



ImmunityBio Advances First-Line BCG Naïve NMIBC Program with Enrollment Exceeding Expectations and Positive Interim Analysis for ANKTIVA® Plus BCG

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- Enrollment of BCG naïve subjects (QUILT-2.005) receiving BCG alone versus BCG plus ANKTIVA exceeding expectations
- 85% enrolled with anticipated completion in Q2 2026 with BLA filing to U.S. Food and Drug Administration (FDA) by year end
- Interim analysis requested by FDA demonstrated statistically significant longer duration of complete response with ANKTIVA + BCG
- Expanded access program (EAP) of recombinant BCG proceeding well

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 16, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX) today announced an update on the status of enrollment in its randomized registrational trial in BCG-naïve non-muscle-invasive bladder cancer (NMIBC), QUILT-2.005. Enrollment has exceeded internal expectations and is now over 85% complete, with full enrollment of the planned study population anticipated by Q2 2026. Based on the current enrollment trajectory, ImmunityBio anticipates submitting a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) by year end 2026.

In 2023, to determine the contribution of effect of ANKTIVA® (nogapendekin alfa inbakicept), the FDA requested that an interim analysis of this randomized controlled trial be performed to assess complete response rate and duration of complete response in subjects treated with ANKTIVA plus BCG compared with BCG alone. These data were submitted to the Agency and publicly presented at the American Urological Association (AUA) Annual Meeting in 2024.

The interim analysis demonstrated that ANKTIVA significantly prolonged the duration of complete response when combined with BCG compared to BCG alone in the BCG-naïve NMIBC setting. At six months, 85% of patients receiving ANKTIVA plus BCG maintained a complete response, compared with 57% of patients receiving BCG alone. At nine months, 84% of subjects in the experimental arm maintained a complete response, while subjects receiving BCG alone demonstrated a complete response rate of 52%. Despite the limited sample size of this interim analysis, the difference in duration of complete response at nine months reached statistical significance ($p=0.0455$).¹

"We look forward to the final accrual of this important registrational randomized trial in patients with BCG-naïve non-muscle-invasive bladder cancer, which represents a substantial proportion of newly diagnosed bladder cancer cases," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman, and Global Chief Medical and Scientific Officer of ImmunityBio. "The interim analysis is encouraging and consistent with findings in the approved BCG-unresponsive setting, where the duration of complete response has exceeded 47 months."

Recognizing the ongoing shortage of TICE BCG, ImmunityBio's Expanded Access Program of recombinant BCG continues to progress and support patient access. The Company has requested consultation with the FDA to address the use of recombinant BCG as an alternative supply source in anticipation of continued clinical need, including patients with BCG-naïve disease.

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](https://www.immunitybio.com/Anktiva.com).

References:

Reddy S, et al. QUILT-2.005: A comparison of intravesical Bacillus Calmette-Guérin (BCG) in combination with the IL-15 superagonist N-803 versus

BCG alone in patients with BCG-naïve NMIBC. Presented at AUA Annual Meeting 2024; May 3–6, 2024; San Antonio, TX.

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](https://www.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 the anticipated timing, progress, and status of enrollment in ImmunityBio's randomized registrational trial in BCG-naïve non-muscle-invasive bladder cancer (NMIBC), QUILT-2.005, the significance of an interim analysis of this randomized controlled trial, the expected impact of faster-than-anticipated patient enrollment, the potential advancement of the Company's development programs and future regulatory, clinical, or development milestones, potential regulatory pathways and approval requests and the BLA submission, the regulatory review process and timing thereof, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, information regarding clinical trials, including potential trial design and timing, potential future uses and applications of ANKTIVA, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. The clinical trial referenced in this release is ongoing, and the data described are interim, subject to change, and based on data available as of a specified data cutoff date. No conclusions regarding efficacy, durability of response, comparative benefit, or long-term clinical outcomes can be drawn at this time. As patient enrollment continues and additional follow-up is obtained, the reported response duration, safety profile, and other clinical outcomes may change materially. There can be no assurance that the interim results will be predictive of final study results or that additional data will confirm or support these observations.

Statements in this presentation 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 preliminary and evolving nature of interim clinical data; potential safety, tolerability, or dosing issues that may emerge with longer follow-up or in additional patients; variability in patient response; limitations related to study design, size, and duration; challenges in clinical trial conduct, enrollment, and retention; the timing and outcome of regulatory submissions and interactions with regulatory agencies; the possibility that the investigational therapy may not demonstrate sufficient safety or efficacy to support further development or regulatory approval; ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates; and ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies.

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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