ImmunityBio Confirms Statistical Power in Pivotal Randomized BCG-Naïve NMIBC Trial to Detect Clinically Meaningful Differences Between ANKTIVA® Plus BCG Versus BCG Alone; Supplemental BLA Submission on Track for 2026

March 26, 2026

- The QUILT-2.005 randomized clinical trial is on track for final analysis and supplemental Biologics License Application (BLA) submission in 2026 for the BCG-naïve NMIBC carcinoma in situ with or without papillary indication with no additional enrollment required
- The Independent Data Monitoring Committee (IDMC) confirmed that the fully enrolled study (N=366) is adequately powered to detect the pre-specified difference in complete response rate between the experimental and control arms, and that no additional enrollment is required
- A planned interim analysis was conducted by the IDMC per the protocol once 50% of enrolled patients (N=183) in Cohort A were evaluable for the primary efficacy endpoint
- The IDMC reviewed the interim complete response data in 183 evaluable patients comparing ANKTIVA® + BCG to BCG alone to assess whether the current enrollment is sufficient to detect the pre-specified clinically meaningful difference between treatment arms at the protocol-specified power and concluded that no additional enrollment is required

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 26, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a vertically integrated, commercial-stage immunotherapy company, today announced that based on the Independent Data Monitoring Committee (IDMC) review of the interim data, the committee recommended that the study is adequately powered to detect the pre-specified clinically meaningful difference in complete response (CR) rate between the experimental arm (ANKTIVA + BCG) and the control arm (BCG alone) at the protocol-specified power, in the randomized QUILT-2.005 (NCT02138734) study. The QUILT-2.005 study was designed to detect the pre-specified difference in CR rate between ANKTIVA® (nogapendekin alfa inbakicept-pmln) plus Bacillus Calmette-Guérin (BCG) and BCG alone in patients with BCG-naïve non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS) with or without papillary disease, based on its review of the planned interim analysis.

On February 26, 2026, ImmunityBio announced enrollment was complete in the pivotal randomized trial. By March 2026, 50% of enrolled patients were evaluable (N=183) for the primary efficacy endpoint. Upon reaching this pre-specified 50% evaluable threshold, a planned interim analysis by an IDMC was initiated per protocol to verify that the 366 patients enrolled to date provides sufficient statistical power to detect the pre-specified clinically meaningful difference in CR rate between the two arms.

Based on the IDMC review of the interim data, the committee recommended that no additional enrollment beyond N=366 is required and that the study is adequately powered to detect the pre-specified clinically meaningful difference in CR rate at the protocol-specified power.

"Over the past decade, our scientific thesis has been that activating natural killer cells and CD8+ cytotoxic T cells through IL-15 receptor agonism would generate durable immunological memory against bladder cancer. The NCI identified IL-15 as the number one ranked immunostimulatory cytokine nearly two decades ago, and this program has been the clinical validation of that thesis. The IDMC's confirmation that QUILT-2.005 is adequately powered to detect clinically meaningful differences when ANKTIVA is combined with BCG. Among participants from the QUILT 2.005 Phase 1b study which began in 2014, those patients who enrolled in long-term follow-up (6 of 9 evaluable), all (6 out of 6, 100%) demonstrated a prolonged duration of complete remission with a median survival of 8.8 years with ongoing bladder preservation to date. In addition, the initial interim analysis of QUILT-2.005 performed in the first 43 patients in 2023, further demonstrated a difference in durable complete response when ANKTIVA is combined with BCG in the BCG-naïve setting. The consistency of durable response from the first 9 patients in 2014, to the next 43 patients in 2023 is encouraging and I am pleased that statistical power of the randomized trial requires no further enrollment," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio. "The combination of ANKTIVA with BCG is approved for adult patients with BCG-unresponsive NMIBC with CIS with or without papillary disease, and the enrollment of QUILT-2.005 is now complete. ImmunityBio is on track to submit a supplemental Biologics License Application based on the final data analysis in 2026."

"The regulatory and commercial development of ANKTIVA in urologic oncology and across solid tumor indications continues to advance. We are grateful to the patients who participated in this trial and to the ImmunityBio team whose work made this milestone possible," said Richard Adcock, President and CEO of ImmunityBio. "With ANKTIVA approved with BCG for adult patients with BCG-unresponsive NMIBC CIS with or without papillary disease in 34 countries and territories, the opportunity to extend its use earlier in the disease course in the BCG-naïve setting represents a substantial expansion of the addressable patient population."

About QUILT-2.005

QUILT-2.005 (NCT02138734) is a randomized, controlled Phase 2b clinical trial evaluating ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) versus BCG alone in patients with BCG-naïve non-muscle invasive bladder cancer (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 whom ANKTIVA is currently FDA approved. The trial is designed to assess whether the addition of ANKTIVA to standard induction BCG improves the complete response (CR) rate in patients with carcinoma *in situ* (CIS) with or without papillary disease. QUILT-2.005 completed enrollment in February 2026. In March 2026, the Independent Data Monitoring Committee determined that the study was adequately powered to detect a clinically meaningful difference between the control and experimental arms. Supplemental BLA submission is anticipated Q4 2026.

About ANKTIVA® (nogapendekin alfa inbakicept-pmln)

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. 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 dendritic cell membrane-bound IL-15 receptor alpha 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.

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 superagonist, ANKTIVA® (nogapendekin alfa inbakicept). 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, including statements regarding the clinical development, therapeutic potential, safety, efficacy, and regulatory pathway of ANKTIVA; the anticipated clinical benefits of ANKTIVA plus BCG in patients with BCG-naïve non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS); the potential for ANKTIVA plus BCG to improve durability of complete response compared to BCG alone; the timing, availability, and results of additional data from the QUILT 2.005 trial; the Company's anticipated submission of a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) by the fourth quarter of 2026; the potential for FDA approval of ANKTIVA in the BCG-naïve setting; the potential for ANKTIVA plus BCG to change the standard of care for NMIBC; the progress and potential regulatory outcome of the Company's Expanded Access Program for recombinant BCG; the potential approval of recombinant BCG as an alternative supply source; and the broader capabilities and expected benefits of the Company's Cancer BioShield™ platform.

These forward-looking statements are based on current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management, and are subject to significant risks and uncertainties. Actual results may differ materially from those expressed or implied by such forward-looking statements due to a variety of factors, including, but not limited to: risks related to clinical trial design, enrollment, timing, interim analyses, and final data outcomes; the possibility that interim results may not be predictive of final trial results; regulatory risks, including the timing and outcome of interactions with the FDA and other regulatory authorities, and the risk that a BLA may not be submitted when anticipated or, if submitted, may not be approved or may require additional data or studies; risks related to safety signals or adverse events that may arise during continued evaluation; the Company's ability to manufacture sufficient quantities of ANKTIVA and recombinant BCG to support clinical development and potential commercialization; risks associated with product supply, including ongoing BCG shortages; competitive developments; changes in standard-of-care treatment; market acceptance; reimbursement; and intellectual property protection.

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 February 23, 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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