ImmunityBio Reports Complete Responses in Non-Hodgkin Waldenstrom Lymphoma Patients with Chemotherapy-Free, First-In-Class CD19 CAR-NK Immunotherapy

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- Single-agent CD19 CAR-NK cell therapy achieved a complete response in third-line Waldenstrom macroglobulinemia (WM), a type of non-Hodgkin lymphoma
- Second patient maintains an ongoing complete response at six months with CD19 CAR-NK in combination with rituximab and a third WM patient has been enrolled in the study
- First study to demonstrate the potential for complete responses with a chemotherapy-free immunotherapy in late-stage WM patients validating the power of NK cells

CULVER CITY, Calif.--(BUSINESS WIRE)--Aug. 13, 2025-- ImmunityBio (NASDAQ: IBRX), a leading immunotherapy company, announced today early findings from its QUILT-106 Phase I trial, showing highly promising complete responses in the first two patients treated to date with late-stage Waldenstrom macroglobulinemia (WM)—a type of non-Hodgkins lymphoma (NHL)—using its CD19 CAR-NK (CD19 t-haNK) natural killer cell therapy.

QUILT-106 (NCT06334991) is a first-in-human trial evaluating the safety and preliminary efficacy of CD19 CAR-NK cell therapy alone and in combination with rituximab in patients with relapsed or refractory (R/R) $CD19^{+}CD20^{+}$ B-cell NHL. The disease remains challenging to treat, and WM is considered incurable with existing treatment options, making novel immunotherapies an important avenue of exploration for potential effective treatments.

In the first two evaluable patients with WM who were heavily pretreated, an entirely chemotherapy-free, immunotherapy regimen induced encouraging responses. Both patients tolerated the regimen with no significant toxicities. Notably, all infusions (including CAR-NK cells and cytokines) were administered in an outpatient setting. One patient achieved a complete response (CR) with CD19 CAR NK monotherapy, while the second patient achieved CR with CD19 CAR-NK in combination with rituximab. Remission was maintained and is ongoing for six months to date.

The open-label study sponsored by ImmunityBio and led by Dr. Glenda Gray, former President and CEO of the South African Medical Research Council (SAMRC) and current Chair of the Global Antibiotic Research and Development Partnership (GARDP), has enrolled 13 patients with NHL at three sites in South Africa. Of the patients enrolled so far, three have WM. Eligible study participants express CD19 and CD20, with active disease after ≥2 chemotherapy-based lines of treatment. All patients receive a lead-in cycle of CD19 CAR-NK cell monotherapy, followed by a 1-week safety observation pause, then a second cycle combining CD19 CAR-NK with rituximab. Key endpoints include safety/tolerability and objective response rate (ORR) by standard criteria.

“The preliminary findings we have submitted for presentation at the American Society of Hematology annual meeting provides the first evidence that novel immunotherapy combinations without chemotherapy lymphodepletion can provide deep and durable remissions in WM even after multiple prior treatments,” said Dr. Jackie Thomson, Wits University Donald Gordan Medical Center, Johannesburg, South Africa and the lead author of the paper. “Recruitment in this rare subset of lymphoma is ongoing to confirm these findings and to establish this chemo-free strategy as a viable treatment option for relapsed WM.”

ImmunityBio’s CD19 CAR-NK Therapy

CD19 CAR-NK is a targeted high-affinity natural killer cell therapy – an off-the-shelf, allogeneic NK cell line engineered to express a CD19-specific chimeric antigen receptor (CAR) and a high-affinity CD16 (FcγRIIIa 158V) receptor. This design enables dual anti-tumor mechanisms: direct CAR-mediated cytotoxicity and augmented antibody-dependent cellular cytotoxicity when paired with anti-CD20 monoclonal antibody rituximab. Combining CD19 CAR-NK cells with rituximab could thereby target $CD19^{+}/CD20^{+}$ lymphoma cells to enhance tumor cell killing.

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, such as statements regarding potential implications to be drawn from preliminary clinical study results, clinical trial enrollment, timing, data and potential results to be drawn therefrom, anticipated components of ImmunityBio’s CancerBioShield™ platform, the development of therapeutics for cancer and infectious diseases, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions

therefrom, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents across multiple tumor types and indications and for potential applications beyond oncology, potential regulatory pathways and the regulatory review process and timing thereof, the application of the Company's science and platforms to treat cancers or develop cancer vaccines, immunotherapies and cell therapies that have the potential to change the paradigm in cancer care, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. 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," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "is," "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) risks and uncertainties regarding participation and enrollment and potential results from the clinical trial described herein, (ii) whether clinical trials will result in registrational pathways, (iii) whether clinical trial data will be accepted by regulatory agencies, (iv) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (v) 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, (vi) potential delays in product availability and regulatory approvals, (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, (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 3, 2025, and the Company's Form 10-Q filed with the SEC on August 5, 2025, 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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