ImmunityBio Announces European Medicines Agency Acceptance of Marketing Authorization Application for ANKTIVA® for the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer Carcinoma In Situ

January 27, 2025

- Application covers 30 countries in the European Union
- Submission is based on the ongoing QUILT 3.032 study in which 100 patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer with carcinoma in situ (NMIBC CIS) have been treated with ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with BCG, achieving a 71% (71/100) complete response (CR) rate
- In these responders, the range of duration is 54 months and ongoing, exceeding all duration of response in approved products in this indication

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 27, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced the European Medicines Agency (EMA) has accepted for review and begun assessing the marketing authorization application (MAA) for ANKTIVA (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors. The EMA covers 27 countries in the European Union (EU), as well as Iceland, Norway and Liechtenstein.

“We are encouraged by the speed in which the EMA accepted our marketing authorization application and determined it would begin its assessment of our innovative treatment for this serious condition, just nine months after it was first approved by the FDA for use in the United States,” said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. “Along with our submission to the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA), this action by the EMA is strong evidence of the momentum for putting ANKTIVA+BCG into the hands of physicians who are treating patients with NMIBC.”

The EMA submission is based on the ongoing QUILT 3.032 study in which the complete response rate for the 100 evaluable patients in Cohort A as of the July 15, 2024 cut-off was 71%. In these responders, the range of duration of response is 0.03 to 54 months and is ongoing. These prolonged duration of complete response results beyond four years with ANKTIVA and BCG exceed the benchmark of 18 months for the magnitude of meaningful clinical results suggested by a panel of experts at the International Bladder Cancer Group.

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.

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 the anticipated timing of the EMA’s review of ImmunityBio’s MAA and ultimate decision regarding whether to approve ANKTIVA for the treatment of patients with BCG-unresponsive NMIBC CIS in the countries under its jurisdiction, additional regulatory submissions and timing thereof,

global expansion efforts, 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) risks and uncertainties regarding the EMA regulatory review process, potential actions required in connection with the same, and whether or not the EMA will ultimately approve ImmunityBio's MAA that has been accepted for review, (ii) risks and uncertainties regarding commercial launch execution, success and timing, (iii) risks and uncertainties related to the regulatory submission, filing and review process and the timing thereof, (iv) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (v) whether clinical trials will result in registrational pathways, (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 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).

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