ImmunityBio Announces Resubmission of Supplemental BLA to the FDA for ANKTIVA® Plus BCG in BCG-Unresponsive NMIBC with Papillary Disease Following Agency Review of Additional Data

March 9, 2026

- Following multiple meetings with the FDA, ImmunityBio submitted additional information requested by the Agency to support its supplemental BLA (sBLA) for papillary disease
- The FDA reviewed the additional data provided by ImmunityBio in February 2026, and based on the Agency's feedback, the Company resubmitted the sBLA
- The FDA has acknowledged receipt of the resubmitted filing
- The sBLA aims to address the unmet need for patients with papillary-only NMIBC, supported by what is believed to be the longest duration of follow-up and bladder preservation data in this patient population
- Approximately 60,000 people are diagnosed with NMIBC annually in the U.S., with approximately 70% presenting with papillary (Ta) disease[1]

CULVER CITY, Calif., March 9, 2026 /PRNewswire/ -- ImmunityBio (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of its supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept-pmln) plus Bacillus Calmette-Guérin (BCG) in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary tumors.

The resubmission follows ongoing discussions with the FDA beginning in January 2026, during which the Agency requested additional data to support its review. The request did not include the initiation or design of any new clinical trials. ImmunityBio submitted the requested information in February 2026. After reviewing the additional data, the FDA provided feedback in March requesting updated efficacy data. The company subsequently resubmitted the sBLA for patients with papillary-only NMIBC, including updated long-term follow-up data, and the Agency has acknowledged receipt of the filing. The long-term safety and efficacy results for ANKTIVA plus BCG in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary tumors have been published in *The Journal of Urology.*

"As far back as 2007, IL-15 was identified by leading scientific and medical organizations, including the NCI, NIH, FDA, AACR, and ASH, as the number one ranked immunotherapy molecule with the potential to cure cancer," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman, and Global Chief Scientific and Medical Officer of ImmunityBio. "The mechanism of action of ANKTIVA's IL-15 superagonist activity was affirmed by the FDA's approval of ANKTIVA in 2024 for BCG-unresponsive NMIBC with carcinoma in situ (CIS), with or without papillary tumors. The long-term data in papillary disease alone demonstrate prolonged disease-free survival and durable bladder preservation, consistent with ANKTIVA's IL-15-based mechanism of action."

Dr. Soon-Shiong added, "We welcome FDA Commissioner Dr. Makary's recent statements in *The New England Journal of Medicine* highlighting the importance of a "plausible mechanism of action" as an emerging regulatory pathway. The mechanism of action of ANKTIVA, which was recognized in the NCI's 2007 report and reaffirmed in the FDA-approved 2024 package insert, embodies the principles underlying this approach."

Based on the IL-15 mechanism of action and results from the QUILT 3.055 study, the Saudi Food and Drug Authority (SFDA) recently approved ANKTIVA in combination with checkpoint inhibitors for patients with second-line and later metastatic non-small cell lung cancer (NSCLC) whose disease has progressed after standard therapies, including checkpoint inhibitor treatment. In this setting, multiple randomized studies of investigational agents compared with docetaxel chemotherapy have failed to demonstrate improved outcomes, underscoring the significant unmet need among patients who experience relapse or progression after checkpoint inhibitor therapy. Notably, the recent randomized PRAGMATICA-LUNG (SWOG S2302) trial in the same disease setting, which compared pembrolizumab plus ramucirumab versus docetaxel, did not demonstrate improved survival compared with docetaxel, reporting a median overall survival of approximately nine months with docetaxel chemotherapy.

ImmunityBio plans to present the clinical data supporting the SFDA approval of the chemotherapy-free regimen of ANKTIVA plus checkpoint inhibitors, which demonstrated nearly double the median overall survival historically observed with docetaxel chemotherapy. The Company also intends to continue discussions with the FDA and other global regulatory authorities regarding potential treatment options for patients with second line and later metastatic NSCLC who have exhausted currently available standards of care, including checkpoint inhibitors.

About the Papillary Indication: The sBLA submission for BCG-unresponsive NMIBC papillary disease is supported by long-term results from the QUILT 3.032 Phase 2/3 trial (Cohort B) 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%)**.** Patients treated with intravesical ANKTIVA plus BCG demonstrated a 96.0% disease-specific survival (DSS) rate at 36 months, with median DSS not yet reached. Progression-free survival (PFS) was 94.9% at 12 months and 83.1% at 36 months, indicating durable prevention of progression to muscle-invasive disease. Bladder preservation remained high, with cystectomy-free survival of 92.2% at 12 months and 81.8% at 36 months, meaning over 80% of patients avoided radical cystectomy through three years of follow-up. These results highlight the potential of ANKTIVA plus BCG to provide durable bladder-sparing outcomes and a chemotherapy-free immunotherapy alternative for patients with high-risk papillary NMIBC.

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. https://pmc.ncbi.nlm.nih.gov/articles/PMC3357503/#:~:text=Among%20NMIBCs%2C%20around%2070%25%20present,NMIBC%20and%20often%20go%20underutilized.

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 other than statements of historical fact contained in this press release are forward-looking statements, including, without limitation, statements regarding the potential approval of this supplemental biologics license application (sBLA) for ANKTIVA in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary tumors; the anticipated regulatory review process and timing thereof; the potential clinical benefit, durability of response, and safety associated with ANKTIVA; the potential to address unmet medical needs in patients with papillary-only NMIBC; the potential mechanism of action and therapeutic impact of ANKTIVA; The Company's plans to present additional clinical data; and the Company's plans to pursue regulatory discussions and potential approvals for ANKTIVA in additional indications, including non-small cell lung cancer (NSCLC).

These forward-looking statements are based on current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management, and are subject to various risks and uncertainties. Actual results may differ materially from those expressed or implied by such forward-looking statements due to a variety of factors, including, but not limited to: the risk that the U.S. Food and Drug Administration (FDA) may determine that the data and information included in the sBLA resubmission are insufficient to support approval; the risk that the FDA may require additional information, analysis, or clinical studies prior to making a determination; the possibility that the FDA may determine that the resubmitted application constitutes a complete response or may issue a complete response letter; uncertainties regarding the timing, outcome, and conduct of the regulatory review process; the possibility that regulatory authorities may not agree with the Company's interpretation of clinical data or assessments of the mechanism of action of ANKTIVA; the possibility that feedback or comments received from the FDA in meetings, written correspondence, or other regulatory interactions may not be predictive of the Agency's ultimate regulatory decision; the risk that information submitted following regulatory meetings may not adequately address FDA questions or concerns; the possibility that additional regulatory interactions may result in new or additional requirements; and uncertainties regarding evolving regulatory standards, policies, or guidance applicable to biologics or oncology therapies; the possibility that clinical trial results may not be replicated in additional studies or real world settings; the potential for delays in regulatory interactions, submissions, or approvals; uncertainties related to the Company's ability to obtain or maintain regulatory approvals in the United States or other jurisdictions; the Company's ability to successfully develop and expand indications for ANKTIVA; competition from other therapies; changes in regulatory requirements standards; and other risks related to the Company's business, operations, and financial condition.

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.

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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