ImmunityBio Announces 78 Percent Complete Response Following Chemotherapy-Free Combination of IL-15 Superagonist Anktiva with Rituxan in Relapsed Non-Hodgkin Lymphoma Patients

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- Durable complete response achieved in 7 of 9 (78%) CD20 sensitive patients who failed Rituxan® therapy in Phase 1 liquid tumor trial
- Of those patients who responded to the combination therapy of Anktiva™ plus Rituxan, 7 out of 7 (100%) achieved a complete response
- Chemotherapy-free regimen with minimal toxicity potentially enhances Rituxan mAb therapy with potential for broad application across liquid tumor indications
- Prolonged duration of disease without progression ranging from 18 to 24 months

CULVER CITY, Calif.--(BUSINESS WIRE)--May 4, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced the launch of the preclinical development of its liquid tumor pipeline with the publication of results from its Phase 1 study evaluating Anktiva™ (N-803), its IL-15 superagonist, in combination with Rituxan® (rituximab), an anti-CD20 monoclonal antibody therapy, in patients with indolent non-Hodgkin lymphoma (iNHL), who had relapsed or were refractory after two lines of therapy.

The peer-reviewed article titled “Phase 1 trial of N-803, an IL-15 receptor agonist, with rituximab in patients with indolent non-Hodgkin lymphoma” (see link HERE) published in the American Association for Cancer Research journal *Clinical Cancer Research*, highlights safety, efficacy, and translational data from the Company’s ongoing open-label, multi-center, dose-escalation Phase 1 study (NCT02384954).

The study was designed to evaluate Anktiva in combination with rituximab in patients with iNHL, to explore the potential of Anktiva to enhance tumor-targeting of anti-CD20 therapeutic antibodies, and to determine the safety and efficacy of subcutaneous (SQ) versus intravenous (IV) administration. Anktiva has been engineered to exhibit a longer half-life and more potent trans-presentation relative to endogenous IL-15 to promote natural killer (NK) cell and T cell expansion to control cancer.

Key study results include:

- The combination regimen of Anktiva and Rituxan was well tolerated with a single reported grade 4 adverse event (AEs) and no reported grade 5 AEs
- For patients with anti-CD20 mAb sensitive disease, the overall response rate (ORR) in the SQ cohort was 78% (7 of 9)
- 7 of 7 (100%) responses in the SQ cohorts were complete remissions (CR)
- Prolonged stable disease (SD) and conversion of SD and/or partial response (PR) to CRs with a prolonged duration without progression were observed, with 8 of 12 patients without progression at 18-24 months
- For the 5 patients with anti-CD20 mAb refractory disease in both IV and SQ cohorts, the ORR was 2 of 5 (40%) with 1 CR, 1 PR, 1 SD, and 2 progressive disease (PD) with the PR and SD are ongoing at over 18 months
- In correlative immunology experiments, Anktiva in combination with Rituxan induced the expansion, activation and modulation of NK cells and CD8+ T cells, with minimal impact on CD4+ T cells and Tregs
- Multi-dimensional mass cytometry studies demonstrated remodeling of iNHL patient immune landscapes by promotion of an activation signature in nearly all main immune cell lineages including NK cells, CD8+ T_{EM}, gd T cells, and CD14 and CD16 monocytes

Todd Fehniger, M.D., Ph.D., Washington University School of Medicine in St Louis, said, “These encouraging data suggest that Anktiva, ImmunityBio’s IL-15 superagonist, has the potential to enhance the activity of an anti-CD20 therapeutic antibody. We believe the excellent safety profile seen in the SQ cohort, when combined with compelling efficacy which includes prolonged progression free survival and a 78% complete response rate in rituximab-sensitive patients, warrants the further exploration of this regimen in iNHL patients. The translational immunology data generated also provide important proof-of-mechanism, with activation of important cell population including NK Cells and CD8+ T cells, which are key in driving immunotherapy responses. Together, these results suggest Anktiva may have broad potential to enhance the activity of therapeutic monoclonal antibodies across a wide range of tumor types.”

The study enrolled patients with iNHL (follicular lymphoma, marginal zone lymphoma, small lymphocytic lymphoma, lymphoplasmacytic lymphoma) that were relapsed or refractory after >2 prior lines of therapy. Patients were considered anti-CD20 mAb refractory if they progressed on anti-CD20 mAb therapy within 6 months of their last dose of anti-CD20 mAb. Treatment consisted of IV rituximab 375 mg/m^2 and IV or SQ N-803 (in increasing dosing cohorts of 1, 3, 6, 10, 15, 20 µg/kg).

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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