ImmunityBio Provides Regulatory Update on Anticipated FDA Submissions in 2025 Following Meeting with the Agency

January 15, 2025

- BCG unresponsive non-muscle invasive bladder cancer (NMIBC) in the papillary indication: Anticipated supplemental biologics license application (BLA) submission in 2025
- Alternative source of BCG in partnership with Serum Institute of India: Anticipated submission for market access as an alternative source in Q1 2025
- Second- and third-line non-small cell lung cancer (NSCLC) progressing on checkpoint inhibitors (QUILT-3.055): Anticipated BLA submission in 2025 with ongoing randomized Phase 3 trial in NSCLC patients who have failed checkpoint inhibitors (ResQ201A-NSCLC)

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 15, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced significant progress in its ongoing discussions with the U.S. Food and Drug Administration (FDA) regarding three areas of its clinical development pipeline in non-muscle invasive bladder cancer (NMIBC) and non-small cell lung cancer (NSCLC).

NMIBC BCG Unresponsive Papillary Disease: ImmunityBio is preparing to submit a supplemental Biologics License Application (sBLA) in 2025 for its innovative treatment targeting Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) in the papillary indication. As published in the Chamie 2022 NEJM[1] publication, the primary endpoint was met with a disease-free rate of 55% at 12 months, 51% at 18 months, and 48% at 24 months. In addition, patients receiving ANKTIVA® + BCG achieved a 93% avoidance of cystectomy with a median follow up of 20.7 months. This immunotherapy of rescuing BCG with ANKTIVA (nogapendekin alfa inbakicept-pmln), now approved in the CIS indication, represents a step towards providing therapeutic options in patients with BCG unresponsive NMIBC in papillary disease who currently have limited treatment choices and face radical total cystectomy (removal of bladder). The addition of the papillary indication could expand the potential patient population benefiting from this therapy and may allow patients to avoid the high morbidity and mortality associated with radical total cystectomy.

Alternative Source of BCG: In collaboration with the Serum Institute of India, ImmunityBio plans a regulatory submission for an alternative source of BCG in the first quarter of 2025. Serum Institute's GMP capacity to manufacture large-scale volumes of BCG, already tested for safety and efficacy in clinical trials in Europe in subjects with NMIBC, aims to address the shortage of BCG, ensuring a reliable supply for patients in need. This initiative underscores ImmunityBio's commitment to addressing critical supply issues and expanding the opportunity for patients and physicians to have access to high quality and quantities of BCG to initialize and maintain treatments for bladder cancer, subject to regulatory approvals.

Second-Line and Third-Line NSCLC Patients Who Have Progressed on Checkpoint Inhibitors: A Phase 2b study (QUILT-3.055) included (N=86) NSCLC patients and demonstrated prolonged overall survival when ANKTIVA was combined with the same checkpoint inhibitors on which patients were progressing, validating the rescue potential of ANKTIVA for T cells and checkpoint inhibitors. Compared to the most frequently used chemotherapy docetaxel in this setting with overall survival ranging from 7 to 10 months and associated with high toxicities of this chemotherapeutic agent, ANKTIVA plus a checkpoint inhibitor represents an immunotherapeutic advance for this disease.

ImmunityBio plans to submit a Biologics License Application (BLA) in 2025 for second- and third-line treatment of patients with NSCLC, who are progressing on checkpoint inhibitors. As presented at the IASLC 2024 World Conference on Lung Cancer by Dr. Wrangle[2], the QUILT-3.055 study (Phase 2b, N=86) has shown promising results demonstrating a median overall survival for all patients at 14.1 months. In PD-L1 negative subjects, the median overall survival extended to 15.8 months.

"The potential to improve outcomes for NSCLC patients who have already relapsed on checkpoints is an unmet need. The combination of administering ANKTIVA plus a checkpoint even after checkpoint relapse/refractory represents a large potential for ANKTIVA to rescue checkpoint failure and prolong overall survival without the toxicities of chemotherapy," said Dr. Patrick Soon-Shiong, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio. "This submission underscores ImmunityBio's dedication to advancing cancer treatment and providing new hope for patients battling this aggressive disease. This BLA submission together with our randomized ResQ201A-NSCLC (NCT06745908) Phase 3 trial in NSCLC is a potential stepping stone towards advancing novel immunotherapies in this indication for patients who have failed checkpoint inhibitor therapy."

Sources:

1. https://evidence.nejm.org/doi/full/10.1056/EVIDoa2200167
2. https://docwirenews.com/post/dr-wrangle-discusses-phase-2b-quilt-3-055-trial-at-iaslc-2024-world-conference-on-lung-cancer

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 ImmunityBio's anticipated submission of a supplemental BLA for ANKTIVA plus BCG in BCG unresponsive NMIBC in the papillary indication, ImmunityBio's anticipated regulatory submission with the FDA for an alternative source of BCG using the BCG manufactured by Serum Institute of India, ImmunityBio's anticipated submission of a BLA for second- and third-line treatment for NSCLC patients who are progressing on checkpoint inhibitors, 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 regulatory pathways and the regulatory review process and timing thereof, potential expansion of patient populations or 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, ImmunityBio's approved product and investigational agents as compared to existing treatment options, and the supply of BCG, 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 FDA will accept the BLAs and other regulatory submissions referenced herein for filing, (ii) whether the FDA will ultimately approve such BLAs and 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, (vi) whether the BCG manufactured by Serum will receive regulatory approval in the U.S. and/or other regions, (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) the risks and uncertainties associated with third party collaborations and agreements and ImmunityBio's reliance upon third parties for manufacturing, shipping, testing and other activities, (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 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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