ImmunityBio Advances Regulatory Discussions with FDA on Potential Resubmission Path for ANKTIVA® in BCG-Unresponsive Papillary Bladder Cancer

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- **Following discussions with the U.S. FDA, the Agency recommended that the Company submit additional information for its evaluation of this information to potentially support a resubmission of the sBLA for BCG-unresponsive papillary NMIBC**
- **The additional information does not include the initiation or design of any new clinical trials, and the Company will provide the requested information in the next 30 days**
- **Long-term data published in *The Journal of Urology* evaluating ANKTIVA in patients with papillary disease (N=80) demonstrate approximately 96% bladder cancer-specific survival and greater than 80% bladder preservation at three years, with median outcomes not yet reached**
- **ImmunityBio commercially launched ANKTIVA for NMIBC CIS with or without papillary tumors in the United States and has since expanded approvals to the United Kingdom and Saudi Arabia, with conditional approval in the European Union**

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 20, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced that it recently held a Type B End-of-Phase meeting with the U.S. FDA regarding the Company's supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept) plus Bacillus Calmette-Guérin (BCG) in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary tumors.

The Company presented an overview of the clinical status of its papillary disease program, including more than five years of follow-up data supporting the papillary indication. Highlights included durable disease-specific survival of approximately 96% at 36 months, with the median survival not yet reached even with five years of follow-up; high rates of cystectomy avoidance of 92% and 82% at one and three years, respectively; and a safety profile consistent with the currently approved indication in CIS disease with or without papillary tumors. In addition, several thought-leading urologists who attended the meeting presented real-world treatment approaches for patients with BCG-unresponsive disease, where the remaining alternative is often radical cystectomy.

Based on these discussions, the FDA recommended that the Company provide certain additional information for its consideration to support a potential resubmission of the sBLA initially submitted in 2025 for the papillary indication. ImmunityBio has compiled the requested information and will submit it to the Agency within the next 30 days. This additional information does not contemplate the initiation or design of a new clinical trial.

This submission follows a productive face-to-face meeting with senior FDA officials, during which the regulatory path forward for ANKTIVA in papillary NMIBC was collaboratively defined. Topics included current standards of care, challenges associated with chemotherapy, patient management considerations, and perspectives on the interpretation of the Company's data. BCG-unresponsive disease remains a serious condition, with risks of progression to muscle-invasiveness disease, higher mortality, and limited bladder-sparing treatment options for patients.

"We appreciate the FDA's collaboration throughout this process and remain fully committed to delivering this much-needed therapy to patients who currently have no approved alternatives when standard of care fails," said Richard Adcock, President and CEO of ImmunityBio. "We have completed the assembly and analysis of the requested additional information and will submit it within the next 30 days for the Agency's review."

About the Papillary Indication: The proposed submission for the BCG-unresponsive NMIBC papillary indication is supported by long-term results from the QUILT-3.032 Phase 2/3 trial (Cohort B) in 80 patients with BCG-unresponsive high-grade papillary-only NMIBC. As recently 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 the 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. Notably, the therapy conferred a bladder-sparing benefit: cystectomy-free survival was 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 long-term outcomes, including ≥82% bladder preservation and ≥96% bladder cancer-specific survival at 36 months, are unprecedented in this high-risk population and underscore the potential of ANKTIVA to offer a curative-intent, chemo-free immunotherapy alternative to surgery. *(Clinical reference: Chang et al., 2025, Journal of Urology)*

"The 12- and 36-month survival rates observed with ANKTIVA plus BCG are higher than those reported for other investigational therapies in this patient population," said Dr. Patrick Soon-Shiong. "Together with the high rate of bladder preservation – with over 80% of patients remaining cystectomy-free at three years – these data demonstrate the effectiveness of ANKTIVA in enhancing the immune response against bladder cancer. We remain committed to bringing this important therapy to patients as quickly as possible. Patients with BCG-unresponsive papillary NMIBC currently have no approved treatment options aside from life-altering radical cystectomy, so our mission is to deliver a safe and effective bladder-sparing treatment to address this urgent unmet need."

Global Regulatory Status: ANKTIVA in combination with BCG is already approved in multiple regions for BCG-unresponsive NMIBC CIS. The product received FDA approval in April 2024 for patients with carcinoma in situ (CIS) with or without papillary tumors. It is also approved by the United Kingdom's MHRA and has a positive opinion for Conditional Marketing Authorization in the European Union for NMIBC with CIS with or without

papillary tumors. Most recently, the Saudi Food and Drug Authority (SFDA) granted approval to ANKTIVA for NMIBC CIS (with or without papillary disease) in January 2026. These approvals reflect ImmunityBio's commitment to expanding patient access to ANKTIVA globally as a potentially bladder-sparing option. The Company is actively engaging with additional regulatory agencies, including the European Medicines Agency (EMA) and authorities in other regions, to extend the label to papillary-only disease pending U.S. approval.

Unmet Medical Need: High-grade papillary NMIBC that is unresponsive to BCG poses a serious treatment challenge, as no targeted therapies are currently approved for these patients. Standard of care for BCG-unresponsive, papillary-only disease has been radical cystectomy (complete removal of the bladder), an invasive surgery associated with significant morbidity and impact on quality of life. ImmunityBio's pursuit of the papillary NMIBC indication is aimed at providing an alternative to cystectomy – a therapy that can eradicate disease while preserving the bladder. The long-term data from QUILT-3.032 suggest that ANKTIVA plus BCG can achieve durable remissions in papillary NMIBC, delaying or avoiding the need for radical surgery in the majority of responders. If approved, ANKTIVA would become the first immunotherapy option for BCG-unresponsive papillary NMIBC, expanding on its existing approved use in CIS and potentially transforming the treatment paradigm for these patients.

About ANKTIVA® (nogapendekin alfa inbakicept)

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.

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 in this press release include, without limitation, statements regarding: the Company's plans and timing to submit additional information to the U.S. Food and Drug Administration (FDA) and any potential resubmission or amendment of the Company's supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept) plus Bacillus Calmette-Guérin (BCG) in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with papillary tumors; the FDA's review of any such submission(s), including whether the FDA will determine that any resubmission is complete and acceptable for review; the timing, outcome, or scope of any regulatory review, potential advisory committee meeting, or potential regulatory action; the Company's ability to obtain approval for an expanded label in the United States or in other jurisdictions; the potential clinical benefits, safety, effectiveness, durability, bladder-sparing outcomes, or therapeutic value of ANKTIVA plus BCG in papillary NMIBC; and the Company's future plans, expectations, and prospects related to ANKTIVA and its regulatory and commercialization strategy.

These forward-looking statements are based on the Company's current expectations and beliefs and are subject to significant risks, uncertainties, and assumptions that could cause actual results to differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially include, among others: the FDA's and other regulators' determinations regarding the sufficiency, completeness, or adequacy of any data or information submitted, including for purposes of accepting or reviewing any resubmission; the risk that the FDA may require additional data, analyses, or clinical studies, including randomized or controlled trials, or may not agree with the Company's interpretations of clinical results; the risk that prior or future regulatory feedback, meeting discussions, or communications may not result in a path to approval on the timelines anticipated or at all; uncertainties inherent in clinical development, including variability of patient outcomes, limitations of study design, and the possibility of adverse events or other safety findings with additional follow-up or broader use; the risk that real-world experience may differ from results observed in clinical trials; the Company's ability to manufacture and supply product at sufficient scale and quality; competitive developments; and the Company's ability to maintain and protect intellectual property and to obtain and maintain coverage and reimbursement.

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.

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