



ImmunityBio to Showcase Advances for Bladder and Prostate Cancer at American Urological Association (AUA) Annual Meeting

April 21, 2025

- Oral presentation provides update from QUILT-3.032 on durable complete responses to ANKTIVA® plus BCG in BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ (NMIBC CIS) with or without Ta/T1 papillary disease and papillary disease alone
- ImmunityBio to present keynote events on NMIBC and experience in prostate cancer, unveiling lymphopenia, the Absolute Lymphocyte Count (ALC) biomarker for all tumor types, and the 'Cancer BioShield'
- Supplemental Biologics License Application for BCG unresponsive NMIBC for papillary disease alone submitted to the FDA
- Updates to be provided on status of Expanded Access Authorization of ANKTIVA as a BioShield

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 21, 2025-- ImmunityBio, Inc. ([NASDAQ:IBRX](#)), a leading immunotherapy company, will announce new clinical findings for ANKTIVA® (nogapendekin alfa inbakicept-pmln) in non-muscle invasive bladder cancer carcinoma in situ (NMIBC CIS) and updated data on papillary disease without CIS at the American Urological Association Annual Meeting (AUA 2025) in Las Vegas, April 26-29. The company will also host an educational and peer-networking event to discuss ImmunityBio's approach to treatment of NMIBC CIS and papillary disease and how they have impacted patients.

"ImmunityBio has made remarkable strides in 2025, marked by groundbreaking long-term efficacy data for ANKTIVA and the launch of our Expanded Access Program to help end the BCG shortage," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman, Global Chief Scientific & Medical Officer of ImmunityBio. "With these critical advancements, we are eager to connect, collaborate, and drive meaningful discussions with the urology community at AUA 2025, shaping the future of bladder and prostate cancer care together. In addition, ImmunityBio has applied for Expanded Access for the use of ANKTIVA as a 'BioShield' in patients receiving chemotherapy, radiation, and immunotherapy to enable access to ANKTIVA across the country for patients in need."

Oral Presentations by Key Opinion Leaders:

Presented research will continue to demonstrate long-term duration of response with ANKTIVA + BCG in an updated analysis of the pivotal QUILT 3.032 trial in CIS and papillary BCG-Unresponsive NMIBC.

- **An Update on QUILT 3.032: Complete Responses to N-803 plus BCG Therapy in BCG-Unresponsive Bladder Carcinoma in Situ (CIS) With or Without Ta/T1 Papillary Disease (PD12-12)**
Chang S. Oral Podium Presentation. Session: Bladder Cancer: Non-Invasive II, Saturday, April 26, 3:30 pm - 5:30 pm PDT, Galileo 1001, The Venetian Convention & Expo Center

Keynote Events by Dr. Soon-Shiong at AUA

Patrick Soon-Shiong, M.D., will participate in a series of presentations showcasing the power and potential of immunotherapy in shaping the future of urological cancers.

- **Embracing the Future: The Power of Innovation in a Changing World**
 - Dr. Patrick Soon-Shiong, Keynote. AUA Innovation Nexus Conference, Friday, April 25, 1:00-1:45 pm PDT, The Venetian Convention & Expo Center
- **The Science of the Triangle Offense: NMIBC Patient and Prostate Cancer Experience**
 - Educational and peer-networking event with Drs. Patrick Soon-Shiong, ImmunityBio Chief Medical Officer Sandeep "Bobby" Reddy, and Senior Vice President of Medical Affairs Bruce Brown, Saturday, April 26, 6:30 pm – 9:00 pm PDT, The Venetian Convention & Expo Center
- **The Missing Link: Overcoming Lymphopenia through NK & Memory T Cells to Achieve Durable Responses in Urological Diseases – ALC Matters, Duration Matters, the Immune System Matters**
 - Dr. Patrick Soon-Shiong, ImmunityBio Product Theater, Sunday, April 27, 1:30 pm – 2:30 pm PDT, Science & Technology Hall, The Venetian Convention & Expo Center

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 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](#) for BCG-unresponsive non-muscle invasive bladder cancer 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](#).

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 the anticipated timing, subject matter, speakers and other information regarding the AUA conference described herein, ImmunityBio's potential growth trajectory and business prospects, ImmunityBio's beliefs regarding the potential for its approach to revolutionize cancer care, ImmunityBio's submission of the EAP to provide ANKTIVA for preventing or reversing lymphopenia and potential results therefrom as well as regulatory review process, decisions and timeline related thereto, clinical trial and expanded access program enrollment, data and potential results to be drawn therefrom, ImmunityBio's strategy to address the BCG shortage and potential results therefrom, potential future uses and applications of ANKTIVA for the prevention or reversal of lymphopenia, potential regulatory pathways and the regulatory review process and timing thereof, 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) risks and uncertainties related to the regulatory submission, filing and review process and the timing thereof, (iv) whether clinical trials will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, review and approval process, (v) whether clinical trial data will be accepted by regulatory agencies, (vi) 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, (vii) potential delays in product availability and regulatory approvals, (viii) ImmunityBio's ability to retain and hire key personnel, (ix) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (x) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xi) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, (xiii) ImmunityBio's ability to obtain, maintain, protect, and enforce patent protection and other proprietary rights for its product candidates and technologies, (xiv) whether the FDA will accept ImmunityBio's recent regulatory submissions for review and filing, the timeline of the FDA's review of these submissions even if accepted for review and filing, and whether the FDA will ultimately approve the submissions in a timely matter, or at all, of which there can be no assurance, (xv) risks and uncertainties regarding limited resources at the FDA and potential delays associated therewith, and (xvi) whether ImmunityBio's clinical trials and/or expanded access programs will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, review and approval process. 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.

Visit [www.FDA.gov/medwatch](#) or call 1-800-332-1088. You may also contact ImmunityBio at 1-877-ANKTIVA (1-877-265-8482).

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