ImmunityBio Announces Comprehensive U.S. Patents Covering Combination of ANKTIVA with BCG for Cancer Treatment, with Terms Through 2035

May 18, 2026

- Five issued U.S. patents cover the combination of ImmunityBio's IL-15 receptor agonist (NAI) with Bacillus Calmette-Guérin (BCG) for non-muscle invasive bladder cancer treatment, with terms extending through at least 2035
- Claims cover methods of treating non-muscle invasive bladder cancer (NMIBC) including BCG-naïve disease, defined-dose pharmaceutical compositions matching the approved NAI + BCG intravesical regimen, and two-vial commercial kits
- Portfolio reinforces ImmunityBio's IL-15 receptor agonist plus BCG position as the Company executes its exclusive U.S. Tokyo-172 BCG supply agreement with Japan BCG Laboratory and continues to develop Recombinant BCG (rBCG) to enhance USA supply

CULVER CITY, Calif.--(BUSINESS WIRE)--May 18, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a vertically integrated commercial-stage immunotherapy company, today announced that five United States patents have been issued to ImmunityBio covering the combination of its IL-15 receptor agonist ANKTIVA® (nogapendekin alfa inbakicept-pmln) with Bacillus Calmette-Guérin (BCG) for the treatment of cancer.

The five patents (U.S. Patent Nos. 11,173,191; 11,679,144; 11,890,323; 12,268,731; and 12,318,432) with terms extending through at least 2035 include compositions of combinations of ANKTIVA and BCG. Together they protect the approved ANKTIVA plus BCG product, the specific intravesical dosing regimen, the two-vial commercial kit, and methods of treating non-muscle invasive bladder cancer (NMIBC) including BCG-naïve disease and bladder cancer.

The issued patent portfolio establishes composition-of-matter and method-of-use protection for ImmunityBio's IL-15 receptor agonist and BCG combination platform through the next decade and beyond. This intellectual property position supports the Company's commercial ANKTIVA plus BCG franchise in BCG-unresponsive NMIBC and bladder cancer, its pending supplemental BLA for BCG-unresponsive papillary-only disease, and the advancing QUILT-2.005 registrational trial evaluating ANKTIVA plus BCG versus BCG alone in BCG-naïve NMIBC carcinoma *in situ*.

The patent portfolio also intersects with ImmunityBio's recently announced exclusive U.S. Development and Supply Agreement with Japan BCG Laboratory for the Tokyo strain of BCG (Tokyo-172), which is supported by the positive Phase III SWOG S1602 results demonstrating non-inferiority of Tokyo-172 BCG versus TICE BCG on high-grade recurrence-free survival (HR 0.82; 95.8% CI 0.63–1.08) in 984 randomized patients with BCG-naïve high-grade NMIBC. As ImmunityBio engages with the FDA to pursue U.S. approval of Tokyo-172 BCG, the issued patent estate protects the combination of any approved BCG strain with the Company's IL-15 receptor agonist platform.

"Over the past decade, we have built an integrated immunotherapy platform grounded in the science of IL-15 and its capacity to activate NK cells, CD8+ T cells, and memory T cells without expanding suppressive regulatory T cells. These five issued patents protect that science at every layer that matters commercially: the compositions of matter, the method of treatment, the wild-type and mutant IL-15 plus BCG compositions, the intravesical dosing regimen, and the two-vial kit physicians administer. The IL-15 and BCG combination is the backbone of our bladder cancer franchise, and this patent estate protects it through at least 2035. In a similar vein, ImmunityBio has received issued patents covering the combination of ANKTIVA with checkpoint inhibitors," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio.

"This patent portfolio provides long-term protection for a cornerstone of ImmunityBio's commercial franchise at a time when we are expanding the clinical utility of ANKTIVA plus BCG across multiple NMIBC settings, securing a second BCG supply source for the U.S. market, and generating 700% year-over-year revenue growth. The combination of durable patent protection, validated clinical data, and supply chain diversification positions ANKTIVA plus BCG as the standard of care in this disease for years to come," said Richard Adcock, President and Chief Executive Officer of ImmunityBio.

- **U.S. Patent No. 11,173,191 (issued November 16, 2021)** covers the core method of treating cancer by administering BCG together with the IL-15N72D:IL-15RαSu/Fc complex (ALT-803/ANKTIVA), with dependent claims specific to bladder cancer, NMIBC, BCG-naïve NMIBC, and intravesical administration. This is the foundational method-of-treatment claim that reads directly on the FDA-approved use of ANKTIVA plus BCG.
- **U.S. Patent No. 11,679,144 (issued June 20, 2023)** covers the pharmaceutical composition combining BCG with a wild-type IL-15:IL-15RαSu complex, including the two-vial kit format (one vial BCG, one vial IL-15:IL-15RαSu, plus directions for use in treating cancer including bladder cancer). This broadens composition and product-form protection beyond the IL-15N72D mutant to wild-type IL-15 combinations.
- **U.S. Patent No. 11,890,323 (issued February 6, 2024)** covers the method of treating NMIBC, including BCG-naïve NMIBC, by intravesical instillation of BCG plus a wild-type IL-15:IL-15RαSu complex. This patent pairs with 11,173,191 to cover both the IL-15 mutant and wild-type forms of the combination, closing a potential design-around route.
- **U.S. Patent No. 12,268,731 (issued April 8, 2025)** covers the defined-dose composition itself: a single intravesical dose, matching the ANKTIVA plus BCG dosing regimen used in the FDA-approved label and in the QUILT-3.032 and QUILT-2.005 trials. Claims also cover the corresponding two-vial bladder cancer treatment kit.

- **U.S. Patent No. 12,318,432 (issued June 3, 2025)** covers the commercial two-vial kit itself: a first vial of BCG and a second vial of ANKTIVA (dimeric IL-15RαSu/Fc plus two IL-15N72D molecules) with instructions for treating neoplasia. This patent protects the as-supplied product configuration that physicians receive and administer.

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 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

U.S. 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.

Investigational Use Notice: The Tokyo strain of BCG (manufactured by Japan BCG Laboratory) and recombinant BCG or rBCG (manufactured by Serum Institute of India under ongoing partnership with ImmunityBio) are investigational in the United States and have not been approved by the FDA. The safety and effectiveness of these investigational products have not been established. Availability of rBCG is limited to ImmunityBio's FDA Expanded Access Program for eligible patients. To enroll in the Expanded Access Program for recombinant BCG, please visit https://immunitybio.com/rbcg/

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. 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 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. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements including, but are not limited to, statements regarding the expected benefits, scope, validity, enforceability, and commercial value of ImmunityBio's patent portfolio; the expected duration of patent protection for ANKTIVA® in combination with BCG through at least 2035; the potential for patent term extensions or adjustments; the commercial and competitive advantages afforded by the issued patents; the Company's ability to maintain and expand its intellectual property position around IL-15 receptor agonist and BCG combinations; expectations regarding the QUILT-2.005 registrational trial and potential supplemental BLA approval for BCG-unresponsive papillary-only disease; anticipated revenue growth and market expansion for the ANKTIVA plus BCG franchise; the successful development and U.S. regulatory approval of Tokyo-172 BCG; and the Company's ability to execute its U.S. supply agreement with Japan BCG Laboratory.

These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties, known and unknown, that may cause actual results to differ materially from those projected. Such risks and uncertainties include, but are not limited to: challenges to the validity or enforceability of our patents in litigation or administrative proceedings; potential infringement claims by third parties; the possibility that competitors may design around our patents or develop alternative therapies; uncertainties regarding patent term extension or adjustment calculations; the risk that regulatory authorities may not approve Tokyo-172 BCG or the supplemental BLA for papillary-only disease; changes in patent laws and regulations; the outcome of ongoing and future clinical trials; market acceptance of ANKTIVA plus BCG; manufacturing and supply chain risks; and other factors discussed in ImmunityBio's filings with the U.S. Securities and Exchange Commission (SEC), including the "Risk Factors" sections of the Company's Annual Report on Form 10-K filed on February 23, 2026 and most recent Quarterly Report on Form 10-Q filed on May 7, 2026.

ImmunityBio undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

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