Connecting the Dots of ANKTIVA's Triangle Offense: A Deep Dive with Dr. Patrick Soon-Shiong and Dr. Ashish Kamat in a Three-Part UroToday Podcast

May 17, 2024

- Three-part podcast interview features
  - The mechanism of action of ANKTIVA® activating NK cells, Killer T cells, and Memory T cells
  - The clinical findings of a durable complete response and implications for nonmuscle invasive bladder cancer patients with the launch of ANKTIVA
  - Addressing the shortage of BCG and collaboration with Serum Institute of India

CULVER CITY, Calif.--(BUSINESS WIRE)--May 17, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX) today announced the publication of three podcasts with *UroToday* highlighting the company's recent FDA approval of ANKTIVA® (N-803, or nogapendekin alfa inbakicept-pmln) plus Bacillus Calmette-Guérin (BCG) for non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS) and advances in bladder cancer research.

Patrick Soon-Shiong, M.D., Executive Chairman and Global Chief Scientific at ImmunityBio, discussed the breaking news of the FDA approval of Anktiva with Ashish Kamat, M.D., MBBS, an Endowed Professor of Urologic Oncology and Cancer Research at University of Texas MD Anderson Cancer Center at the recent American Urological Association (AUA) Annual Meeting.

In a three-part interview with Dr. Kamat, Dr. Soon-Shiong provided an in-depth overview of ANKTIVA's unique mechanism of action, the implications of this mechanism for cancer immunotherapy, supply updates, and ImmunityBio's new partnership with the Serum Institute of India (SII), which will help ensure BCG supply is available for patients treated with ANKTIVA. Dr. Soon-Shiong introduced the concept of a MHC-negative bladder cancer cell, attacked by the natural killer cell and Anktiva's property to restore killer T cells and memory T cells as the mechanism of achieving durable complete responses.

"The reports that BCG induces loss of MHC has only been recently discovered, resulting in progression of the cancer with cancer immune evasion from the T cells. These MHC-negative cells are the exact target for natural killer cells which ANKTIVA activates. The potential to convert a MHC-negative (cold) tumor to a MHC-positive (hot) tumor with NK cell activation, and restoring CD8+ killer T cells and memory T cells, may have important implications in addressing cancers that have reached this stage of escape and progression," said Dr. Soon-Shiong.

"The approval of this treatment represents a next-generation immunotherapy beyond checkpoint inhibitors and provides a new treatment option for patients with BCG-unresponsive NMIBC," he said.

ANKTIVA, a first-in-class IL-15 receptor agonist, received approval from the FDA on April 22 for the treatment of patients with BCG-unresponsive NMIBC CIS. ANKTIVA's unique mechanism of action activates the body's natural killer cells and killer T-cell immune system to attack tumor cells. It also stimulates memory T cells, leading to long-lasting complete responses.

The podcasts are available for viewing below:

Addressing BCG Supply Shortages, Workflow, and Enhancing Bladder Cancer Treatment through Strategic Partnerships - Patrick Soon-Shiong
https://www.urotoday.com/video-lectures/non-muscle-invasive-bladdercancer/video/mediaitem/4038-addressing-bcg-supply-shortages-workflow-and-enhancing-bladder-cancer-treatment-through-strategic-partnerships-patrick-soon-shiong.html

New Bladder Cancer Treatment: Mechanisms, Clinical Findings, and Implications - Patrick Soon-Shiong
https://www.urotoday.com/video-lectures/non-muscle-invasive-bladdercancer/video/mediaitem/4037-new-bladder-cancer-treatment-mechanisms-clinical-findings-and-implications-patrick-soon-shiong.html

The Triangle Offense: Harnessing NK Cells, T-Cells, and Memory Cells in Bladder Cancer - Patrick Soon-Shiong
https://www.urotoday.com/video-lectures/non-muscle-invasive-bladdercancer/video/mediaitem/4036-the-triangle-offense-harnessing-nk-cells-t-cells-and-memory-cells-in-bladder-cancer-patrick-soon-shiong.html

How ANKTIVA (N-803) Works

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.

N-803 is a novel IL-15 superagonist 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 mimics the natural biological properties of dendritic cells, and drives the generation of memory killer T cells that have specifically been trained to recognize the cancer cells, resulting in activation and proliferation of these killing cells with durable complete response. N-803 has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

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 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, please visit: www.immunitybio.com

Forward Looking Statements

This press release and the publications referred to herein contain 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, commercialization plans and timelines, product availability, potential regulatory pathways and approvals, the regulatory review process and timing thereof, BCG supply shortages and related strategies, market and prevalence data, potential benefits to patients, potential treatment actions for patients, the described mechanism of action and results and contributions therefrom, information regarding ongoing pre-clinical studies and clinical trials, potential future uses and applications of ANKTIVA in additional indications and use in cancer vaccines, methods, the collaboration between ImmunityBio and the Serum Institute of India and expected results therefrom, 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," "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) potential delays in product availability and regulatory approvals, (ii) whether the BCG manufactured by Serum will receive regulatory approval in the U.S. and/or other regions, (iii) the risks and uncertainties associated with commercial launch execution, success and timing, (v) additional risks and uncertainties related to the regulatory submission and review process, (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) ImmunityBio's ability to retain and hire key personnel, (viii) ImmunityBio's ability to successfully develop and commercialize its product candidates and uncertainties around regulatory reviews and approvals, (ix) the risks and uncertainties associated with third party collaborations and agreements, (x) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xi) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (xiii) 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 19, 2024 and the Company's Form 10-Q filed with the SEC on May 9, 2024, 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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