ImmunityBio Announces 12-Month Overall Survival Probability of 83% in NCI-Led Phase 1 Study of Multi-Targeted hAd5 Immunotherapy Vaccine in Patients with Advanced Metastatic Prostate Cancer

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- Second-generation human adenovirus (hAd5) targeting multiple tumor associated antigens (PSA, MUC-1, Brachyury) demonstrated safety, with no dose-limiting toxicities in patients with advanced prostate cancer
- Positive immune activation to PSA, MUC-1, and Brachyury with 100% of 17 patients evaluated mounting T-cell responses to at least one of these tumor-associated antigens encoded by the vaccine
- Preliminary signals of activity include a 60% disease control rate of at least six months and a 12-month probability of survival of 83% with median survival not yet reached

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 29, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced the publication of Phase I data in *The Journal of ImmunoTherapy of Cancer* (JITC). The publication, titled "Phase I study of a multitargeted recombinant Ad5 PSA/MUC-1/ brachyury-based immunotherapy vaccine in patients with metastatic castration-resistant prostate cancer (mCRPC)" highlighted the safety, T-cell immunogenicity, and clinical activity of ImmunityBio's second-generation human adenovirus (hAd5) in patients with incurable mCRPC. ImmunityBio's hAd5 is designed to deliver tumor-associated antigens, or TAAs, and neoepitopes (expressed only by cancer cells) and has the capability to induce T-cell memory due to the activation of both CD4+ and CD8+ T cells along with antibody (or humoral) responses.

"The finding of T-cell-mediated immunity induced in 100% of 17 prostate cancer patients whose white blood cells were evaluated in the study validates the ability of our hAd5 vaccine platform to generate a potent response to antigens delivered," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "Furthermore, the demonstration that the vaccine can be administered repeatedly, without adverse effects at the dose of 5x 10^{11} viral particles, supports the application of this hAd5 platform in both cancer and infectious diseases such as COVID-19. These early results, which include signals of clinical activity and durable stable disease, are encouraging for patients with highly resistant advanced metastatic prostate cancer and warrants further study."

Study Highlights:

- Eligible patients had to have incurable metastatic castration-resistant prostate cancer with radiologic evidence of progression or PSA progression
- The vaccine was safe and well tolerated with no grade >3 treatment-related adverse events or dose-limiting toxicities (DLTs) observed
- The recommended Phase II dose was 5×10^{11} viral particles (VPs) administered three times repeatedly every 3 weeks
- One patient achieved a partial response (PR), 5 patients had confirmed stable disease (SD) for greater than 6 months, with confirmed PSA decline
- Median progression-free survival (PFS) was 22 weeks (95% confidence interval: 19.1 to 34)
- Median overall survival (OS) was not reached, and the 12-month OS probability for all patients was 83.3% (95% confidence interval: 56.8% to 94.3%)
- 100% (17 out of 17) of patients mounted T-cell responses to at least one tumor-associated antigen and 16 of 17 (94%) patients developed T-cell responses to >1 antigen encoded by the vaccine

In the Phase 1 study undertaken in collaboration with Investigators at the Genitourinary Malignancy Branch of the National Cancer Institute, 18 patients with mCRPC who had advanced, incurable disease were given concurrently three hAd5 vaccines targeting PSA, brachyury, and MUC-1 at 5×10^{11} (VPs) each, subcutaneously every 3 weeks for a maximum of three doses (dose de-escalation cohort), followed by a booster vaccine every 8 weeks for 1 year (dose-expansion cohort only). Additional trial details can be found at clinicaltrials.gov-NCT03481816.

ImmunityBio has developed multiple product candidates that use this hAd5 viral vector to deliver tumor-associated antigens, which are being studied in multiple Phase I and Phase II clinical trials as potential vaccines for the treatment of solid tumors including breast, pancreatic, lung, head and neck, and prostate cancers. Importantly, these hAd5-based vaccines have shown an ability to overcome previous adenovirus immunity in cancer patients and in preclinical models. This same hAd5 viral vector has been applied for the treatment of infectious diseases and is in clinical trials for SARS-CoV-2 using hAd5 S+N as antigen constructs.

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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