ImmunityBio Announces Permanent J-code (J9028) for ANKTIVA® Is Now Effective

January 6, 2025

CULVER CITY, Calif.--(BUSINESS WIRE)--Jan. 6, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced the unique, permanent Healthcare Common Procedure Coding System (HCPCS) J-code assigned by the Centers for Medicare & Medicaid Services (CMS) for ANKTIVA® (nogapendekin alfa inbakicept-pmln) became effective January 1, 2025. The U.S. Food and Drug Administration (FDA) approved ANKTIVA with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.

Healthcare providers may now use the permanent J-code, J9028 (Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram), when submitting claims for ANKTIVA. J-codes are unique identifiers used by U.S. government and commercial payers, as well as physicians and their office staff, to streamline the billing and reimbursement process for intravesically administered therapies and certain other treatments.

“The unique J-code for ANKTIVA is another milestone in our quest to deliver the next generation of immunotherapy beyond T cell activation and enables patients with bladder cancer to benefit from the power of natural killer (NK) cells,” said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio.

“In approximately 30-40% of patients with NMIBC, standard therapy with BCG will fail, while in 50% of patients who initially respond to BCG, their cancer will come back,” said Richard Adcock, President and CEO of ImmunityBio. “This permanent J-code supports our efforts to increase patient access to ANKTIVA, which in our ongoing QUILT 3.032 study demonstrated a 71% complete response rate in patients with BCG-unresponsive NMIBC CIS, as of November 2024, with a duration of response of up to 54 months.”

Since its launch in May 2024, ANKTIVA has become widely accessible to patients through commercial and government insurance programs (VA, DoD, Medicare). ImmunityBio has secured coverage for over 200 million medical lives through medical reimbursement policies.

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.

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 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 commercial launch activities and market access initiatives, medical insurance coverage and reimbursement, 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) 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, 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 November 12, 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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