ImmunityBio Announces Full Accrual of First Two Phases of Cancer Vaccine Trial in Participants with Lynch Syndrome and Initiation of Randomized Controlled Phase of the Trial

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- The first 20 participants have been enrolled in an important national, multicenter trial to test whether ImmunityBio's Nant Cancer Vaccine (NCV) comprising a tri-valent Adenovirus (Tri-Ad5) in combination with the company's IL-15 superagonist N-803 could potentially prevent colon and other cancers in individuals with Lynch syndrome. With enrollment of the first two open-label phases of the trial completed, the study will now proceed to the randomized controlled phase.
- When fully enrolled, the completed randomized Phase 2 study will include up to 186 individuals. In the randomized controlled phase 138 participants will be randomized to ImmunityBio's NCV or placebo.
- Lynch syndrome is associated with a genetic mutation present in an estimated one million Americans[1] who are more likely to be diagnosed with cancer at a younger age and are at increased risk of developing multiple types of cancers during their lifetime.
- This NCV study is the first to evaluate vaccines, delivered by an adenovirus vaccine platform, combined with an immune-enhancer, N-803, to target cancer-specific proteins and activate natural killer (NK) and T cells to prevent cancer.

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 21, 2024-- ImmunityBio (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced that enrollment and initial follow-up has been completed for the safety portions of a clinical trial that is studying ImmunityBio's investigational cancer vaccine of a tri-valent combination of antigens delivered by a second-generation Adenovirus vector (Tri-Ad5 CEA/MUC1 /brachyury) together with its IL-15 superagonist N-803 for participants with Lynch syndrome. The study, sponsored by the National Cancer Institute, part of the National Institutes of Health, will include up to 186 participants when fully enrolled and is now open to the randomized controlled portion of the trial.

Each of the three vaccines in Tri-Ad5 targets different proteins associated with precancer and cancer cells. The vaccine combination is studying whether activation of dendritic cells and training the immune system to recognize those proteins will destroy the precancer cells before the cancer occurs. The IL-15 superagonist N-803 is designed to enhance the effects of the vaccines by increasing proliferation and activation of natural killer (NK) and T cells, thereby increasing the potential for cancer prevention in study participants.

"We are pleased to be selected to participate in this important and innovative cancer prevention study, one that could provide insights into how the immune system could be harnessed to prevent cancer in individuals with hereditary risk," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "With an estimated 5 to 10 percent of cancers inherited, understanding mechanisms that might prevent or delay their onset could potentially change the prospects for tens of thousands of people annually."

Lynch syndrome (also called hereditary non-polyposis colorectal cancer or HNPCC) is one of the most common hereditary cancer syndromes occurring in 1 in every 300 Americans.[2] Not only can people with Lynch syndrome develop colorectal cancer 20 years before the average age of diagnosis for this cancer, they are also at an increased risk of developing multiple types of other cancers, including endometrial, stomach, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain, and small intestinal cancers. Colorectal cancer is the second-deadliest cancer type in the U.S., and approximately 3% to 5% of the 153,000 cases of colorectal cancer annually are thought to be due to Lynch Syndrome, as are 2% to 3% of all cases of endometrial cancer.3

"We are encouraged by how rapidly this study has been able to enroll participants," said Asad Umar, D.V.M., Ph.D., a senior advisor to the Director for Translational Research in NCI's Division of Cancer Prevention (DCP) and a scientific lead for the trial. "It is a strong indication of an unmet need and of the willingness of participants to help science make new discoveries in the area of cancer prevention."

To learn more about this study, please visit https://clinicaltrials.gov/ct2/show/NCT05419011.

For patients interested in enrolling in this study, please contact NCI's toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615) and/or the website: https://trials.cancer.gov and/or NCIMO_referrals@mail.nih.gov.

ImmunityBio's Tri-Ad5 Vaccines and N-803 are investigational. Safety and efficacy of these investigational agents have not been established by any Health Authority, including the FDA.

About ImmunityBio's Tri-Ad5 Vaccines

ImmunityBio's Tri-Ad5 vaccines target three tumor-associated antigens: brachyury, carcinoembryonic antigen (CEA), and mucin-1 (MUC1). Pre-clinical studies have demonstrated Tri-Ad5 vaccines elicit cytotoxic T cell-mediated tumor cell death and the establishment of memory T cells, and thus may provide protection against the growth and metastasis of cancer. Tri-Ad5 vaccines utilize a second-generation replication-defective human adenovirus serotype 5 (Ad5) vector with viral genes deleted to allow for production of the antigen and a vigorous immune response, without generating a host response to the vector and with the ability to overcome previous adenovirus immunity in cancer patients. Notably, in a phase 1 NCI trial, Tri-Ad5 generated antigen-specific T cells to MUC1, CEA, and/or brachyury in all 10 patients with no evidence of antigenic competition. The safety of multiple ImmunityBio product candidates utilizing the Ad5 technology has been demonstrated in phase 1 and 2 clinical trials for cancers across several tumor types.

About ImmunityBio

ImmunityBio is a vertically-integrated, clinical-stage biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

For more information, please visit: www.immunitybio.com

[1-3.] American Society of Clinical Oncology (ASCO) Cancer.net

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding clinical trial protocols, phases and patient enrollment, information regarding potential patient population, potential benefit to patients, potential additional studies and trials, methods, regulatory pathways, and ImmunityBio's investigational agents as compared to existing treatment options, among others. 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," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "seeks," "should," "will," "strategy," and variations of such words or similar expressions. Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. 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 information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. 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) the risks and uncertainties associated with the regulatory review process including without limitation the Company's BLA resubmission following receipt of the complete response letter (CRL) from the FDA and the ability of ImmunityBio and its third party contract manufacturing organizations to adequately address the issues raised in the CRL, (ii) whether or not the clinical trial referenced in this release will continue to progress as anticipated, including without limitation the ability to enroll additional patients, (iii) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (iv) ImmunityBio's ability to retain and hire key personnel, (v) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vi) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (viii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies. 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 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 2023 and the Company's Form 10-Q filed with the SEC on November 9, 2023, 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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Investors
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1 858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Greg Tenor
Salutem
+1 717-919-6794
Gregory.Tenor@Salutem.com

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