NIAID-Sponsored Study Shows N-803 Combined with Neutralizing Antibodies Could Lead to Sustained HIV Viral Control After Discontinuation of Antiretroviral Therapy

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CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 6, 2024-- ImmunityBio (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced the recent publication of preclinical data in the online issue of *Science, First Release* indicating that combination therapy with N-803, an IL-15 superagonist, and broadly neutralizing antibodies may potentially enable the immune system to manage human immunodeficiency virus (HIV) without the need for antiretroviral treatment.

In the preclinical non-human primate study, researchers led by Dr. James Whitney, Ph.D. and funded by the National Institutes of Health and the National Institute of Allergy and Infectious Diseases (NIAID) demonstrated that using N-803, in combination with broadly neutralizing antibodies (bNAbs), led to sustained viral control after discontinuation of antiretroviral therapy (ART) in ART-suppressed rhesus macaques infected with simian-human immunodeficiency virus AD8 (SHIV-AD8). Treatment with N-803 and bNAbs led to immune activation and transient viremia, but only limited reductions in the SHIV reservoir. Upon ART discontinuation, all animals experienced viral rebound, followed by long-term virus control for up to 10 months in approximately 70% of those treated with N-803 and bNAbs.

"The viral reservoir in people with HIV is established within the first few days of infection and cannot be eliminated by the body's immune system or currently available treatments, representing a significant obstacle in curing an established HIV infection," said James B. Whitney, M.D., study author and researcher at the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center and Harvard Medical School. "When combined with broadly neutralizing antibodies, N-803 has the potential to provide viral control without significant reduction in the viral reservoir, which further suggests that the complete eradication of this reservoir may not be required to induce sustained remission after discontinuing antiretroviral therapy."

Following on from and directly attributable to these preclinical results, two clinical trials were designed to investigate the ability of N-803 and bNAbs to reduce viral loads in HIV-infected individuals on antiretroviral therapy. These Phase 1 clinical trials are investigating N-803 in combination with bNAbs in HIV-infected individuals and will include an analytical treatment interruption (ATI) to determine the effect of the immunotherapies on post therapy viral loads. (ACTG A5386, NCT04340596: and NCT05245292 at the Rockefeller University). The studies are actively enrolling participants.

To learn more about ImmunityBio's HIV research, please visit our website.

ImmunityBio's IL-15 superagonist N-803 (also called Anktiva® and 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 the natural killer (NK) and T cells. N-803 is a novel investigational IL-15 superagonist complex consisting of an IL-15 mutant (IL-15N72D) bound to an IL-15 receptor α/IgG1 Fc fusion protein. Its proposed mechanism of action is direct specific stimulation of CD8+ T cells and NK cells through beta gamma T-cell receptor binding with generation of memory T-cells while avoiding T-reg stimulation. N-803 is designed to have improved pharmacokinetic properties, longer persistence in lymphoid tissues and enhanced anti-tumor activity compared to native, non-complexed IL-15 in vivo.

N-803 is currently being evaluated in adult patients in two clinical NMIBC trials. QUILT-2.005 is investigating use of N-803 in combination with BCG for patients with BCG-naïve NMIBC; QUILT-3.032 is studying N-803 in combination with BCG in patients with BCG-unresponsive NMIBC CIS and Papillary Disease.

N-803 is investigational. Safety and efficacy have not been established by any Health Authority or Agency, including the FDA.

About ImmunityBio

ImmunityBio is a vertically-integrated, clinical-stage 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. We are applying our 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 pre-clinical study results and plans, information regarding potential benefit to patients, potential additional studies and trials, methods, regulatory pathways, and ImmunityBio's 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," "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 the regulatory review process including without limitation the Company's BLA resubmission following receipt of the complete response letter (CRL) from the FDA and the ability of ImmunityBio and its third party contract manufacturing organizations to adequately address the issues raised in the CRL, (ii) whether or not the pre-clinical study referenced in this release will continue to progress as anticipated, (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 and planned regulatory submissions, (iv) ImmunityBio's ability to retain and hire key personnel, (v) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vi) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (viii) 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 1, 2023 and the Company's Form 10-Q filed with the SEC on November 9, 2023, 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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Investors
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1 858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Greg Tenor
Salutem
+1 717-919-6794
Gregory.Tenor@Salutemcomms.com

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