ImmunityBio Announces ANKTIVA® Plus BCG Meets Primary Endpoint in BCG-Naïve Non-Muscle Invasive Bladder Cancer Randomized QUILT-2.005 Trial

November 9, 2026

- ANKTIVA® plus BCG met the primary efficacy endpoint in the randomized registrational trial of 370 subjects comparing intravesical ANKTIVA plus BCG with BCG alone; additional study details will be presented at an upcoming medical congress
- ANKTIVA plus BCG is the first chemotherapy-free immunotherapy administered directly into the bladder to prolong BCG therapy, the current standard of care, in patients with BCG-naïve non-muscle invasive bladder cancer (NMIBC)
- The most common treatment-emergent adverse events with ANKTIVA plus BCG were consistent with BCG alone; no treatment-related deaths were reported
- Patient-reported quality of life was maintained, and median duration of response had not yet been reached with ANKTIVA plus BCG
- A supplemental Biologics License Application (sBLA) remains on track for submission to the FDA by year-end 2026, potentially expanding ANKTIVA's indication to include patients with NMIBC earlier in their disease course

CULVER CITY, Calif.--(BUSINESS WIRE)--Nov. 9, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced positive results from the final analysis of the primary endpoint in Cohort A of QUILT-2.005 (NCT02138734), a randomized, controlled, registrational trial evaluating intravesical ANKTIVA® (nogapendekin alfa inbakicept-pmln/N-803) in combination with Bacillus Calmette-Guérin (BCG) versus BCG alone in patients with BCG-naïve, high-grade non-muscle invasive bladder cancer (NMIBC). The chemotherapy-free combination demonstrated a statistically significant improvement in efficacy compared with BCG alone in patients with carcinoma in situ (CIS), with or without papillary tumors.

The trial involved over 75 clinical trial sites with three largest enrolling sites at US Urology Partners, Dartmouth-Hitchcock, and University of California Los Angeles. Additional study details will be presented at an upcoming medical congress.

“For nearly 40 years, BCG has been the gold standard for patients newly diagnosed with high-risk NMIBC, with limited innovation in the frontline setting,” said Christopher Pieczonka, M.D., Corporate Director of Clinical Research at U.S. Urology Partners and Global Principal Investigator of the QUILT-2.005 trial. “For patients with carcinoma in situ with or without papillary tumors, the meaningful improvement in response rates when intravesical ANKTIVA is administered with BCG represents an important practice-changing advance. By improving responses earlier in the disease course, this combination has the potential to help more patients remain disease-free longer, avoid additional treatments.”

“As an NCI-designated Comprehensive Cancer Center, we are committed to advancing innovative research and clinical trials that have the potential to improve outcomes for patients,” said Einar F. Sverrisson, MD, Assistant Professor of Surgery at Dartmouth’s Geisel School of Medicine and urologist at Dartmouth Hitchcock Medical Center. “For patients with NMIBC, recurrence following standard-of-care BCG remains a significant challenge. This study was designed to investigate whether adding N-803 to BCG could increase the patient response rate and reduce the risk of early recurrence. We are proud to have contributed to this important research, which has the potential to reshape the treatment landscape for patients living with NMIBC.”

“These results build on the clinical findings observed in patients with BCG-unresponsive NMIBC and underscore the potential of ANKTIVA plus BCG to become the first chemotherapy-free immunotherapy combination to improve treatment outcomes for patients with BCG-naïve bladder cancer,” said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. “The statistically significant improvement in efficacy supports our efforts to extend this therapeutic approach to patients earlier in their treatment journey. We are grateful to the patients, families and clinical teams who made this study possible.”

Safety of N-803 plus BCG versus BCG Alone

The most common treatment-emergent and treatment-related adverse events were consistent with those observed with BCG alone. No treatment-related deaths were reported.

About the QUILT-2.005 Study

QUILT-2.005 (NCT02138734) is a randomized, controlled registrational trial comparing the intravesical chemotherapy-free combination of ANKTIVA® (nogapendekin alfa inbakicept-pmln) with BCG versus BCG alone in patients with BCG-naïve NMIBC. BCG-naïve patients are those receiving BCG-based therapy for the first time, representing an earlier stage of treatment than the BCG-unresponsive population for which ANKTIVA is currently approved. Enrollment was completed in February 2026 with 370 randomized patients. Following a protocol-specified interim review in March 2026, the IDMC determined that no additional enrollment was required to maintain the study’s prespecified statistical power. Database lock occurred on October 20, 2026 and the supplemental BLA is on track to be submitted to the FDA before year end 2026. Full details can be found on clinicaltrials.gov.

About ANKTIVA® (nogapendekin alfa inbakicept-pmln)

The interleukin-15 (IL-15) cytokine 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 independent of 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.

In April 2024, ANKTIVA plus BCG was approved for BCG unresponsive NMIBC CIS with or without papillary disease. In October 2026, ANKTIVA plus BCG indication was expanded and approved for BCG unresponsive NMIBC including both CIS and papillary disease.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).

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 BCG-unresponsive NMIBC have evidence of high-grade disease 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.

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, please see the Prescribing Information for ANKTIVA® at Anktiva.com.

About ImmunityBio

ImmunityBio, Inc. is a biotechnology company focused on innovating, developing, and commercializing next-generation immunotherapies designed to activate the patient's immune system and deliver durable protection against cancer and infectious diseases. Our approach harnesses both the adaptive and innate immune systems with the goal of restoring immune function and generating lasting immunological memory in patients. At the core of our strategy is the Cancer BioShield ™ platform, which is designed to stimulate critical lymphocytes, including natural killer (NK) cells, cytotoxic T cells, and memory T cells via our proprietary IL-15 receptor agonist, ANKTIVA® (nogapendekin alfa inbakicept-pmln). Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by a portfolio that includes adenovirus-vectored vaccines, allogeneic (off-the-shelf) and autologous NK-cell therapies, and additional immunomodulators intended to promote immunogenic cell death and support durable immune responses while potentially reducing reliance on high-dose chemo-radiation therapy. 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, as amended. All statements contained in this press release other than statements of historical fact, including statements regarding the results of the final analysis of the primary endpoint in Cohort A of the QUILT-2.005 trial, including the durability of response as follow-up continues; the planned submission of a supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept-pmln) to the FDA by year-end 2026 and the timing and outcome of the FDA's review thereof; the potential expansion of ANKTIVA's indication to include patients with BCG-naïve NMIBC earlier in their disease course and, if approved, the potential clinical and commercial impact thereof; the anticipated presentation of additional study details at an upcoming medical congress; and the potential clinical benefits of ANKTIVA® in combination with BCG for patients with BCG-naïve NMIBC, are forward-looking statements.

Forward-looking statements include, without limitation, statements regarding the Company's expectations, beliefs, plans, objectives, strategies, prospects, and future performance relating to: the results and implications of the final analysis of Cohort A of the QUILT-2.005 trial; the planned submission of an sBLA to the FDA by year-end 2026 and the acceptance, review, and potential approval thereof; the potential clinical benefits, safety profile, and efficacy of ANKTIVA® in combination with BCG for BCG-naïve NMIBC; the significance and implications of the clinical trial results as they are further analyzed, presented at medical congresses, and submitted to regulatory authorities; the potential for ANKTIVA® to address unmet medical needs in earlier lines of therapy and to impact clinical practice in the BCG-naïve setting; and, if the FDA approves the sBLA, the potential for the expanded indication to broaden the addressable patient population and affect the Company's future revenues, market position, and financial performance.

These forward-looking statements are based on the Company's current expectations, estimates, forecasts, assumptions, and beliefs as of the date of this press release and involve known and unknown risks, uncertainties, assumptions, and other factors, many of which are outside the Company's control, that could cause actual results, developments, performance, or achievements to differ materially from those expressed, implied, or anticipated by such statements. Such risks and uncertainties include, among others: the possibility that the results from the QUILT-2.005 trial reported in this release, including measures of response durability, may change as patient follow-up continues and as additional data become available, are further analyzed, or are presented or published; the risk that clinical trial results, including in light of the open-label design of QUILT-2.005, may not support regulatory approval or further development of ANKTIVA® for BCG-naïve NMIBC; the risk that the timing for submitting the sBLA may be delayed; the timing, outcome, and unpredictability of regulatory review by the FDA and other regulatory authorities, including whether the FDA will accept, review, or approve the sBLA on the anticipated timeline or at all; manufacturing and supply risks, including risks related to the availability of BCG; competition from existing or future therapies; clinical experience that may differ from results observed in clinical trials; the Company's ability to successfully commercialize ANKTIVA® for any expanded indication, including market acceptance, coverage, pricing, and reimbursement; risks and uncertainties associated with evolving most favored nation pricing policies in the U.S. and their potential impact on pricing and reimbursement, product launch timing, market access, and future revenues in the U.S. and internationally; and that additional safety, efficacy or other product-related information, including adverse events or previously unidentified risks, may emerge from the final analysis of QUILT-2.005 or additional studies.

More details about these and other risks that may impact ImmunityBio's business are 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 (the SEC) on February 23, 2026, the Company's Quarterly Report on Form 10-Q filed with the SEC on August 4, 2026, 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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