UK MHRA Approves ImmunityBio's ANKTIVA® Plus BCG for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer Carcinoma In Situ

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- ANKTIVA, a first-in-class, lymphocyte-stimulating agent, works synergistically with BCG to activate and proliferate natural killer (NK) and T cells, helping eliminate cancer
- Already approved in the U.S. and designated as a Breakthrough Therapy by the FDA, this marks ANKTIVA's first marketing approval outside the U.S.
- ANKTIVA plus BCG offers a new option for eligible patients among the 16,400 to 18,000 people diagnosed with NMIBC in the UK each year[1]

CULVER CITY, Calif.--(BUSINESS WIRE)--Jul. 7, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX) today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) for the treatment of certain bladder cancer patients. This is the first marketing approval outside the U.S. for this novel lymphocyte-stimulating agent.

"With the MHRA's authorization of ANKTIVA plus BCG, we can now offer our immunotherapy outside the U.S. to help patients with a disease that, if not effectively treated, can lead to bladder removal," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "This immune-boosting, lymphocyte-stimulating agent, the first of its kind, is central to our Cancer BioShield platform, which is designed to restore immune function and support long-term disease control."

"ImmunityBio is honored to have received this important authorization from the UK MHRA. In light of the United States Most-Favored-Nation Prescription Drug Pricing policy implemented on May 12, 2025, we are actively evaluating our go-to-market strategy for the UK," said Richard Adcock, CEO and President of ImmunityBio.

ANKTIVA is a first-in-class IL-15 agonist that activates and proliferates natural killer (NK) cells and CD4+ and CD8+ T cells. It is designed to restore immune competence by reversing lymphopenia—a condition in which cancer and conventional therapies, such as chemotherapy, radiation and checkpoint inhibitors, reduce the number and function of immune cells. Restoring immune function is essential for immunosurveillance, immunogenic cell death, and sustained tumor control. The BioShield platform's effectiveness can be monitored using a routine complete blood count (CBC).

ANKTIVA was designated a Breakthrough Therapy by the FDA and received approval from both the FDA and MHRA based on its safety and efficacy outcomes of complete response (CR) and duration of response (DOR). In a single-arm, multicenter trial, 77 evaluable patients received ANKTIVA with BCG for up to 37 months.

As of the November 2023 data cutoff, the duration of complete response for some patients exceeded 47 months and remains ongoing. These extended duration of complete responses beyond 24 months with ANKTIVA and BCG surpasses the benchmark for meaningful clinical results set by experts from the International Bladder Cancer Group.

ImmunityBio has also submitted regulatory applications to the European Medicines Agency (EMA) to expand availability of ANKTIVA across the 27 European Union (EU) member states, as well as Iceland, Norway and Liechtenstein.

About NMIBC CIS

Bladder cancer is the 10th most commonly-diagnosed cancer globally,[2] and in the UK, the Action Bladder Cancer UK estimates approximately 23,000 patients are diagnosed annually.[1] At the time of diagnosis, about 80% of cases are non-muscle invasive bladder cancer (NMIBC), wherein the cancer is found only on the inner layer of the bladder wall.[3] The standard therapy for NMIBC is intravesical instillation (delivery to the bladder via a catheter) of Bacillus Calmette-Guerin (BCG).[4,5] BCG is a benign bacteria that induces an immune response in the bladder in proximity to the cancer cells, leading to clearance of the cancer in many patients. In ~30-40% of patients, however, BCG will fail, and in ~50% that initially respond, cancer will recur.[6]

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 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.

ANKTIVA was approved by the FDA in 2024 for BCG-unresponsive non-muscle invasive bladder cancer CIS with or without papillary tumors. For more information, visit Anktiva.com.

INDICATION AND IMPORTANT SAFETY INFORMATION FROM THE FDA LABEL

INDICATION AND USAGE: ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (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 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)

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 (Founder's Vision) and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

References:

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2. World Cancer Research Fund. Bladder Cancer Statistics. 2022. Available at: https://www.wcrf.org/preventing-cancer/cancer-statistics/bladder-cancer-statistics/
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4. 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.
5. Grabe-Heyne, et al. Intermediate and high-risk non-muscle-invasive bladder cancer: an overview of epidemiology, burden, and unmet needs. Front Oncol. 2023 Jun 2;13:1170124. doi: 10.3389/fonc.2023.1170124.
6. Kodera A, Mohammed M, Lim P, Abdalla O, Elhadi M. The Management of Bacillus Calmette-Guérin (BCG) Failure in High-Risk Non-muscle Invasive Bladder Cancer: A Review Article. Cureus. 2023 Jun 26;15(6):e40962. doi: 10.7759/cureus.40962. PMID: 37503461; PMCID: PMC10369196.

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 clinical trial data and potential results and implications to be drawn therefrom, the belief that the MHRA authorization leads to increased revenue, the expectation that the EAP as previously reported will enable access to ANKTIVA for patients across all solid tumor types who have exhausted first-line therapy including chemo, radiation or immunotherapy, the RMAT designation as previously reported and potential results therefrom and regulatory submissions in connection therewith, the belief that ALC levels and NLR levels obtained from a CBC are predictors of clinical benefit and outcomes relating to overall survival, the belief that improving ALC levels and NLR levels correlates with enhanced overall survival and clinical benefit, the belief that reversal of lymphopenia correlates with improved survival, clinical trial and expanded access program enrollment, data and potential results to be drawn therefrom, anticipated components of ImmunityBio's Cancer BioShield platform, 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 alone or in combination with other therapeutic agents for the prevention or reversal of lymphopenia, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents across multiple tumor types and indications and for potential applications beyond oncology, potential regulatory pathways and the regulatory review process and timing thereof, 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, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, and the impact of the MHRA on the Company's ex- United States go to market strategy, including in light of the recently

implemented United States Most Favored Nation pricing policy on the Company's go-to-market strategy in the United Kingdom, 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) risks and uncertainties regarding the FDA regulatory submission, filing and review process and the timing thereof, (ii) risks and uncertainties regarding regulatory submissions in foreign jurisdictions, filing and review process and the timing thereof, (iii) whether the RMAT designation will lead to an accelerated review or approval, of which there can be no assurance, (iv) risks and uncertainties regarding commercial launch execution, success and timing, (v) risks and uncertainties regarding participation and enrollment and potential results from the expanded access clinical investigation program described herein, (vi) whether clinical trials will result in registrational pathways and the risks, (vii) whether clinical trial data will be accepted by regulatory agencies, (viii) 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, (iv) potential delays in product availability and regulatory approvals, (x) ImmunityBio's ability to retain and hire key personnel, (xi) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xii) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xiii) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xiv) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xv) 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 3, 2025, and the Company's Form 10-Q filed with the SEC on May 12, 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.

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