ImmunityBio Announces First Participants Have Been Enrolled in Lung-MAP Trial Studying Anktiva to Activate NK and T Cells in Non-Small Cell Lung Cancer

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- Novel combination therapy of Anktiva, an IL-15 superagonist, and Keytruda targeted at patients with lung cancer who have failed checkpoint inhibitor therapy
- The study currently includes nearly 200 U.S. sites and will involve 478 patients when fully enrolled
- Nearly 237,000 new cases of lung cancer estimated to be diagnosed in the U.S. this year, making it the second most common cancer in the U.S.

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 25, 2022-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, announced today that the first participants have been enrolled in a study that is part of an 800-site master protocol trial for non-small cell lung cancer (NSCLC). The Lung Cancer Master Protocol trial (Lung-MAP) includes a study of Anktiva™ (N-803) plus Keytruda (pembrolizumab) versus investigator choice of standard-of-care chemotherapy in patients with non-small cell lung cancer (NSCLC) whose cancer has progressed after prior checkpoint-inhibitor-containing regimens. The study, which opened in March and currently includes nearly 200 sites across the U.S., will involve 478 patients when fully enrolled.

“The Lung-MAP master protocol is an important and innovative national multicenter trial and we’re grateful to be working with this national network to validate our hypothesis that both NK and T cells are needed to establish durable responses in patients with lung cancer,” said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. “This large trial will provide valuable information on the role Anktiva could potentially play in bolstering the effectiveness of checkpoint inhibitors such as Keytruda. Since Anktiva acts by activating and proliferating both NK and memory T cells, the combination with a checkpoint inhibitor that takes the brakes off T cells could result in improved durable outcomes. This combination therapy will be offered as a treatment option to patients with tumors that do not have druggable mutations, which is the case for the majority of NSCLC patients.”

About the Anktiva (N-803) Lung-MAP Trial

The trial protocol is enrolling patients to a randomization schema of N-803 + pembrolizumab versus investigator choice of standard-of-care chemotherapy (docetaxel, gemcitabine, pemetrexed, or docetaxel + ramucirumab). The two cohorts are being studied independently: 1. Primary checkpoint inhibitor resistant patients, 2. Previous responders to checkpoint inhibitors who then subsequently progress.

The current standard-of-care for NSCLC without targetable mutations is pembrolizumab (Keytruda). This Lung-MAP study will look at how N-803 could potentially bolster the effectiveness of Keytruda for patients with non-targetable cancer cell mutations. The current standard of care for patients who progress on Keytruda is chemotherapy, which has significant toxicities associated with its use. Data presented by Wrangle and colleagues at ASCO 2021 showed the N-803/Keytruda combination as a chemotherapy-free alternative that has produced lower rates of adverse events than chemotherapy in the second-line setting https://ascopubs.org/doi/10.1200/JCO.2021.39.15_suppl.2596.

To learn more about the Lung-MAP study, please visit https://www.lung-map.org/patients or clinicaltrials.gov (NCT05096663).

“We are incredibly excited to begin a randomized trial of N-803 plus pembrolizumab compared to second line chemotherapy,” said John Wrangle, M.D., a researcher at the Medical University of South Carolina who developed the study. “Lung-MAP S1800D will let us study if we can prolong the duration of benefit a patient experiences from immunotherapy while delaying use of cytotoxics. We have already observed that the combination is safe and that it can shrink tumors that have progressed on immunotherapy. Now it's time for a rigorous trial to determine if that means patients experience prolonged survival in the real-world setting that the Lung-MAP mechanism provides.”

Incidence of Lung Cancer

According to the American Cancer Society, lung cancer is the second most common cancer in the U.S. and remains a significant cause of death. It is estimated that nearly 237,000 new cases of lung cancer will be diagnosed in the U.S. this year, leading to some 130,000 deaths attributed to the disease. Non-small cell lung cancer accounts for about 80% to 85% of all lung cancer diagnoses; there are very few successful treatment options for these patients once the cancer spreads beyond the lungs. The development of checkpoint inhibitors in NSCLC has been revolutionary, doubling the median overall survival in some settings; however, patient response may be short lived, due to late response and/or progression after achieving an initial response.

ImmunityBio’s IL-15 superagonist Anktiva (N-803)

The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of the natural killer (NK) and T cells. Anktiva is a novel IL-15 superagonist complex consisting of an IL-15 mutant (IL-15N72D) bound to an IL-15 receptor α/IgG1 Fc fusion protein. Its mechanism of action is direct specific stimulation of CD8+ T cells and NK cells through beta gamma T-cell receptor binding (not alpha) while avoiding T-reg stimulation. Compared to native, non-complexed IL-15 in vivo, Anktiva has better pharmacokinetic properties, due to longer persistence in lymphoid tissues, and enhanced anti-tumor activity.

Anktiva is currently being studied in 21 clinical trials across 14 indications.

About Lung-MAP

Launched in 2014, Lung-MAP, or the Lung Cancer Master Protocol, is a precision medicine clinical trial for people with advanced non-small cell lung cancer that has continued to grow after treatment. As the largest “umbrella” lung cancer trial in the U.S., Lung-MAP is simultaneously studying how well multiple investigational or new drugs work in NSCLC with specific gene mutations or biomarkers. Open at almost 800 sites across the U.S., Lung-MAP is a unique public-private collaboration among the National Cancer Institute (NCI), which is part of the National Institutes of Health, SWOG Cancer Research Network, Friends of Cancer Research, the Foundation for the National Institutes of Health (FNIH), and 13 pharmaceutical companies.

About ImmunityBio

ImmunityBio is a 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.

ImmunityBio’s clinical pipeline consists of 26 actively recruiting clinical trials—17 of which are in Phase 2 or 3 development—across 13 indications in liquid and solid tumors (including bladder, pancreatic, and lung cancers) and infectious diseases (including SARS-CoV-2 and HIV). Anktiva™, ImmunityBio’s lead cytokine fusion 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 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, such as statements regarding the information and data to be provided by the Lung-MAP trial, whether the combination of Anktiva with a checkpoint inhibitor could result in improved durable outcomes, the potential use and efficacy of ImmunityBio’s product candidates for the treatment of lung cancer, clinical trial protocol design, enrollment, advancement and potential results, and potential regulatory approval, commercialization and commercial success of ImmunityBio’s product candidates, 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,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “seeks,” “should,” “will,” 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) ImmunityBio’s ability to retain and hire key personnel, (iii) ImmunityBio’s ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (iv) ImmunityBio’s ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (v) ImmunityBio’s ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, (vi) ImmunityBio’s ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (vii) 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, 2022, 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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