FDA Authorizes ImmunityBio to Conduct a Trial of its First-in-Human, Cryopreserved, Memory Cytokine-Enriched NK Cell (m-ceNK) Platform in Solid Tumors

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- The first-in-class, memory cytokine-enriched Natural Killer (m-ceNK™) cells are the patient's own NK cells that have been enriched with cytokines, including ImmunityBio's IL-15 superagonist Anktiva (N-803)
- The resulting cryopreserved m-ceNK cells have an enhanced ability to recognize and kill cancer targets with longer persistence
- An initial study inolving 20 subjects (15 healthy donors and five cancer patients) showed that healthy and patient-derived m-ceNK cells killed NK-resistant tumor cells with equal potency in preclinical models
- Over 3000 percent m-ceNK cell expansion was achieved from a single blood draw enabling the potential for 10 to 20 infusions of a billion cells per dose
- The Phase 1 open-label study authorized by the FDA will begin enrolling participants with metastatic solid tumors in Q2 2021

CULVER CITY, Calif.--(BUSINESS WIRE)--May 17, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has received FDA authorization to conduct a Phase 1 study to evaluate the safety and preliminary efficacy of its m-ceNK™ platform combined with its IL-15 superagonist Anktiva (N-803) in subjects with locally advanced or metastatic solid tumors. These NK cells retrieved from the patient and enriched with cytokines have the ability to recognize and kill cancer targets with increased production of interferon-g (IFN-γ), a cytokine demonstrating high activity.

"Nearly two million Americans, including children, will be diagnosed with locally advanced or metastatic solid tumors this year alone and many of these tumor types are difficult to treat," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "Our m-ceNK cells, which are isolated and enriched from the patient after a simple blood draw (apheresis), are characterized by their unique cell-surface marker profile, by their highly desirable feature of immune-memory, and marked by their pronounced anti-cancer activity for weeks to months in duration. These unique properties have made these memory NK cells a research focus for more than a decade and a promising candidate in immunotherapy for solid tumors," said Soon-Shiong.

"We are excited to launch this next evolution of our NK platform. Based on the novel techniques and cytokine expansion developed at ImmunityBio, a single apheresis will enable 10 to 20 doses of m-ceNK infusions of 0.5 billion NK cells per dose. These autologous and allogeneic cryopreserved memory NK cells could synergize with our engineered off-the-shelf NK-92 cells, as well as with our IL-15 Anktiva superagonist, which stimulates both NK and T cells. We believe the combination of these tools has the potential to place ImmunityBio in a leading position to activate the patient's immune system in the fight against cancer across both solid and liquid tumors."

About Memory Cytokine-Enhanced NK Cells (m-ceNK):

In an initial, proof-of-concept clinical study, memory-like NK cells with freshly isolated cytokine-stimulated NK cells demonstrated encouraging results in patients with liquid tumors.[1.] ImmunityBio has successfully enriched and expanded donor natural killer cells obtained from peripheral blood of donors using a technique called apheresis, to generate a unique NK cell phenotype which exhibits both high cytotoxicity and interferon-g production together with a memory–like effect. These m-ceNK cells, or memory-cytokine enriched NK cells, have been designed for autologous cell therapy, but have also been generated as an allogeneic product from cord blood. m-ceNK provides a unique opportunity in clinics due to its ease of use and potential suitability for use in the ambulatory setting.

NK cells from aphaeretic blood from 20 subjects, 15 healthy and 5 cancer patient donors, were successfully used to generate m-ceNK cells in an Independent Review Board-approved volunteer study. Mononuclear cells obtained from the apheresis procedure were stimulated in the presence of ImmunityBio's proprietary cytokine, N-803, for enrichment of primary natural killer cells. A 2 to 3 log-fold expansion of activated NK cells was achieved by the third week of the protocol. These NK Cells are then briefly exposed to a proprietary cytokine cocktail to impart the critical memory-like phenotype, characterized by higher effector responses after a resting period—a key feature of ImmunityBio's m-ceNK cells. The m-ceNK product is characterized as CD56+ cells that are armed with NK cell activating surface receptors required for proliferation, homing and tumor recognition and binding. Both the healthy- and cancer patient-derived m-ceNK cells killed NK-resistant tumor cells with equal potency when tested against tumor cells of different origins, including breast, Merkel, ovarian, adenocarcinoma, and lymphoma.

ImmunityBio has also developed a novel method of production, which yields multiple clinical-dose forms from a single apheresis product using the company's proprietary NANT 001 Bioreactor (GMP-in-a-Box), thereby alleviating pressures on supply of starting material. A tailored cryopreservation protocol for maximum shelf-life and potency upon recovery was also established, a necessary precedent for any off-the-shelf product. ImmunityBio is leveraging the unique properties of m-ceNK—including potent cytotoxicity, increased IFN-gamma production, proliferative capacity, activation surface markers and memory response—to establish a propriety autologous product.

QUILT 3.076 Study Details

Cryopreserved m-ceNK cells in combination with Anktiva (N-803) will be tested in this phase 1 study designed to evaluate safety in subjects with locally advanced or metastatic solid tumors. The study will compare the quantity and quality of the m-ceNK cells collected and manufactured from

newly diagnosed patients who have not received prior treatment to the m-ceNK cells collected and manufactured from patients who have received at least two prior treatments for their cancer.

The study consists of two cohorts and there will be 10 participants in each cohort. Cohort 1 includes participants with newly diagnosed high-risk solid tumors who have not received prior treatment; and cohort 2 includes participants with relapsed/refractory (r/r) solid tumors who have progressive disease after receiving ≥ 2 prior therapies. Participants will be enrolled in the two cohorts simultaneously.

- Participants in cohort 1 will participate in apheresis collection of lymphocytes (part A) and will not receive any investigational therapy in this study.
- Participants in cohort 2 will undergo an apheresis collection of lymphocytes (part A) prior to receiving approximately four weeks of disease-specific therapy per their Oncologists' recommendations.

Solid tumors represent approximately 90% of adult cancers and 40% of all cancers in children, according to data collected from the American Cancer Society. Tumors can develop in many parts of the human body including the breast, lung, prostate, colon, skin, bladder and kidney.

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

1. Romee, R., Rosario, M., Berrien-Elliott, M., Fehniger, T., et al. (2016) Cytokine-induced memory-like natural killer cells exhibit enhanced responses against myeloid leukemia. *Science Translational Medicine*, doi: 10.1126/scitranslmed.aaf2341

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. These 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) potential adverse effects or changes to relationships with employees, suppliers or other parties resulting from the completion of the recent merger of the ImmunityBio with NantCell (the "Merger"), (ii) the outcome of any legal proceedings that may be instituted against the parties and others related to the Merger, (iii) unexpected costs, charges or expenses resulting from the Merger, (iv) uncertainty of the expected financial performance of the combined company following completion of 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, (v) 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, (vi) inability to retain and hire key personnel, and (vii) the unknown future impact of the COVID-19 pandemic delay on certain clinical trial 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 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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