ImmunityBio Announces Single Prime hAd5 COVID-19 Vaccination Induces a 10-Fold Increase in T Cell Response Equivalent to T Cell Responses from Patients Previously Infected with SARS-CoV-2

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- Preliminary Phase 1b findings in participants receiving the dual antigen hAd5 S + N vaccine generated Th1 dominant S and N specific T cells after a single prime subcutaneous injection
- The magnitude of this T cell response was equivalent to those seen for S & N T cell responses from previously infected convalescent SARS-CoV-2 patients
- These findings provide the potential of the hAd5 S + N T cell vaccine for use as a “Universal T Cell Booster” to enhance T cell immunity in healthy recipients of current vaccines or in previously infected convalescent subjects
- Phase 1b study ongoing to explore the safety and immunogenicity of subcutaneous, oral and sublingual prime boost combinations of hAd5 S + N vaccine

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 8, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today reported initial data indicating that a *single subcutaneous injection* of the company’s COVID-19 vaccine candidate in healthy Phase 1 clinical study participants stimulates the generation of T cells that are reactive to the spike (S) and nucleocapsid (N) protein antigens delivered by the vaccine. Just 14-16 days after the single dose, the mean level of T cells generated in response to the hAd5 S+N T cell vaccine were ten times higher for N specific T cells. By day 21, both S and N T cell responses achieved levels ten times higher as compared to pre-vaccination levels. These preliminary findings were published in a preprint server medRxiv (link) titled, “*Single Prime hAd5 Spike (S) + Nucleocapsid (N) Dual Antigen Vaccination of Healthy Volunteers Induces a Ten-Fold Increase in Mean S and N T Cell Responses Equivalent to T Cell Responses from Patients Previously Infected with SARS-CoV-2*”.

The mean T cell levels seen in the vaccinated participants were equivalent to those for patients recovered from infection by the SARS-CoV-2 virus. ImmunityBio reported previously that T cells isolated from previously infected individuals react to the antigens delivered by the vaccine, indicating that immune responses to the vaccine could be protective against SARS-CoV-2 infection and COVID-19 illness.

The company also announced that it employed *in silico* techniques to examine T cell epitopes of SARS-CoV-2 variants as compared to the first-wave strain. The analysis indicated that T cell epitopes from the first wave and the variants largely overlapped, indicating that the hAd5 S+N vaccine has the potential to provide protection against both the first wave SARS-CoV-2 as well as against variants of SARS-CoV-2, including the B.1.1.7 variant (N501Y mutation) in the United Kingdom and the B.1.351 variant (E484K, K417N and N501Y mutations) identified in South Africa.

This T cell epitope analysis provides additional evidence of the potential for the vaccine candidate to serve as an universal booster for patients who have received an initial S protein only vaccine by not only fortifying S activated T cells, but also broadening protection by the addition of N activated T cells. This could provide additional protection against variants and longer-term protection against the virus.

“These data further validate the path we have taken in designing our vaccine candidate to target both the S and N proteins in order to increase T cell responses,” said Dr. Patrick Soon-Shiong, Founder and Executive Chairman of ImmunityBio. “Current vaccines target the S protein, leaving open the potential for antigen drift (mutation) and rendering these vaccines to be less effective against variants. Our goal is to develop the second-generation COVID-19 vaccine which is room temperature stable, can be self-administered orally and generates both antibody and long-term T cell immunity. Our Phase Ib clinical trials are ongoing to explore which combination of subcutaneous, oral or sublingual forms of hAd5 S+N would provide maximum protection against SARS-CoV-2.”

About the T Cell Based, Viral Vector Vaccine Candidate

This second generation hAd5 vectored vaccine targets both spike (S) and nucleocapsid (N) SARS-CoV-2 proteins to generate B and T cell memory to these antigens and 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 has already mutated several times. The vaccine is currently being studied in different forms of administration – subcutaneous, oral and sublingual. Another differentiated characteristic of the hAd5 design is its use of a second-generation hAd5 viral vector 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 vaccine is designed to overcome cold-chain hurdles with a room-temperature oral capsule. Studies in non-human primates demonstrate that the combination of a subcutaneous prime followed by oral boosts provide protection through T cell and memory B cell responses with clearance of viral replication in both nose and lungs to undetectable levels within 7 days of a virus challenge.

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 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 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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