ImmunityBio Announces Study of ANKTIVA® in Combination with the AdHER2DC Cancer Vaccine as a Potential Therapy to Control Endometrial Cancer

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- The QUILT 502 trial is testing ImmunityBio's N-803 (ANKTIVA®) in combination with the AdHER2DC investigational vaccine for endometrial cancer, a gynecological cancer with lower survival rates and limited effective post-second-line treatment.
- The AdHER2DC vaccine targets the HER2 protein, which is elevated in 30% of endometrial cancer.
- ANKTIVA, recently approved for BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ, is designed to activate the immune cells that kill tumor cells to provide long-term immune response.
- The Phase1/2 interventional study will enroll 60 participants with HER2-positive endometrial cancer (EC), who will also receive pembrolizumab and lenvatinib, two FDA approved drugs for endometrial cancer.
- The study is expected to be completed in 2026.

CULVER CITY, Calif.--(BUSINESS WIRE)--Aug. 6, 2024-- Immunotherapy company ImmunityBio, Inc. (NASDAQ: IBRX), today announced the opening of a clinical trial to study ANKTIVA® (nogapendekin alfa inbakicept-pmln) together with the investigational AdHER2DC vaccine (autologous dendritic cells transduced with HER2 expressing adenovirus), in individuals with HER2-expressing endometrial cancer. It marks the latest trial involving ANKTIVA, the company's IL-15 superagonist immune enhancer, to evaluate ANKTIVA as an agent to replace the short-term activity of checkpoint inhibitor immunotherapies with long-term effectiveness. ANKTIVA was recently approved by the FDA for BCG-unresponsive non-muscle invasive bladder cancer CIS with or without papillary tumors.

This Phase 1/2 QUILT 502 trial (NCT06253494) sponsored by the National Cancer Institute, part of the National Institutes of Health, will study whether the AdHER2DC vaccine in combination with ANKTIVA, pembrolizumab (checkpoint inhibitor), and lenvatinib (kinase inhibitor) can be safely administered in combination and provide preliminary clinical efficacy before a larger, more definitive study.

Endometrial cancer is the most common gynecological cancer in the U.S., and affects more than 65,000 women each year with incidence peaking around 50-60 years of age. The 5-year overall survival rate in patients with metastasis is around 20 percent; treatment options after the second-line treatment are limited.

The AdHER2DC vaccine targets the HER2 protein, which is elevated in 30% of patients with endometrial cancer and in more than 50% of high risk subtypes. The AdHER2DCs are autologous, using each participant's own blood cells obtained through apheresis, a "loop" where blood is removed from one vein, passed through a machine to filter out target cells and then returned to the patient through another vein. The AdHER2DC is a proprietary agent of the NCI and it will be manufactured at the NIH Clinical Center for each study participant. The single agent AdHER2DC demonstrated safety profile and immunogenicity in a phase 1 clinical trial conducted by the NCI. The first treatment cycle is 28 days and each cycle after that will be 21 days. All participants will receive the vaccine and the two FDA approved drugs pembrolizumab and lenvatinib, and some participants will receive ANKTIVA.

Phase 1 of the open-label, two-arm Phase 1/2 study will determine recommended dose of pembrolizumab, lenvatinib, ANKTIVA and AdHER2DC in participants with HER2 positive endometrial cancer. The Phase 2 portion of the study will assess the efficacy of the combination of pembrolizumab, lenvatinib, ANKTIVA and the AdHER2DC vaccine in qualified participants as determined by the proportion of participants without disease progression at six months. The study will enroll 60 subjects and is expected to be completed in 2026.

"We are pleased to partner with the NCI on this important cancer control study involving ANKTIVA, which has demonstrated in clinical trials that activation of memory T cells may help deliver long-duration response well beyond that of checkpoint inhibitors alone," said Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "We are hopeful that the AdHER2DC investigational vaccine plus ANKTIVA will 'rescue' the checkpoint inhibitor pembrolizumab and kinase inhibitor lenvatinib and lead to an improved response compared with the current standard of care in this high risk population."

ImmunityBio is already partnered with the NCI to study the use of ANKTIVA in cases of Lynch syndrome, a genetic condition that is linked with significantly increased incidence of cancers, particularly colon cancer. These studies along with the recent approval of ANKTIVA for bladder cancer signal the advent of the era of cytokines as the next-generation of immunotherapies.

To learn more about this study, please visit https://clinicaltrials.gov/study/NCT06253494.

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.

The AdHER2DC vaccine is investigational. Safety and efficacy of this investigational agent have not been established by any health authority, including the FDA.

How ANKTIVA Works

The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells—NK and CD8+ killer T cells—that are involved in killing cancer cells. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells and restores memory T cell activity with resultant prolonged duration of complete response.

ANKTIVA is a first-in-class IL-15 agonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA mimics the natural biological properties of the membrane-bound IL-15 receptor alpha, delivering IL-15 by dendritic cells and drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. The proliferation of the trifecta of these immune killing cells and the activation of trained immune memory results in immunogenic cell death, inducing a state of equilibrium with durable complete responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

About ImmunityBio

ImmunityBio is a vertically-integrated 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. Designated an FDA Breakthrough Therapy, ANKTIVA® is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer that activates natural killer cells, T cells, and memory T cells for a long-duration response. The company is applying its 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

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 commercial launch activities and timing, product demand, patient treatment, data and results from clinical trials and potential implications therefrom, product availability and supply, potential regulatory pathways and approval requests and submissions, the regulatory review process and timing thereof, market and prevalence data, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, information regarding ongoing pre-clinical studies and clinical trials, potential future uses and applications of ANKTIVA and use in cancer vaccines and across multiple tumor types, ImmunityBio's financial condition, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. Statements in this presentation 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 commercial launch execution, success and timing, (ii) risks and uncertainties related to the regulatory submission and review process, (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, patient enrollment and planned regulatory submissions, (iv) potential delays in product availability and regulatory approvals, (v) risks and uncertainties associated with third party collaborations and agreements, (vi) potential delays in sales activity and pace, (vii) ImmunityBio's ability to retain and hire key personnel, (viii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (ix) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (x) ImmunityBio's ability to successfully commercialize its approved product and product candidates and uncertainties around regulatory reviews and approvals, (xi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xii) 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 19, 2024 and the Company's Form 10-Q filed with the SEC on May 9, 2024, 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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