ImmunityBio Reports 700% Year-Over-Year Revenue Growth, Expanded ANKTIVA® Approvals in Lung Cancer and Global Commercial Partnerships in 33 Countries with Label Expansion Plans Globally

February 23, 2026

- **2025 Sales Momentum:** ANKTIVA net product revenue increased 20% quarter-over-quarter, with full-year net product revenue of $113 million, representing an approximately 700% increase year-over-year
- **ANKTIVA Unit Growth:** 750% unit sales volume increase in 2025 compared to 2024
- **Global Approvals in Bladder Cancer:** ANKTIVA in combination with BCG for the treatment of BCG-unresponsive NMIBC CIS with or without papillary tumors is now authorized across four major regulatory jurisdictions: United States, United Kingdom, European Union, and Saudi Arabia encompassing 33 countries in total
- **First Approval for Lung Cancer:** ANKTIVA in combination with checkpoint inhibitors approved by the Saudi Food and Drug Authority (SFDA) for the treatment of metastatic non-small cell lung cancer, with commercial launch planned within 60 days; label expansion plans underway across multiple tumor types and for the treatment of lymphopenia
- **Long Term Patent Protection:** ANKTIVA combinations with checkpoint inhibitors are protected by multiple issued patents, including U.S. Patent Nos. 9,925,247 and 11,071,774, with patent terms extending beyond 2035
- **Commercial Partnerships:** Formed a distribution partnership with Accord Healthcare in the European Union, with an 85-person sales force deployed across 30 countries, and established an Irish subsidiary in Dublin to support the European launch; partnering with BioPharma & Cigalah to expand access to ANKTIVA in Saudi Arabia and, over time, in the Middle East North Africa (MENA) region; formed a Kingdom of Saudi Arabia subsidiary to support KSA launch
- **3-Year Global Strategy: ANKTIVA as a Backbone to the Cancer BioShield Platform:** Growing enrollment in ongoing and planned key clinical trials in BCG-naïve bladder cancer, non-small cell lung cancer (NSCLC), glioblastoma, sepsis, Non-Hodgkin lymphoma, and treatment of lymphopenia

CULVER CITY, Calif.--(BUSINESS WIRE)--Feb. 23, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced full-year 2025 financial and operational highlights, including approximately $113 million in net product revenue for ANKTIVA, representing an approximately 700% increase year-over-year. The Company also reported a 750% increase in unit sales volume and a 20% quarter-over-quarter increase in net product revenue, demonstrating sustained commercial momentum. In parallel, ImmunityBio expanded its global regulatory footprint to 33 countries across four jurisdictions and secured the first approval for ANKTIVA in combination with checkpoint inhibitors for lung cancer.

Global Regulatory Approvals

ANKTIVA in combination with BCG for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS), with or without papillary tumors, is now authorized across four major regulatory jurisdictions encompassing 33 countries:

- **United States:** FDA approval (April 2024)
- **United Kingdom:** MHRA authorization (July 2025)
- **Kingdom of Saudi Arabia:** SFDA accelerated approval for BCG-unresponsive NMIBC CIS (January 2026) and conditional accelerated approval for metastatic NSCLC in combination with checkpoint inhibitors (January 2026), the first jurisdiction globally to authorize ANKTIVA for lung cancer
- **European Union:** European Commission conditional marketing authorization covering all 27 EU member states plus Iceland, Norway, and Liechtenstein (February 2026)

This global regulatory footprint of 33 countries was established in under two years from initial 2024 FDA approval, representing the most rapid international expansion for an immunotherapy in this indication.

First Approval for Lung Cancer and Label Expansion Plans

In January 2026, the SFDA granted conditional accelerated approval for ANKTIVA® in combination with checkpoint inhibitors for the treatment of metastatic NSCLC, making Saudi Arabia the first jurisdiction globally to authorize ANKTIVA outside of bladder cancer. The commercial launch in Saudi Arabia is planned within 60 days of approval. Submissions to multiple additional regulatory authorities (Ex-USA) for accelerated approval are planned for 2026, with discussions with the U.S. FDA regarding an accelerated approval pathway also planned for 2026. The Company is pursuing further label expansion across multiple tumor types and for the treatment of chemotherapy-induced lymphopenia, supported by ongoing clinical trial programs.

Long-Term Patent Protection

Multiple issued patents, including U.S. Patent Nos, protect the combination of ANKTIVA plus checkpoint inhibitor therapy. 9,925,247 and 11,071,774, with patent terms extending beyond 2035. These patents cover the combination of IL-15 receptor agonist therapy with anti-PD-1 and anti-PD-L1

checkpoint inhibitors across multiple tumor types, providing long-term exclusivity protection for ANKTIVA's expanding combination indications.

"In under two years from initial FDA approval, ImmunityBio has built a global commercial footprint spanning 33 countries across four regulatory jurisdictions, with $113 million in full-year net product revenue representing 700% year-over-year growth," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman, and Global Chief Scientific and Medical Officer of ImmunityBio. "The SFDA's accelerated approval of ANKTIVA in combination with checkpoint inhibitors for metastatic NSCLC marks a defining moment for the Company, the first authorization of ANKTIVA beyond bladder cancer and the first validation of its role as a lymphocyte-stimulating agent in solid tumors. We are now pursuing accelerated approvals in multiple additional jurisdictions and engaging with the U.S. FDA on a regulatory pathway for this indication. In parallel, our pipeline spans over 30 active and planned clinical trials across 10 tumor types, including randomized trials in BCG-naïve bladder cancer, first-line NSCLC, glioblastoma, and pancreatic cancer. ANKTIVA's mechanism activating NK cells, CD8+ T cells, and memory T cells without expanding regulatory T cells positions it as a backbone immunotherapy across the oncology landscape, and our expanding patent portfolio protecting these combinations through 2035 and beyond ensures long-term commercial exclusivity."

Commercial Partnerships and Global Infrastructure

ImmunityBio has established strategic partnerships and infrastructure to support the global commercial launch of ANKTIVA:

- **European Union and United Kingdom:** Partnered with Accord Healthcare to deploy over 100 sales, medical, and marketing professionals across 30 countries in the EU, UK, and European Free Trade Association (EFTA) member states. ImmunityBio also established an Irish subsidiary in Dublin to support European distribution and commercialization strategy.
- **Kingdom of Saudi Arabia:** Partnering with BioPharma & Cigalah to expand access to ANKTIVA in Saudi Arabia and, over time, throughout the MENA region. ImmunityBio has formed a KSA subsidiary to support commercial launch operations in the Kingdom.

"Our 2025 financial results reflect the growing clinical adoption of ANKTIVA as a foundational backbone of immunotherapy for bladder cancer," said Richard Adcock, President and CEO of ImmunityBio. "Our partnership with Accord Healthcare deploys over 100 commercial professionals across 30 European countries, and our collaboration with BioPharma & Cigalah positions us for rapid commercial execution in Saudi Arabia and the broader MENA region. With subsidiaries now established in Dublin and the Kingdom of Saudi Arabia, we have the infrastructure to support sustained commercial growth across all 33 countries where ANKTIVA is authorized. As we advance toward initial international commercial activities, we remain focused on disciplined execution: completing enrollment in our BCG-naïve randomized trial with a BLA filing targeted by Q4 2026, expanding the ANKTIVA label into lung cancer and lymphopenia, and converting our 700% revenue growth trajectory into durable, long-term value for shareholders."

3 Year Global Strategy: ANKTIVA as a Backbone to the Cancer BioShield Platform

ImmunityBio is advancing enrollment in ongoing and planned key randomized clinical trials across multiple therapeutic areas, with anticipated submissions of completed single-arm trials as summarized below to implement the 3-year global strategy of ANKTIVA as the backbone in the following protocols:

A. ANKTIVA + Standard of Care

B. ANKTIVA + CAR-NK / M-ceNK

C. ANKTIVA in the Treatment of Lymphopenia

A. ANKTIVA + STANDARD OF CARE

1. Non-Muscle Invasive Bladder Cancer (NMIBC): ANKTIVA + BCG

- **QUILT-2.005 Randomized Trial (BCG-Naïve CIS):** ANKTIVA + BCG; BLA filing targeted by Q4 2026
- **QUILT-3.032 Single Arm Trial (BCG-Unresponsive Papillary):** Response submitted to U.S. FDA regarding additional data for BCG-unresponsive papillary-only NMIBC; awaiting Agency review
- **ResQ133A-NMIBC Single Arm Trial:** Intravesical recombinant Mycobacterium (rBCG) in participants with NMIBC eligible to receive intravesical Tice BCG, addressing the global BCG shortage
- **ResQ132EX-NMIBC Expanded Access:** Expanded access use of rBCG in NMIBC; over 570 patients dosed to date at 58 sites
- **ResQ132 Clinical Trial:** Ablation therapy in participants with intermediate-risk non-muscle invasive papillary bladder cancer
- **Recombinant BCG Regulatory:** Planned submission to SFDA and U.S. FDA meeting scheduled for March 2026

2. Non-Small Cell Lung Cancer (NSCLC): ANKTIVA + Chemotherapy + Checkpoint Inhibitor

- **QUILT-3.055 Single Arm Trial (2L+ NSCLC):** ANKTIVA + checkpoint inhibitor. Accelerated approval by SFDA (January 2026). Planned submissions to multiple regulatory authorities (Ex-USA) for accelerated approval in 2026. Discussions planned with the U.S. FDA in 2026 for the accelerated approval pathway
- **QUILT-2.023 Randomized Trial (1L NSCLC):** ANKTIVA + chemotherapy/checkpoint inhibitor versus chemotherapy/checkpoint inhibitor alone
- **ResQ201A Randomized Trial (2L NSCLC):** ANKTIVA in combination with tislelizumab + 2 cycles of docetaxel versus docetaxel alone

3. Pancreatic Cancer: ANKTIVA + Chemo + CAR-NK

- **QUILT-88 Single Arm Trial (2L+ Metastatic):** ANKTIVA + CAR-NK (PD-L1 t-haNK) + chemotherapy. Clinical trial completed. RMAT Designation granted
- **ResQ108B-PANC Single Arm Trial (Neoadjuvant Locally Advanced 1L):** ANKTIVA + zabadinostat + sotevtamab
- **Planned Randomized Trial (1L Metastatic):** ANKTIVA + CAR-NK (PD-L1 t-haNK) + Abraxane + gemcitabine versus Abraxane + gemcitabine, trial design pending finalization

4. Hepatocellular Carcinoma (HCC): ANKTIVA + Checkpoint Inhibitor

- **Planned 2L+ HCC Randomized Trial:** ANKTIVA + zabadinostat + checkpoint inhibitor

5. Colorectal Cancer: ANKTIVA + Checkpoint

- **ResQ203D-CRC Randomized Phase 3:** Colorectal patients undergoing resection/ablation of colorectal metastases: ANKTIVA + zabadinostat + tislelizumab versus standard of care

6. Multiple Tumor Types: ANKTIVA + Checkpoint Inhibitors

- **QUILT-3.055 Single Arm Trial (2L+ NSCLC and Multiple Tumor Types):** Clinical trial completed. Accelerated approval for advanced NSCLC (SFDA, January 2026). Planned submissions for the expansion of the label in the Middle East, North Africa (MENA), for multiple tumor types

B. ANKTIVA + CAR-NK / M-ceNK-Designated Clinical Trials

1. Pancreatic Cancer: ANKTIVA + CAR-NK

- **QUILT-88 Pancreatic Cancer ANKTIVA + CAR-NK:** 2L+ metastatic pancreatic cancer; ANKTIVA + CAR-NK (PD-L1 t-haNK) + chemotherapy. Clinical trial completed. RMAT Designation

2. Triple Negative Breast Cancer: ANKTIVA + CAR-NK

- **QUILT-3.067 Triple Negative Breast Cancer (TNBC) ANKTIVA + haNK:** Single arm trial. Clinical trial completed
- **Planned Randomized Trial (2L+ TNBC): ANKTIVA + CAR-NK (PD-L1 t-haNK) + Trop2 Antibody**: Trial design pending finalization

3. Glioblastoma: ANKTIVA + CAR-NK

- **QUILT-3.078 Glioblastoma Single Arm Trial (Recurrent) ANKTIVA + +CAR-NK:** CAR-NK (PD-L1 t-haNK) + ANKTIVA + bevacizumab. Enrollment completed
- **Planned Randomized Trial (Neoadjuvant Glioblastoma) ANKTIVA + CAR-NK:** ANKTIVA + CAR-NK (PD-L1 t-haNK) versus standard of care
- **Planned Randomized Trial (2L Recurrent Glioblastoma) ANKTIVA + CAR-NK:** ANKTIVA + CAR-NK (PD-L1 t-haNK) + bevacizumab + TTF versus standard of care

4. Non-Hodgkin Lymphoma: ANKTIVA + CAR-NK

- **QUILT-106 Relapsed Refractory Non-Hodgkin's Lymphoma (iNHL) Single Arm Trial CAR-NK (CD-19 t-haNK):** No lymphodepletion. Relapsed/refractory NHL: CAR-NK (CD19 t-haNK) + rituximab. Enrolling
- **ResQ215A Relapsed Refractory NHL Single Arm Trial ANKTIVA + CAR-NK (CD19 t-haNK):** Lymphodepletion. Flu/Cy + CAR-NK (CD19 t-haNK) + ANKTIVA + rituximab. Enrolling
- **ResQ215B Indolent Non-Hodgkin's Lymphoma (Including Waldenstrom's) Single Arm Trial:** No lymphodepletion. CAR-NK (CD19 t-haNK) + ANKTIVA + rituximab
- **Planned Randomized Trial Relapsed/Refractory NHL:** Lymphodepletion. Flu/Cy + CAR-NK (CD19 t-haNK) + ANKTIVA + rituximab versus Flu/Cy + CAR-NK (CD19 t-haNK) + rituximab

5. Multiple Tumor Types: M-ceNK (World Bank of Natural Killer Cells)

- **NK2022 & NK2023 (Cancer Patients & Healthy Donors):** 64 subjects completed apheresis and M-ceNK manufacturing cell therapy process development for robotic training and future AI robot manufacturing. Cells cryopreserved and stored.
- **QUILT-3.076 Safety Phase 1 of Apheresis and M-ceNK + ANKTIVA Completed:** Solid tumor: apheresis followed by M-ceNK + ANKTIVA. 10 patients treated with autologous M-ceNK infusion
- **ResQ209 Phase 2 Platinum Resistant Ovarian Cancer M-ceNK + ANKTIVA Single Arm Trial:** Ovarian cancer: apheresis followed by M-ceNK + ANKTIVA + gemcitabine

LYMPHOPENIA STRATEGY

1. Sepsis: Community Acquired Pneumonia (CAP): ANKTIVA + iNKT

- **ResQ219-CAP Phase 2 Single Arm Trial (N=20):** ANKTIVA + iNKT. Clinical trial protocol submitted to the FDA. USA trial sites
- **ResQ218-CAP Planned Phase 3 Randomized Trial:** ANKTIVA + iNKT versus standard of care. To be initiated in Saudi Arabia, United States and planned UAE.

2. Radiation-Induced Lymphopenia: ANKTIVA

- Real-World Evidence: Radiation-induced lymphopenia (Completed)
- **ResQ210 Randomized Trial Radiation-Induced Lymphopenia in Biochemical Recurrent and Localized Prostate Cancer:** Radiation alone versus radiation + ANKTIVA. To be submitted.

3. Treatment Induced Infection: Multiple Myeloma: ANKTIVA

- **Planned Single Arm, Relapsed Multiple Myeloma:** Bispecific antibody + ANKTIVA

2025 Financial Highlights

Metric	2025	YoY Change
Full-Year Net Product Revenue	$113M	~700%
Unit Sales Volume	3,745	~750%
Q4 2025 Net Product Revenue	$38.3M	431%

Cash and Marketable Securities Position

As of December 31, 2025, the Company had consolidated cash, cash equivalents, and marketable securities of $242.8 million.

Fourth-Quarter 2025 Financial Summary

Product Revenue, Net

Product revenue, net increased $31.1 million during the three months ended December 31, 2025, as compared to the three months ended December 31, 2024, due to an increase in sales of ANKTIVA, which was approved in April 2024.

Research and Development Expense

Research and development (R&D) expense increased $28.7 million to $63.9 million during the three months ended December 31, 2025, as compared to $35.2 million during the three months ended December 31, 2024. The increase was due to a $14.0 million one-time write-off of fixed assets, higher manufacturing and distribution costs driven by increased production and clinical trial activities, higher license fees, and higher salaries and benefits, partially offset by lower stock based compensation.

Selling, General and Administrative Expense

Selling, general and administrative (SG&A) expense decreased $3.0 million to $38.7 million during the three months ended December 31, 2025, as compared to $41.7 million during the three months ended December 31, 2024. The decrease was due to lower litigation settlement and commercial consulting costs, partially offset by higher headcount costs driven by growing sales and marketing activities.

Net Loss Attributable to ImmunityBio Common Stockholders

Net loss attributable to ImmunityBio common stockholders was $61.9 million during the three months ended December 31, 2025, as compared to $59.2 million during the three months ended December 31, 2024. The increase in loss was primarily driven by higher R&D expense described above, changes in the fair value of a related-party convertible note, and fixed asset write-offs, partially offset by higher product revenue, lower SG&A expense, lower related-party interest expense, and changes in the fair value of warrant liabilities.

Full-Year 2025 Financial Summary

Product Revenue, Net

Product revenue, net increased $98.8 million during the year ended December 31, 2025, as compared to the year ended December 31, 2024, due to an increase in sales of ANKTIVA, which was approved in April 2024.

Research and Development Expense

R&D expense increased $28.4 million to $218.6 million during the year ended December 31, 2025, as compared to $190.2 million during the year ended December 31, 2024. The increase was mainly due to a $14.0 million one-time write-off of fixed assets, higher clinical trial costs, salaries and benefits, and manufacturing costs driven by increased production activities.

Selling, General and Administrative Expense

SG&A expense decreased $18.8 million to $150.0 million during the year ended December 31, 2025, as compared to $168.8 million during the year

ended December 31, 2024. The decrease was primarily driven by lower costs related to litigation settlements and commercial consulting activities, partially offset by higher stock-based compensation expense, recruiting and training expenses, salaries, benefits and commissions, and travel expenses due to growing sales and marketing activities.

Net Loss Attributable to ImmunityBio Common Stockholders

Net loss attributable to ImmunityBio common stockholders was $351.4 million during the year ended December 31, 2025, compared to $413.6 million during the year ended December 31, 2024. This reduction of loss was primarily driven by increased product revenue, lower SG&A expense described above, lower related-party interest expense, and changes in the fair value of warrant liabilities, partially offset by higher R&D expense described above, changes in the fair value of derivative liabilities and a related-party convertible note, an increase in interest expense related to the revenue interest liability, and lower interest and investment income.

ImmunityBio, Inc.

Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
(Unaudited; in thousands, except per share amounts)	**2025**	**2024**	**2025**	**2024**
Revenue				
Product revenue, net	$ 38,272	$ 7,206	$ 112,982	$ 14,150
Other revenues	13	346	306	595
Total revenue	38,285	7,552	113,288	14,745
Operating costs and expenses				
Cost of sales	382	—	753	—
Research and development	60,808	33,657	207,875	182,230
Research and development – related parties	3,049	1,564	10,684	7,914
Selling, general and administrative	37,833	40,680	147,180	165,801
Selling, general and administrative – related parties	896	1,051	2,823	2,982
Total operating costs and expenses	102,968	76,952	369,315	358,927
Loss from operations	(64,683)	(69,400)	(256,027)	(344,182)
Other income (expense), net:				
Interest and investment income, net	2,298	1,187	6,405	7,975
Change in fair value of warrant and derivative liabilities, and related-party convertible note	29,152	46,598	12,714	76,904
Interest expense – related party	(14,843)	(26,020)	(60,886)	(114,588)
Interest expense related to revenue interest liability	(12,299)	(11,503)	(51,540)	(39,657)

Interest expense	(50)	(51)	(99)	(82)
Other (expense) income, net	(1,668)	10	(2,174)	(15)
Total other expense, net	2,590	10,221	(95,580)	(69,463)
Loss before income taxes and noncontrolling interests	(62,093)	(59,179)	(351,607)	(413,645)
Income tax benefit	135	—	135	—
Net loss	(61,958)	(59,179)	(351,472)	(413,645)
Net loss attributable to noncontrolling interests, net of tax	(14)	(17)	(74)	(81)
Net loss attributable to ImmunityBio common stockholders	$ (61,944)	$ (59,162)	$ (351,398)	$ (413,564)
Net loss per ImmunityBio common share – basic	$ (0.06)	$ (0.08)	$ (0.38)	$ (0.59)
Net loss per ImmunityBio common share – diluted	$ (0.06)	$ (0.09)	$ (0.38)	$ (0.62)
Weighted-average number of common shares used in computing net loss per share – basic	989,679	733,204	919,863	697,312
Weighted-average number of common shares used in computing net loss per share – diluted	989,679	734,542	919,863	700,443

ImmunityBio, Inc.

Selected Balance Sheet Data

	As of December 31,	
(Unaudited; in thousands)	**2025**	**2024**
Cash and cash equivalents, and marketable securities	$ 242,818	$ 149,809
Total assets	501,898	382,933
Related-party convertible note payable, at fair value	477,093	461,877
Revenue interest liability	324,615	284,404
Total liabilities	1,001,472	871,062
Total ImmunityBio stockholders' deficit	(500,469)	(489,098)
Total liabilities and stockholders' deficit	501,898	382,933

ImmunityBio, Inc.

Summary Reconciliations of Cash Flows

	Three Months Ended December 31,		Year Ended December 31,	
(Unaudited; in thousands)	**2025**	**2024**	**2025**	**2024**
Cash (used in) provided by:				
Net cash used in operating activities	$ (70,378)	$ (85,144)	$ (304,936)	$ (391,236)
Net cash provided by (used in) investing activities	43,573	9,834	(149,801)	(12,246)
Net cash provided by financing activities	54,894	106,929	400,241	281,630
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	5	(7)	15	(23)
Net change in cash and cash equivalents, and restricted cash	28,094	31,612	(54,481)	(121,875)
Cash and cash equivalents, and restricted cash, beginning of period	61,337	112,300	143,912	265,787
Cash and cash equivalents, and restricted cash, end of period	$ 89,431	$ 143,912	$ 89,431	$ 143,912

About ImmunityBio

ImmunityBio, Inc. is a biotechnology company focused on innovating, developing, and commercializing next-generation immunotherapies designed to activate the patient's immune system and deliver durable protection against cancer and infectious diseases. Our approach harnesses both the adaptive and innate immune systems with the goal of restoring immune function and generating lasting immunological memory in patients. At the core of our strategy is the Cancer BioShield platform, which is designed to stimulate critical lymphocytes, including natural killer (NK) cells, cytotoxic T cells, and memory T cells via our proprietary IL-15 superagonist, ANKTIVA® (nogapendekin alfa inbakicept). Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by a portfolio that includes adenovirus-vectored vaccines, allogeneic (off-the-shelf) and autologous NK-cell therapies, and additional immunomodulators intended to promote immunogenic cell death and support durable immune responses while potentially reducing reliance on high-dose chemo-radiation therapy.

About ANKTIVA

ANKTIVA (nogapendekin alfa inbakicept) is our lead biologic product and a first-in-class IL-15 receptor superagonist antibody-cytokine fusion protein. We are commercializing ANKTIVA for the treatment of BCG-unresponsive NMIBC with CIS, with or without papillary tumors. ANKTIVA has received U.S. Food and Drug Administration (FDA) *Breakthrough Therapy* designation for use in BCG-unresponsive NMIBC with CIS in adult patients with or without papillary tumors.

ANKTIVA is now approved in the U.S., UK, and Saudi Arabia for BCG-unresponsive NMIBC with CIS with or without papillary tumors. In February 2026, the European Commission granted conditional marketing authorization in the EU for ANKTIVA for the same indication. In addition, ANKTIVA is conditionally approved in Saudi Arabia, for use in combination with a CPI, for the treatment of adult patients with metastatic NSCLC whose disease has progressed following standard-of-care therapy. The approved labels highlight ANKTIVA's ability to simultaneously activate NK cells, cytotoxic T cells, and memory T cells.

ANKTIVA in combination with our CAR-NK therapy (PD-L1 t-haNK) has received RMAT designation from the FDA for use in combination with chemotherapy/radiotherapy for reversal of lymphopenia and treatment of relapsed locally advanced or metastatic pancreatic cancer. Separately, the FDA has authorized an EAP for ANKTIVA to treat lymphopenia in adult patients with refractory or relapsed solid tumors, regardless of tumor type, who have progressed following first-line standard-of-care treatment, including chemotherapy, radiation, or immunotherapy. The EAP includes patients with solid tumors who have failed first-line therapy and have a low ALC (ALC <1,000/μL).

Important Safety Information

INDICATION AND USAGE:

ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated 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.

WARNINGS AND PRECAUTIONS: Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the development of muscle-invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA® with BCG, reconsider cystectomy.

DOSAGE AND ADMINISTRATION: For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes.

USE IN SPECIFIC POPULATIONS: Pregnancy: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact ImmunityBio at 1-877-ANKTIVA (1-877-265-8482).

Please see the full Prescribing Information for ANKTIVA at www.anktiva.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, without limitation, statements regarding future operating results and prospects, global commercialization activities and expansion efforts and anticipated timelines, sales momentum and growth, market data, market access initiatives and coverage under medical reimbursement policies, the potential that approval in the European Union and entering into a commercial distribution agreement with a partner covering that territory may lead to increased revenue, the potential that approval in Saudi Arabia may lead to regulatory approvals throughout the broader MENA region, the potential that entering into a commercial distribution agreement with a partner covering Saudi Arabia and MENA may lead to increased revenue, continued efforts regarding clinical trial enrollment for various global trials, the Company's submission of further data to FDA regarding the use of ANKTIVA for BCG unresponsive NMIBC papillary disease only, 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 for the reversal of lymphopenia and use in combination with checkpoint inhibitors, in combination with our CAR-NK therapy (PD-L1 t-haNK), or 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 the FDA regulatory submissions, filings, and review processes and the timing thereof, as well as other global regulatory agencies; (iii) the risk that the FDA may require additional data, analyses, or clinical studies, including randomized or controlled trials, or may not agree with the Company's interpretations of clinical results; (iv) the risk that prior or future regulatory feedback, meeting discussions, or communications may not result in a path to approval on the timelines anticipated or at all; (v) the risk that real-world experience may differ from results observed in clinical trials; (vi) ImmunityBio's ability to submit the regulatory submissions referenced herein on the anticipated timeline or at all; (vii) foreign currency fluctuations, geopolitical or economic conditions in the region, and other risks related to international commercialization of an innovative biologic product; (viii) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials; (ix) whether clinical trials will result in registrational pathways; (x) whether clinical trial data will be accepted by regulatory agencies; (xi) risks and uncertainties regarding changes in personnel at the FDA and limited resources at the FDA and potential delays associated therewith; (xii) 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; (xiii) potential delays in product availability and regulatory approvals; (xiv) ImmunityBio's ability to retain and hire key personnel; (xv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates; (xvi) potential product shortages or manufacturing disruptions that may impact the availability and timing of product; (xvii) risks and uncertainties associated with third-party collaborations and agreements; (xviii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products; and (xix) 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, the Company's Form 10-Q filed with the SEC on November 5, 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.

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