ImmunityBio and Rafa Announce Israeli Ministry of Health Approval of ANKTIVA® Plus BCG for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ

November 9, 2026

- Partnership brings first-in-class IL-15 receptor agonist immunotherapy to patients in Israel
- Israeli Ministry of Health grants approval for ANKTIVA® (nogapendekin alfa inbakicept) in combination with BCG for adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors
- Approval granted four months after submission under an accelerated review pathway; registration license expected within the coming weeks
- ANKTIVA® is now authorized in 35 countries; Rafa Laboratories to lead commercialization in Israel as exclusive partner

JERUSALEM & CULVER CITY, Calif.--(BUSINESS WIRE)--Nov. 9, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX) ("ImmunityBio") and Rafa Laboratories Ltd. (TASE: RAFA) ("Rafa") today announced that the Israeli Ministry of Health (MoH) has granted approval for ANKTIVA® (nogapendekin alfa inbakicept), indicated in combination 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. The approval was granted four months after submission under an accelerated review pathway. The registration license is expected within the coming weeks.

Under the distribution agreement between the companies, Rafa will be the exclusive commercialization partner for ANKTIVA in Israel, bringing together ImmunityBio's innovative immunotherapy platform and Rafa's established capabilities and presence in the Israeli healthcare market.

ANKTIVA is a first-in-class IL-15 receptor agonist immunotherapy designed to activate natural killer (NK) cells and T cells and drive their proliferation. In the United States, ANKTIVA was approved by the U.S. Food and Drug Administration in April 2024 in combination with BCG for BCG-unresponsive NMIBC with CIS, with or without papillary tumors. The FDA subsequently expanded the label for ANKTIVA in combination with BCG to include adults with BCG-unresponsive NMIBC, including those with papillary-only disease.

"Patients with BCG-unresponsive bladder cancer have historically faced limited treatment options, underscoring the urgent need for new therapeutic approaches," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio. "We developed ANKTIVA based on the understanding that the immune system has the innate ability to recognize and destroy cancer, and that activating natural killer cells and memory T cells is fundamental to sustaining an immune response. This approval in Israel represents another important step in our mission to expand global access to a chemotherapy-free immunotherapy combination for patients facing this challenging disease. We look forward to working with Israel's physicians to bring this innovative treatment option to patients in need."

"The approval of ANKTIVA in Israel represents an important milestone for patients with non-muscle invasive bladder cancer and reflects Rafa's commitment to bringing meaningful therapeutic innovation to patients in Israel," said Iddo Leshem, CEO of Rafa Laboratories. "We are proud to partner with ImmunityBio to make this novel immunotherapy available locally and to combine their scientific innovation with Rafa's experience and capabilities in the Israeli healthcare system."

"Expanding access to ANKTIVA internationally is a key part of our mission to transform cancer care by harnessing the power of the immune system," said Richard Adcock, President and CEO of ImmunityBio. "Rafa's strong presence and experience in the Israeli healthcare market make them an excellent partner to bring ANKTIVA to eligible patients in Israel. This approval represents another step in expanding access to ANKTIVA for patients with BCG-unresponsive NMIBC around the world."

Unmet Medical Need in Israel

Bladder cancer is a significant public health concern in Israel. It has been reported as the fourth most common cancer among Israeli men,[1] and 1,775 patients were diagnosed in 2018, more than 80% of them men.[2] That same year, 401 deaths from bladder cancer were recorded.[2] Over the past two decades, the incidence of in situ bladder cancer has increased, while the incidence of invasive bladder cancer has declined.[1] For patients with BCG-unresponsive high-risk NMIBC, radical cystectomy is the standard treatment recommended by the European Association of Urology guidelines.[3] It is a major surgical procedure and is not suitable for every patient. Bladder-preserving treatment options for this population therefore remain an area of high unmet medical need.

About ANKTIVA® (nogapendekin alfa inbakicept)

The interleukin-15 (IL-15) cytokine 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 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 U.S. SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC).

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 BCG-unresponsive NMIBC have evidence of high-grade disease 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.

ADVERSE REACTIONS: The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills, and pyrexia.

About Rafa

Rafa is a fully integrated, TASE-listed pharmaceutical company at the forefront of healthcare innovation. Through its commercial partnership engine, Rafa brings deep expertise in launching and scaling innovative medicines across Israel, Central & Eastern Europe, and, more recently, Canada. Trusted by leading biopharmaceutical companies including United Therapeutics, Acadia, Helsinn and others, Rafa offers a highly capable platform spanning market access, medical affairs, regulatory, supply chain, and commercialization. Rafa also enables rapid Named Patient Access programs across more than 50 markets, helping patients gain timely access to transformative therapies while creating a bridge to long-term market development.

In parallel, through its biodefense and critical-care engine, Rafa is a global leader in preparedness and response solutions that protect populations against chemical, biological, radiological, and nuclear (CBRN) threats. Leveraging decades of expertise, advanced manufacturing capabilities, and strategic partnerships with governments and health authorities worldwide, Rafa plays a vital role in strengthening national resilience, emergency readiness, and public health security.

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 agonist, ANKTIVA® (nogapendekin alfa inbakicept). 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.

References

1. Taylor N, Heering G, Icht O, Kozlova D, Silverman BG. Changing trends in bladder cancer epidemiology in the Israeli population: 1996–2016. Isr Med Assoc J. 2025;27(11):684-690.

2. Israel Cancer Association and Israel Ministry of Health. The ICA launches 2021 World Cancer Day: updated statistics on cancer morbidity and mortality in Israel (data from the Israel National Cancer Registry, 2018). 7 February 2021.

3. Babjuk M, et al. European Association of Urology guidelines on non-muscle-invasive bladder cancer (Ta, T1, and carcinoma in situ). Eur Urol. 2022;81(1):75–94.

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 Israel and other jurisdictions; the timing, issuance and scope of the anticipated registration license and the potential commercialization of ANKTIVA in Israel; the timing, scope and success of the commercialization, launch, availability and adoption of ANKTIVA in Israel; Rafa's role as exclusive commercialization partner and the parties' performance under their distribution agreement; pricing, reimbursement and patient access; and the Company's 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 the Israeli Ministry of Health, the U.S. Food and Drug Administration (FDA), and other global health authorities; the possibility that additional data, analyses, or clinical studies may be required; the possibility that the registration license may be delayed, conditioned or not issued as anticipated; the ability to obtain and maintain regulatory approvals, licenses, pricing and reimbursement; risks associated with commercial launch, market acceptance and product demand; the parties' ability to successfully perform their respective obligations under the distribution agreement; 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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