FDA Authorizes ImmunityBio to Provide Recombinant BCG (rBCG) to Urologists to Address TICE® BCG Shortage

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- Next-generation recombinant Bacillus Calmette-Guérin (rBCG) has undergone Phase 2 clinical trials in Europe in non-muscle invasive bladder cancer (NMIBC)
- Supplies of rBCG are now available, with shipments set to begin immediately via an FDA Expanded Access Program
- Multiple U.S. patents issued and allowed on combination of BCG plus ANKTIVA®
- Thousands of vials of rBCG available to end shortage of TICE® BCG

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 19, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced the U.S. Food and Drug Administration (FDA) has authorized an expanded access program (EAP) that will bring a vital alternative source of BCG, a standard-of-care medicine in bladder cancer, to patients in the U.S.

Supply shortages of TICE® BCG in the U.S. have become a significant impediment to the treatment of bladder cancer patients. In a recent Sermo survey of 100 U.S. urologists, 57 percent indicated they were unable to treat patients in the last 12 months due to a lack of access to TICE® BCG.

The alternative BCG source has been developed by the Serum Institute of India, the world's largest manufacturer of vaccines by volume. In bladder cancer clinical trials in Europe, the recombinant BCG vaccine has demonstrated potent immunogenicity with CD8+ and CD4+ T cell stimulation and improved safety compared to earlier BCG strains and formulations.

"With the increasing threat of supply shortages of essential medicines, the biopharmaceutical industry must innovate and secure new means of ensuring uninterrupted access to vital therapeutics," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "Our collaboration with the FDA and Serum Institute to ensure a reliable supply of this vital drug for bladder cancer patients underscores ImmunityBio's commitment to addressing critical access issues that affect so many patients."

About Recombinant BCG (rBCG)

BCG is a benign bacterium originally developed as a live vaccine against tuberculosis (TB). It is based on the well-known Mycobacterium bovis (M. bovis) Bacillus Calmette-Guérin (BCG) strain. It has been in use since 1921 and administered to more than 4 billion individuals worldwide. BCG given via intravesical instillation (delivery to the bladder via a catheter) has been the standard of care for patients with non-muscle invasive bladder cancer (NMIBC) since 1977. BCG induces an immune response in the bladder in proximity to the cancer cells, leading to clearance of the cancer in many patients.

Two gene modifications have been implemented in rBCG to improve its immunogenicity and safety in comparison to earlier strains and formulations of BCG. Recombinant rBCG has completed Phase 1/2 human clinical studies in Europe as an immunotherapy in patients with NMIBC. The findings from those studies demonstrate that rBCG is well-tolerated when administered intravesically with a safety profile similar to placebo, and reduced rates of adverse events observed in earlier strains and formulations of BCG.

Supportive clinical data of rBCG as a TB vaccine are available from four clinical trials. Two studies in healthy adult volunteers and one Phase IIa study in healthy newborn infants were performed with rBCG. Additionally, a Phase II clinical trial was conducted with rBCG in HIV-unexposed and HIV-exposed, BCG-naïve newborn infants for clinical bridging. Clinical trials have also been conducted to assess the effect of rBCG vaccination on TB recurrence and on the susceptibility or severity of respiratory diseases during the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) pandemic.

BCG is one of the most widely used vaccines worldwide. However, because BCG is a biologic drug that uses benign bacteria, it is more complicated to make than many other types of drugs. Serum Institute of India is the largest manufacturer of BCG vaccines in the world, while Merck & Co., based in New Jersey, currently is the only manufacturer of BCG (TICE® BCG) in the U.S.

ImmunityBio has been awarded multiple patents covering the composition and methods of use for the combination of BCG plus ANKTIVA in bladder cancer (US 11,173,191 B2; US 11,679,144 B2; US 11,890,323 B2).

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 ImmunityBio.com (Founder's Vision) and 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 (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, such as statements regarding the timing of shipments under the EAP, the expectation that the EAP will enable ImmunityBio to reliably bring an alternative source of BCG to patients in the U.S., the utility of rBCG to improve immunogenicity and safety in comparison to earlier strains and formulations of BCG, 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 timing of shipments under the EAP and ImmunityBio's ability to establish and maintain a reliable source of BCG under the EAP, (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) the risks and uncertainties associated with third party collaborations and agreements, including that with the Serum Institute of India, (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 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-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).

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