ImmunityBio Launches Phase 2 Chemotherapy-Free CAR-NK Cell Therapy Trial with ANKTIVA® (ResQ215B) in Indolent Lymphomas

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- First Phase 2 chemotherapy-free, lymphodepletion-free, off-the-shelf CAR-NK cell therapy plus ANKTIVA® and rituximab regimen to be evaluated in indolent non-Hodgkin lymphoma (iNHL), including Waldenström's Macroglobulinemia
- ResQ215B builds on a Phase 1 study that demonstrated that CAR-NK cell therapy plus rituximab administered without chemotherapy or ANKTIVA in iNHL, including Waldenström's Macroglobulinemia, resulted in durable complete responses
- CD19 t-haNK, an off-the-shelf CAR-NK cell therapy, is designed to induce direct tumor cell killing and enhance antibody-dependent cellular cytotoxicity (ADCC) when combined with anti-CD20 antibody rituximab
- The addition of ANKTIVA aims to further enhance NK and T-cell activity and potentially overcome tumor resistance to rituximab, thereby improving the depth and durability of responses in indolent lymphomas

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 2, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced the launch of ResQ215B, a Phase 2 clinical study evaluating a novel chemotherapy-free and lymphodepletion-free combination immunotherapy in patients with indolent B-cell non-Hodgkin lymphoma (iNHL), including Waldenström's Macroglobulinemia.

The outpatient study evaluates ImmunityBio's novel, off-the-shelf CD19-targeted high-affinity natural killer (NK) cell therapy (CD19 t-haNK) in combination with nogapendekin-alfa inbakicept (NAI; ANKTIVA®), an IL-15 superagonist, and the anti-CD20 monoclonal antibody rituximab. Notably, the regimen *does not require* any lymphodepleting chemotherapy, distinguishing it from conventional CAR-T cell therapies.

ResQ215B builds on promising results from the Phase 1 QUILT-106 study (NCT06334991), which evaluated CD19 CAR-NK cell therapy in combination with the anti-CD20 rituximab (without ANKTIVA). In that study, durable complete responses were observed in heavily pretreated patients with iNHL, including Waldenström's Macroglobulinemia.

In an initial chemotherapy-free cohort of patients with Waldenström's Macroglobulinemia treated with CD19 CAR-NK cells plus rituximab *without* any lymphodepletion, all four patients achieved clinical disease control. Two patients achieved rapid complete remissions (CR) that remain ongoing at 7 and 15 months of follow-up, respectively, without additional therapy beyond the planned treatment courses. The other two patients achieved stable disease, including one patient with declining IgM levels. These early findings demonstrated a 100% disease control in this small cohort using an outpatient, off-the-shelf CAR-NK cell therapy plus antibody combination without chemotherapy or inpatient hospitalization.

With the addition of ANKTIVA, ResQ215B is designed to evaluate whether further stimulation of innate and adaptive immune responses may enhance the depth and durability of anti-tumor activity. ANKTIVA is designed to promote the proliferation and activation of NK cells and CD8* T cells, potentially augmenting CAR-NK-mediated cytotoxicity and rituximab-driven ADCC.

Preclinical and clinical data suggests that IL-15 agonists may help restore immune function in the face of antibody resistance. In a previously published Phase 1 study (NCT02384954) Foltz et al. reported that combining an IL-15 superagonist with rituximab achieved a 78% complete response rate in patients with relapsed iNHL who had previously failed rituximab therapy.

"Our BioShield platform, which combines cell therapy, our IL-15 superagonist, and a monoclonal antibody in an outpatient, chemotherapy-free setting, represents our vision for Immunotherapy 2.0," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman, and Global Chief Medical and Scientific Officer of ImmunityBio. "Building on the durable complete remissions observed with our CD19 CAR-NK cell therapy plus rituximab in Waldenström's Macroglobulinemia, we are now adding ANKTIVA to further arm the immune system. We believe this off-the-shelf immunotherapy platform can trigger powerful anti-tumor activity without the toxicities of traditional treatments, potentially transforming the treatment paradigm for patients with indolent B-cell malignancies."

"A therapy that does not require apheresis, individualized manufacturing, chemotherapy, or inpatient hospitalization would represent an important advance for patients with iNHL, who are regarded as having incurable lymphomas," said Lennie Sender, M.D., Chief Medical Officer for Cell Therapy and Liquid Tumors at ImmunityBio. "To date, all treated patients have received the therapy in an outpatient setting without significant immune-related toxicities, demonstrating the feasibility of delivering potent cellular therapy without hospital admission. With ResQ215B, we will evaluate whether adding ANKTIVA can further improve response rates and durability while maintaining this favorable safety profile. This could open the door to a more patient-friendly immunotherapy option for follicular lymphoma, Waldenström's, and other indolent NHL subtypes that currently rely on more aggressive or continuous treatments. Indolent B-cell lymphomas, such as Waldenström's Macroglobulinemia, remain an area of high unmet medical need."

About the ResQ215B Study

ResQ315B is a Phase 2, open-label study designed to evaluate whether the addition of ANKTIVA can enhance immune-mediated tumor control when combined with CD19 CAR-NK cells and rituximab. The study will enroll adults with $CD19^{+}/CD20^{+}$ indolent NHL, including Waldenström's Macroglobulinemia, who are relapsed or are refractory after at least two prior lines of therapy. Treatment will be administered in 21-day outpatient cycles without preconditioning chemotherapy.

About CD19 t-haNK

ImmunityBio's CD19 t-haNK is an off-the-shelf, allogeneic NK-92-based cell therapy genetically engineered to express a CD19-specific chimeric antigen receptor (CAR) and a high-affinity CD16 (FcγRIIIa 158V) receptor. This dual-engineered design enables two complementary mechanisms of action: direct CAR-mediated cytotoxicity against CD19-expressing malignant B cells, and augmented antibody-dependent cellular cytotoxicity (ADCC) when paired with an anti-CD20 antibody such as rituximab. By targeting both CD19 and CD20, the combination is designed to reduce immune escape and improve overall response rates.

About ImmunityBio

ImmunityBio is a vertically integrated commercial stage biotechnology company developing next-generation therapies 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 CIS that activates NK 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, visit **ImmunityBio.com** (Founder's Vision) and connect with us on **X** (Twitter), **Facebook**, **LinkedIn**, and **Instagram**.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, without limitation, statements regarding: the interpretation, significance, and potential implications of clinical data from the Company's Phase 1 and Phase 2 clinical studies, including the ResQ215B Phase 2 trial evaluating a chemotherapy-free, lymphodepletion-free combination of CD19 CAR-NK cell therapy, ANKTIVA® (nogapendekin alfa inbakicept), and rituximab in patients with indolent B-cell non-Hodgkin lymphoma, including Waldenström's Macroglobulinemia; the potential safety, tolerability, efficacy, and therapeutic profile of this investigational combination regimen; the potential for observed clinical activity, including disease control or responses observed in early or limited patient cohorts, to translate into durable clinical benefit; the potential immunologic effects of combining CAR-NK cells, ANKTIVA®, and monoclonal antibodies; anticipated future clinical development plans, including the initiation, design, timing, enrollment, and outcomes of ongoing or future studies; regulatory interactions and potential regulatory pathways; manufacturing, scalability, and outpatient administration of cell therapy products; and the potential role of the Company's BioShield platform in the treatment of cancer and other diseases.

Forward-looking statements are based on the Company's current expectations, assumptions, and beliefs and involve risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, among others: the early, preliminary, and limited nature of clinical data; the small number of patients treated in early-phase studies; the possibility that results observed in Phase 1 studies or limited cohorts may not be replicated or may differ in Phase 2 or later-stage trials; variability in patient responses; the potential emergence of unexpected safety signals or adverse events; challenges related to clinical trial enrollment, conduct, and completion; the risk that clinical trial results may not support continued development, regulatory approval, or commercialization; uncertainties related to regulatory review, timing, and requirements; manufacturing, supply, and distribution risks associated with cell therapies; and competition from existing or future therapies.

The investigational product candidates discussed in this press release have not been approved by the U.S. Food and Drug Administration or any other regulatory authority, and their safety and efficacy have not been established.

More information regarding these and other risks that may impact the Company's business is described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 3, 2025, the Company's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2025, and in subsequent filings made by ImmunityBio with the SEC, which are available at www.sec.gov. ImmunityBio cautions you not to place undue reliance on forward-looking statements, which speak only as of the date hereof. ImmunityBio undertakes no obligation to update or revise any forward-looking statements, except as required by law.

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