ImmunityBio's ANKTIVA® Now Covered By More Than a Dozen Insurance Plans Representing Over 100 Million Lives Within Months of FDA Approval

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- ANKTIVA® reaches U.S. commercial and Medicare insurance coverage milestone within three months of FDA approval
- Global expansion of commercial and clinical bladder cancer programs
  - Filing process initiated with European Medicines Agency (EMA) for regulatory approval of ANKTIVA in European Union countries
  - Global filing for BCG naïve trial initiated (QUILT-2.005) in India
- ANKTIVA Non-Small Cell Lung Cancer (NSCLC) FDA meeting held in June 2024

CULVER CITY, Calif.--(BUSINESS WIRE)--Aug. 12, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX), today announced significant progress in market access, making ANKTIVA® (nogapendekin alfa inbakicept-pmln) widely available to patients through both commercial and government insurance programs. The company also announced plans to expand its bladder cancer program globally, notably in the European Union and India.

Commercial Update

ImmunityBio's commercial team continues to execute on key market access initiatives, which have resulted in more than 100 million medical lives being covered by medical reimbursement policies that include eligibility for ANKTIVA reimbursement since the therapeutic became available and was added to the National Comprehensive Cancer Network (NCCN) guidelines in May 2024. The company anticipates that it will achieve agreements to extend the number of lives covered in the coming months, and is currently working with the top insurance plans and academic institutions in the U.S. to increase ANKTIVA accessibility. This availability and reimbursement together have enabled the first patients to begin receiving ANKTIVA within eight weeks of FDA approval and resulted in initial product revenue for the company primarily in the last 30 days of Q2.

"We are encouraged by the keen interest that physicians are showing in ANKTIVA as a treatment option for their patients with non-muscle invasive bladder cancer with carcinoma in situ (CIS), as well as by our conversations with payers as we see them adding our approved product into their policies," said Richard Adcock, President and CEO of ImmunityBio. "Our team continues to focus on streamlining the processes for bringing this specialty medication to more qualified patients. We are acutely aware that with cancer, every day matters."

European Regulatory Filing

ImmunityBio has begun the filing process for obtaining regulatory approval for ANKTIVA in the European Union (EU) and United Kingdom. The filing will include 30 countries, including 27 in the EU and three in the European Economic Area. The company anticipates completing the submission of the initial EMA filing in Q4 2024.

BCG Naïve Trial Global Expansion

ImmunityBio continues to add U.S. sites to the BCG naïve trial (QUILT-2.005) and enroll patients in the study. Further, the company has received regulatory approval to begin patient enrollment in QUILT-2.005 in India and the necessary medicines have been successfully imported into the country for use in the trial. Additionally, the company plans to submit an application to the South Africa regulatory authorities in Q3 2024 to initiate the QUILT-2.005 trial in that country.

NSCLC FDA Meeting Results

On April 25, 2024, the company announced positive overall survival results of ANKTIVA combined with checkpoint inhibitors in NSCLC from the completed QUILT 3.055 trial. In that trial, the median overall survival was almost double that of standard-of-care chemotherapy in second- and third-line NSCLC patients whose cancer did not respond to checkpoint inhibitors, with or without chemotherapy. After a meeting with the FDA in June 2024 to discuss a path to a registration filing for ANKTIVA plus checkpoint inhibitors for this indication, the company is preparing additional study information responsive to the Agency's input on a NSCLC pivotal trial. ImmunityBio plans a subsequent meeting with the FDA to discuss the study end points for a potential approval on various timelines.

"The approval of ANKTIVA with a first-in-class mechanism of action of activating natural killer cells, CD8 killer T cells, and memory T cells, marks the beginning of a next-generation immunotherapy beyond checkpoint inhibitors," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer at ImmunityBio. "The quest of developing a cancer vaccine by orchestrating the innate and adaptive immune system has begun and we look forward to developing ANKTIVA as the foundation across multiple tumor types and even in subjects without cancer but at high risk such as in Lynch syndrome."

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 event referenced herein may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding commercial launch activities and timing, market access initiatives and insurance reimbursement efforts, global expansion of the QUILT-2.005 clinical trial, regulatory submissions and filings outside of the United States and timing thereof, data and results from clinical trials and potential implications therefrom, commercialization plans and timelines, potential regulatory pathways and approval requests and submissions, FDA meetings, timelines and potential results therefrom, the regulatory review process and timing thereof, potential benefits to patients, potential treatment outcomes 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 and use in cancer vaccines and across multiple tumor types, ImmunityBio's financial condition, 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," "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) the risks and uncertainties associated with commercial launch execution, success and timing, (ii) risks and uncertainties related to the regulatory submission and review process including without limitation outside of the United States, and associated potential delays, (iii) 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, (iv) risks and uncertainties associated with third party collaborations and agreements, (v) ImmunityBio's ability to retain and hire key personnel, (vi) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vii) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (viii) ImmunityBio's ability to successfully commercialize its approved product and product candidates and uncertainties around regulatory reviews and approvals, (ix) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (x) 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 August 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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