ImmunityBio Completes Enrollment in Pivotal Randomized Trial Evaluating ANKTIVA® Plus BCG Versus BCG Alone in BCG-Naïve Non-Muscle Invasive Bladder Cancer Carcinoma In Situ

February 26, 2026

- Study fully enrolled ahead of schedule, with 366 of 366 BCG-naïve NMIBC patients randomized to receive BCG alone or ANKTIVA plus BCG
- Interim analysis requested by the FDA demonstrated a statistically significant improvement in duration of complete response with ANKTIVA plus BCG, with no significant safety signals observed
- Company anticipates submitting a biologics license application (BLA) to the U.S. FDA by Q4 2026
- Expanded access program (EAP) of recombinant BCG is ongoing, with 580 patients currently enrolled throughout the U.S.

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 26, 2026-- ImmunityBio (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced completion of enrollment in its Phase 2 clinical trial evaluating ANKTIVA® (nogapendekin alfa inbakicept-pmln) plus Bacillus Calmette-Guérin (BCG) versus BCG alone in patients with BCG-naïve non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS), with or without papillary tumors.

The QUILT 2.005 trial (NCT02138734), which completed enrollment ahead of schedule, includes 366 patients randomized to receive either BCG alone, the current standard-of-care for NMIBC CIS, or ANKTIVA in combination with BCG. An interim analysis requested by the U.S. Food and Drug Administration (FDA) demonstrated that treatment with ANKTIVA plus BCG resulted in a statistically significant improvement in the duration of complete response compared with BCG alone, with no significant safety concerns reported.

The interim analysis demonstrated that at six months, 85% of patients receiving ANKTIVA plus BCG maintained a complete response, compared with 57% of patients treated with BCG alone. At nine months, 84% of subjects in the ANKTIVA plus BCG arm maintained a complete response, compared with 52% of patients in the BCG-alone arm. Despite the limited sample size of the interim analysis, the difference in duration of complete response at nine months reached statistical significance (p=0.0455).[1]

“The interim results from this randomized study are encouraging and suggest that ANKTIVA plus BCG may improve the durability of response in patients with BCG-naïve NMIBC,” said Dr. Christopher Pieczonka, Corporate Director of Clinical Research at U.S. Urology Partners and Global Principal Investigator of the trial. “Given the historical limitations of BCG alone, continued evaluation of this combination has the potential to inform future treatment strategies and potentially change the current standard-of-care recommendations for NMIBC. Importantly, no new or worsening safety signals have been observed to date, which is encouraging when considered alongside prior studies evaluating BCG in combination with checkpoint inhibitors in this disease setting.”

Additional study results are expected to be available in the fourth quarter of 2026. Based on these data, ImmunityBio anticipates submitting a biologics license application (BLA) to the FDA by Q4 2026.

“We are encouraged by these interim results and await the final unblinding of the completed trial,” said Patrick Soon-Shiong, Founder, Executive Chairman, and Global Chief Scientific and Medical Officer of ImmunityBio. “If approved, ANKTIVA plus BCG could offer a new treatment option earlier in the disease course for patients with NMIBC CIS, building on the therapy’s existing approval in the BCG-unresponsive setting.”

In parallel, ImmunityBio continues to address the ongoing shortage of TICE® BCG through its Expanded Access Program (EAP) for recombinant BCG (NCT06810141), which is progressing and supporting patient access. The Company has requested consultation with the FDA regarding the potential approval of recombinant BCG as an alternative supply source in anticipation of continued clinical need, including for patients with BCG-naïve disease.

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. 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.

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, 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 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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