ImmunityBio Announces Novel ACE2 Decoy COVID-19 Therapeutic that Shows High Binding to SARS-CoV-2 Variants and Neutralizes Live Viruses

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- A recombinant 'ACE2 Decoy' shows robust binding to current SARS-CoV-2 variants and potential to outsmart viral evolution against antibodies
- Traps and neutralizes live SARS-CoV-2 viruses with the potential of a hAd5 ACE2 Decoy to serve both as a therapeutic and a protective vaccine
- Preclinical studies and GMP manufacturing of hAd5 ACE2 decoy COVID therapeutic in progress

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 11, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it is developing a novel hAd5 ACE2 Decoy therapeutic vaccine to neutralize the SARS-CoV-2 virus, including the E484K and N501Y mutations. The company presented the results in an oral presentation at the 28th Conference on Retroviruses and Opportunistic Infections (CROI) and published the positive findings of high binding affinity to the variants in preprint server, bioRxiv entitled: "A recombinant ACE2 triple decoy that traps and neutralizes SARS-CoV-2 shows enhanced affinity for highly transmissible SARS-CoV-2 variants."

The hAd5 ACE2 Decoy candidate is based on modified ACE2 receptors that would compete with ACE2 on the cells of respiratory tract for binding of the SARS-CoV-2 virus. The ACE2 Decoy would trap the virus, preventing it from infecting cells and facilitate clearance of the virus from the body. ImmunityBio's advanced molecular dynamic simulation capability previously reported in December was leveraged to design the ACE2 Decoy so it would have higher affinity for the virus, including SARS-CoV-2 variants, than natural ACE2 found on cells.

"The rapid mutation of the SARS-CoV-2 virus, predominantly in the structure of the spike protein, and the emergence of variants over-taking the 'first wave' virus poses a real threat to our ability to end the pandemic," said Patrick Soon-Shiong, M.D., Executive Chairman of ImmunityBio. "Our goal is to outsmart these variants by trapping them with decoy versions of the ACE2 receptor, and the findings we presented at CROI show our lead ACE2 Decoy binds with even greater affinity to the concerning viral variants with E484K and N501Y mutations. These promising results warrants our decision to advance a second hAd5 therapeutic vaccine into clinical development."

hAd5 ACE2 Decoy Therapeutic

The CROI presentation, titled "A SARS-CoV-2 Neutralizing ACE2 Decoy Shows High Affinity for N501Y and L452R Variants," highlighted ImmunityBio's development of a recombinant protein construct designed to act as a 'decoy' human angiotensin converting enzyme 2 (ACE2) receptor that would compete with ACE2 on cells of the respiratory tract to bind the receptor binding domain (RBD) of the SARS-CoV-2 spike protein. An effective, high-affinity decoy could potentially be used as a COVID-19 therapeutic by out-competing human ACE2 receptors for binding to SARS-CoV-2 S RBD, thereby inhibiting infection events *in vivo*. It also has the potential to be used as a prophylactic that might be administered to individuals at high risk for infection as a complement to vaccination to assure protection.

Given the recent emergence and rapid spread of COVID-19 cases due to several SARS-CoV-2 variants with mutations in the S RBD, including variants originating in the United Kingdom, South Africa and California, ImmunityBio scientists sought to identify a single ACE2 decoy candidate with robust binding affinity across wild-type and variant SARS-CoV-2 S RBDs, which might thus demonstrate efficacy in neutralizing infection with SARS-CoV-2 of any known genotype.

The ACE2 Decoy not only maintains its high affinity for S RBD expressing these mutations, but shows enhanced affinity for S RBD expressing the N501Y or L452R mutations and the highest affinity for S RBD expressing both the E484K and N501Y mutations. The candidate warrants continued development, beginning with testing in challenge studies.

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 an unparalleled 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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