ImmunityBio Announces Positive Results Demonstrating ANKTIVA® as a Lymphocyte Stimulating Agent in Combination With Checkpoint Inhibitors in Non-Small Cell Lung Cancer

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- ANKTIVA® plus checkpoint inhibitor (CPI) therapy demonstrated statistically significant immune restoration across two clinical trials in 151 patients with non-small cell lung cancer (NSCLC)
- In first-line NSCLC (QUILT-2.023), a randomized study demonstrated a statistically significant and sustained increase in absolute lymphocyte count (ALC) from baseline with ANKTIVA plus CPI compared with CPI alone (p=0.0065), establishing ANKTIVA's contribution as a lymphocyte-stimulating agent
- In second- and later-line NSCLC (QUILT-3.055), a single-arm study demonstrated restoration or maintenance of ALC ≥1.0 × 10^3 cells/µL in 77% of patients receiving ANKTIVA plus CPI (responders)
- Responders receiving ANKTIVA plus CPI experienced significantly longer overall survival compared with non-responders (median OS 16.2 vs 11.8 months; HR 0.52; p=0.0369), directly linking immune restoration to clinical benefit
- Patients achieving higher immune competence (ALC ≥1.2 ×10^3 cells/µL) demonstrated additional survival benefit, with median OS of 21.1 months (HR 0.33; p=0.0009), independent of PD-L1 status, exceeding historical overall survival of 7-9 months with standard of care chemotherapy
- A randomized Phase 3 confirmatory trial (ResQ201A) comparing ANKTIVA plus CPI versus docetaxel in second-line NSCLC is ongoing

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 13, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced positive results from its ANKTIVA (nogapendekin alfa inbakicept) clinical program in non-small cell lung cancer (NSCLC) based on two studies, QUILT-2.023 and QUILT-3.055. Across 151 patients spanning first-, second-, and later-line disease, ANKTIVA demonstrated statistically significant immune restoration and a consistent association between lymphocyte recovery and improved survival in checkpoint-experienced patients.

Checkpoint inhibitors such as pembrolizumab (Keytruda®) and nivolumab (Opdivo®) have transformed the treatment landscape for lung cancer; however, clinical benefit is often transient, and effective treatment options remain limited once patients progress following standard-of-care chemo-radiation and checkpoint inhibition.

QUILT-2.023 and QUILT-3.055 were designed to test the hypothesis that disease recurrence after checkpoint therapy reflects immune exhaustion and lymphocyte depletion, and that restoration of immune competence through activation of natural killer cells and CD8* cytotoxic T cells with ANKTIVA, in combination with checkpoint inhibitors, could improve outcomes.

"Today, the default standard of care for these patients remains cytotoxic chemotherapy such as docetaxel, which is associated with substantial toxicity and limited survival benefit," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman, and Global Chief Scientific and Medical Officer of ImmunityBio. "Large, randomized trials have demonstrated median overall survival of approximately nine months with docetaxel. The results from these studies support a potential paradigm shift toward what we define as Immunotherapy 2.0, which is the coordinated activation of the innate immune system through natural killer cells and the adaptive immune system through T cells to restore immune competence and extend survival."

Detailed results from QUILT-2.023 and QUILT-3.055 are being prepared for peer-review publication and future scientific presentations and serve as foundational safety and efficacy data demonstrating meaningful clinical benefit in patients with NSCLC who have failed all standards of care including checkpoint inhibitors.

The combination of ANKTIVA plus checkpoint inhibitor therapy is protected by multiple issued patents, including U.S. Patent Nos. 9,925,247 and 11,071,774, with patent terms extending into 2032–2039.

About QUILT-2.023

QUILT-2.023 (NCT03520686) is a Phase 3, open-label, multicohort study evaluating ANKTIVA® in combination with approved checkpoint inhibitor–based regimens as first-line treatment for patients with advanced or metastatic NSCLC. The study included three randomized cohorts and one exploratory cohort, each analyzed independently.

The primary randomized cohort enrolled patients with stage III or IV squamous or nonsquamous NSCLC with PD-L1 expression ≥1% and no prior systemic therapy for advanced disease. Patients were randomized 1:1 to CPI alone or CPI plus ANKTIVA®. Stratification factors included CPI regimen, ECOG performance status, histology, and PD-L1 tumor proportion score. The primary endpoint was progression-free survival assessed by RECIST v1.1, with longitudinal absolute lymphocyte count prospectively incorporated as a key biological endpoint.

Enrollment was closed early following changes in the first-line NSCLC treatment landscape. All analyses were conducted according to the finalized protocol and statistical analysis plan.

About QUILT-3.055

QUILT-3.055 (NCT03228667) is a Phase 2b, multicohort, open-label study evaluating the addition of nogapendekin alfa inbakicept to continued

PD-1/PD-L1 inhibitor therapy in patients with advanced solid tumors who progressed after prior checkpoint inhibition. The study enrolled heavily pretreated patients, including second- and later-line NSCLC.

Patients continued the same checkpoint inhibitor to which they had previously responded or stabilized, with ANKTIVA® administered subcutaneously in repeated six-week cycles. The primary objective prospectively linked immune biology to clinical outcomes by evaluating overall survival in relation to absolute lymphocyte count response, defined as achieving or maintaining a mean on-treatment ALC ≥1,000 cells/μL. Secondary endpoints included objective response rate, progression-free survival, duration of therapy, and safety.

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 data and results from clinical trials and potential implications therefrom, potential regulatory pathways and approval requests and submissions, the regulatory review process and timing thereof, potential benefits to patients, potential treatment outcomes for patients, information regarding clinical trials, including potential trial design and timing, potential future uses and applications of ANKTIVA, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. Statements in this presentation 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 related to the regulatory submission and review process, (ii) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (iii) whether clinical trials will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, review and approval process, (iv) 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, (v) potential delays in product availability and regulatory approvals, (vi) ImmunityBio's ability to retain and hire key personnel, (vii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (viii) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (ix) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (x) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xi) 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 November 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. The publication of off-label data does not imply regulatory approval or an intention to promote any product for an unapproved use.

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