# ImmunityBio Provides Regulatory Update on Global Submission for ANKTIVA + BCG in BCG Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma in situ in Europe and United Kingdom

January 15, 2025

- Marketing authorization application for BCG Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) with Carcinoma in situ (CIS) submitted to European Medicines Agency (EMA) in December 2024 and anticipated acceptance of application in 2025
- Marketing authorization application for BCG Unresponsive NMIBC CIS submitted to United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) in November 2024 and anticipated acceptance of application in 2025
- ImmunityBio responding to requests for information from both Agencies and the potential for approval in European Union and United Kingdom by 2026

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 15, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX) today announced the completion of the submissions of its marketing authorization applications (MAA) for ANKTIVA® (nogapendekin alfa inbakicept) plus 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, to both the European Union (EU) European Medicines Agency (EMA) and the United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency (MHRA).

The EMA covers 27 countries in the EU, as well as Iceland, Norway, and Liechtenstein. The assessment is expected to be complete by the fourth quarter of 2025. Similarly, the UK assessment of the MAA is anticipated to be completed by the fourth quarter of 2025. ImmunityBio is in continued dialog for requests for information from the two agencies, with the potential of approval by 2026.

"The submission of our applications to EMA and MHRA represents a significant milestone in our efforts to address this critical need and improve patient outcomes globally," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio.

ImmunityBio continues to make strides in its mission to provide innovative therapies for patients with limited treatment options. The U.S. launch of ANKTIVA for NMIBC CIS has gained momentum, with the product now widely accessible through commercial and government insurance programs. The company recently announced the unique, permanent Healthcare Common Procedure Coding System (HCPCS) J-code (J9028) assigned by the Centers for Medicare & Medicaid Services (CMS) in the United States for ANKTIVA® (nogapendekin alfa inbakicept-pmln) under J9028 (Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram). To date, commercial and governmental insurance cover over 240 million lives for ANKTIVA.

**About ANKTIVA**

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 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 drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. The proliferation of the trifecta of these immune killing cells and the activation of trained immune memory results in immunogenic cell death, inducing a state of equilibrium with durable complete responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

**About ImmunityBio**

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines 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 natural killer 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 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, such as statements

regarding EMA and MHRA regulatory submissions and the potential acceptance and review thereof, including timing associated with such review, commercial launch activities and market access initiatives, medical insurance coverage and reimbursement, market data, clinical trial data and potential results to be drawn therefrom, the development of therapeutics for cancer and infectious diseases, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, potential future uses and applications of ANKTIVA and use in cancer vaccines and across multiple tumor types, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. Statements in this press release that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as "anticipates," "believes," "continues," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "is," "seeks," "should," "will," "strategy," and variations of such words or similar expressions.

Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about ImmunityBio, including, without limitation, (i) whether the EMA and/or MHRA will accept the submissions referenced herein for filing on the anticipated timeline or at all, (ii) whether the EMA and/or MHRA will ultimately approve such submissions and the risks and uncertainties associated with the regulatory review process and timing thereof, (iii) risks and uncertainties regarding commercial launch execution, success and timing, (iv) risks and uncertainties regarding market access initiatives and timing, (v) whether clinical trials will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, review and approval process, (vi) whether clinical trial data will be accepted by regulatory agencies, (vii) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development, patient enrollment and planned regulatory submissions, (viii) potential delays in product availability and regulatory approvals, (ix) ImmunityBio's ability to retain and hire key personnel, (x) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xi) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xii) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xiii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xiv) ImmunityBio's ability to obtain, maintain, protect, and enforce patent protection and other proprietary rights for its product candidates and technologies. 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 19, 2024 and the Company's Form 10-Q filed with the SEC on November 12, 2024, 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.

**Indication and 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 nonmuscle 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 patient 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. Instill intravesically only after dilution. Total time from vial puncture to the completion of the intravesical instillation should not exceed 2 hours.

**USE IN SPECIFIC POPULATIONS:** Pregnancy: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

**ADVERSE REACTIONS:** The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

For more information about ANKTIVA, please see the Full Prescribing Information at www.anktiva.com.

You are encouraged to report negative side effects of prescription drugs to FDA.

Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact ImmunityBio at 1-877-ANKTIVA (1-877-265-8482)

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