ImmunityBio Announces Launch of Phase 2 Trial of IL-15 Superagonist Anktiva With Antiretroviral Therapy to Inhibit HIV Reservoirs

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Phase 2 Study Sponsored by U.S. Military HIV Research Program, Thai Red Cross AIDS Research Centre

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 29, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced that the U.S. Military HIV Research Program (MHRP) at the Walter Reed Army Institute of Research has launched a Phase 2 clinical trial in Thailand to evaluate ImmunityBio's interleukin-15 (IL-15) superagonist Anktiva® (also called N-803) administered 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. Researchers will compare levels of HIV RNA and DNA in lymph node samples pre- and post-treatment and evaluate the therapy's effects on CD8+ T and natural killer (NK) immune cells. The study is being conducted at the Thai Red Cross AIDS Research Centre in Bangkok.

The trial's participants are being recruited through MHRP's acute HIV infection cohort, which identifies individuals in the earliest post-infection stages. The cohort serves as a foundation to help researchers conduct investigations into long-term remission of HIV and to understand ways to suppress HIV without long-term antiretroviral treatment.

"Our current strategy to not just treat but cure HIV infection involves both inducing HIV out of its latent state in host T cells and removing or killing infected cells via an immune response or immunotherapy," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "Anktiva is capable of triggering both of these mechanisms, as it can both activate viral transcription in CD4+ T cells—i.e., remove the virus from latency—and activate CD8+ memory cells and natural killer cells that recognize and kill HIV-infected host cells. We look forward to discovering whether or not this activity is correlated with reduction of viral load and inhibition of establishment of the HIV reservoir during acute infection in HIV."

In preliminary data from a separate Phase I study of Anktiva in HIV-infected subjects, the IL-15 superagonist was shown to be safe and to significantly activate proliferation of T cells and natural killer (NK) cells. There was also evidence that Anktiva activated viral transcription and reduced the viral reservoir in peripheral blood mononuclear cells. In addition, in foundational preclinical studies, ImmunityBio observed that Anktiva plus one or two anti-HIV broadly neutralizing antibodies, or bNAbs, suppressed simian/human immunodeficiency virus replication in 9 of 13 animals evaluated. Following these and other preclinical results, the AIDS Clinical Trials Group of the NIH is beginning a Phase I clinical trial (n=46) of Anktiva plus two bNAbs to explore whether the combination affects long-term viral remission.

The clinical study is designed to investigate safety, tolerability and immunostimulatory effects of Anktiva administration during acute HIV infection. Anktiva will be administered subcutaneously at weeks zero, three and six and 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.

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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