ImmunityBio Announces FDA Submissions of Supplemental BLA for NMIBC Papillary Disease and for Expanded Access of ANKTIVA® to Treat Lymphopenia

April 15, 2025

Company to Provide Regulatory, Sales, and Platform Updates at Investor Day including:

- In Q1, the company submitted a supplemental Biologics License Application (sBLA) for use of ANKTIVA® plus Bacillus Calmette-Guérin (BCG) in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) for the indication of papillary disease.
- In Q2, the company submitted to the U.S. Food and Drug Administration (FDA) an Expanded Access Protocol (EAP) for ANKTIVA for the treatment of lymphopenia as a BioShield against the adverse effects of chemotherapy, radiation and checkpoint inhibitors, following authorization of a Regenerative Medicine Advanced Therapy (RMAT) designation for this indication in Q1.
- With a permanent J-code (J9028) awarded in January 2025, ImmunityBio's Q1 2025 ANKTIVA unit sales volume grew 150% over unit sales volume in Q4 2024.
- For the three-month period ended March 31, 2025, ImmunityBio achieved estimated net product revenue of approximately $16.5 million, surpassing net product revenue of $7.2 million in the prior quarter, a 129% quarter-over-quarter increase.
- ANKTIVA sales momentum continues to trend upward in 2025, with sales volume in March representing a 69% increase month-over-month from February.
- Fireside chats with thought leaders covering ImmunityBio's platform to be held during the investor day program.

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 15, 2025--

ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced that it has completed multiple submissions to the FDA including an sBLA for BCG-unresponsive NMIBC in papillary disease and an EAP for ANKTIVA® (nogapendekin alfa inbakicept-pmln) for the treatment of lymphopenia.

Supplemental Biologics License Application (sBLA):

In Q1, ImmunityBio completed the submission to the FDA of an sBLA for the use of ANKTIVA plus BCG in BCG-unresponsive NMIBC in the papillary indication. Subject to regulatory approvals, the addition of the papillary indication expands the patient population benefiting from this therapy beyond the currently approved indication of bladder carcinoma in situ (CIS) with or without papillary disease and allows more patients to avoid the high morbidity and mortality associated with radical cystectomy. The data submitted to the FDA included efficacy results demonstrating durable complete remissions in patients with BCG unresponsive NMIBC papillary disease. In 88% and 82% of subjects, the probability of avoiding surgical removal of the bladder was achieved for as long as 2 and 3 years respectively, following treatment with ANKTIVA plus BCG. The mortality and morbidity associated with a radical total cystectomy is high and this long-term bladder sparing therapy has the potential to provide a significant benefit and quality of life to patients suffering from BCG unresponsive papillary disease.

In a pivotal study published in NEJM Evidence, BCG plus ANKTIVA resulted in a disease-free survival (DFS) rate of 55% at 12 months, 51% at 18 months, and 48% at 24 months in participants with papillary NMIBC. In addition, patients receiving the novel treatment achieved a 93% avoidance of cystectomy (surgical removal of the bladder) with a median follow up of 20.7 months. This combination immunotherapy wherein ANKTIVA rescues BCG efficacy, currently approved in the BCG-unresponsive carcinoma in situ (CIS) indication, may provide an effective therapeutic option for papillary patients who did not respond to BCG alone and face the prospect of a radical cystectomy. 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.

Expanded Access Protocol for ANKTIVA in the Treatment of Lymphopenia:

The company also announced it has submitted to the FDA an EAP to make available ANKTIVA for the treatment of lymphopenia. Lymphopenia is the loss of natural killer cells and T cells, the very cells necessary to fight cancer. To date, no treatment exists to overcome lymphopenia which is induced by the cancer itself and by the standards of care including chemotherapy, radiation, steroids and checkpoint inhibitors. ImmunityBio received designation from the Agency for Regenerative Medicine Advanced Therapy (RMAT) for the indication of ANKTIVA to treat lymphopenia. The EAP, subject to authorization, would provide early access to patients and physicians desiring ANKTIVA in combination with standards of care.

Update of Product Revenue, Net Preliminary Results of Operations:

With the issuance of the permanent J-code (J9028) in January 2025, ImmunityBio has seen increased sales momentum supporting a trend of increases month-over-month as well as quarter-over-quarter, with March unit sales volume increasing 69% over February, and Q1 2025 unit sales exceeding unit sales achieved for all of FY 2024. ImmunityBio earned net product revenue of approximately $16.5 million during the three-month period ended March 31, 2025, which represented an increase of 129% over the $7.2 million of net revenue earned during the fourth quarter of 2024.

The amounts reported in this press release reflect the company's preliminary estimates based solely upon information available to it as of the date of this press release, and the amounts reported are not a comprehensive statement of its financial results or position as of March 31, 2025. Any actual

amounts that the company reports in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, will be subject to its financial closing procedures and any final adjustments that may be made prior to the time its financial results for the period ended March 31, 2025 are finalized. As a result, these preliminary estimates may differ materially from the actual results that will be reflected in the company's consolidated financial statements for the quarter when they are completed and publicly disclosed.

Update on ImmunityBio Platforms

Fireside chats with Dr. Patrick Soon-Shiong and the following Key Opinion Leaders (KOLs) discussing the science and current status of ImmunityBio platforms are expected to take place during the Investor Day program:

- **Dr. Christopher Pieczonka** – Chief Executive Officer, Associated Medical Professionals of New York & Corporate Director of Clinical Research of US Urology Partners
- **Dr. Steven Finkelstein** – National Director of Radiation Oncology, US Urology Partners. Director of the Center of Advanced Radiation Excellence (CARE) and Director Radiation Oncology Research
- **Dr. Mark Lanasa** – Senior Vice President, Chief Medical Officer, Solid Tumors, BeiGene
- **Dr. Jennifer Buell** – President & Chief Executive Officer, MiNK Therapeutics
- **Dr. Krishnansu Tewari** – Gynecologic Oncology, Obstetrics & Gynecology at UC Irvine Health
- **Dr. David Kerr -** Professor of Cancer Medicine Genetics and Genomics, University of Oxford
- **Dr. Timothy Henrich** – Professor, School of Medicine UC San Francisco
- **Dr. Carlos Cordon-Cardo** – Chairman for the Mount Sinai Health System Dept. of Pathology

The live stream can be found at:

https://viavid.webcasts.com/starthere.jsp?ei=1713505&tp_key=40dc7065b5

Participant Listening (Listen Only)

1-844-539-3703 or 1-412-652-1273

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 company's estimated product revenue for Q1 2025 and certain monthly and quarterly sales unit volume and other information regarding operating results and prospects, commercialization activities, momentum and market data, 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, the company'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, the development of therapeutics for cancer and infectious diseases, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, potential future uses and applications of ANKTIVA for the prevention or reversal of lymphopenia, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents across multiple tumor types and indications, potential regulatory pathways and the regulatory review process and timing thereof, potential expansion of patient populations or benefits to patients, potential market sizes, and the application of the Company's science and platforms to treat cancers or develop cancer vaccines, immunotherapies and cell therapies that reduce or eliminate the need for standard high-dose chemotherapy. 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) whether the FDA will accept the sBLA and other regulatory submissions referenced herein for review and filing, (ii) uncertainties regarding the timeline of the FDA's review of these submissions even if accepted for review and filing, (iii) whether the FDA will ultimately approve the sBLA, expanded access protocol or other submissions in a timely matter, or at all, of which there can be no assurance, (iv) risks and uncertainties regarding limited resources at the FDA and potential delays associated therewith, (v) whether the 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, (vi) whether clinical trial data will be accepted by regulatory agencies in support of the submissions referenced herein or otherwise, (vii) the company's financial closing procedures and whether the estimated results reported herein will differ from the results ultimately reported by the company in its quarterly report on Form 10-Q for Q1 2025, (viii) whether the RMAT designation received and previously reported by the company will

lead to an accelerated review or approval, of which there can be no assurance, (ix) risks and uncertainties regarding commercial launch execution, success and timing, and market access initiatives, (x) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (xi) 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, (xii) potential delays in product availability, regulatory approvals, and reimbursement decisions, (xiii) ImmunityBio's ability to retain and hire key personnel, (xiv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xv) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xvi) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xvii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xviii) 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250415357850/en/

Investors
Hemanth Ramaprakash, PhD, MBA
+1-858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Sarah Singleton
+1-415-290-8045
Sarah.Singleton@ImmunityBio.com

Source: ImmunityBio, Inc.