ImmunityBio Reports Productive Regulatory Engagement with Saudi Food and Drug Authority at USA-Saudi Biotech Alliance Meeting Hosted by the Ministry of Investment of Saudi Arabia

February 17, 2026

Saudi FDA (SFDA) Encouraged Company to Submit Regulatory File for Recombinant BCG and Discussions Initiated for the Expansion of ANKTIVA® in Combination with Checkpoint Inhibitors Across Multiple Tumor Types in the Kingdom of Saudi Arabia (KSA)

- ImmunityBio held productive regulatory discussions with the Saudi Food and Drug Authority (SFDA) in Riyadh convened under the Saudi-USA Biotech Alliance, hosted by the Ministry of Investment of Saudi Arabia (MISA)
- SFDA encouraged the company to submit a regulatory package for ImmunityBio's recombinant BCG (rBCG) to expand BCG access for Saudi Arabia to overcome the BCG shortage
- ImmunityBio and SFDA initiated discussion for expansion of ANKTIVA® (nogapendekin alfa inbakicept) plus checkpoint inhibitor (CPI) combination for additional tumor types beyond NSCLC, building on the accelerated approval granted in January 2026 for metastatic non-small cell lung cancer (NSCLC) in the CPI relapsed population
- The QUILT-3.055 basket trial has demonstrated that ANKTIVA rescues checkpoint inhibitor activity across multiple tumor types, including NSCLC, urothelial, head and neck, melanoma, renal, gastric, and cervical cancers, with a median overall survival of 14.1 months in CPI relapsed NSCLC patients
- SFDA has now approved ANKTIVA across two indications in Saudi Arabia: BCG unresponsive non muscle invasive bladder cancer and metastatic NSCLC in combination with checkpoint inhibitors
- Company expects to submit the rBCG regulatory package to the SFDA within the coming weeks

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 17, 2026-- ImmunityBio, Inc. (NYSE: IBRX), a commercial stage immunotherapy company developing next generation therapies that drive immunological memory and restore immune competence, today announced that the Company held productive regulatory discussions with the Saudi Food and Drug Authority (SFDA) in Riyadh, convened under the Saudi-USA Biotech Alliance hosted by the Ministry of Investment of Saudi Arabia (MISA). The engagement advanced two regulatory priorities: (1) SFDA encouraged the Company to submit a regulatory package for its recombinant BCG (rBCG) to expand BCG access in Saudi Arabia and address the ongoing global BCG shortage, and (2) ImmunityBio and SFDA initiated discussions regarding the expansion of ANKTIVA® (nogapendekin alfa inbakicept) in combination with checkpoint inhibitors (CPIs) to additional tumor types in the CPI relapsed population.

Recombinant BCG: SFDA Encouragement and Planned Submission

During the meeting, the SFDA encouraged ImmunityBio to submit a regulatory package for rBCG to support access to a new source of BCG in the Kingdom and help address the global BCG shortage that has affected bladder cancer patients worldwide including the Middle East. The Company expects to submit the complete regulatory package to the SFDA within the coming weeks.

ImmunityBio's rBCG is manufactured by the Serum Institute of India, the world's largest vaccine manufacturer by number of doses produced, under an exclusive global licensing and supply arrangement announced in May 2024. The Serum Institute's manufacturing facility in Pune, India, has been inspected and certified by multiple global regulatory authorities, including the World Health Organization (WHO), the European Medicines Agency (EMA), and the U.S. Food and Drug Administration (FDA). This established regulatory pedigree provides a foundation for the SFDA's review of the manufacturing and quality data contained in the submission dossier.

In the United States, the FDA has authorized an Expanded Access Program for rBCG to address the ongoing national shortage of TICE® BCG. The program is now active at 57 urology centers across the country, with over 500 patients enrolled and thousands of doses of rBCG administered to date.

Phase 1/2 clinical trials conducted in Europe, rBCG demonstrated potent immunogenicity with CD8+ and CD4+ T cell stimulation and an improved safety profile compared to standard BCG, with fewer adverse events compared to earlier formulations.

ANKTIVA Plus Checkpoint Inhibitors in Patients with Multiple Tumor Types who Failed Keytruda (Pembrolizumab)

ImmunityBio and the SFDA initiated discussions for the expansion of ANKTIVA plus CPI into multiple tumor types in patients who have relapsed following checkpoint inhibitor therapy. These discussions build on the accelerated approval granted by the SFDA in January 2026 for ANKTIVA in combination with immune checkpoint inhibitors for adult patients with metastatic non-small cell lung cancer (NSCLC) whose disease has progressed following standard of care therapy including checkpoint inhibitors, the first approval of this indication anywhere in the world and the first approval for subcutaneous administration of ANKTIVA plus a checkpoint inhibitor. ImmunityBio holds multiple issued patents covering the ANKTIVA plus checkpoint inhibitor combination, including U.S. Patent Nos. 11,071,774 (NANT Cancer Vaccine) and 9,925,247 B2 (IL-15 based molecules and methods of use in combination with checkpoint inhibitors), providing intellectual property protection with terms extending beyond 2035.

The scientific rationale for expanding into additional tumor types in the CPI relapsed population is supported by data from the QUILT-3.055 Phase 2b basket trial (N=147), which enrolled patients across multiple tumor types, including NSCLC, urothelial, head and neck, melanoma, renal, gastric, and cervical cancers, who had progressed on prior checkpoint inhibitor therapy. In the NSCLC cohort (N=86), the addition of ANKTIVA to the same checkpoint inhibitor on which patients had progressed demonstrated a median overall survival of 14.1 months (95% CI 11.7, 17.4), with 12 month and 18 month survival rates of 57% and 34%, respectively. These results were observed independent of PD-L1 tumor status and independent of line of

therapy.

"The SFDA's encouragement to submit our recombinant BCG dossier, together with the initiation of discussions to expand ANKTIVA plus checkpoint inhibitors across additional tumor types, reflects the deepening regulatory relationship between ImmunityBio and the Kingdom of Saudi Arabia," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "Saudi Arabia was the first country in the world to grant approval for ANKTIVA in metastatic lung cancer. The QUILT-3.055 basket trial provides data that ANKTIVA rescues checkpoint activity across multiple tumor types, and we look forward to working with the SFDA to extend this approach to additional malignancies. In parallel, our exclusive global arrangement with the Serum Institute of India, whose manufacturing facilities have been certified by the WHO and European regulatory authorities, positions us to address the critical BCG shortage affecting patients in Saudi Arabia and globally."

Tumor resistance to checkpoint therapy occurs when T cells are unable to recognize tumor cell antigens due to MHC-I downregulation. ANKTIVA, as an IL-15 superagonist, activates natural killer (NK) cells that can overcome this resistance, restoring the activity of checkpoint inhibitor therapy regardless of tumor type or location. The QUILT-3.055 data across multiple tumor types supports the hypothesis that NK cell activation through IL-15 stimulation can rescue checkpoint activity broadly, forming the basis for the initiated discussions with the SFDA regarding expanded tumor type indications in the Kingdom.

"The Kingdom of Saudi Arabia continues to demonstrate regulatory leadership in advancing access to innovative immunotherapies," said Richard Adcock, President and Chief Executive Officer of ImmunityBio. "With two approved indications for ANKTIVA, a clear pathway for rBCG to address the BCG shortage, and discussions now initiated regarding additional tumor types, Saudi Arabia is becoming a critical market for ImmunityBio's portfolio. The Saudi-USA Biotech Alliance, hosted by MISA, provides an important framework for accelerating these regulatory and commercial milestones, and we are committed to investing in our regional presence to support physicians and patients across the Middle East."

Strategic Context

This regulatory engagement builds on ImmunityBio's growing presence in the Kingdom of Saudi Arabia. The SFDA has granted accelerated approvals for ANKTIVA in two indications: BCG unresponsive non muscle invasive bladder cancer carcinoma in situ and metastatic NSCLC in combination with checkpoint inhibitors. The Saudi-USA Biotech Alliance, launched with the inaugural summit held in conjunction with the 44th Annual J.P. Morgan Healthcare Conference in January 2026 and hosted by MISA, reflects a broader bilateral commitment to accelerating the development, manufacturing, and deployment of next generation immunotherapies. ImmunityBio plans to open a regional office in the Kingdom of Saudi Arabia to support physicians and health systems across the Middle East and North Africa.

To support the execution of its regional strategy, ImmunityBio has established a wholly owned subsidiary in the Kingdom of Saudi Arabia, providing direct operational infrastructure to advance regulatory submissions, commercial launch activities, and clinical development across the Middle East and North Africa.

About ImmunityBio

ImmunityBio is a leading late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio has a comprehensive immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated)—of which 25 are at Phase II and III stage of development—across 19 indications in solid and liquid cancers and infectious diseases. Currently 17 first-in-human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. Anktiva™ (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC).

The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform.

ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams. For more information, please visit: www.immunitybio.com

About ANKTIVA® (nogapendekin alfa inbakicept)

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. A key component in the Company's BioShield platform, 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 driving the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones.

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 patients 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.

Please see the complete Indication and Important Safety Information and Prescribing Information for ANKTIVA® at Anktiva.com.

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).

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 expected timing of the regulatory submission of rBCG to the SFDA and ImmunityBio's ability to complete such submission, the potential review and approval of rBCG in Saudi Arabia, the potential expansion of ANKTIVA plus checkpoint inhibitor indications to additional tumor types in Saudi Arabia, the belief that SFDA engagement may lead to future regulatory approvals or expansion into additional indications or territories, the utility of rBCG to improve immunogenicity and safety in comparison to earlier strains and formulations of BCG, the Company's Middle East expansion strategy and wholly owned subsidiary operations, the anticipated benefits of rBCG and ANKTIVA to patients, the described mechanism of action of ANKTIVA in rescuing checkpoint inhibitor activity across tumor types, clinical trial data and potential results and implications to be drawn therefrom, global expansion efforts, potential future uses and applications of ANKTIVA alone or in combination with checkpoint inhibitors across multiple tumor types, and ImmunityBio's approved products 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," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "seeks," "should," "will," "strategy," and variations of such words or similar expressions. Statements of past performance, efforts, or results of 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 and acceptance of the rBCG regulatory submission to the SFDA and the outcome of any such review, (ii) risks and uncertainties regarding the potential expansion of ANKTIVA indications in Saudi Arabia, including whether the SFDA will accept additional submissions or grant additional approvals, (iii) the Company's ability to successfully commercialize ANKTIVA in Saudi Arabia or other markets, (iv) uncertainties relating to pricing, reimbursement, and market adoption in the Kingdom of Saudi Arabia and the broader Middle East region, (v) risks and uncertainties regarding commercial launch execution, success and timing, (vi) risks and uncertainties related to the regulatory submission, filing and review process in foreign jurisdictions and the timing thereof, (vii) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (viii) whether clinical trials will result in registrational pathways, (ix) whether clinical trial data will be accepted by regulatory agencies, (x) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs, and the timing and success of any such continued development, patient enrollment and planned regulatory submissions, (xi) potential delays in product availability and regulatory approvals, (xii) the risks and uncertainties associated with third party collaborations and agreements, including that with the Serum Institute of India, (xiii) ImmunityBio's ability to retain and hire key personnel, (xiv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xv) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xvi) ImmunityBio's ability to successfully operate its wholly owned subsidiary in Saudi Arabia, (xvii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved products and future approved products, (xviii) competition from existing or new therapies, (xix) changes in foreign or domestic regulatory, political, or economic conditions, and (xx) 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 most recent Form 10-K and Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC), 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.

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