Saudi FDA Grants Accelerated Approval to ImmunityBio's ANKTIVA® In Combination with Checkpoint Inhibitors for Metastatic Non-Small Cell Lung Cancer

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- ANKTIVA, in combination with an immune checkpoint inhibitor, has received accelerated approval from the Saudi Food and Drug Authority for the treatment of metastatic non-small cell lung cancer, marking the first approval in the world of a subcutaneously administered IL-15 receptor superagonist that restores immune competence
- ANKTIVA + checkpoint inhibitor represents the first approved chemotherapy-free immunotherapy that activates both natural killer cells and killer T cells, heralding the era of immunotherapy 2.0
- Accelerated approval was granted following SFDA review of clinical data from QUILT-3.055 in second-line and greater NSCLC patients and QUILT-2.023 in first-line NSCLC demonstrating significant immune restoration and a consistent association between lymphocyte recovery with improved survival in checkpoint-experienced patients
- Newly approved therapy supports ImmunityBio's mission to provide access to patients globally who could benefit from this chemotherapy-free combination treatment

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 14, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the Saudi Food and Drug Authority (SFDA) has granted accelerated approval of ANKTIVA® (nogapendekin alfa inbakicept) for use in combination with immune checkpoint inhibitors for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose disease has progressed following standard-of-care therapy. This marks the first approval of the Company's innovative treatment for this indication anywhere in the world, and the first approval for subcutaneous administration.

"This approval represents a significant step forward for lung cancer patients in the Kingdom of Saudi Arabia and a meaningful milestone that we hope will pave the way toward additional approvals across a region where lung cancer claims far too many lives each year," said Patrick Soon-Shiong, M.D., ImmunityBio's Founder, Executive Chairman, and Global Chief Scientific and Medical Officer. "This combination of ANKTIVA plus a checkpoint inhibitor serves as a foundational backbone to immunotherapy 2.0, enabling activation of the complex immune system through subcutaneous outpatient therapy."

Dr. Soon-Shiong added, "We are pleased that the Saudi FDA recognized the significance of ANKTIVA in restoring and maintaining immune competence and achieving prolonged survival in patients with lung cancer who have exhausted all standards of care. Clinical studies are ongoing to build on this ANKTIVA plus CPI backbone, as well as to evaluate CAR-NK cell therapy plus this combination in other indications. The goal of this combination immunotherapy approach is to orchestrate the immune system as a paradigm shift in the treatment of cancer across all tumor types. The NANT Cancer Vaccine (Patent #11,071,774) describes this vision of a next-generation immunotherapy designed to achieve durable remission and improved quality of life for patients with cancer."

In the Kingdom of Saudi Arabia, lung cancer is one of the most prevalent cancer types overall, according to the Saudi Ministry of Health, and is the third most common cancer among males over 45 years of age, as discussed at the Inaugural Summit: USA-Saudi Biotech Alliance meeting.[1]

ImmunityBio plans to open a regional office in the Kingdom of Saudi Arabia to support physicians and health systems across the Middle East and North Africa. The company will collaborate with Biopharma Cigalah as its commercial and distribution partner in the region. Founded in 2007, BioPharma Cigalah provides the commercial infrastructure and capabilities needed to support therapies for serious diseases and expand patient access throughout the Middle East and North Africa.

"The incidence of lung and other cancers in the Middle East and North Africa is large and growing, demonstrating a significant unmet need for the kind of innovative treatments ImmunityBio is developing," added Richard Adcock, President and CEO of ImmunityBio. "We are pursuing approvals across the region to fill that need, as well as investing in a regional office in Saudi Arabia in order to support our expansion into these growing markets."

The accelerated approval for NSCLC is based on an observed increase in absolute lymphocyte count (ALC) associated with overall survival in single-arm clinical study (QUILT 3.055) together with the randomized trial QUILT 2.023 demonstrating the biological activity of ANKTIVA in restoring and maintaining lymphocyte count (see related announcement here). An ongoing confirmatory randomized trial in NSCLC is actively recruiting patients who have failed chemoradiation and checkpoint inhibitors (ResQ 201A).

The combination of ANKTIVA plus checkpoint inhibitor therapy is protected by multiple issued patents, including U.S. Patent Nos. 9,925,247 and 11,071,774, with patent terms extending into 2032–2039.

About ANKTIVA® (nogapendekin alfa inbakicept)

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.

1. AlOmar RS, AlAbdulKader AM. Epidemiology of Lung Cancer in Saudi Arabia, Saudi Cancer Registry, 2015-2020. *J Epidemiol Glob Health*. 2025 Dec 4;15(1):143. doi: 10.1007/s44197-025-00491-PMID: 41340013; PMCID: PMC12678664.

About ImmunityBio

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies that bolster the natural immune system to defeat cancers and infectious diseases. The Company's range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. Designated an FDA *Breakthrough Therapy*, ANKTIVA is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer CIS that activates NK cells, T cells, and memory T cells for a long-duration response. The Company is applying its science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases. For more information, visit **ImmunityBio.com** (Founder's Vision) 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, such as statements regarding clinical trial data and potential results and implications to be drawn therefrom, the belief that Saudi FDA authorization may lead to increased revenue, market acceptance, clinical utility, future regulatory approvals, or potential expansion into additional indications or territories, the expected impact of the approval of ANKTIVA in the Saudi Arabia on the Company's business, financial condition, and results of operations, potential benefits to patients, potential treatment outcomes for patients, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents for the prevention or reversal of lymphopenia, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents across multiple tumor types and indications and for potential applications beyond oncology, potential regulatory pathways and the regulatory review process and timing thereof, the application of the Company's science and platforms to treat cancers, immunotherapies and cell therapies that has the potential to change the paradigm in cancer care, and the impact of the Saudi FDA approval on the Company's ex- United States go to market strategy. Statements in this press release that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as "anticipates," "believes," "continues," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "is," "seeks," "should," "will," "strategy," and variations of such words or similar expressions.

Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about ImmunityBio, including, without limitation, the Company's ability to successfully commercialize ANKTIVA in Saudi Arabia or other markets; uncertainties relating to pricing, reimbursement, and market adoption; the outcome of post-approval commitments or other regulatory requirements; the potential for adverse safety findings or manufacturing issues; competition from existing or new therapies; reliance on third-party manufacturers, distributors, or partners; changes in foreign or domestic regulatory, political, or economic conditions. 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 March 3, 2025, and the Company's Form 10-Q filed with the SEC on November 5, 2025 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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