Unmatched Long-Term Bladder Preservation for 36 Months in over 80 percent of Responders with ANKTIVA® Plus BCG in BCG-Unresponsive NMIBC CIS and Papillary Disease Alone – Best in Disease and Best in Class with 5 Year Follow-Up

April 28, 2025

CIS with or without Papillary:

- Oral presentation from QUILT-3.032 study showed 71% complete response rate (N=100), with duration of response ranging up to more than 53 months, in BCG-unresponsive NMIBC CIS with or without papillary disease
- Probability of duration of complete response of at least 45 months in the FDA label population (N=77) is 51%, with median duration of complete response of 45.4 months
- Cystectomy avoidance rate in responders of 84% at 36 months
- Disease-specific overall survival rate of 99% at 36 months
- Longest follow-up of BCG-unresponsive CIS patients with unmatched more than 5 years data available (as of July 2024 data cutoff)

Papillary without CIS:

- Disease-free survival rate of 58% at 12 months (primary endpoint) and 52% at 24 months
- Cystectomy avoidance rate of 82% at 36 months—unmatched by any product in the field to date
- Disease-specific overall survival rate of 96% at 36 months
- Supplemental BLA submitted for FDA approval for this indication

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 28, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced positive long-term results from its QUILT-3.032 study of ANKTIVA® (nogapendekin alfa inbakicept-pmln) plus Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS), with or without papillary disease. The findings were shared during an oral presentation at the American Urological Association Annual Meeting (AUA 2025) in Las Vegas, April 26-29.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20250428844244/en/

AUA 2025 Presentation by Sam Chang, MD

At the 2025 AUA Annual Meeting, ImmunityBio presented updated clinical data highlighting the durability and impact of ANKTIVA in combination with BCG. The results demonstrated the longest duration of complete response and highest rate of cystectomy avoidance among therapies studied in BCG-unresponsive NMIBC, including both CIS with or without papillary disease and papillary-only disease without CIS.

The latest results from Cohort A (N=100) of the QUILT-3.032 study showed treatment with ANKTIVA plus BCG resulted in a complete response rate of 71% in patients with BCG-unresponsive NMIBC CIS with or without papillary tumors. Responses ranged up to more than 53 months, with 60% of responses having a duration of at least 12 months. Exceptional ongoing complete response data were presented for the FDA label population (N=77), which has a longer follow-up time of 29.3 months and showed a 51% probability of duration of complete response of at least 45 months. The rate of cystectomy avoidance in responders was 84.2% at 36 months, with disease-specific overall survival of 99% at 36 months.

In study Cohort B (N=80) of patients with BCG-unresponsive NMIBC papillary disease without CIS, ANKTIVA plus BCG demonstrated a 58.2% disease-free survival (DFS) rate at 12 months (primary endpoint), with a median DFS of 25.3 months. The cystectomy avoidance rate was 82% at 36 months, with a disease-specific overall survival rate of 96% at 36 months.

“While BCG is the commonly used first-line therapy for newly diagnosed high-risk non-muscle invasive bladder cancer, many patients will be refractory or relapse after an initial response and be diagnosed as BCG-unresponsive,” said QUILT-3.032 principal investigator and study presenter Sam S. Chang, M.D., Professor of Urology and Chief Surgical Officer of the Vanderbilt Ingram Cancer Center. “Our latest findings, including an 82% cystectomy avoidance rate, provide additional evidence that ANKTIVA has the ability to restore BCG activity and promote durable complete responses and, most importantly, help patients preserve their bladder for a prolonged duration from surgery in both CIS, as well as papillary without CIS disease.”

The latest findings from the QUILT-3.032 study also show that therapy with ANKTIVA plus BCG was well tolerated in both CIS and papillary NMIBC (N=180). Most treatment-related adverse events (TRAEs) were grade 1 or 2 and related to intravesical instillation consistent with BCG alone - dysuria, pollakiuria, hematuria and micturition urgency. TRAEs of grade 3 occurred at a rate of 3% (6 subjects out of 180). No grade 4 or 5 TRAEs were observed.

“We are pleased with these unmatched long-term follow up results which further illustrate ANKTIVA’s potential to improve outcomes and quality of life

for patients with non-muscle invasive bladder cancer in both indications of CIS, as well as papillary disease without CIS," said Dr. Patrick Soon-Shiong, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio. "The cystectomy avoidance rate of greater than 82% at 36 months in both BCG-unresponsive CIS with or without papillary disease and in BCG-unresponsive papillary without CIS disease is the highest percentage of bladder sparing and longest duration of complete response and disease-free status seen in this patient population to date, as confirmed by all the studies presented in the field at the AUA 2025 conference. We look forward to the national guidelines (NCCN) for BCG-unresponsive papillary disease without CIS to align with these long-term data of cystectomy avoidance and the data presented at AUA supporting Anktiva as the best in class and best in disease for this indication."

Based on findings from the QUILT-3.032 study, ImmunityBio recently submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for use of ANKTIVA plus BCG in BCG-unresponsive NMIBC for the indication of papillary disease.

Papillary disease is estimated to be approximately 6-10 times more common than bladder cancer CIS, representing a large patient population that may benefit from ANKTIVA plus BCG.[1]

About the QUILT-3.032 Study

QUILT-3.032 (NCT03022825) is a Phase II/III, open-label, single-arm, multicenter study of intravesical BCG plus ANKTIVA or ANKTIVA only in patients with BCG unresponsive high grade non-muscle invasive bladder cancer (NMIBC). All participants receive BCG plus ANKTIVA (Cohorts A and B) or ANKTIVA only (Cohort C) via a urinary catheter in the bladder for 6 consecutive weeks (initial induction treatment period). After the first disease assessment, eligible patients receive either a 3-week maintenance course or a 6-week re-induction course (second treatment period) at Month 3. Eligible patients will continue to receive maintenance treatment in the third treatment period at Months 6, 9, 12, and 18. Eligible patients have the option to receive maintenance treatment in the fourth treatment period at Months 24, 30, and 36. The study duration is 60 months.

Cohort A (N=100) includes patients with histologically-confirmed BCG-unresponsive NMIBC CIS with or without Ta/T1 papillary disease. The primary endpoint is biopsy-confirmed complete response (CR) rate at any time. Secondary endpoints include duration of CR, progression-free survival (PFS), time to cystectomy, safety and overall survival. Cohort B (N=80) enrolled participants with histologically-confirmed BCG-unresponsive high-grade Ta/T1 papillary NMIBC. The primary endpoint is disease-free rate at 12 months. Secondary endpoints include disease-free survival, PFS, time to cystectomy, safety and overall survival.

About ANKTIVA®

The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells—NK and CD8+ killer T cells—that are involved in killing cancer cells. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells and restores memory T cell activity with resultant prolonged duration of complete response.

ANKTIVA is a first-in-class IL-15 receptor agonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA mimics the natural biological properties of the membrane-bound IL-15 receptor alpha, delivering IL-15 by dendritic cells and drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. The proliferation of the trifecta of these immune killing cells and the activation of trained immune memory results in immunogenic cell death, inducing a state of equilibrium with durable complete responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

ANKTIVA was approved by the FDA in 2024 with BCG for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer with CIS with or without papillary tumors. For more information, visit ImmunityBio.com (Founder's Vision) and Anktiva.com.

About ImmunityBio

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines 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 natural killer 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.

References:

1. https://pmc.ncbi.nlm.nih.gov/articles/PMC10813486/

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 commercial launch activities and market access initiatives, the company's submission of the sBLA for use of ANKTIVA plus BCG in BCG-unresponsive NMIBC for the indication of papillary disease and potential results therefrom as well as regulatory review process, decisions and timeline related thereto, NCCN guidelines, presentations at the AUA meeting, market data, clinical trial data and potential results to be drawn therefrom, 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 and use in cancer vaccines and across multiple tumor types, 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 commercial launch execution, success and timing, (ii) risks and uncertainties regarding market access initiatives and timing, (iii) whether the FDA will accept the sBLA and other regulatory submissions for review and filing, (iv) uncertainties regarding the timeline of the FDA's review of these submissions even if accepted for review and filing, (v) whether the FDA will ultimately approve the sBLA, or other submissions in a timely matter, or at all, of which there can be no assurance, (vi) risks and uncertainties regarding limited resources at the FDA and potential delays associated therewith, (vii) whether clinical trials will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, filing, review and approval process, (viii) whether clinical trial data will be accepted by regulatory agencies, (ix) 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, (x) potential delays in product availability and regulatory approvals, (xi) ImmunityBio's ability to retain and hire key personnel, (xii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xiii) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xiv) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xv) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xvi) 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 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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