



ImmunityBio Announces Database Lock for Registrational Trial of Locally Delivered, Chemotherapy-Free ANKTIVA® Plus BCG in BCG-Naïve Non-Muscle Invasive Bladder Cancer

October 21, 2026

- Database lock completed for Cohort A of QUILT-2.005 (NCT02138734), a randomized, controlled registrational trial comparing ANKTIVA® plus BCG with BCG alone in 366 patients with BCG-naïve non-muscle invasive bladder cancer (NMIBC)
- ANKTIVA plus BCG is being evaluated as the first locally delivered, chemotherapy-free combination immunotherapy for BCG-naïve NMIBC
- Final analysis of the trial's primary efficacy endpoint is underway, with topline results expected in November 2026
- Supplemental Biologics License Application (sBLA) submission remains on track for the fourth quarter of 2026, potentially expanding ANKTIVA's indication to include patients with BCG-naïve NMIBC earlier in their disease course

CULVER CITY, Calif.--(BUSINESS WIRE)--Oct. 21, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), an immunotherapy company, today announced completion of the database lock for Cohort A of QUILT-2.005 (NCT02138734), its randomized, controlled, registrational trial evaluating ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) versus BCG alone in patients with BCG-naïve NMIBC. The chemotherapy-free combination is delivered directly into the bladder.

The database lock follows the completion of the data review, verification, and reconciliation of all 366 randomized patients, allowing the final efficacy analysis to proceed. The trial is designed to determine whether adding ANKTIVA to standard BCG therapy improves CR rates compared with BCG alone.

An [interim analysis](#) requested by the U.S. Food and Drug Administration (FDA) demonstrated statistically significant longer duration of complete response with ANKTIVA plus BCG compared to BCG alone. With the database lock complete for all patients enrolled, the final analysis is now underway and will assess the trial's primary endpoint and key secondary endpoints, including the duration of response, in accordance with the prespecified statistical analysis plan.

ImmunityBio anticipates reporting topline results in November 2026 and remains on track to submit an sBLA to the FDA in the fourth quarter of 2026 for ANKTIVA plus BCG in patients with BCG-naïve NMIBC.

Cohort A completed enrollment in February 2026, with 366 patients randomized to receive ANKTIVA plus BCG versus BCG alone. In March 2026, following a protocol-specified interim review of the data from 183 evaluable patients, the Independent Data Monitoring Committee (IDMC) determined that the enrolled population provided sufficient statistical power to detect the prespecified clinically meaningful difference between treatment arms, with no additional enrollment required.

"QUILT-2.005 was designed to investigate whether, ANKTIVA, an IL-15 receptor agonist, could build upon the trained immunity induced by BCG by activating natural killer (NK) cells and CD8+ cytotoxic T cells with upregulating memory T cells to enhance therapeutic effectiveness earlier in the bladder cancer treatment journey," ^{1,2} said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio. "With the database lock now complete in this randomized trial of 366 patients, we are entering a critical phase of validating the important role an IL-15 superagonist plays in the next evolution of immunotherapy. It has been established that chemotherapeutic approaches for the treatment of bladder cancer result in a reduction of NK and T cells, lymphocytes that are important for durable responses. The final analysis of this study will determine whether adding ANKTIVA to BCG improves complete response rates and the durability of those responses when compared with BCG alone, potentially resulting in the first intravesical, chemotherapy-free treatment approach for patients with BCG-naïve NMIBC. We look forward to sharing the findings once the analysis is complete."

"Achieving database lock brings us another step closer to our planned sBLA submission and our goal of expanding chemotherapy-free treatment options for patients with NMIBC," said Richard Adcock, President and Chief Executive Officer of ImmunityBio. "This progress reflects the coordinated efforts of our clinical development team, investigators, and site personnel across 110 U.S. and global clinical sites. We are especially grateful to the patients whose participation has made this important research possible."

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 of Cohort A was completed in February 2026 with 366 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. 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.

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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf).

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-plmn). 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](https://www.immunitybio.com) and connect with us on [X](#) (Twitter), [Facebook](#), [LinkedIn](#), and [Instagram](#).

References:

1. van Puffelen JH, et al., **Trained immunity as a molecular mechanism for BCG immunotherapy in bladder cancer**. Nat Rev Urol. 2020 Sep;17(9):513-525. doi: 10.1038/s41585-020-0346-4. Epub 2020 Jul 16. PMID: 32678343.
2. **ANKTIVA Mechanism of Action**, Section 12.1 https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf

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 anticipated timing of topline results from the QUILT-2.005 trial, the planned submission of a supplemental Biologics License Application (sBLA) for ANKTIVA® (nogapendekin alfa inbakicept-plmn), 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 anticipated timing, conduct, and outcomes of the final analysis of Cohort A of the QUILT-2.005 trial; the planned submission of an sBLA to the FDA; 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 once analyzed and published; and the potential for ANKTIVA® to address unmet medical needs in earlier lines of therapy.

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 early and preliminary nature of clinical data; the possibility that interim or topline results from the QUILT-2.005 trial may change as additional data become available or as data are further analyzed; the risk that clinical trial results may not support regulatory approval or further development of ANKTIVA® for BCG-naïve NMIBC; the risk that the timing for announcing topline results or submitting the sBLA may be delayed; the timing, outcome, and unpredictability of regulatory review by the FDA and other regulatory authorities; manufacturing and supply risks, competition from existing or future therapies; clinical experience that may differ from results observed in clinical trials; 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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