ImmunityBio Receives Authorization from the European Commission for ANKTIVA® with BCG for Non-Muscle Invasive Bladder Cancer Carcinoma in Situ, Expanding Global Access to 33 Countries

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- ANKTIVA plus BCG, with a 71% complete response rate, is the first immunotherapy to receive marketing authorization in Europe for non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors, where no treatment was previously authorized for BCG-unresponsive disease
- European Commission conditional marketing authorization enables commercial availability across all 27 European Union (EU) member states plus Iceland, Norway, and Liechtenstein, bringing the total number of countries where ANKTIVA is authorized to 33
- ANKTIVA is now authorized across four regulatory jurisdictions: the United States (FDA, April 2024), United Kingdom (MHRA, July 2025), Kingdom of Saudi Arabia (SFDA, January 2026), and the European Union (EC, February 2026)
- More than 150,000 patients are diagnosed annually with NMIBC across Europe; the European Commission's decision addresses an unmet medical need where the primary alternative for BCG-unresponsive patients has been radical cystectomy
- Global regulatory footprint of 33 countries built in under two years from initial FDA approval

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 18, 2026-- ImmunityBio (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the European Commission has granted conditional marketing authorization for ANKTIVA® (nogapendekin alfa inbakicept) in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS), with or without papillary tumors.

ANKTIVA in combination with BCG is the first authorized treatment in Europe for BCG-unresponsive NMIBC CIS. With this authorization, ANKTIVA is now approved in 33 countries spanning four regulatory jurisdictions, establishing a global commercial footprint in under two years from initial U.S. Food and Drug Administration (FDA) approval.

The conditional marketing authorization follows the positive opinion adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) on December 11, 2025, which recommended authorization based on its determination that the benefit of making ANKTIVA available to patients—with a complete response rate of 71%, a median duration of complete response of 26.6 months, and individual responses ranging up to 54+ months and ongoing outweighs the risks associated with earlier access from a single-arm trial. The authorization covers all 27 EU member states Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden as well as Iceland, Liechtenstein, and Norway. ANKTIVA plus BCG is the first immunotherapy to receive marketing authorization in Europe for this NMIBC indication.

As part of the conditional authorization, ImmunityBio will continue to follow up with trial participants and submit long-term safety and efficacy data to the EMA.

"The European Commission's authorization of ANKTIVA in combination with BCG marks a defining moment for patients with BCG-unresponsive NMIBC CIS across Europe, who until now have had no authorized treatment and faced radical cystectomy as their only alternative," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman, and Global Chief Scientific and Medical Officer of ImmunityBio. "With ANKTIVA now authorized in 33 countries from the United States and United Kingdom to the European Union and Saudi Arabia, we have built the broadest global access platform for an immunotherapy in this indication. With more than 80% of treated patients preserving their bladder through three years of follow-up, ANKTIVA represents a meaningful advance designed to strengthen the immune response and extend the durability of BCG."

Global Regulatory Footprint

ANKTIVA in combination with BCG for BCG-unresponsive NMIBC CIS is now authorized across four regulatory jurisdictions encompassing 33 countries:

- **United States**: FDA approval, April 2024 (NMIBC CIS with or without papillary tumors)
- **United Kingdom**: MHRA approval, July 2025 (NMIBC CIS with or without papillary tumors)
- **Kingdom of Saudi Arabia**: SFDA accelerated approval, January 2026 (NMIBC CIS with or without papillary tumors; metastatic non-small cell lung cancer)
- **European Union (30 countries):** European Commission conditional marketing authorization, February 2026 (NMIBC CIS with or without papillary tumors). Covers all 27 EU member states plus Iceland, Liechtenstein, and Norway.

The Kingdom of Saudi Arabia remains the only jurisdiction where ANKTIVA has received authorization in two indications, including the first approval globally for ANKTIVA in metastatic non-small cell lung cancer and the first approval for subcutaneous administration.

Unmet Medical Need in Europe

Bladder cancer represents a significant public health burden in the European Union, ranking as the fifth most common cancer overall and the seventh most frequently diagnosed cancer among men.[1,2] The European Association of Urology and the World Bladder Cancer Patient Coalition estimate that more than 200,000 new cases of bladder cancer will be diagnosed in 2025.[3] Approximately 75% of these cases are NMIBC, the most common form of the disease, which is confined to the bladder lining and has not invaded the underlying muscle layer. For patients whose NMIBC does not respond to BCG therapy, there were no authorized treatment options in the European Union prior to this authorization. The primary alternative has been radical cystectomy, which carries significant morbidity, affects quality of life, and is not suitable for all patients.

Notably, unlike the United States, where only one BCG strain is approved, Europe recognizes and has approved approximately six major BCG strains, making standard-of-care BCG therapy broadly available across the region and supporting a reliable supply for the ANKTIVA plus BCG combination regimen.[4]

“Reaching 33 countries in under two years from our first regulatory approval is a testament to the strength of the clinical evidence and the urgency of the unmet need in BCG-unresponsive bladder cancer,” said Richard Adcock, President and CEO of ImmunityBio. “We are now focused on working with EU member states to ensure timely pricing, reimbursement, and patient access across Europe. Six BCG strains are available in Europe for use in combination with ANKTIVA, and we are expeditiously developing our recombinant BCG candidate to address ongoing BCG shortages in the U.S. and help ensure that all eligible patients can benefit from this treatment.”

Clinical Evidence Supporting Authorization

The conditional marketing authorization was based on results from the QUILT-3.032 study (NCT03022825), a single-arm, open-label, multicenter phase 2/3 clinical trial in 100 adults with BCG-unresponsive NMIBC CIS with or without papillary tumors who received ANKTIVA in combination with BCG administered intravesically.[5, 6]

Key Efficacy Findings:

- **Complete response (CR) rate:** 71% (95% CI: 61%, 80%), with responses ranging up to 54+ months and ongoing
- **Median duration of complete response:** 26.6 months (95% CI: 13.0, 49.9 months)
- **Complete response rate among responders at 12 months:** 66%; at 24 months: 42%
- **Cystectomy-free survival among responders:** 96% at 12 months, 90% at 24 months, and 84% at 36 months
- **Disease-specific survival for all patients:** 99% at 24 months and 99% at 36 months

Key Safety Findings (Cohorts A and B combined, n=180):

- Most treatment-related adverse events were grade 1 to 2
- Grade 3 treatment-related adverse events occurred in 3% of patients; no grade 4 or 5 treatment-related adverse events were reported
- Most common adverse reactions: dysuria, hematuria, pollakiuria, urinary tract infection, micturition urgency, fatigue, chills, musculoskeletal pain, and pyrexia

About ANKTIVA® (nogapendekin alfa inbakicept)

ANKTIVA is a first-in-class interleukin-15 (IL-15) receptor agonist (ATC code: L03AC03) consisting of an IL-15 mutant (IL-15N72D) bound to an IL-15 receptor alpha Fc fusion protein. In the European Union, ANKTIVA is available as a 400 µg concentrate for intravesical suspension. ANKTIVA binds with high affinity to IL-15 receptors on natural killer (NK) cells, CD4+ T cells, and CD8+ T cells, activating and expanding these immune effector populations. By activating NK cells, ANKTIVA addresses tumor immune escape mechanisms, while simultaneously restoring memory T cell activity to generate durable antitumor responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced antitumor activity compared to native IL-15 in vivo.

About Conditional Marketing Authorization

A conditional marketing authorization is an EU regulatory mechanism designed to facilitate early access to medicines that address an unmet medical need. This pathway allows the European Commission to grant marketing authorization when the benefit of a medicine’s immediate availability to patients outweighs the risk inherent in the fact that additional data are still required. The European Commission’s implementing decision for ANKTIVA (EU marketing authorization number: EU/1/25/2002/001; EMA product number: EMEA/H/C/006622/0000), referenced as C(2026)1197 and dated Brussels, February 16, 2026, was issued by the Director-General for Health and Food Safety under Regulation (EC) No. 726/2004 of the European Parliament and of the Council. As a condition of the authorization, ImmunityBio is required to submit long-term follow-up results from ongoing studies to confirm the efficacy and safety of ANKTIVA. The conditional marketing authorization is subject to annual renewal.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA in combination with Bacillus Calmette-Guérin (BCG) is indicated for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

WARNINGS AND PRECAUTIONS: The possibility of severe systemic BCG-infections with the necessity of anti-tuberculosis therapy should be considered before initiating the BCG-therapy.

Delaying cystectomy in patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumours, treated with ANKTIVA therapy in combination with BCG could lead to development of muscle invasive or metastatic bladder cancer.

If patients with CIS that are medically eligible for cystectomy have not achieved a CR (absence of disease or low-grade Ta) to treatment after an induction course of ANKTIVA in combination with BCG at the 12-weeks assessment, cystectomy should be reconsidered as an alternative to re-induction. The risk of developing muscle-invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of

persisting CIS.

DOSAGE AND ADMINISTRATION: For intravesical use only. ANKTIVA should NOT be administered by subcutaneous or intravenous or intramuscular use.

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

ANKTIVA is administered intravesically as a mixture with BCG.

USE IN SPECIFIC POPULATIONS: Pregnancy: Treatment is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

Please see the Summary of Product Characteristics for ANKTIVA® available on the European Medicines Agency website at www.ema.europa.eu.

About ImmunityBio

ImmunityBio is a commercial-stage biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The Company's immunotherapy and cell therapy platforms act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. 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 and is now authorized in 33 countries across the United States, United Kingdom, European Union, and Kingdom of Saudi Arabia. The Company is applying its platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies designed to reduce or eliminate the need for standard high-dose chemotherapy. For more information, visit ImmunityBio.com.

References

1. European Association of Urology. EAU Guidelines on Muscle-invasive and Metastatic Bladder Cancer. Limited Update March 2025.

2. European Association of Urology. Bladder Cancer: The Forgotten Cancer. Sep 2022.

3. World Bladder Cancer Patient Coalition, EAU. Tackling Bladder Cancer in Europe. February 2025. https://worldbladdercancer.org/wp-content/uploads/2025/03/WBCPC-EAU-Bladder-Cancer-MEP-A4-2025-Digital59.pdf Accessed Feb 17, 2026

4. Guallar-Garrido S. and Julián E. Bacillus Calmette-Guérin (BCG) Therapy for Bladder Cancer: An Update. *Immunotargets Ther.* 2020;9:1–11.

5. Chang SS, Chamie K, Kramolowsky E, et al. An update on QUILT-3.032: Complete responses to N-803 plus BCG therapy in BCG-unresponsive bladder carcinoma in situ (CIS) with or without Ta/T1 papillary disease. *J Urol.* 2025;213(5S): e392.

6. Summary of Product Characteristics for ANKTIVA® available on the European Medicines Agency website at www.ema.europa.eu.

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, statements regarding the benefits and availability of ANKTIVA following the European Commission's grant of conditional marketing authorization, the Company's ability to distribute treatment to patients across 33 countries, ongoing and planned clinical development activities, the submission of long-term safety and efficacy data to the EMA as required under the conditional marketing authorization, the development of therapeutics for cancer and infectious diseases, potential benefits to patients, potential treatment outcomes, the described mechanism of action and results therefrom, the application of the Company's platforms to treating cancers or developing cancer vaccines, immunotherapies, and cell therapies, the Company's development of a recombinant BCG candidate, 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," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "seeks," "should," "will," and variations of such words and similar expressions. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on the Company's current beliefs, expectations, and assumptions regarding the future of its business, future plans and strategies, clinical results, projections, anticipated events and trends, the economy, and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict, and many of which are outside of the Company's control.

The Company's actual results and financial condition may differ materially from those indicated in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated in such forward-looking statements include, among others: the Company's ability to successfully commercialize ANKTIVA in the European Union and other jurisdictions; the Company's ability to obtain and maintain pricing and reimbursement approvals across EU member states; the Company's ability to satisfy post-authorization commitments, including the submission of long-term follow-up data to the EMA; potential delays or difficulties in manufacturing, supply chain, or distribution of ANKTIVA; the outcome of ongoing and planned clinical trials; the potential for adverse events or safety signals; changes in applicable laws or regulations; the Company's ability to obtain and maintain intellectual property protection; and general economic and market conditions.

More information regarding these and other risks that may impact the Company's business is described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 3, 2025, the Company's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2025, and in subsequent filings made by ImmunityBio with the SEC, which are available at www.sec.gov.

Any forward-looking statement made by the Company in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. ImmunityBio undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments, or otherwise, except as required by law.

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