ImmunityBio Addresses FDA Correspondence and Reaffirms Commitment to Advertising Compliance

April 6, 2026

- Company initiated a comprehensive review of promotional materials and is implementing enhanced advertising compliance measures, including expanded promotional review protocols, executive training, and external regulatory oversight
- Company has removed the identified podcast from its corporate website and formally requested its removal from all third-party hosting platforms
- Company confirmed that the television advertisement cited in the FDA correspondence was never broadcast, aired, or disseminated to the public

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 6, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced it has submitted a comprehensive response to the U.S. Food and Drug Administration (FDA) Office of Prescription Drug Promotion (OPDP) regarding issues raised on March 13, 2026 related to a television advertisement and a podcast. The company addressed the concerns related to the podcast and informed OPDP that the television advertisement was never aired.

The response outlines the company's immediate and planned corrective actions and its ongoing commitment to ensuring all promotional communications for ANKTIVA® (nogapendekin alfa inbakicept-pmln) are accurate, balanced, and compliant with FDA regulations.

Commitment to Advertising Compliance and Resolution

ImmunityBio has taken proactive steps to address the OPDP's concerns, including the removal of the identified podcast from its corporate website and requesting its removal from third-party platforms. Additionally, the company confirmed that a television advertisement mentioned in the OPDP letter was never broadcast or disseminated to the public.

"ImmunityBio takes promotional compliance with the utmost seriousness," said Richard Adcock, President and CEO of ImmunityBio. "We are dedicated to maintaining a clear distinction between our investigational pipeline aspirations and the promoted indications for our approved therapies. We believe our substantive remedial actions and enhanced internal protocols address the Agency's concerns."

Upon receipt of the letter from OPDP, ImmunityBio initiated a comprehensive review of all promotional materials and external communications claims with its legal and regulatory teams.

The company is implementing a robust suite of corrective actions and compliance enhancements, including mandatory executive training, expanded Promotional Review Committee (PRC) protocols, and the engagement of external regulatory counsel to audit future high-visibility communications.

Clarifying the Context of Scientific Innovation

In its response, ImmunityBio also provided background regarding the statements cited by the Office of Prescription Drug Promotion, which occurred during a podcast appearance by Founder and Executive Chairman Dr. Patrick Soon-Shiong. The company noted that these remarks were intended to convey Dr. Soon-Shiong's aspirational and forward-looking opinions regarding his vision for the company's drug development pipeline and the underlying science supporting the strategy of treating patients with cancer.

Other key points of clarification include:

- The characterization of the IL-15 molecule, the foundation of ANKTIVA, as a highly promising agent was based on an independent assessment by the National Cancer Institute (NCI) during its Immunotherapy Agent Workshop dated July 12, 2007.[1]
- The discussion focused on the investigational applications of the IL-15 platform across multiple oncology indications, where it is currently being studied under FDA-authorized investigational programs.
- References to "cancer vaccines" were intended to describe the mechanistic potential of immunotherapies that induce memory T cells, a fundamental goal of the company's long-term research strategy, as stated in multiple scientific publications.[2]

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

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 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. Forward-looking statements include, without limitation, statements regarding our planned corrective actions and compliance enhancements. These statements are based on the Company's current expectations, beliefs, assumptions, and plans and involve significant risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, among others, the Company's ability to successfully execute on these corrective action and compliance enhancement plans and the reliance on the cooperation of third-parties for certain corrective actions. 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.

References:

1. Cheever, Martin A. Twelve immunotherapy drugs that could cure cancers. Immunological Reviews. 2008;222(1):357–368. doi:10.1111/j.1600-065X.2008.00604.x.
2. Kartikasari AER, Prakash MD, Cox M, Wilson K, Boer JC, Cauchi JA, Plebanski M. *Therapeutic Cancer Vaccines—T Cell Responses and Epigenetic Modulation*. Front Immunol. 2019 Jan 25;9:3109.

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