National Cancer Institute Selects ImmunityBio's N-803 IL-15 Receptor Agonist to Combine with Keytruda in 700-Site Lung-MAP Clinical Trial of a Chemo-Free Therapy

October 4, 2021

- Lung-MAP trials are studying how well investigational or new drugs work in non-small cell lung cancer (NSCLC) patients and will study how N-803 (Anktiva) could bolster the current standard of care, checkpoint inhibitors.
- ImmunityBio's study will test its IL-15 receptor superagonist complex N-803 (Anktiva) in combination with Merck's pembrolizumab (Keytruda) in up to 478 second-line patients with tumors that are not targetable with a drug, which accounts for the majority of NSCLC cases.
- The study is one of the National Cancer Institute's largest lung cancer clinical trials with more than 700 sites and enrollment is anticipated to begin in Q4 2021.

CULVER CITY, Calif.--(BUSINESS WIRE)--Oct. 4, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced the Lung Cancer Master Protocol (Lung-MAP) public-private partnership—which includes the National Cancer Institute (NCI), the National Clinical Trials Network (NCTN) Cooperative Groups (SWOG, ECOG-ACRIN, Alliance, and NRG), Friends of Cancer Research, and the Foundation for the National Institutes of Health (FNIH)—will study the company's IL-15 receptor superagonist complex, N-803 (Anktiva), in the Lung-MAP trial. Anktiva will be given in combination with Merck's pembrolizumab (Keytruda) to participants with non-small cell lung cancer who have failed previous treatments. The combination therapy will be offered as a treatment to patients with tumors that do not have mutations targetable with a drug, which is the case for the majority of NSCLC patients.

The Lung-MAP trial is open at more than 700 sites in the U.S. When fully enrolled, this trial group will include 478 patients.

"While some patients with lung tumors have targetable genetics, the majority do not, and for them there are fewer treatment options," said John Wrangle, M.D., one of the researchers at the Medical University of South Carolina who developed the study. "The Lung-MAP study aims to change that by combining different therapies such as Anktiva and Keytruda in an effort to discover highly effective and targeted therapies for these patients."

About the N-803 (Anktiva) Lung-MAP Trial
The trial protocol will enroll 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. Current standard of care for patients who progress on Keytruda is chemotherapy with significant toxicities associated. 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.

"Despite the tremendous progress we've made over the last few years, lung cancer continues to claim more than 130,000 lives annually, making it one of the deadliest cancers," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "Lung-MAP is a game-changing program because it tests the efficacy of multiple therapeutics and allows patients with targetable tumors to receive the best treatment based on their biomarkers and it gives patients without biomarkers access to treatments they would not normally be able to have without gene mutations."

Lung cancer is the second most common cancer in the United States. In 2021, in the United States alone it is estimated that 235,760 new cases of lung cancer will be diagnosed, and 131,880 deaths will be attributed to the disease.[1] Non-small cell lung cancer accounts for 85 percent of all lung cancer diagnoses and there are very few successful treatment options for these patients once the cancer spreads beyond the lungs.[2] To learn more about ImmunityBio's Lung-MAP study, please visit https://www.lung-map.org/patients

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 studying how well investigational or new drugs work in NSCLC patients with different gene mutations or biomarkers. Lung-MAP is open in more than 700 sites across the U.S. Lung-MAP is a unique public-private collaboration among the National Cancer Institute (NCI), parts of the National Institutes of Health, SWOG Cancer Research, Friends of Cancer Research, the Foundation for the National Institutes of Health (FNIH), and 13 pharmaceutical companies.

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 stages 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 currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform.

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, such as statements regarding the development of therapeutics for cancer and infectious diseases, the advancement of our Phase II and III trials, the anticipated timing of enrollment for the Lung-MAP clinical trial, and regulatory approval, commercialization and commercial success of ImmunityBio's product candidates and related matters. 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 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 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) inability to retain and hire key personnel, (iii) uncertainty of the expected financial performance and successful integration of the combined company following completion of the recent merger of ImmunityBio with NantCell (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, (iv) whether interim, initial, "top-line" and preliminary data from ImmunityBio's clinical trials that it announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, (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 obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, (vii) ImmunityBio's ability to successfully commercialize its product candidates and (viii) the unknown future impact of the COVID-19 pandemic delay on certain clinical trials or their 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, Form 10-Q filed with the SEC on August 12, 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.

1. https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html
2. https://www.cancer.org/cancer/lung-cancer/about/what-is.html

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