ImmunityBio Announces Phase 2 Study of ANKTIVA® in Patients with Long COVID

August 19, 2025

- Approximately one in five American adults who had COVID-19 still experience symptoms of long COVID, a serious illness that can result in chronic conditions and disability[1,2]
- Long COVID remains a significant public health challenge with no currently available established treatments
- Study explores ANKTIVA's therapeutic potential as an IL-15 agonist in boosting NK cell responses against viral infections

CULVER CITY, Calif.--(BUSINESS WIRE)--Aug. 19, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced the opening of a new Phase 2 study to assess the BioShield™ platform, anchored by ANKTIVA® (nogapendekin alfa inbakicept-pmln), in patients with long COVID. An estimated one in five Americans with a previous COVID-19 infection has long COVID, which is comprised of a broad range of symptoms that can substantially impact a patient's quality of life. Long COVID remains a significant public health challenge with no currently available established therapies.

The new study, called COVID-4.019-Long, further expands the company's clinical research efforts to assess ANKTIVA's potential beyond cancer or cancer-related diseases. Currently, ANKTIVA is being evaluated alone and with other agents in multiple studies for different forms of bladder cancer, non-small cell lung cancer, glioblastoma, non-Hodgkin lymphoma, Lynch syndrome, ovarian cancer and Human Papillomavirus (HPV) associated tumors. ANKTIVA is also being studied in Human Immunodeficiency Virus (HIV) and lymphopenia.

The primary objective of the exploratory, single-arm study (NCT07123727) is to evaluate the safety of ANKTIVA, injected under the skin (subcutaneously), in participants with long COVID. The secondary objective is to assess the effect of ANKTIVA on absolute lymphocyte count. Exploratory objectives include evaluation of ANKTIVA's ability to improve post-COVID natural killer (NK) cell and CD8+ T cell counts, and assessment of the immunological function of NK cells and CD8+ T cells.

"We are excited to study ANKTIVA for the treatment of long COVID, a substantial public health concern," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "Early in the pandemic, the common assumption was SARS-CoV-2 would prove to be a transient infection, as is the case with coronaviruses in general. But we now know viral nucleic acid and proteins can be in the gut mucosa months after infection. As such, an antiviral strategy looks insufficient to treat or cure long COVID. Based on clinical insights to date, we believe ANKTIVA may be a new therapeutic option for this chronic and potentially disabling condition by enhancing immune function, facilitating viral clearance, and addressing underlying contributions to long COVID."

The study, which is being conducted by ImmunityBio and aims to recruit up to 40 participants who meet the long COVID criteria, as established by the World Health Organization (WHO), is now accepting patients for initial screening to determine study eligibility. The safety and tolerability of ANKTIVA for long COVID is also being assessed in a separate Phase 2 study conducted at the University of California – San Francisco. Both studies are supported by ImmunityBio. To learn more, visit https://immunitybio.com/find-a-trial/.

ANKTIVA is currently approved by the U.S. Food and Drug Administration with Bacillus Calmette-Guérin (BCG) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.

About Long COVID

Long COVID is a serious illness that can cause chronic health conditions requiring comprehensive care. It may also lead to disability.[2] Long COVID impacts approximately 1 in 5 Americans adults who had a previous COVID-19 infection.[1] It can include a wide range of ongoing symptoms and conditions that can last weeks, months, or even years after COVID-19 illness.[1] Some of the common among the more than 200 identified symptoms include fatigue, brain fog, coughing, shortness of breath, heart palpitations and change in smell or taste.[3] Anyone who had a SARS-CoV-2 infection, the virus that causes COVID-19, can experience Long COVID, including children.[1] Long COVID remains a significant public health challenge with no currently available established treatments.

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. 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.

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 Prescribing Information for ANKTIVA® at Anktiva.com.

References:

1. Robertson MM, Qasmieh SA, Kulkarni SG, et al. The Epidemiology of Long Coronavirus Disease in US Adults. *Clin Infect Dis*. May 3 2023;76(9):1636-1645.
2. U.S. Centers for Disease Control and Prevention. Long COVID Basics. July 2025. Available at https://www.cdc.gov/long-covid/about/index.html.
3. U.S. Centers for Disease Control and Prevention. Long COVID Signs and Symptoms. July 2025. Available at https://www.cdc.gov/long-covid/signs-symptoms/index.html.

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 potential implications to be drawn from preliminary clinical study results, clinical trial enrollment, timing, data and potential results to be drawn therefrom, anticipated components of ImmunityBio's CancerBioShield™ platform, the potential health conditions associated with Long COVID, potential patient populations and implications thereof, the development of therapeutics for cancer and infectious diseases, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, 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 or develop cancer vaccines, immunotherapies and cell therapies that have the potential to change the paradigm in cancer care, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. 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, (i) risks and uncertainties regarding participation and enrollment and potential results from the clinical trial described herein, (ii) whether clinical trials will result in registrational pathways, (iii) whether clinical trial data will be accepted by regulatory agencies, (iv) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (v) 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, (vi) potential delays in product availability and regulatory approvals, (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, (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 3, 2025, and the Company's Form 10-Q filed with the SEC on August 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250819968042/en/

ImmunityBio Contacts:
Investors
Hemanth Ramaprakash, PhD, MBA

ImmunityBio, Inc.
+1 858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Sarah Singleton
ImmunityBio, Inc.
+1 415-290-8045
Sarah.Singleton@ImmunityBio.com

Source: ImmunityBio, Inc.