ImmunityBio Announces HIV Clinical Pipeline with Opening of a Phase 1 'HIV Cure Study' in Patients Off Therapy and a Phase 2 Study in Acutely Infected Patients

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- Sponsored by the NIAID and AIDS Clinical Trials Group, an "HIV cure study" will evaluate whether IL-15 superagonist AnktivaÔ (N-803) alone or together with broadly neutralizing antibodies can control HIV following interruption of antiretroviral therapy (ART).
- The Phase 1 open-label, randomized study will enroll 46 people living with HIV whose virus has been suppressed by ART for approximately two years, including at least 30 percent cisgender women or transgender men.
- A second clinical trial studying Anktiva in HIV is being conducted by the U.S. Military HIV Research Program in Thailand. The Phase 2 study is evaluating Anktiva in combination with antiretroviral therapy (ART) during acute HIV infection as an experimental therapy to target and inhibit early establishment of HIV reservoirs in infected individuals.

CULVER CITY, Calif.--(BUSINESS WIRE)--Jun. 10, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced its HIV clinical pipeline with an HIV cure study using Anktiva™ (N-803), which is now enrolling participants in the U.S. The trial will study whether Anktiva can control HIV alone or together with combination broadly neutralizing antibodies (bNABs) after participants stop their antiretroviral therapy (ART) and they are carefully monitored. The study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) and conducted by the AIDS Clinical Trials Group (ACTG), the largest global HIV research network.

The second study, which was announced earlier this year and is in Phase 2, will evaluate Anktiva in combination with antiretroviral therapy during acute HIV infection. This study is being conducted by the Walter Reed Army Institute of Research's U.S. Military HIV Research Program (MHRP) at the Thai Red Cross AIDS Research Centre in Bangkok.

In both pre-clinical and clinical research, ImmunityBio's IL-15 superagonist Anktiva has exhibited three activities that could potentially help the immune system to eliminate HIV reservoirs or to control virus rebound. First, Anktiva has been shown to reverse HIV latency—by activating HIV replication within long-lived cells in the immune system thus allowing the infected cells to be recognized and cleared by the immune system. Second, it activates natural killer (NK) cells and CD8+ T-cells, two elements of the immune system that specialize in killing virus-infected cells. Finally, it enables NK cells and CD8+ T-cells to move to lymphoid tissues where they will encounter and hopefully eliminate HIV-infected cells.

The actions of bNAbs (or antibodies that neutralize a broad number of variants of HIV) are well-matched to that of Anktiva. bNAbs can neutralize HIV that is produced upon reactivation, preventing new infections; target (label) HIV-infected cells for destruction by NK cells; and may act to boost CD8+ T-cell responses. The ACTG study (A5386) will use an array of virologic and immunologic tests to evaluate the degree to which each of these expected activities is induced in study participants. Ultimately, the study will test whether this approach results in immune control of HIV when ART is paused, with careful monitoring.

"An estimated 38 million people globally are living with HIV and the majority of these individuals reside in low- and middle-income countries that are contending with strained healthcare budgets. The current standard of care for HIV is the use of antiretroviral drugs that can be expensive and must be taken for a patient's lifetime. While these antiretroviral therapies developed over the last several years are helping many people with HIV live longer, healthier lives, we still lack a cure," said Patrick Soon-Shiong, M.D. Founder and Executive Chairman of ImmunityBio. "As we mark the somber 40th anniversary of the first HIV/AIDS cases in the U.S., we are pleased to work with the ACTG on this important study and, hopefully, develop a treatment that will eliminate HIV for good."

A5386 Study Details:

A5386 is a Phase 1, open-label, randomized study evaluating the safety, tolerability, and efficacy of N-803 both with and without combination bNAbs. It will enroll 46 people living with HIV (23 in each study arm) whose virus has been suppressed by ART for approximately two years, including at least 30 percent cisgender women or transgender men. Participants will undergo leukapheresis (a medical procedure in which white blood cells, or leukocytes, are separated from the blood) to measure their HIV reservoirs and a subset will undergo optional lymph node fine needle aspirations to assess the effect of N-803 on lymphoid tissue. They will then be randomized to one of two arms: N-803 alone or N-803 with combination bNAbs. After receiving treatment, participants will stop taking ART and will be followed closely to monitor for signs that they need to restart ART. Most participants will be followed for approximately 100 weeks after receiving treatment.

A5386 is led by Timothy Wilkin, M.D., M.P.H. (Weill Cornell Medicine), Marina Caskey, M.D., (The Rockefeller University) and Richard Brad Jones, Ph.D., (Weill Cornell Medicine). It is funded by NIAID, part of the National Institutes of Health, and N-803 is provided by ImmunityBio, Inc. NIAID and collaborating NIH Institutes fund the ACTG.

"Living with HIV means taking medication lifelong. We hope this study will be an important step towards controlling HIV without this need," said Timothy Wilkin, M.D., at Weill Cornell Medicine and trial investigator. "The study builds upon years of research from my colleagues to provide the rationale and support for this trial."

NCT04505501 Study Details:

The MHRP-sponsored clinical study is designed to investigate the safety, tolerability and immunostimulatory effects of Anktiva administration during acute HIV infection. Anktiva will be administered subcutaneously at weeks zero, three and six and it will be used along with antiretroviral therapy (ART) to determine whether Anktiva's immunostimulatory effects reduce HIV titers during the acute stage of infection. The study duration is 12 weeks and will enroll 15 participants.

About the ACTG

Founded in 1987, the AIDS Clinical Trials Group (ACTG) was the world's first HIV research network. The ACTG conducts groundbreaking studies to improve the treatment of HIV and its complications, including tuberculosis and viral hepatitis; reduce new infections and HIV-related illness; and advance new approaches to prevent, treat, and ultimately cure HIV in adults and children. ACTG investigators and research units in 15 countries serve as major resources for HIV/AIDS research, treatment, care, and training/education in their communities. ACTG studies have helped establish current paradigms for managing HIV disease, and have informed HIV treatment guidelines, resulting in dramatic decreases in HIV-related mortality worldwide.

About ImmunityBio

ImmunityBio is a leading late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio has a comprehensive immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated)—of which 25 are at Phase II and III stage of development—across 19 indications in solid and liquid cancers and infectious diseases. Currently 17 first-in-human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. Anktiva™ (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC).

The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform.

ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams. 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. 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", "could", "estimates," "expects," "intends," "may," "plans," "potential", "predicts", "projects," "seeks," "should," "will," and variations of such words or similar expressions. These 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 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) potential adverse effects or changes to relationships with employees, suppliers or other parties resulting from the completion of the recent merger of the ImmunityBio with NantCell (the "Merger"), (ii) the outcome of any legal proceedings that may be instituted against the parties and others related to the Merger, (iii) unexpected costs, charges or expenses resulting from the Merger, (iv) uncertainty of the expected financial performance of the combined company following completion of the Merger, including the possibility that the expected synergies and value creation from the Merger will not be realized or will not be realized within the expected time period, (v) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (vi) inability to retain and hire key personnel, and (vii) the unknown future impact of the COVID-19 pandemic delay on certain clinical trial milestones and/or ImmunityBio's operations or operating expenses. 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 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 10, 2021 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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