ImmunityBio Announces Authorization to Proceed with Phase 1/2/3 Randomized Trial in South Africa of Their Dual-Antigen T-Cell Vaccine as a Universal Boost in Previously Vaccinated Participants Against COVID-19

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- The Phase 1/2/3 trial will study the efficacy, safety, and immunogenicity of ImmunityBio's T-Cell COVID-19 vaccine as a boost in participants who have already received a spike-only antibody-based vaccine
- The study is designed to explore whether the T-cell-based vaccine could prevent breakthrough infections from the Delta variant in health care workers who are already vaccinated
- Goal of the second-generation hAd5 S+N T-Cell COVID-19 vaccine is to potentially provide increased protection and long-term immunity against the multiple variants and third wave infections currently affecting South Africa and other countries
- Phase 1 studies of subcutaneous dosing in the US have demonstrated no serious adverse events and potent T-cell responses after a single prime dose

CULVER CITY, Calif.--(BUSINESS WIRE)--Jul. 14, 2021-- ImmunityBio, Inc., (NASDAQ: IBRX), a publicly traded immunotherapy company, today announced authorization from the South Africa Health Products Regulatory Authority (SAHPRA) to proceed with the South Africa Sisonke T-Cell Universal Boost trial. The Phase 1/2/3 study, which will begin in Q3 2021, is designed to evaluate hAd5 Spike + Nucleocapsid (S+N) as a boost for South African healthcare workers previously vaccinated with an S-only vaccine.

"With the virus continuing to spread, moving forward with this boost trial is crucial," said Leonard Sender, M.D., Chief Operating Officer of ImmunityBio. "We are encouraged by the preliminary safety findings in our ongoing Phase 1 studies in both the U.S. and South Africa. In addition, our U.S. data show that just a single prime subcutaneous vaccination with our COVID-19 vaccine candidate induces a 10-fold increase in T cell response —equivalent to T cell responses from patients previously infected with SARS-CoV-2. We have also shown that theT-cell responses are maintained against variants, which is critical to providing protection against this ever-changing virus."

In the trial, the effect of combining vaccination by two routes of administration—subcutaneous (SC) and sublingual (SL)—will be assessed. This combination has the potential to deliver protection from the virus with a single jab followed by droplets placed under the tongue. Methods that do not require injection such as SL, intranasal, and oral capsule offer potential advantages depending on the participant's needs or situation. Sublingual administration results in the most rapid absorption, while nasal spray or oral capsule delivery have the potential to provide mucosal immunity, which could reduce both the chance of infection and potential spread of the virus via the respiratory tract. The three non-jab formulations also can be administered without a trained healthcare worker and are easier to transport and store. The SL and nasal routes of administration are also currently being tested in a separate Phase 1 trial in South Africa.

"The number of new cases in South Africa is frightening, particularly when you consider recent data suggesting currently available COVID-19 vaccines may not provide the immune memory needed to fend off infection from future variants. This highlights an urgent need for a boost dose that confers long-term protection by activating both antibodies and T cells, " said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio.

"Several peer-reviewed studies demonstrate that patients who have recovered from SARS-CoV in the 2003 outbreak possess long lasting memory T cells reactive to the nucleocapsid protein of SARS-CoV 17 years after infection. While antibodies block infection when present, T cells are vital for long-term immune memory. We are excited to begin this controlled, randomized trial of boosting a previously administered DNA-based viral vector vaccine with our own Ad5 dual-antigen S plus N vaccine to see if it can augment protection in participants who have received the S-based vaccine alone," continued Soon-Shiong.

ImmunityBio's COVID-19 Trials
ImmunityBio is addressing the serious need for a boost vaccine by conducting or imminently planning five COVID-19-related studies, three in South Africa and two in the U.S.

This is to our knowledge the first randomized control trial to study a heterologous boost of an S-only vaccine with an Ad5 S+N vaccine boost versus a single S-only prime vaccine as control. The endpoints of the Sisonke T-cell Boost trial are to examine whether the boost could reduce breakthrough infections currently occurring in South Africa at a rapid rate.

About hAd5 T-Cell-Based, Viral-Vector Vaccine Candidate
This second-generation hAd5 viral-vector vaccine is unique in targeting both S and N SARS-CoV-2 proteins to generate B and T cell memory to these antigens and, potentially, long-term immunity to the virus. Most of the COVID-19 vaccines approved by the FDA or in late-stage clinical trials deliver only the S protein which, by some estimates, has already mutated thousands of times.

Another unique characteristic of the hAd5 design is its use of a second-generation hAd5 platform that was developed to elicit anti-SARS-CoV-2 immune responses even in Ad-immune individuals, meaning subjects can receive the vaccine multiple times, if necessary. The stimulation of anti-hAd5 immune responses is attenuated with the second-generation platform in comparison with the first-generation platforms due to additional genetic deletions.

Finally, ImmunityBio's novel hAd5 vaccine candidate has been developed in four formulations for different routes of administration: SC injection, SL drops, intranasal spray, and a room-temperature-stable oral capsule that could potentially overcome the cold-chain distribution hurdles affecting many current COVID-19 vaccines.

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, including the planned timing of the initiation of the Company's trial in South Africa and the development of a boost. 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. Statements of past performance, efforts, or results of our 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 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 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, (ii) inability to retain and hire key personnel, (iii) uncertainty of the expected financial performance and successful integration of the combined company following completion of the recent merger of ImmunityBio with NantCell (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, (iv) whether interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, (v) our ability to obtain additional financing to fund our operations and complete the development and commercialization of our various product candidates, and (vi) the unknown future impact of the COVID-19 pandemic delay on certain clinical trials or their 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, Form 10-Q filed with the SEC on May 14, 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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