ImmunityBio Announces Positive Interim Phase I Safety Data of hAd5 T-Cell COVID-19 Vaccine Candidate in Oral and Sublingual Formulations

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- Safety assessments completed for first 12 participants and no serious adverse events (SAEs) reported; trials expected to be fully enrolled in Q2
- First COVID-19 vaccine trials designed to deliver both S and N SARS-CoV-2 viral proteins via multiple routes —subcutaneous, sublingual, and oral
- Pre-clinical data from SARS-CoV-2 challenge study involving subcutaneous and oral immunization shows ImmunityBio's lead hAd5-COVID-19 T-cell vaccine candidate is protective in non-human primates (NHP) against high SARS-CoV-2 titer exposures
- Robust T cell and Memory B cell response to virus challenge results in inhibition of virus growth in nose and lungs with subcutaneous/oral vaccine combination in NHP study

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 15, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has met the safety requirements for the first 12 participants in its Phase Ib human adenovirus (hAd5)-based T-cell COVID-19 vaccine trials in sublingual and oral formulations. The independent Safety Review Committee recommended the study continue with no modifications to the trial design. The trials, which will involve 80 participants, are expected to be fully enrolled in Q2.

The two U.S. Phase Ib trials are studying a combination of subcutaneous/ sublingual (under the tongue) (NCT04591717) and subcutaneous/oral (NCT04732468) formulations of ImmunityBio's hAd5 T-cell COVID-19 vaccine candidate. Six participants have been dosed in each trial to date and the trial is anticipated to be fully enrolled in Q2 (prime plus boost). Based on the findings of these trials, the optimal combination of administration route and dose will be determined and entered into the Phase II/III design.

"We have not seen any serious adverse events in the participants who have received the hAd5 vaccine subcutaneously," said Philip Robinson, M.D., the trial Principal Investigator and Medical Director of Infection Protection at Hoag Memorial Hospital Presbyterian in Newport Beach, California where the vaccine trials are being conducted. "Unlike most of the COVID-19 vaccines currently available, ImmunityBio's hAd5 generates T-cell immunity, which is important for long duration immunity. Based on the results of subcutaneous/oral regimen in the nonhuman primate study where the vaccine provided complete protection against the virus challenge, we are excited to explore with ImmunityBio the potential for the vaccine to provide a T-cell boost to currently available vaccines. I am particularly encouraged by the immune response to the nucleocapsid protein, which may mean this vaccine will remain effective against the many emerging spike protein variants."

Additional Data from BARDA-Funded Non-Human Primate Study
At the recent 2021 Conference on Retroviruses and Opportunistic Infections (CROI), ImmunityBio scientists presented pre-clinical data from SARS-CoV-2 challenge study involving subcutaneous and oral immunization that shows hAd5-COVID-19 T-cell vaccine candidate is completely protective in non-human primates against high SARS-CoV-2 titer exposures. This data is critically relevant to NCT0473468 mentioned above which is testing various combinations of subcutaneous and oral capsule administration in a Phase I clinical trial.

The vaccine-focused presentation, titled "Dual-Antigen Covid-19 Vaccination with Oral Boost Protects NHP from Viral Challenge", detailed the results of a BARDA-funded COVID-19 challenge study in rhesus macaques assessing the antibody- and T cell-mediated immune responses to vaccination and protection against live SARS-CoV-2 challenge with ImmunityBio's human adenovirus (hAd5)-based T-cell COVID-19 vaccine candidate in serial subcutaneous and oral administrations.

Key presentation results include:

- ImmunityBio's vaccine candidate is a bivalent construct incorporating genes encoding a modified SARS-CoV-2 spike fusion protein and the SARS-CoV-2 nucleocapsid fusion protein. The second-generation, non-replicating hAd5 vector platform is being used has been manufactured in both subcutaneous and oral formulations.
- Ten rhesus macaques received either a subcutaneous (SC) prime dose followed by two oral boost doses (n=5) or two SC primes followed by one oral dose (n=5), with a two-subject placebo group.
- Neutralizing anti-spike antibodies and activated T cells activated against both the spike and nucleocapsid proteins were detected.
- Following a high-titer (106 TCID50) viral challenge, viral replication was assessed in nasal and respiratory passages.
- In all vaccinated rhesus macaques, investigators observed inhibition of viral replication in both lung and nasal passages within 24 hours of viral challenge, with viral load undetectable within 7 days compared to placebo controls. Enhanced antibody neutralization was noted in the days following the challenge, suggesting that memory B cells had been activated at the time of dosing.
- ImmunityBio's COVID-19 vaccine candidate protects non-human primates from high-titer SARS-CoV-2 challenge when

administered as subcutaneous prime with oral boost administration.

- The efficacy of the oral capsule formulation of the vaccine candidate is especially encouraging, as its stability at room temperate would facilitate cold chain-free vaccine distribution around the world.

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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