Saudi FDA Grants Accelerated Approval to ImmunityBio's ANKTIVA® for Non-Muscle Invasive Bladder Cancer with Carcinoma In-Situ

January 14, 2026

- Approval of ANKTIVA was granted for BCG-unresponsive non-muscle-invasive bladder cancer (NMIBC) with carcinoma in situ, with or without papillary disease, based on review of data from QUILT-3.032
- Adding to existing ANKTIVA NMIBC approvals in the U.S. and U.K., and conditional approval in the European Union, the SFDA's action reflects ImmunityBio's mission to provide access to patients globally with a potentially bladder surgery-sparing option
- Enrollment in randomized trial of ANKTIVA in BCG naïve NMIBC patients is ahead of schedule with full enrollment anticipated by Q2 2026 and BLA submission targeted by year-end

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 14, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the Saudi Food and Drug Authority (SFDA) has granted approval of ANKTIVA® (nogapendekin alfa inbakicept) plus Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer carcinoma *in situ*, with or without papillary disease. This regulatory action by the SFDA adds to the existing approvals in the United States and United Kingdom, as well as conditional approval in the European Union.

"We are pleased to bring ANKTIVA to Saudi patients with NMIBC, who otherwise have no viable options but life-altering surgery," said Rich Adcock, Chief Executive Officer, ImmunityBio. "At ImmunityBio, we're committed to using our innovative science to improve the health of people around the world, and we continue investing in research and clinical trials that we believe are essential to fulfilling that mission."

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. The company will collaborate with Biopharma Cigalah as its commercial and distribution partner in the region. Founded in 2007, BioPharma Cigalah provides the commercial infrastructure and capabilities needed to support therapies for serious diseases and expand patient access throughout the Middle East and North Africa.

"The incidence of bladder and other cancers in the Middle East and North Africa is large and growing, demonstrating a significant unmet need for the kind of innovative treatments ImmunityBio is developing," added Mr. Adcock. "We are pursuing approvals across the region to fill that need, as well as investing in a regional office in Saudi Arabia in order to support our expansion into these growing markets."

The randomized QUILT-2.005 trial in BCG-naïve patients comparing BCG alone to BCG plus ANKTIVA is ongoing, and enrollment has exceeded expectations. Enrollment is on track to be completed by Q2 2026, with a potential BLA submission by year-end.

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 ImmunityBio

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies 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 NK 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 clinical trial data and potential results and implications to be drawn therefrom, the belief that Saudi FDA authorization may lead to increased revenue, market acceptance, clinical utility, future regulatory approvals, or potential expansion into additional indications or territories, the expected impact of the approval of ANKTIVA in the Saudi Arabia on the Company's business, financial condition, and results of operations, potential benefits to patients, potential treatment outcomes for patients, 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, immunotherapies and cell therapies that has the potential to change the paradigm in cancer care, and the impact of the Saudi FDA approval on the Company's ex- United States go to market strategy. 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, the Company's ability to successfully commercialize ANKTIVA in Saudi Arabia or other markets; uncertainties relating to pricing, reimbursement, and market adoption; the outcome of post-approval commitments or other regulatory requirements; the potential for adverse safety findings or manufacturing issues; competition from existing or new therapies; reliance on third-party manufacturers, distributors, or partners; changes in foreign or domestic regulatory, political, or economic conditions. 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 November 5, 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. 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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