ImmunityBio Expands Trials of T-Cell-Based COVID-19 Vaccine Candidate as a 'Universal Boost' in Vaccinated Subjects and Receives Approval to Test Intranasal Spray in South Africa

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- Studies will provide data on T-cell-based COVID-19 vaccine candidate as a universal boost with four potential routes of administration (subcutaneous shot, sublingual droplet, oral capsule, and intranasal spray)
- The goal of the vaccine is to activate the entire immune system and potentially provide longer-lasting immune response and head off future variants
- South African Health Products Regulatory Authority (SAHPRA) has approved an expanded study to test intranasal administration of ImmunityBio's T-cell-based COVID-19 vaccine candidate hAd5 S+N in subjects previously infected with SARS-CoV-2
- Phase 1/2/3 Universal Boost trial is designed to evaluate hAd5 S+N as a boost for South African healthcare workers previously vaccinated with a currently available spike-only antibody-based vaccine
- In preclinical studies, hAd5 administered subcutaneously plus intranasally (SC + IN) as a dual prime without a boost was as effective in generating humoral and T-cell responses as the SC + IN prime with a boost

CULVER CITY, Calif.--(BUSINESS WIRE)--May 25, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced two South African studies to examine the potential for using its hAd5 T-cell-based COVID-19 vaccine candidate to provide extended protection for subjects with prior COVID-19 vaccinations or infections. One trial will study the use of ImmunityBio's hAd5 candidate as a "Universal Boost" for healthcare workers previously vaccinated with a currently available spike-only antibody-based vaccine. The other will study the safety and effectiveness of the vaccine candidate intranasally in previously infected subjects.

The multiple administration methods for the vaccine candidate offer the potential for protecting patients with a single jab followed by a nasal spray. The nasal spray and oral capsule routes also have the potential to provide mucosal immunity, which could reduce both the chance of infection and the potential spread of the virus via the respiratory tract.

"The COVID-19 pandemic continues to be a major public health crisis in South Africa and in other parts of the world. It requires new solutions," said Glenda Gray, M.D., President and CEO of the South African Medical Research Council. "Providing people with long-term immunity is vital as is making it easier for people to become vaccinated in circumstances where jabs are difficult to administer. These new trials will provide important data on a potential path forward to dealing with this crisis."

"We are encouraged by the preliminary safety findings in our ongoing Phase 1 studies in the U.S., which show that just a single prime subcutaneous vaccination of 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," said Leonard Sender, M.D., Chief Operating Officer of ImmunityBio.

"The pre-clinical finding that our COVID-19 vaccine candidate administered via a jab and a nasal spray has the potential to provide the same level of immune protection from SARS-CoV-2 as a prime plus boost has important implications for vaccination efforts in rural and disadvantaged communities and countries," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "Reducing the frequency of vaccine boosts and simplifying the distribution and administration of vaccines is critical to ending the COVID-19 pandemic globally and preventing future ones. These findings taken together with our studies in non-human primates, which showed that our COVID-19 vaccine candidate when administered as a jab followed by oral capsules conferred complete protection from a viral challenge, provide encouraging evidence that our vaccine via multiple needle-free routes could enhance its distribution and access globally."

ImmunityBio's COVID-19 Trials

The first study, which will be conducted at the Khayelitsha Clinical Research Site in South Africa, will involve 40 subjects previously infected with SARS-CoV-2 and evaluate ImmunityBio's T-cell-based vaccine administered via multiple routes including an intranasal spray, sublingual (SL) droplet, and subcutaneous (SC) shot.

The second study, which is currently under review by SAHPRA, is designed as a Phase 1/2 trial and will evaluate the vaccine candidate as a dual SC + SL boost in subjects who have been previously vaccinated with a currently available spike-only, antibody-based vaccine. The ImmunityBio "boost" could potentially provide subjects with longer-term protection and defend against the growing number of variants.

The potential of a subcutaneous-plus-oral combination is currently under review in the U.S. (NCT04732468, NCT04591717) and the final combination of route administration to achieve maximum humoral, T cell, mucosal, and memory cell immunity will be determined upon completion of these extensive studies.

Upon completion of these trials, the optimal route of administration will be determined and a pivotal, Phase 3 "universal boost" trial involving 9,670 subjects will be activated across multiple sites.

About hAd5 T-Cell-Based, Viral-Vector Vaccine Candidate

This second-generation hAd5 viral-vector vaccine is unique in targeting both spike (S) and nucleocapsid (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 spike protein, which has already mutated thousands of times by some estimates.

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 provides four potential routes of administration, including a room-temperature stable oral capsule, potentially overcoming 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. 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 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, (vii) regulatory approval of planned clinical trials, (viii) the results of any clinical trials, and (ix) 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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