ImmunityBio Announces Approval in Macau SAR, China for ANKTIVA® in BCG-Unresponsive NMIBC with CIS ± Papillary Tumors

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- Macau SAR, China regulator grants approval for ANKTIVA® (nogapendekin alfa inbakicept-pmln) in patients with BCG-unresponsive NMIBC with CIS ± papillary tumors
- Authorization follows a reliance-based review referencing prior FDA and EMA decisions
- First ANKTIVA authorization in Asia, supporting ongoing global expansion across 34 countries and territories

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 20, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), today announced that the Pharmaceutical Administration Bureau (ISAF) of the Macau Special Administrative Region of the People's Republic of China has granted regulatory approval for ANKTIVA® (nogapendekin alfa inbakicept-pmln).

The approval establishes ANKTIVA's initial presence in Asia and reflects the Company's strategy to expand global access through reliance-based regulatory pathways. In Macau, ANKTIVA is approved in combination with Bacillus Calmette-Guérin (BCG) for adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) ± papillary tumors, consistent with its approved use in the United States.

The authorization was granted following a review that considered prior regulatory decisions by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), in accordance with applicable local requirements.

"This approval in Macau reflects the strength of the clinical and regulatory foundation supporting ANKTIVA in BCG-unresponsive NMIBC CIS, with or without papillary tumors," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "The data from QUILT 3.032, published in NEJM Evidence and The Journal of Urology, demonstrate durable responses in this disease setting. As we continue to work with regulatory authorities, our focus remains on enabling global access to an immunotherapy designed to activate NK and T-cell function and address the underlying immune deficit in bladder cancer."

This approval in Macau represents the first authorization for ANKTIVA in Asia. The Company continues to engage with additional health authorities across the region as part of its international regulatory strategy.

"This authorization marks an important step in establishing ANKTIVA in Asia and advancing our broader international expansion strategy," said Richard Adcock, President and CEO of ImmunityBio. "We are engaging with additional health authorities across the Asia-Pacific region and, in parallel, beginning to prepare for potential commercial distribution, recognizing there is still meaningful work ahead as we pursue further regulatory authorizations. Our focus is on executing this expansion in a disciplined manner, building on our existing approvals to support long-term global access for patients."

About ANKTIVA®

ANKTIVA® (nogapendekin alfa inbakicept-pmln) is a first-in-class interleukin-15 (IL-15) receptor agonist designed to activate and proliferate natural killer (NK) cells and CD8+ T cells. In the QUILT-3.032 study in patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors, ANKTIVA in combination with BCG demonstrated a complete response rate of 71%, with a median duration of response of 26.6 months.

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 ImmunityBio's regulatory activities in Macau and other jurisdictions; the potential pursuit, timing, and outcome of additional regulatory submissions and authorizations; the Company's plans for potential commercial distribution; and its broader international expansion strategy for ANKTIVA.

These forward-looking statements are based on the Company's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially from those described herein. Such risks and uncertainties include, among others, the determinations of regulatory authorities, including ISAF, the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other global health authorities;

the possibility that additional data, analyses, or clinical studies may be required; risks related to manufacturing, supply, and distribution; and other factors affecting the Company's business.

Additional information regarding these and other risks can be found under the heading "Risk Factors" in ImmunityBio's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, as well as in subsequent filings with the SEC, which are available at www.sec.gov. ImmunityBio cautions you not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release, and the Company undertakes no obligation to update any forward-looking statements except as required by law.

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