# ImmunityBio Announces Insurance Coverage of ANKTIVA® Across Multiple States with First Commercial Doses Administered Just Weeks After FDA Approval—Opening New Era for Immunotherapy Beyond Checkpoint Inhibitors

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- Multiple patients treated across the U.S. with ANKTIVA less than eight weeks after FDA approval of first-in-class cytokine immunotherapy for BCG unresponsive non-muscle invasive bladder cancer
- ANKTIVA launch initiates the next era of immunotherapy beyond checkpoint inhibitors that is based on cytokines and natural killer (NK) cells
- ANKTIVA's novel mechanism of action activates the body's immune system of natural killer and killer T cells to attack BCG resistant tumor cells and induce memory T cells resulting in a long duration of complete response exceeding 47 months[1]
- ANKTIVA reimbursement now covered by multiple healthcare plans
- Urologists treating eligible bladder cancer patients can learn more about the treatment option and access support program ImmunityBio CARE™ at Anktiva.com

CULVER CITY, Calif.--(BUSINESS WIRE)--Jun. 20, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX) today announced the initial treatment of multiple patients in the United States to receive therapy with ANKTIVA® (nogapendekin alfa inbakicept-pmln), ImmunityBio's recently approved immunotherapy for Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ. ANKTIVA was approved by the U.S. Food and Drug Administration (FDA) on April 22, 2024 for the treatment of patients with BCG-unresponsive NMIBC CIS with or without papillary tumors.

The intravesical therapy employs a combination of ANKTIVA, an IL-15 agonist in combination with BCG. The combination is the first FDA-approved immunotherapy in NMIBC that functions by activating the body's NK and killer T-cell immune system to attack tumor cells, while simultaneously activating memory T cells, leading to a prolonged duration of complete response exceeding 47 months for some patients.

"We are grateful to be able to offer this first-in-class immunotherapy to qualified bladder cancer patients less than two months after the therapeutic was approved by the FDA," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "The interest in this next era of immunotherapy beyond checkpoint inhibitors—the era of cytokines—from urologists treating NMIBC patients has been strong and we look forward to offering more patients an alternative to bladder removal."

The first patients to receive commercial doses are located throughout the U.S. and several are being treated by community urologists, as the therapy does not require any special handling or equipment that would limit its use to specialty medical centers.

"In addition to its unique mechanism of action, ANKTIVA can be readily administered by urologists in their own offices and clinics enabling more patients to receive it in familiar settings from their own providers," said Richard Adcock, President and CEO of ImmunityBio. "We look forward to ANKTIVA reaching more and more eligible NMIBC patients and for our science to deliver even more therapies from our pipeline."

ANKTIVA received Breakthrough Therapy Designation and approval from the FDA based on the safety and efficacy outcome of complete responses (CR) and duration of complete response (DOR) in BCG-unresponsive NMIBC CIS. The 77 evaluable patients in this single-arm, multicenter trial received ANKTIVA with BCG maintenance therapy for up to 37 months. The tumor status was assessed with cystoscopy and urine cytology and will continue for up to five years after each patient began their participation in the trial.

The CR rate for the 77 evaluable patients was 62% with the upper end of the confidence interval being 73%. The duration of complete response as of the November 2023 cut-off was more than 47 months and is ongoing to date. These prolonged duration of complete response results beyond 24 months with ANKTIVA and BCG exceed the benchmark for the magnitude of meaningful clinical results suggested by a panel of experts at the International Bladder Cancer Group.

In May, ImmunityBio announced it had drug substance sufficient for 170,000 doses of ANKTIVA for commercial and clinical trial use.

**ImmunityBio CARE™**

The ImmunityBio CARE™ program is designed to help patients access ImmunityBio's innovative treatment for NMIBC CIS. The program offers services and resources for benefits investigation, prior authorization support and tracking, coding and billing assistance, claim denial guidance and payer specific appeal assistance. More information for patients and healthcare professionals is available on Anktiva.com.

**How ANKTIVA Works**

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 drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. The proliferation of the trifecta of these immune killing cells and the activation of trained immune memory results in immunogenic cell death, inducing a state of equilibrium with durable complete responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

**Selected Safety Information for ANKTIVA**

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 ImmunityBio**

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines 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 that activates natural killer 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, please visit: www.immunitybio.com

**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 commercial launch activities and timing, product demand, patient treatment, data and results from clinical trials and potential implications therefrom, product availability and supply, potential regulatory pathways and approval requests and submissions, the regulatory review process and timing thereof, market and prevalence data, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, information regarding ongoing pre-clinical studies and clinical trials, potential future uses and applications of ANKTIVA and use in cancer vaccines and across multiple tumor types, ImmunityBio's financial condition, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. Statements in this presentation 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," "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, (i) the risks and uncertainties associated with commercial launch execution, success and timing, (ii) risks and uncertainties related to the regulatory submission and review process, (iii) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development, patient enrollment and planned regulatory submissions, (iv) potential delays in product availability and regulatory approvals, (v) risks and uncertainties associated with third party collaborations and agreements, (vi) potential delays in sales activity and pace, (vii) ImmunityBio's ability to retain and hire key personnel, (viii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (ix) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (x) ImmunityBio's ability to successfully commercialize its approved product and product candidates and uncertainties around regulatory reviews and approvals, (xi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies. 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 19, 2024 and the Company's Form 10-Q filed with the SEC on May 9, 2024, 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.

1. ANKTIVA Prescribing Information. ImmunityBio Inc.; 2024

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