ImmunityBio to Present Preliminary Phase 2 Data of 68% Durable Disease Control with Anktiva Plus Checkpoint Inhibitor in First 140 Patients Enrolled with Lung Cancer and Multiple Tumor Types Who Failed Prior Checkpoint Therapy at ASCO 2021

May 20, 2021

- Chemotherapy free regimen (with NK and T cell activation via Anktiva) in patients across multiple tumor types who failed checkpoint inhibitor therapy
- 140 patients accrued to date in this basket trial of checkpoint failures in lung cancer, melanoma, urothelial, head & neck, gastric and cervical cancer
- Out of 140 patients, 121 patients evaluable to date with 68% (82 out of 121) demonstrating durable disease control following Anktiva (IL-15 superagonist) plus checkpoint therapy after checkpoint failure
- Adverse events (AE) rates (12% grade 3 or above) of the chemo-free combination were better than historical standard of care alternative of combination chemotherapy
- Promising data forms the basis for the actively recruiting randomized Phase 3 clinical trials of Anktiva combination therapy in lung cancer patients (NCT03520686)

CULVER CITY, Calif.--(BUSINESS WIRE)--May 20, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced an upcoming poster presentation highlighting its chemotherapy free regimen of interleukin-15 (IL-15) superagonist Anktiva® (also called N-803) in combination with checkpoint therapy in patients who had relapsed from checkpoint inhibitors, at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place virtually this year from June 4 through June 8, 2021.

The Phase 2 study, titled "Preliminary data from QUILT 3.055: A Phase 2 multi-cohort study of N-803 (IL-15 superagonist) in combination with Checkpoint Inhibitors (CPI)", details data highlighting the safety and clinical benefit of adding Anktiva to checkpoint inhibitor therapy in second-line or greater treatment regimens in multiple cancer types, a basket trial.

Anktiva is designed to activate natural killer cells and CD8+ T cells, without the activation of T-reg cells that can suppress anti-tumor activity. In this Phase 2 study, Anktiva was administered to each patient in combination with a checkpoint inhibitor that had previously yielded a complete response, partial response, or six months of stable disease in that patient in the setting of first-, second- and third-line therapy before disease progression resumed.

"We are encouraged by the trend to date toward Anktiva's safety, tolerability and clinical benefit that is robust across several types of historically difficult-to-treat cancers, which aligns with Anktiva's mechanism of action being agnostic with respect to cancer type," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "We hope to see durable benefit as the study progresses, which would suggest that Anktiva can confer long-term re-sensitization of tumor tissue to checkpoint inhibitor therapy across several cancer types and patterns of patient history."

Human solid tumors are made of multiple clones of tumor cells, some of which harbor genomic alterations that make them invisible to T cells. These resistant clones accomplish this "cloaking ability" by preventing the presentation of the tumor antigens on MHC-I receptors, thus "hiding" from killer T cells. For these patients, maximum activation of T cells with immunotherapy is unlikely to lead to durable tumor control or a cure. However, when NK cells are activated, tumor recognition and targeting is restored. Anktiva activates both NK and T cells and a potential mechanism of rescuing patients from checkpoint relapse is the administration of Anktiva together with the same checkpoint therapy.

"We hypothesize that checkpoint therapy alone is insufficient and that the combination of Anktiva with or without PD-L1 t-haNK may advance the strategy of developing a chemotherapy free immunotherapy protocol for the treatment of multiple tumors. We have previously demonstrated that PD-L1 t-haNK plays an important role in checkpoint failures. The encouraging data from this Phase 2 exploratory trial has formed the basis of our randomized Phase 3 clinical trials in lung cancer (QUILT 2.023, NCT03520686)" said Dr. Soon-Shiong.

Study highlights to date include:

- 140 patients with checkpoint relapse accrued across multiple tumor types: NSCLC, Small Cell, Urothelial, Head & Neck, Melanoma, Renal, Gastric, and Cervical cancer
- 121 evaluable patients to date with preliminary data demonstrating 68% (82 out of 121) disease control (partial response and stable disease >6 weeks)
- Anktiva exhibits a favorable toxicity profile in combination with several different checkpoint inhibitors in second-line or greater settings, across a variety of tumor types
- Adverse events, 12% of which were grade 3 or above, that were related to the chemotherapy-free combination regimen were favorable to the historical standard of care comprising combination therapies that include chemotherapy
- Treatment-related serious adverse events (SAEs) were seen in 8% of study participants

- Combination regimens that included Anktiva demonstrated clinical benefit in the majority of subjects, with cessation of progression, prolonged stable disease, and occasional partial responses per RECIST were observed in different tumor types

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. 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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