



ImmunityBio Reports Phase 3 Data Showing 84% Cystectomy Avoidance at Three Years and Complete Responses Beyond 53 Months with ANKTIVA® Plus BCG in BCG-Unresponsive NMIBC With CIS, With or Without Papillary Tumors

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Peer-reviewed publication reports long-term outcomes from the QUILT-3.032 study supporting durable disease control and bladder preservation

CULVER CITY, Calif.--(BUSINESS WIRE)--Oct. 16, 2026-- ImmunityBio, Inc. ([NASDAQ:IBRX](#)), a commercial-stage immunotherapy company, today announced the publication of long-term data from the Phase 2/3 QUILT-3.032 study (N=100) in the *Journal of Urology*. The study evaluated ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) in patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary disease.

Highlights:

- 71% complete response (CR) rate in patients with BCG-unresponsive NMIBC CIS, with or without papillary disease
- Median duration of CR of 26.6 months, with responses extending beyond 53 months
- More than half of responding patients in the FDA-reviewed population maintained complete responses beyond 45 months
- 84% cystectomy-free survival at 36 months among responders
- 98.2% disease-specific survival at three years
- No Grade 4 or Grade 5 treatment-related adverse events reported

"The QUILT-3.032 study represents one of the longest follow-up data sets in BCG-unresponsive NMIBC to date, and the results continue to support the durability of ANKTIVA's unique mechanism of action in generating sustained immune responses," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "These long-term findings are encouraging, suggesting the potential for prolonged disease control and the possibility of avoiding or delaying radical cystectomy for some patients."

The publication also reported:

- 63.8% of responders maintained CR for at least 12 months
- 52.3% maintained CR for at least 24 months
- 44.2% maintained CR for at least 36 months
- Progression-free survival remained 80.9% at three years
- In BCG refractory (never responded) patients, the CR rate was 66%
- 4% of responders progressed to muscle-invasive disease

The treatment continued to demonstrate a favorable safety profile. Most treatment-related adverse events were Grade 1 or Grade 2 and consisted of localized bladder symptoms associated with intravesical therapy. Grade 3 treatment-related adverse events occurred in 4% of patients, with no Grade 4 or Grade 5 treatment-related adverse events reported.

"Achieving a durable response and avoiding cystectomy are important treatment goals for patients with BCG-unresponsive NMIBC," said Richard Adcock, President and CEO of ImmunityBio. "These peer-reviewed results add to the growing body of evidence supporting ANKTIVA plus BCG and highlight its potential to provide sustained disease control and meaningful cystectomy avoidance for patients with limited treatment options. We thank the patients and clinical teams who contributed to this long-term follow-up."

The publication builds upon the growing body of clinical evidence supporting ANKTIVA plus BCG, which was initially approved by the U.S. Food and Drug Administration (FDA) in 2024 for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. In October 2026, the FDA expanded the approved indication to include patients with BCG-unresponsive NMIBC with papillary-only disease. ANKTIVA is the first FDA-approved IL-15 receptor agonist and the first approved immunotherapy in NMIBC designed to activate natural killer (NK) cells and T cells to generate durable immune responses.

About the QUILT 3.032 Study

QUILT-3.032 (NCT03022825) is a multicenter Phase 2/3 study evaluating ANKTIVA plus BCG in patients with BCG-unresponsive NMIBC. The published analysis includes 100 patients with CIS with or without papillary disease and represents one of the longest follow-up datasets reported in this disease setting, with outcomes extending beyond five years in some patients.

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 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](https://www.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®. Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by an investigational 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](#).

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding: the potential for ANKTIVA® plus BCG to provide prolonged disease control and bladder preservation; expectations regarding cystectomy avoidance and sustained complete responses in BCG-unresponsive NMIBC patients; future commercialization efforts and market acceptance of ANKTIVA; the potential expansion of indications or patient populations for ANKTIVA; future clinical development plans and regulatory submissions; and the potential benefits of ANKTIVA's mechanism of action and the Cancer BioShield™ platform.

These forward-looking statements are based on the beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to various risks, uncertainties, and assumptions. Actual results may differ materially from those described in these forward-looking statements due to a variety of factors, including: the risks that the long-term data from the QUILT 3.032 study may not be predictive of future results or real-world outcomes; challenges in commercializing ANKTIVA and achieving market acceptance; manufacturing and supply chain risks; competition from other therapies; the impact of reimbursement and pricing decisions by third-party payors; the risk of unexpected safety or efficacy findings; uncertainties regarding intellectual property protection; general economic and market 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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 23, 2026, 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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