FDA Authorizes ImmunityBio Study of Anktiva and PD-L1 t-haNK to Increase Effectiveness of Trodelvy in Triple-Negative Breast Cancer

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- Open-label Phase 1b/2 study will evaluate the safety and preliminary efficacy of Anktiva (N-803) and PD-L1 t-haNK in combination with antibody-drug conjugate Trodelvy and low-dose chemotherapy in subjects with advanced triple-negative breast cancer (TNBC) after prior therapy
- The FDA approved Trodelvy for TNBC in April 2020 based on an overall response rate of 33.3%, with a median duration of response of 7.7 months; 55.6% maintained their response for 6 or more months and 16.7% maintained their response for 12 or more months.
- Study design is based on results of Phase 1 trial of haNK cells combined with Anktiva and low dose chemo in refractory triple negative breast cancer, where disease control rate of 78% and overall response rate of 67% was reached
- Enrollment expected to begin in Q3 2021

CULVER CITY, Calif.--(BUSINESS WIRE)--Jun. 15, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has received FDA authorization to conduct a Phase 1b/2 open-label study to evaluate the safety and preliminary efficacy of its superagonist Anktiva (N-803, an IL-15 superagonist) and PD-L1 targeted high-affinity natural killer (t-haNK) cells in combination with standard chemo and Trodelvy (sacituzumab govitecan-hziy), in subjects with advanced triple-negative breast cancer (TNBC). The study may provide data indicating whether this combination can increase the effectiveness of Trodelvy in patients who have failed to respond to other treatments.

Triple-negative breast cancer is a serious, aggressive cancer with a high mortality rate. While Trodelvy displayed efficacy against TNBC in phase 3 testing, only a third of third-line patients respond to it, and less than 17% of them continue to respond after a year. ImmunityBio proposed this new study based on data from a Phase 1 trial (NCT03387085) with Anktiva and the company's haNK cells that elicited a significant response rate in refractory TNBC. Anktiva and PD-L1 t-haNK when used in combination with Trodelvy may show additive or even synergistic effects, greatly increasing the response rate and, importantly, durability of responses.

"Antibody-drug conjugates like Trodelvy have made tremendous progress in giving patients with TNBC more and higher-quality time, but we believe Anktiva could potentially fill remaining treatment gaps and offer patients additional hope," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "We're conducting multiple studies with Anktiva across different tumor types, in some cases in combination with our NK cell line, that are designed to determine if they can enhance the activity of therapeutic monoclonal antibodies like Trodelvy—and, ultimately, provide patients with longer, progression-free survival."

The strategy behind this approach is to attack the tumor in two distinct, complementary ways—with Trodelvy delivering the initial blow by targeting the protein Trop-2 displayed by many TNBC cells and delivering a chemotherapy payload while Anktiva recruits key cells of the immune system, including NK and T cells, to continue fighting the tumor. To further unleash the power of the immune system, PD-L1 t-haNK will be introduced.

QUILT 3.058 Study Details

This phase 1b/2 open-label study will evaluate the safety and efficacy of sacituzumab govitecan-hziy in combination with chemoimmunotherapy (cyclophosphamide, N-803, and PD-L1 t-haNK) in subjects with TNBC after at least two prior treatments for metastatic disease.

The study consists of two phases and the maximum total enrollment for this study is 79 subjects.

- The phase 1b portion of the study will be conducted in 2 parts: part 1 will involve dose escalation using a 3 + 3 design, and part 2 will involve the expansion of the recommended phase 2 dose (RP2D) to further evaluate the safety and efficacy of sacituzumab govitecan-hziy plus chemoimmunotherapy. The phase 2 portion of the study will be based on Simon's two-stage optimal design.
- In phases 1b and 2, all subjects will receive sacituzumab govitecan-hziy plus chemo- and immuno-therapy: cyclophosphamide, N-803, and PD-L1 t-haNK on a 3-week schedule. . The dose of sacituzumab govitecan-hziy will be dependent on dose level cohort for phase 1b and will be set at the RP2D for phase 2. The doses of cyclophosphamide, N-803, and PD-L1 t haNK will remain the same in all dose level cohorts and phases.

An estimated 2.3 million women globally were diagnosed with breast cancer last year and 685,000 died from it. Triple negative breast cancer is an especially aggressive form of the disease and accounts for 10% to 15% of breast cancers, according to the American Cancer Society. TNBC tests negative for estrogen receptors (ER), progesterone receptors (PR) and human epidermal growth factor receptor 2 (HER2) protein. Therefore, TNBC does not respond to hormonal therapy or medicines that target ER, PR, or HER2 and other treatment options are limited, particularly after initial lines of therapy have failed. Innovative treatment approaches, such as the combination of Trodelvy, Anktiva, and PD-L1 t-haNK with chemotherapy described here may offer new hope to these advanced TNBC patients.

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 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. 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 our clinical trials that we announce or publish 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) our ability to obtain additional financing to fund our operations and complete the development and commercialization of our various product candidates, and (vi) 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 May 14, 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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