National Multicenter Trial Opens to Study ImmunityBio's Tri-Ad5 Cancer Vaccines Plus N-803 to Prevent Cancer in People with Lynch Syndrome

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- The Phase 2b cancer vaccine trial will study a multiple vaccination approach called 'Tri-Ad5' that uses three ImmunityBio vaccines in combination with the company's IL-15 superagonist N-803, to potentially reduce the risk of developing colorectal and other cancers in patients with hereditary Lynch syndrome.
- An estimated 1 in every 300 people may be carriers of a mutation in a gene associated with Lynch syndrome[1]. People with this syndrome 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 is the first study to assess the ability of vaccines, delivered by an adenovirus vaccine platform, combined with an immune-enhancer, N-803, to target cancer-specific proteins and activate NK and T cells to prevent cancer, with the goal of enrolling 186 participants at 14 centers throughout the U.S.

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 25, 2023-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced the opening of a clinical trial to study its investigational Tri-Ad5 vaccine combination (Adenovirus 5 CEA/MUC1/brachyury) together with its IL-15 superagonist N-803, an immune-enhancer, for people with a hereditary condition known as Lynch syndrome. This Phase 2b trial (NCT05419011) sponsored by the National Cancer Institute, part of the National Institutes of Health, will study whether Tri-Ad5 in combination with N-803 works to prevent colorectal and other cancers in study participants.

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 advances. 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 excited to partner with the NCI on this important cancer vaccine study to potentially prevent or delay the onset of cancer for people who carry the gene associated with Lynch syndrome," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "Lynch syndrome affects tens of thousands of people each year and the average age of cancer diagnosis for them is just 44. People known to have the gene for Lynch syndrome can be followed closely by their doctors with regular examinations and scans to watch for the development of cancer but, currently, there is no treatment that prevents the development of cancer in these patients. We hope to change that with this innovative study developed by the NCI."

Lynch syndrome is one of the most common hereditary cancer syndromes. Not only can people with Lynch syndrome develop colorectal cancer some 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.[2] "The Tri-Ad5 vaccine trial will be the largest Lynch syndrome cancer prevention study done in the U.S.," 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.

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.

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 multiple 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. 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.

N-803 (Anktiva™), ImmunityBio's lead cytokine fusion protein, is a novel 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). N-803 is currently under review by the FDA for this indication with a Prescription Drug User Fee Act (PDUFA) target date of May 23, 2023.

The company has established GMP manufacturing capacity at scale with cutting-edge cell therapy 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, such as statements regarding the information and data to be provided by the clinical trial described herein, the potential effects of the Tri-Ad5 vaccine combination together with N-803, the potential use and efficacy of ImmunityBio's product candidates for the prevention and/or treatment of cancer, clinical trial protocol design, enrollment, advancement and potential results, potential regulatory pathway for certain of ImmunityBio's product candidates and target indications, data from the clinical trials for certain of ImmunityBio's product candidates, potential implications to be drawn from clinical trials, potential commercialization of product candidates, and ImmunityBio's product candidates 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 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, (ii) the risks and uncertainties associated with the regulatory submission, review and approval process, (iii) ImmunityBio's ability to retain and hire key personnel, (iv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (v) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, (vii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (viii) the unknown future impact of the COVID-19 pandemic on certain clinical trials or their milestones and/or ImmunityBio's business 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 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 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.

[1&2] American Society of Clinical Oncology (ASCO) Cancer.net

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Investors
Sarah Singleton
ImmunityBio, Inc.
844-696-5235, Option 5
Sarah.Singleton@ImmunityBio.com

Media
Katie Dodge
Salutem
978-360-3151
Katie.Dodge@Salutem.com

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