal of Urology), as well as accepted by NCCN with a Category 2A designation for patients treated with intravesical ANKTIVA plus BCG with BCG unresponsive non-muscle invasive bladder cancer and papillary disease alone demonstrated:

- **Progression-Free Survival (PFS):** 94.9% at 12 months and 82.0% at 36 months, indicating durable prevention of progression to muscle-invasive disease.
- **Cystectomy Free Survival:** Bladder preservation remained high, with cystectomy-free survival of 92.2% at 12 months and 83.1% at 36 months, meaning over 80% of patients avoided radical cystectomy through three years of follow-up.
- **Disease-Specific Survival (DSS)**: 96.0% Disease-Specific Survival (DSS) rate at 36 months, with median DSS not yet reached at time of submission of the sBLA.

The safety data submitted in this supplemental BLA was consistent with the safety data of the indication already approved, demonstrating qualitatively that the serious adverse events of ANKTIVA when combined with BCG was consistent with that of BCG alone.

ANKTIVA plus BCG was previously approved by the FDA in April 2024 for the treatment of adult patients with BCG-unresponsive NMIBC with carcinoma in situ (CIS), with or without papillary tumors. Non-muscle-invasive bladder cancer (NMIBC) represents approximately 80% of all bladder cancer diagnoses in the United States, approximately 85% of people diagnosed with NMIBC in the U.S. each year present with papillary disease. Patients with papillary disease who become unresponsive to BCG therapy face a high risk of recurrence and progression and often have limited bladder-sparing treatment options available.

"Today's acceptance of the supplemental BLA represents an important milestone for ImmunityBio and for patients with BCG-unresponsive NMIBC,” said Richard Adcock, President and CEO of ImmunityBio. “ANKTIVA is already approved for patients with CIS with or without papillary disease, and this application has the potential to expand access to patients with papillary-only disease, the larger segment of the BCG-unresponsive population. The revelation by the clinicians at the FDA workshop that they treat patients today with papillary disease alone by offering off-label FDA approved therapies for papillary and CIS disease, emphasizes the urgent need for this therapy to be made available to patients suffering from high-grade NMIBC. If approved, this expanded indication would further position ANKTIVA plus BCG as an important immunotherapy option across the NMIBC treatment landscape, enabling insurance reimbursement, making this chemotherapy free treatment available to more patients.”

About ANKTIVA® (nogapendekin alfa inbakicept-pmln)

The interleukin-15 (IL-15) cytokine 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 receptor 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.

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.

1. https://pmc.ncbi.nlm.nih.gov/articles/PMC3263923/

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 potential timing and outcome of the FDA's review of the supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept-pmln) plus BCG in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary disease, including the PDUFA target action date of January 6, 2027; the potential for FDA approval of the sBLA and the expansion of the ANKTIVA label to include patients with BCG-unresponsive NMIBC with papillary disease; the potential commercial impact and market opportunity of such an expanded indication; the ability of ANKTIVA plus BCG to provide durable, bladder-sparing treatment options for patients with BCG-unresponsive NMIBC; and the Company's expectations regarding the role of ANKTIVA as a foundational IL-15 immunotherapy for NMIBC.

These forward-looking statements are based on management's current expectations, estimates, forecasts, and projections as of the date of this release and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated. Factors that could cause actual results to differ include, but are not limited to: the risk that the FDA may not approve the sBLA on the anticipated timeline or at all; the risk that the FDA may require additional clinical data or impose other conditions that delay or prevent approval; uncertainties regarding the FDA's evaluation of the scientific data supporting extrapolation between papillary and CIS disease; risks related to the Company's ability to successfully commercialize ANKTIVA for an expanded indication, including market acceptance, reimbursement, and competition; risks associated with manufacturing and supply chain; the potential for safety or efficacy concerns to arise; general economic and market conditions; and other risks described in the Company's filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K filed on February 23, 2026, and its Quarterly Report on Form 10-Q filed on May 7, 2026, as well as current reports on Form 8-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

ImmunityBio undertakes no obligation to update any forward-looking statement to reflect new information, future events, or circumstances, except as required by law.

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