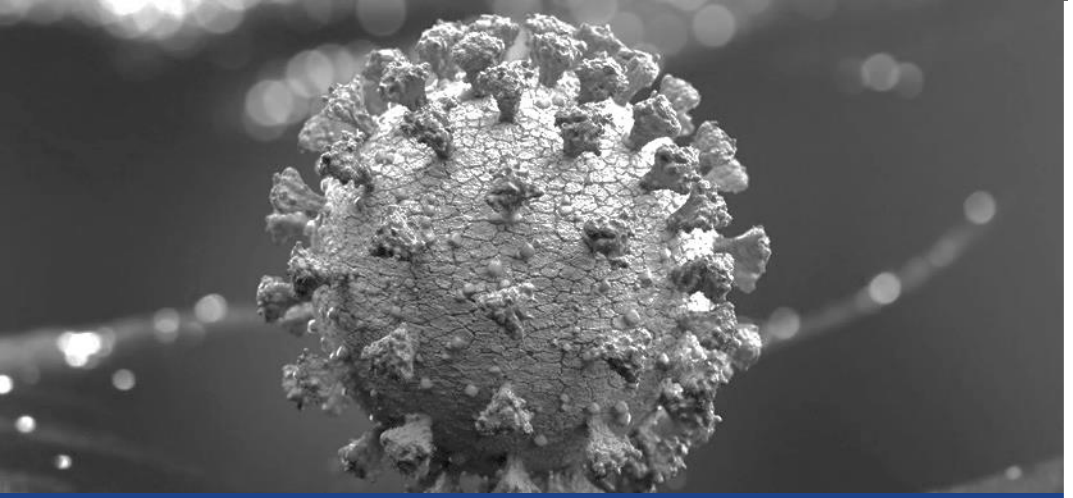
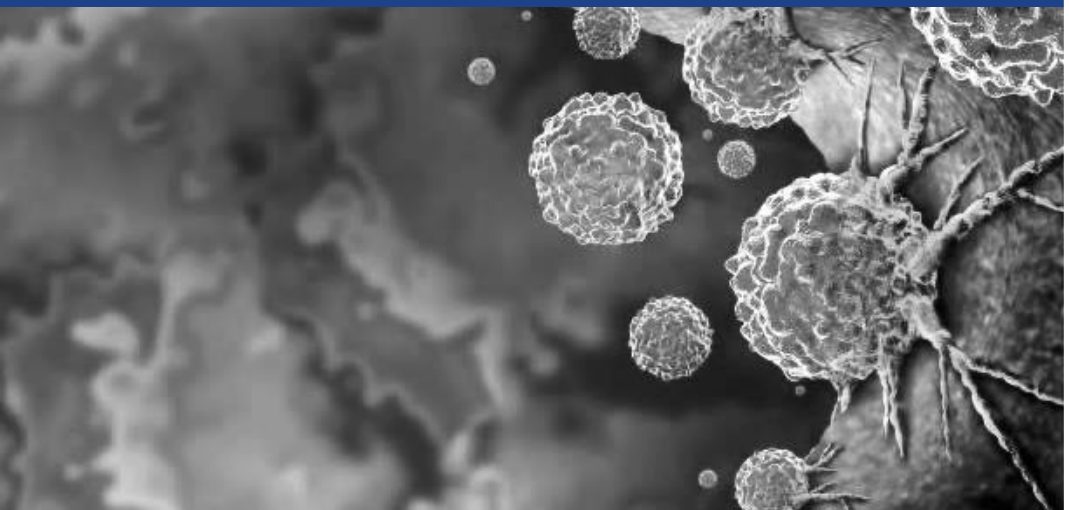


ImmunityBio®



ImmunityBio Investor Presentation

November 2026

Forward-Looking Statements and Intended Use

This presentation and the accompanying verbal remarks 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, including product availability and shipments, potential regulatory pathways and approval requests and submissions, FDA and other regulatory agency meetings, timelines and potential results therefrom, global expansion efforts, strategic collaborations and expected results therefrom, the regulatory review process and timing thereof, market and prevalence data, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, information regarding potential benefit to patients, 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, methods, 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, review and approval process, (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) potential delays in product availability and regulatory approvals, (v) risks and uncertainties associated with third party collaborations and agreements, (vi) whether ImmunityBio's and/or its collaborators' investigational agents will receive regulatory approval in the U.S. and/or other regions, (vii) ImmunityBio's ability to retain and hire key personnel, (viii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (ix) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (x) ImmunityBio's ability to successfully commercialize its approved product and product candidates and uncertainties around regulatory reviews and approvals, (xi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xii) 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 February 23, 2026 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.

Our product candidates are investigational agents that are restricted by federal law to investigational use only. Except as set forth in specific product approvals, safety and efficacy have not been established by any agency, including the FDA.

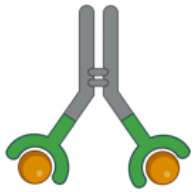
This presentation contains references to our trademarks and trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this presentation, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us, by any other companies.

This presentation is intended to provide a company overview and is intended for investor use only. It is not promotional and should not be used with patients or health care professionals.

ImmunityBio Platforms

Immunotherapy 2.0: Cytokines + Vaccine + Cellular Therapy Platforms

Fusion Proteins



NK & T Cell Activator
Memory T Cell

ANKTIVA

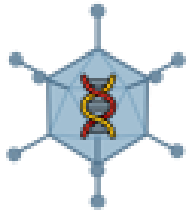
In-Vivo Lymphocyte Rescue

NMIBC CIS
US FDA Approved 2024
UK MHRA Approved 2025
EU EMA Conditional Authorization 2026
Israel Ministry of Health Approved 2026

NMIBC Papillary
US FDA Approved 2026
UAE Approved 2026

NMIBC CIS & NSCLC
Saudi FDA Approved 2026
UAE Approved 2026

DNA Vaccine



Adenovirus (hAd5)

hAd5 CEA, MUC1, Brachyury

hAd5 PSA

hAd5 HPV

In-Vivo Lymphocyte Education

Phase 2

Cellular Therapy

CAR-NK



Off-The-Shelf
CAR-NK

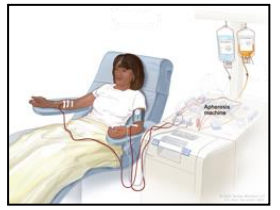
PD-L1 t-haNK

CD19 t-haNK

Ex-Vivo Lymphocyte Rescue

Phase 2

Apheresis



Ex-Vivo Cytokine Proliferation

M-ceNK

Ex-Vivo Lymphocyte Rescue

Phase 2

NASDAQ:IBRX - A Comprehensive Immunotherapy Company with Platforms Orchestrating Natural Killer, CD4+, CD8+ Killer T Cells and Memory T Cells for Durable Complete Responses Across Multiple Tumor Types

IL-15: Immunotherapy 2.0: The Potential Next Blockbuster From Treating Cancer Across Multiple Tumor Types to Lymphopenia to Sepsis to Cancer Vaccine

IL-15 Backbone to Checkpoint Inhibitors

19

Tumor Types Approved for Keytruda

Keytruda is FDA-approved in 19 tumor types across 44 indications, yet only about 1 in 5 patients with advanced cancer responds to a checkpoint inhibitor. ANKTIVA + CPI patent term 2035 / 2037

Keytruda (pembrolizumab) US Prescribing Information, Merck, 2026; Haslam et al., Int J Cancer, 2025 ImmunityBio US Patent Nos. 9,925,247, 11,071,774, 12,318,432, 11,992,516

Lymphopenia

1 in 5

US Adults ~54 million

1 in 5 U.S. adults has a low lymphocyte count (ALC ≤1,500/μL), and it is associated with a 30% higher risk of death.

Zidar et al., JAMA Network Open, 2019

Sepsis

1.7 Million

Sepsis Annually 350,000 Deaths

At least 1.7 million U.S. adults develop sepsis each year, and at least 350,000 die in hospital or are discharged to hospice.

Centers for Disease Control and Prevention, About Sepsis; underlying data from Rhee C, et al. JAMA. 2017;318(13):1241-1249.

Cancer Vaccine

1 in 279

US Adults w/ Lynch Syndrome 1.2 million Americans

1 in 279 people carries a Lynch syndrome mutation, roughly 1.2 million Americans with lynch syndrome.

Win et al., Cancer Epidemiology, Biomarkers & Prevention, 2017

IL-15, a NK and T Cell Growth Factor

2025-2026 ANKTIVA Growth*

	Indication	Agent	Progress	Status
NMIBC	**BCG Unresponsive CIS with or without Papillary**	**ANKTIVA + BCG**	• ~700% Revenue Growth with J-Code and NCCN Guidelines • Approved in UK / MHRA; EMA (Feb 2026); Israel (Nov 2026) • Saudi FDA Approved Jan 2026 (NMIBC + NSCLC) • UAE Approved July 2026 (NMIBC + NSCLC)	✅ ✅ ✅ ✅
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ANKTIVA (nogapendekin alfa inbakicept) Best-in-Class Duration of Response in BCG Unresponsive NMIBC Representing Overall Cost-Benefit Value

Nadofaragene	Pembrolizumab	ANKTIVA
DURATION	DURATION	DURATION
9.7	16.2	53+*
Months	Months	Months & Ongoing
		Median Not Reached



DURATION is the key efficacy element to avoidance of cystectomy and represents overall cost-benefit value

Data from Individual Registration Trials and Package Inserts with No Direct Comparisons of Trials
Data from each respective FDA Approved product label

* N=77, FDA Label

NMIBC Key Highlights

Anktiva®
(nogapendekin alfa inbakicept-pmln)

- **84%** of patients who responded to ANKTIVA were able to keep their bladders at 36 months[1, 2] (n=100)
- **71%** of study participants had a complete response, meaning their cancer was eliminated[1] (n=100)(95% CI=61.1,79.6)
- **53+** Months Duration of Response, meaning some study participants remained NMIBC-free for over 4 years[1]
- **99%** Disease-Specific Overall Survival at 36 Months[1, 2]

1. Chang, S. (2025, April 26-29). An Update on QUILT-3.032: Durable Complete Responses to NAI (ANKTIVA) Plus BCG Therapy in BCG-Unresponsive CIS With or Without Ta/T1 Papillary Disease and in Papillary Disease without CIS. [Conference Presentation]. AUA2025, Las Vegas, Nevada, United States.
2. These data on time to cystectomy and disease specific survival represent prespecified secondary endpoints in QUILT-3.032. These results should be interpreted with caution and in the context of the study's limitations of a single-arm study.

ANKTIVA Commercial Progress Since Launch

1. ANKTIVA Approval April 2024



2. Anktiva Launched May 2024

3. NCCN Guidelines May 2024

4. J-Code 9028, Effective Jan 2025

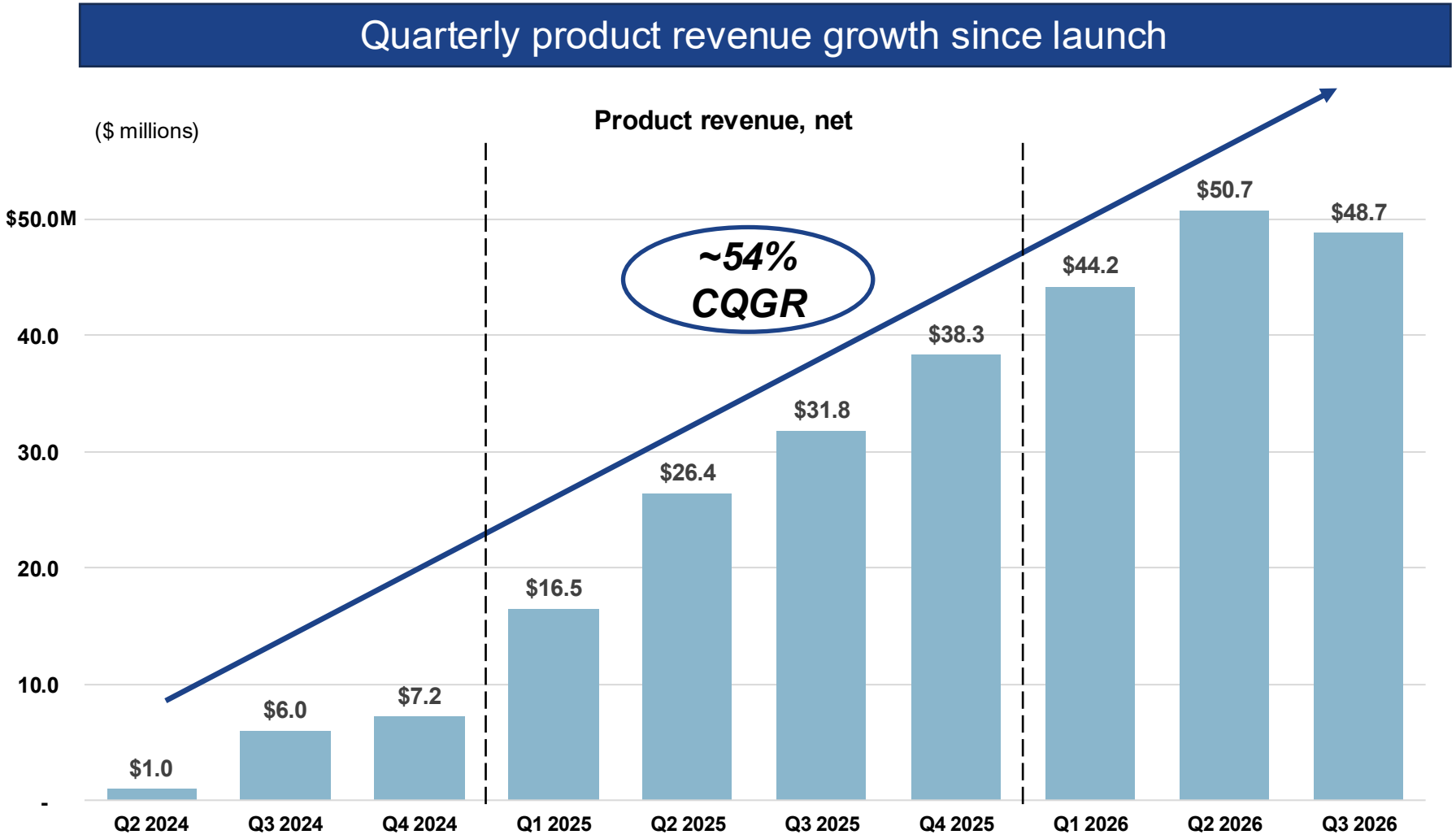
5. Global Approvals:
   - UK July 2025:
   - EU EMA Approved Feb 2026:
   - Saudi Arabia Jan 2026:
   - UAE July 2026:
   - Israel Nov 2026:

Comprehensive Market Access

Florida Blue · VA | U.S. Department of Veterans Affairs · CVS caremark · cigna healthcare · EXPRESS SCRIPTS® · KAISER PERMANENTE® · United Healthcare · CENTENE® Corporation · Horizon · HIGHMARK. · Humana · HCSC Health Care Service Corporation · ucare · Anthem · of Tennessee · Independence · Optum · Blue Cross Blue Shield of Michigan · Elevance Health · EmblemHealth · BlueCross BlueShield of North Dakota · aetna® COVENTRY® · Blue Cross Blue Shield of Hawai'i · BlueCross BlueShield of North Carolina · BlueCross BlueShield of Alabama · BlueCross BlueShield Minnesota

Continued Commercial Execution with Substantial Growth Potential

Quarterly Product Revenue Growth



Anktiva®
(nogapendekin alfa inbakicept-pmln)

2024

BCG Unresponsive NMIBC, CIS with or without Papillary

- FDA Approval
- NCCN Guidelines Category 2A
- MHRA, EMA, SFDA, UAE, Israel Approval

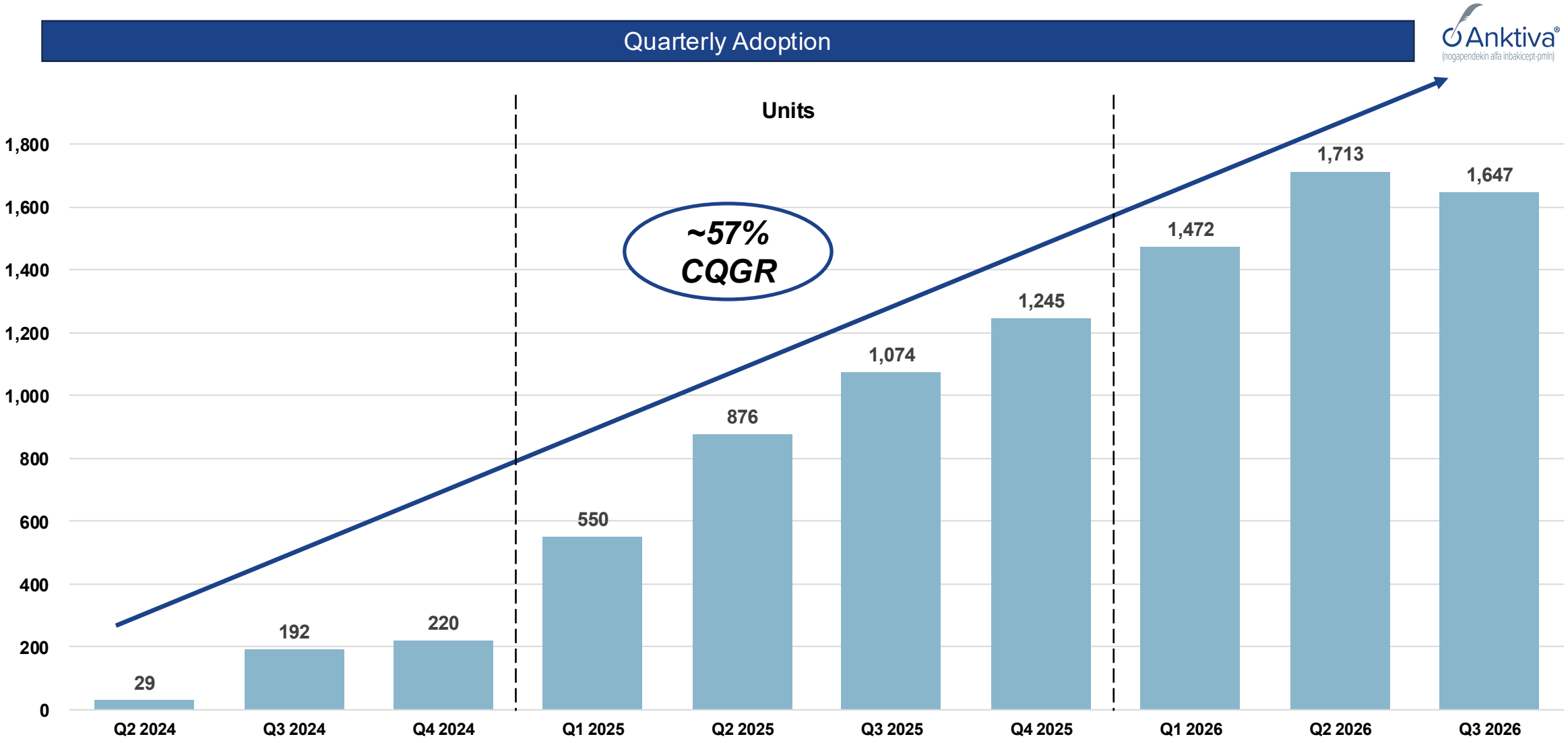
2026

BCG Unresponsive NMIBC

- FDA and UAE Approval
- NCCN Guidelines Category 2A

Continued Commercial Execution with Substantial Growth Potential (Contd.)

Quarterly Unit Volume Growth Since Launch

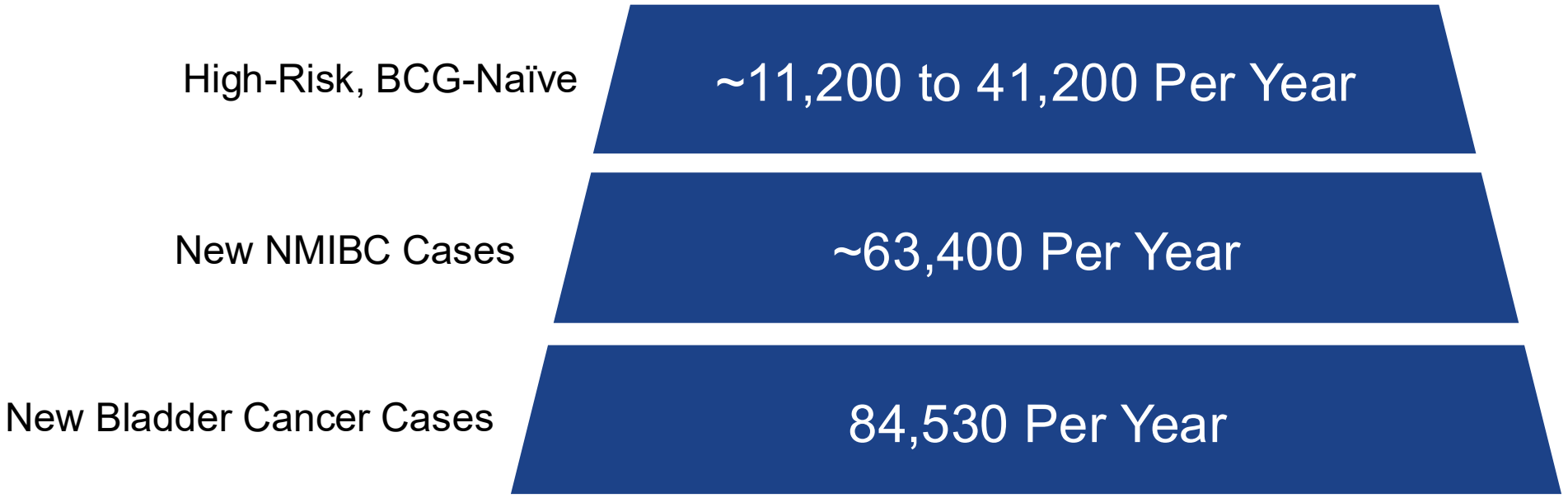


BCG Naïve Opportunity to Increase NMIBC Market for ANKTIVA

BCG Naïve | **ANKTIVA + BCG vs BCG Alone**

- Enrollment Complete Feb 2026 (N=370)
- Primary Endpoint Met Nov 2026
- Significant Difference Between ANKTIVA plus BCG vs BCG Alone (P=0.01)
- Supplemental BLA Filing on Track for Q4 2026

US NMIBC Patient Funnel



Supplemental BLA Planned Q4 2026

Significant Difference (P=0.01)* Between BCG Alone Versus BCG Plus ANKTIVA

First-in-Class Intravesical Chemotherapy-Free IL-15 Receptor Agonist

All figures are annual US estimates of newly diagnosed patients. New NMIBC (63,400) is 75% of new bladder cancer cases and includes low-risk patients who do not receive BCG. High-risk range reflects published shares of 17.6% to 65%. QUILT-2.005 Cohort A enrolled BCG-naïve, high-grade CIS with or without papillary tumors, an estimated 1,300 to 4,700 patients per year (11.4% of the high-risk tier; assumption). sBLA submission is planned and has not been filed. Sources: ACS Cancer Statistics 2026; Grabe-Heyne et al., Front Oncol 2023; Seo and Langabeer 2018 (SEER); AQUA Registry, ASCO 2024 abstract e16607; SEER-Medicare, Clin Genitourin Cancer 2026; ImmunityBio press release, November 9, 2026. * Data on File

ANKTIVA + BCG in the NMIBC BCG Naïve Setting Durable Complete Response and Disease Free ≥ 9.5 Years

QUILT-205 (Phase Ib/II) Trial[1, 2]

- **Complete Response and Disease Free in 9 out of 9 (100%) 2-year trial**
- 6 out of 9 were evaluable in 2023
- 2 subjects died of natural causes independent of bladder cancer
- 1 lost to follow up
- All 6 out of 6 (100%) remain in complete response (CIS) or disease free (Papillary) for >9.5 years
- **All 6 patients avoided cystectomy for >9.5 years**

As of 2024

6 out of 6 (100%) Remain Disease Free

≥ 9.5 Years

Conclusion: ANKTIVA + BCG in BCG Naïve Patients Results in Durable Complete Response and Adverse Events Consistent with BCG Alone

1. Adapted From Rosser CJ, et al., Safety, Tolerability, and Long-Term Clinical Outcomes of an IL-15 analogue (N-803) Admixed with Bacillus Calmette-Guérin (BCG) for the Treatment of Bladder Cancer. Oncoimmunology. 2021 May 2. Data on File

Video

BCG + ANKTIVA: Durable Response



Pivotal Phase 3 Trial of ANKTIVA in NMIBC BCG Naïve Enrollment Complete – Full Accrual Achieved Feb 2026

Trial Design

BCG Alone N=188 **vs.** **ANKTIVA + BCG N=188**

FDA Randomized Control Trial Cohort A

FDA Requested Interim Analysis (n=43)

BCG Alone 52% CR **vs.** **ANKTIVA + BCG 84% CR**

Data on File, BLA Submission at 9 months, FDA Interim Analysis Requested

Status Update

- **Primary Endpoint Met**
- **sBLA on Track for Q4 Filing**

Significant difference (P=0.01) in efficacy in BCG naïve subjects receiving ANKTIVA plus BCG versus BCG alone

Potential Courses of Treatment in BCG Naïve Same as Current FDA Label for BCG Unresponsive (Up to 36 Doses Over 37 Months)

Tokyo Strain of BCG: Second Potential U.S. BCG Source

1 **ImmunityBio Holds the U.S. IND**

Exclusive U.S. Development and Supply Agreement with Japan BCG Laboratory (May 2026). ImmunityBio is the sole U.S. BLA applicant.

2 **FDA Meeting in December 2026**

Meeting to define the U.S. regulatory path for intravesical Tokyo-172 BCG.

3 **Phase 3 SWOG S1602: Non-Inferior to TICE BCG**

NCI-sponsored randomized trial in 984 eligible patients with BCG-naïve high-grade NMIBC.

SWOG S1602 Phase 3 Results

Endpoint	Tokyo-172 (n=327)	TICE (n=330)
5-Year High-Grade RFS	**64%**	58%
High-Grade RFS Events	**104**	130
CIS Complete Response at 6 Months	**66.4%**	70.2%

Hazard Ratio 0.82

95.8% CI 0.63 to 1.08; non-inferiority margin 1.34

Conclusion: Tokyo-172 BCG Met Non-Inferiority to TICE BCG in a Randomized Phase 3 Trial

Tokyo strain of BCG is investigational in the United States and has not been approved by the FDA. Grade 3 to 4 adverse events were more frequent with Tokyo-172 than with TICE. RFS, recurrence-free survival.
Sources: Svatek RS, et al. SWOG S1602 (NCT03091660), 2026 ASCO Genitourinary Cancers Symposium, Abstract LBA629; ImmunityBio press release, May 16, 2026.

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Cancer Vaccine	**Lynch Syndrome**	**ANKTIVA + Ad CEA, MUC1, Brachyury**	• Phase 2b Randomized • Fully Enrolled	✅ ✅

Addressing Alternative Source of BCG

FDA Authorized Expanded Access Program for rBCG (Feb 2025)

Addressing BCG Shortage

ImmunityBio, Serum Institute of India Agree on an Exclusive Arrangement for Global Supply of Bacillus Calmette-Guerin (BCG) Across All Cancer Types

Thursday, May 2, 2024

- Collaboration will result in BCG manufacture at large scale for use in combination with ANKTIVA®, ImmunityBio's recently approved treatment for non-muscle invasive bladder cancer (NMIBC)



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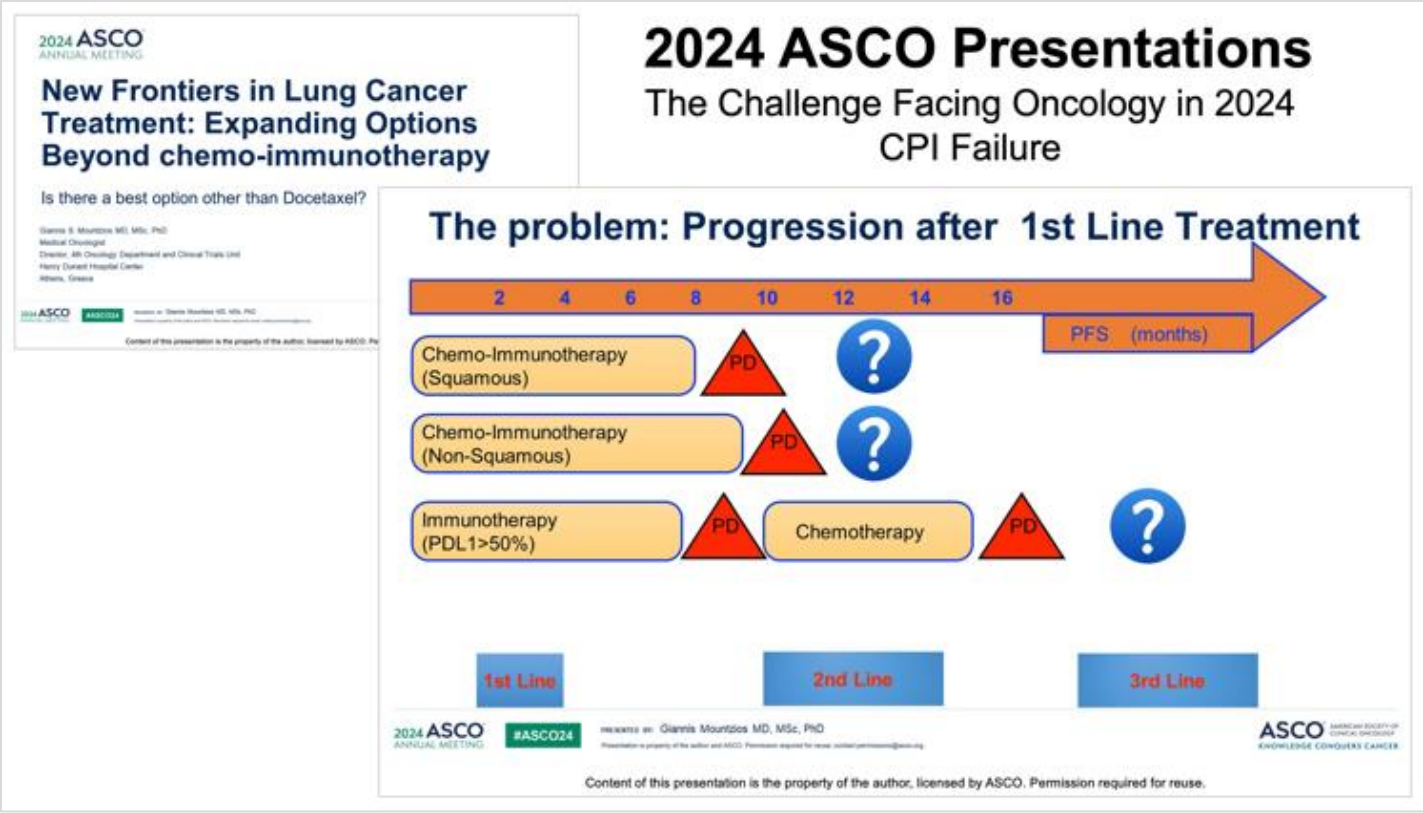
Checkpoint (CPI) Failures in Lung Cancer: The Oncology Challenge in 2025



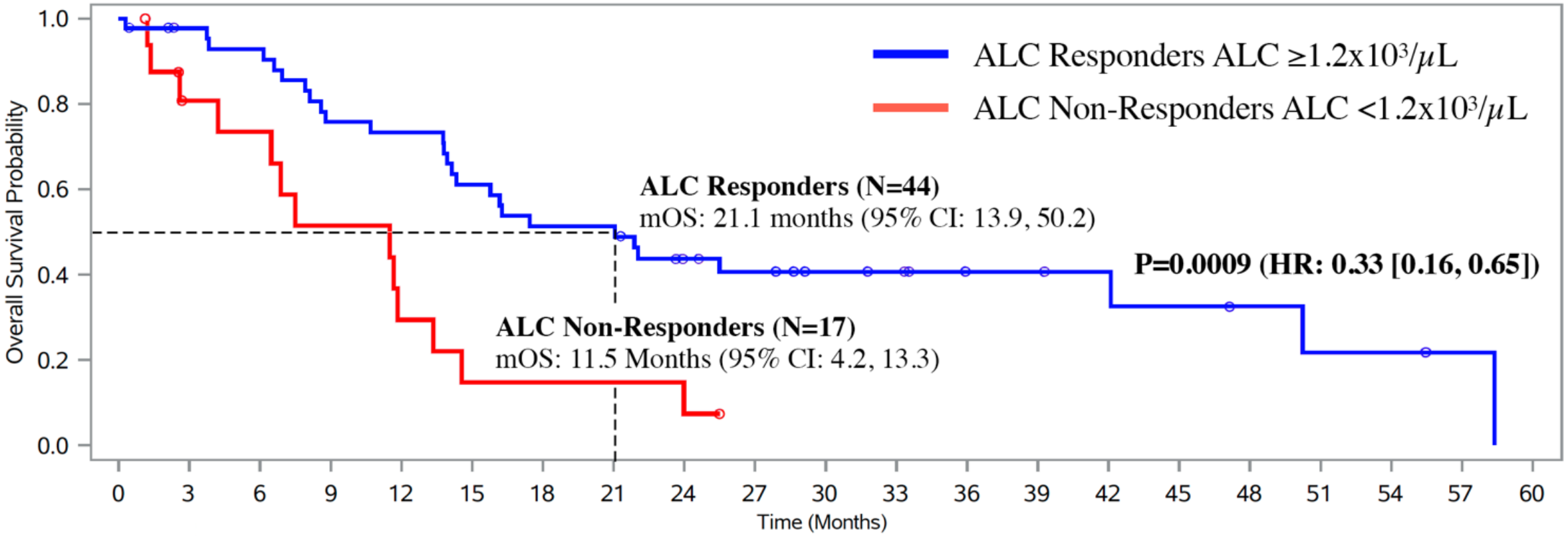
NSCLC: Current SOC patients progressing after checkpoint therapy +/- chemotherapy have a dismal prognosis

- Overall survival ≤ 10 months
- Treatment options are limited
- NCCN does not recommend retreatment with checkpoint therapy after checkpoint failure

The challenge facing oncology in 2024: CPI Failures

The Potential Role of IL-15 in Combination with Checkpoints

QUILT-3.055: Restoration and Maintenance of ALC Correlated with Prolonged Overall Survival in 2L and 3L+ NSCLC



Video

QUILT-2.023: Prolonged Survival



World's First Approval for Immunotherapy 2.0 in NSCLC Activation of NK and T Cells in Lung Cancer: ANKTIVA + Checkpoint Inhibitor

ImmunityBio®

NEWS RELEASE

Saudi FDA Grants Accelerated Approval to ImmunityBio's ANKTIVA® In Combination with Checkpoint Inhibitors for Metastatic Non-Small Cell Lung Cancer

- ANKTIVA, in combination with an immune checkpoint inhibitor, has received accelerated approval from the Saudi Food and Drug Authority for the treatment of metastatic non-small cell lung cancer, marking the first approval in the world of a subcutaneously administered IL-15 receptor superagonist that restores immune competence
- ANKTIVA + checkpoint inhibitor represents the first approved chemotherapy-free immunotherapy that activates both natural killer cells and killer T cells, heralding the era of immunotherapy 2.0
- Accelerated approval was granted following SFDA review of clinical data from QUILT-3.055 in second-line and greater NSCLC patients and QUILT-2.023 in first-line NSCLC demonstrating significant immune restoration and a consistent association between lymphocyte recovery with improved survival in checkpoint-experienced patients
- Newly approved therapy supports ImmunityBio's mission to provide access to patients globally who could benefit from this chemotherapy-free combination treatment

CULVER CITY, Calif., January 14, 2026 – ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage

Non-Small Cell Lung Cancer (NSCLC):

Therapeutic indication:

ANKTIVA is indicated in combination with immune checkpoint inhibitors for the treatment of adult patients with metastatic NSCLC with disease progression on or after standard of care (immune checkpoint inhibitors alone or in combination with chemotherapy). Patients with actionable genomic alteration should have disease progression on approved therapy for these alterations, before using ANKTIVA in combination with immune checkpoint inhibitors.

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Lymphopenia	**Solid Tumors (ALC)**	**ANKTIVA**	• Expanded Access Program Granted By the FDA	✅
	Sepsis: Lymphopenia Rescue	**ANKTIVA vs SOC**	• FDA Authorized, Phase 1b/2 Open Label Randomized • Sites Initializing	✅ ✅
Cancer Vaccine	**Lynch Syndrome**	**ANKTIVA + Ad CEA, MUC1, Brachyury**	• Phase 2b Randomized • Fully Enrolled	✅ ✅

Standard of Care
Destroys the Very Cells that Kill Cancer

Lymphopenia and Low ALC Results in Reduced Overall Survival

The Longstanding Recognition of the Impact of Global Lymphopenia (NK and T Cells) on Relapse Free Survival and Overall Survival in Patients with Solid Tumors Across All Tumor Types

2019

Ménétrier-Caux *et al. Journal for ImmunoTherapy of Cancer* (2019) 7:85
https://doi.org/10.1186/s40425-019-0549-5

Journal for ImmunoTherapy of Cancer

REVIEW Open Access

Lymphopenia in Cancer Patients and its Effects on Response to Immunotherapy: an opportunity for combination with Cytokines?

Christine Ménétrier-Caux[1,2*], Isabelle Ray-Coquard[3], Jean-Yves Blay[1,3†] and Christophe Caux[1,2†]

The potential of a lymphocyte stimulating agent in combination with SOC to overcome lymphopenia

Table 1 Different published studies exploring the impact of the global lymphopenia or NK and T cell subsets on relapse-free survival (RFS) or overall survival (OS) in patients with solid tumors

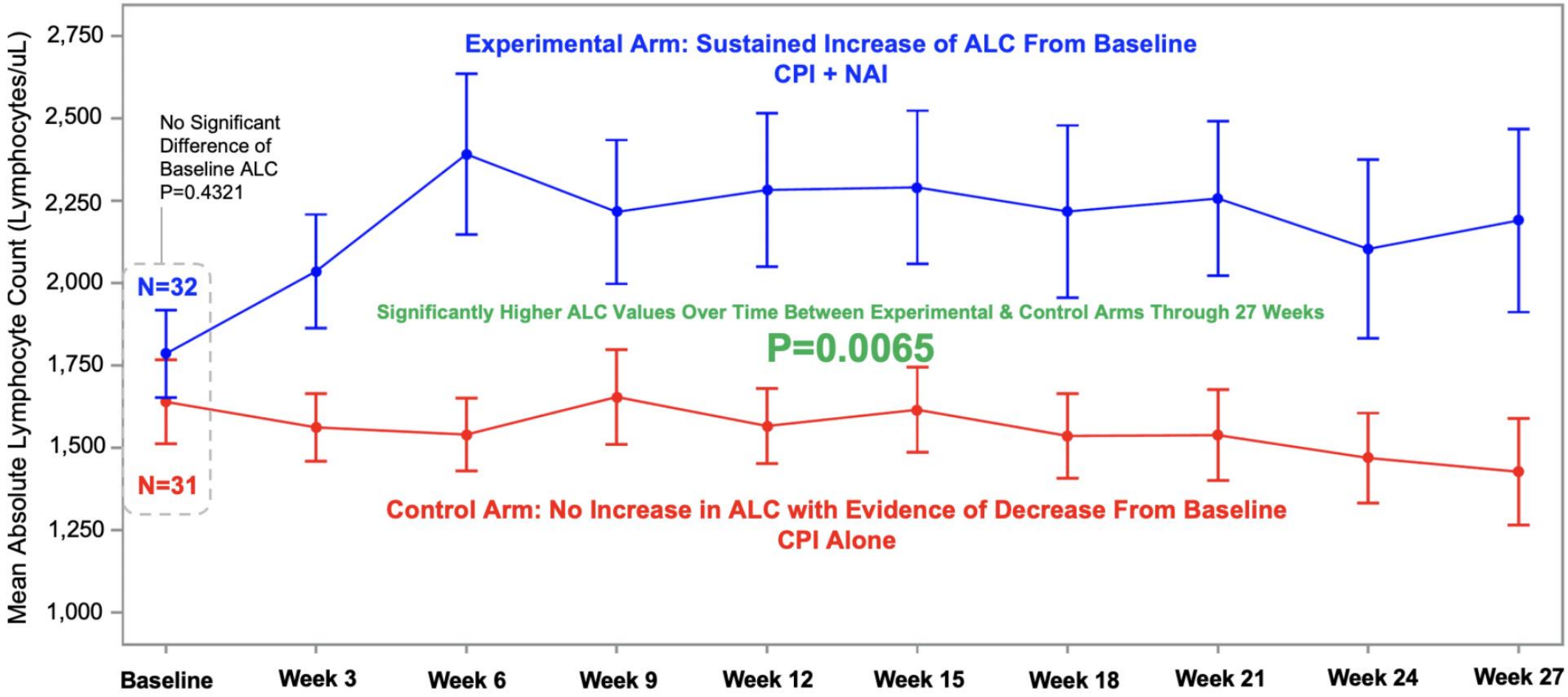
Tumor Type	N	Type of lymphopenia evlauated	Lymphocyte Threshold (% lymphopenia)	RFS (Cox Analysis)			OS (Cox Analysis)			References
				RR	IC 95%	P value	RR	IC 95%	P value	
Sarcoma	193	Overall Lymphopenia	<1000 (24%)	Not evaluated			1.46	1.0-2.1	0.05	[68]
Ewing Sarcoma	24	Overall Lymphopenia	<500 (33%)	Not evaluated			4.34	1.35-14.28	0.007	[75]
Renal Cell Carcinoma	424	Overall Lymphopenia	≤1300 (28.06%)	Not evaluated			1.75	1.14-2.67	0.0102	[65]
Colon Carcinoma	260	Overall Lymphopenia	<1000 (19%)	1.56	1.0-2.43	0.048	2.35	2.34-4.14	0.003	[66]
Breast Carcinoma	195	Overall Lymphopenia	<1000 (28.7%)	1.82	1.27-2.59	0.001	2.23	1.36-3.65	0.001	[89]
Non Hodgkin Lymphoma	322	Overall Lymphopenia	<1000 (25%)	1.71	1.2-2.4	0.002	1.48	1.03-2.21	0.04	[68]
Diffuse large B cell lymphoma (DLBCL)	151	Overall Lymphopenia	≤1000 (35.8%)	Not evaluated			2.38	1.29-4.34	0.005	[90]
DLBCL	221	Overall Lymphopenia	<1000 (38.9%)	2.72	1.61-4.60	<0.001	2.51	1.38-4.58	0.003	[80]
DLBCL	89	Overall Lymphopenia	<840 (23%)	3.81	1.72-8.42	0.0009	4.38	1.88-13.28	0.0012	[79]
Follicular Lymphoma	228	Overall Lymphopenia	≤1000 (28%)	Not evaluated			1.72	1.33-2.24	$<10^{-4}$	[70]
Hodgkin Lymphoma	476	Overall Lymphopenia	<600 (18.06%)	1.59	0.96-2.58	0.06	1.25	0.74-2.15	0.4	[82]
Hodgkin Lymphoma	2497	Overall Lymphopenia	<600 (11%)	1.38		0.002	Not evaluated			[81]
Multiple Myeloma	537	Overall Lymphopenia	<1400 (62%)	Not evaluated			1.71	1.53-2.35	$<10^{-4}$	[92]
ATLL	60	Overall Lymphopenia	<1000 (35.6%)	1.93		0.004	2.37		0.0003	[93]
PTCLU	69	Overall Lymphopenia	<1000 (38%)	Not evaluated			4.0	1.9-8.3	$<10^{-4}$	[71]
PTCL-NOS	118	Overall Lymphopenia	1000 (30.5%)	1.94	1.19-3.18	0.008	2.24	1.33-3.78	0.002	[72]
Breast Carcinoma	287	Overall Lymphopenia	<1000 (27%)	1.48	1.1-2.0	0.01	1.8	1.3-2.4	0.0002	[68]
Breast Carcinoma	195	Overall Lymphopenia	<1000 (28.7%)	1.82	1.27-2.59	0.001	2.23	1.36-3.65	0.001	[89]
Breast Carcinoma 1st relapse	128	Overall Lymphopenia	<1000 (44.27%)	Not evaluated			1.8	1.15-2.82	0.01	[50][b]
Breast Carcinoma 1st relapse 1st relapse	103	Overall Lymphopenia	<700 (22.3%)	Not evaluated			2.03	1.17-3.50	0.016	[21][b]
Breast Carcinoma 1st relapse 1st relapse	103	$CD4^+$ Lymphopenia	≤450 (53.4%)	Not evaluated			2.50	1.57-3.98	$<10^{-4}$	[21][b]
Breast Carcinoma >2nd relapse	101	$CD4^+$ Lymphopenia	≤450 (70.3%)	1.35	0.87-1.1	0.183	1.69	1.04-2.78	0.036	[21]
Metastatic Solid Tumors	219	$CD4^+$ Lymphopenia	≤450 (47.9%)	Not evaluated			1.5	1.1-2.1	0.017	[20]
Metastatic Solid Tumors	213	$CD4^+$ Lymphopenia	<450 (49.7%)	Not evaluated			7.7[a]	1.6-35[a]	0.007[a]	[19][a]
Non Hodgkin Lymphoma	88	$CD8^+$ Lymphopenia	<200	Not evaluated			3.30	1.21-9.0	0.01	[88]
Follicular Lymphoma	75	NK cells Lymphopenia	<150 (44%)	Not evaluated			6.73	0.76-59	0.08	[69]
DLBCL	136	NK cells Lymphopenia	≤80 (37.5%)	1.81	1.27-2.57	0.001	Not evaluated			[94]

[a] Analysis of the risk of early death; [b] Univariate analysis only

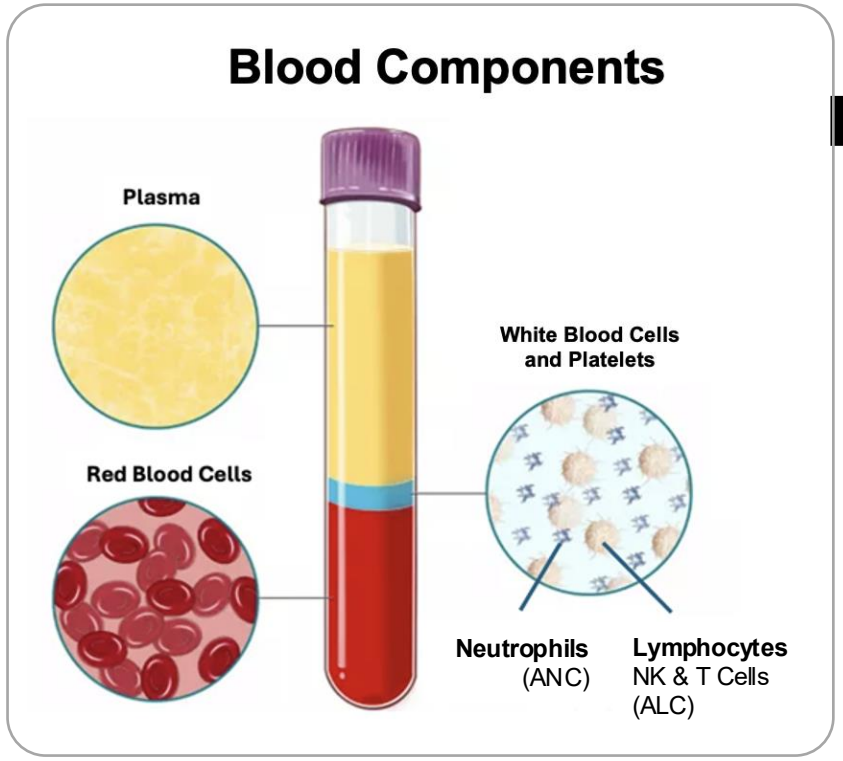
Lymphopenia Results in Significant Reduction of Survival Across All Cancer Types

QUILT-2.023: Randomized Clinical Trial: First Line NSCLC N-803 (NAI) + CPI versus CPI Alone

Randomized Control Study Demonstrates Significant Difference (p=0.0065) in ALC Increase Over Time with N-803 + CPI versus CPI Alone



Introducing Absolute Lymphocyte Count (ALC) and Lymphopenia



ANC: Absolute Neutrophil Count
ALC: Absolute Lymphocyte Count

Red Blood Cell



Low Red Blood Count

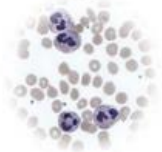
Anemia

EPOGEN



Treats Anemia
Increases Red Blood Cell Production
1989

Neutrophils



Low Neutrophil Count

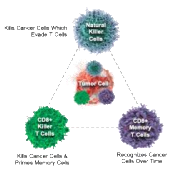
Neutropenia

NEUPOGEN



Prevents Infection
Increases Neutrophil Production
1991

NK & T Cells



Low Lymphocyte Count

Lymphopenia

Loss of NK & T Cells
Which Kill Cancer &
Induce T Cell Memory

No Treatment for Over 50 Years
The Missing Link

Proliferation and Activation
Regenerates NK and T cells and
Induces T Cell Memory

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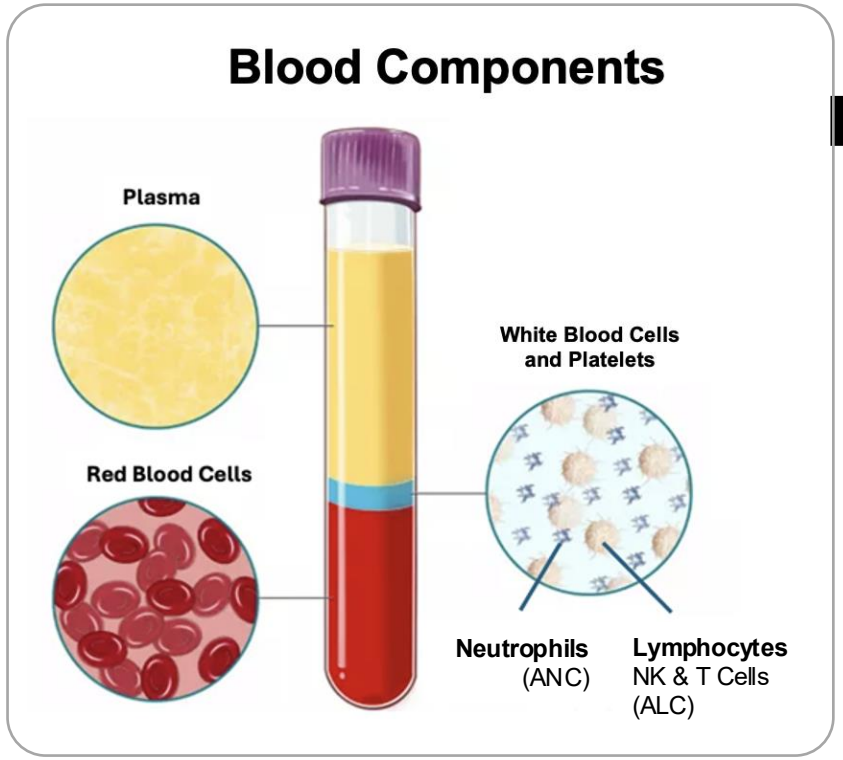
First Lymphocyte Rescue Agent in 50+ Years as Backbone to Chemo-Immunotherapy and Radiotherapy



ANC: Absolute Neutrophil Count
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Red Blood Cell



Low Red Blood Count

Anemia

EPOGEN



Treats Anemia
Increases Red Blood Cell Production
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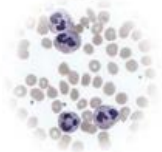


Low Neutrophil Count

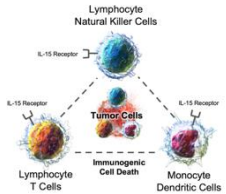
Neutropenia

NEUPOGEN



Prevents Infection
Increases Neutrophil Production
1991

NK & T Cells



Low Lymphocyte Count

Lymphopenia

ANKTIVA



Proliferation and Activation
Regenerates NK and T cells and Induces T Cell Memory
ANKTIVA Approved 2024

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2019: Excess Mortality Risk with Lymphopenia in the US General Population: "…Immunological Hazard in the General Population"

2019

JAMA Network Open

Original Investigation | Immunology

Association of Lymphopenia With Risk of Mortality Among Adults in the US General Population

David A. Zidar, MD, PhD; Sadeer G. Al-Kindi, MD; Yongmei Liu, MD, PhD; Nikolas I. Krieger, MS; Adam T. Perzynski, PhD; Michael Osnard, MD; Christopher Nmai, BA; Donald D. Anthony, MD; Michael M. Lederman, MD; Michael L. Freeman, PhD; Robert A. Bonomo, MD; Daniel I. Simon, MD; Jarrod E. Dalton, PhD

Abstract

IMPORTANCE Immune dysregulation can increase the risk of infection, malignant neoplasms, and cardiovascular disease, but improved methods are needed to identify and quantify immunologic hazard in the general population.

CONCLUSIONS AND RELEVANCE These findings suggest that lymphopenia is associated with reduced survival independently of and additive to traditional risk factors, especially when accompanied by altered erythropoiesis and/or heightened inflammation. Immune risk may be analyzed as a multidimensional entity derived from routine tests, facilitating precision medicine and population health interventions.

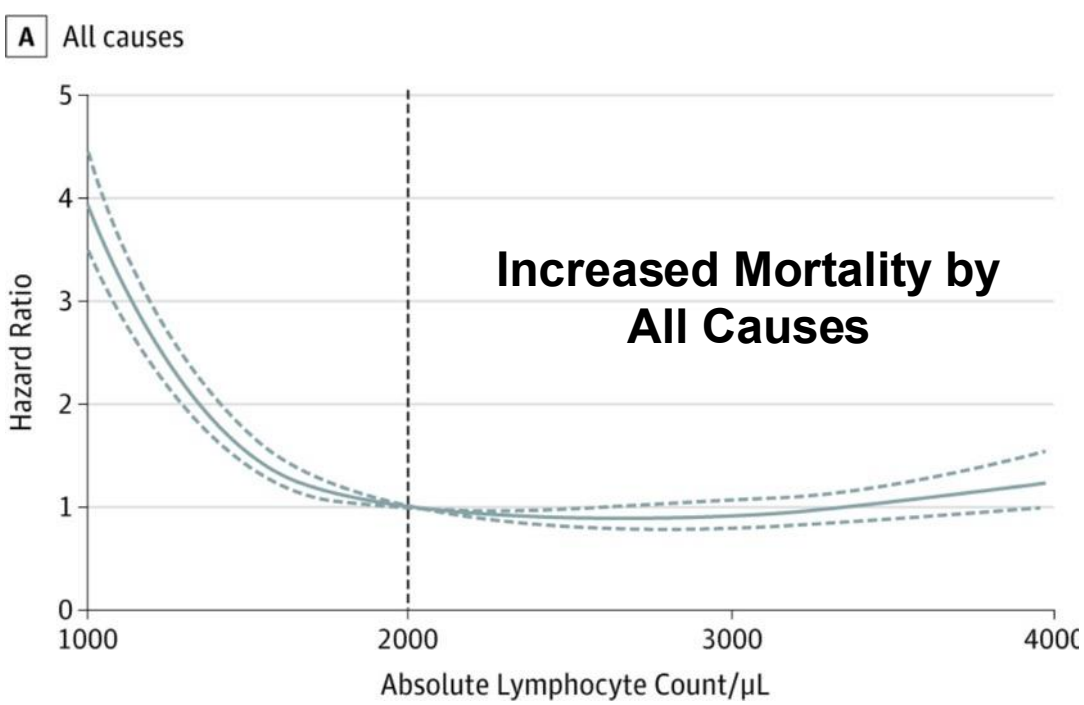
Key Points

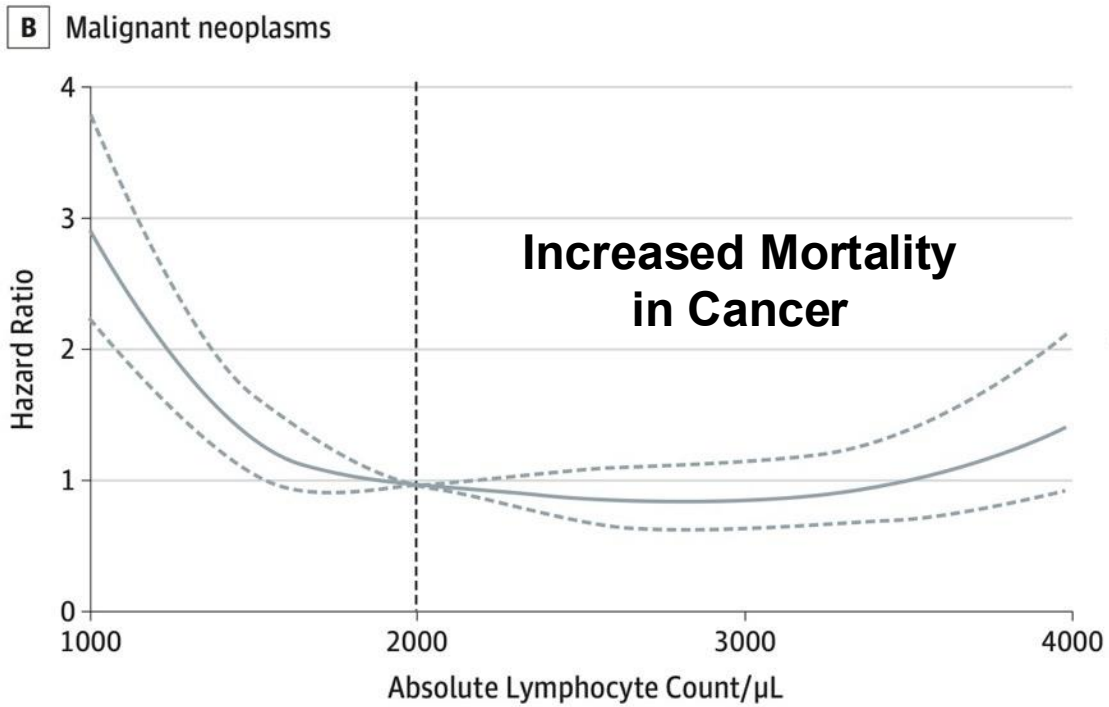
Question Are low lymphocyte levels associated with reduced survival in the general population?

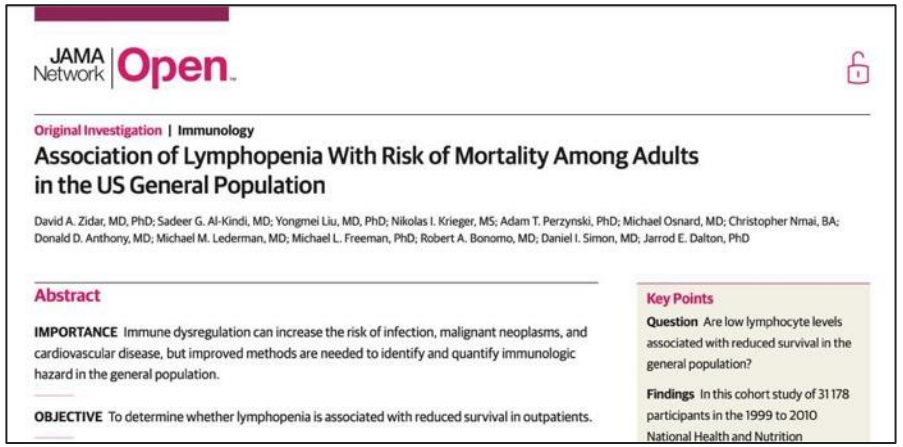
Findings In this cohort study of 31 178 participants in the 1999 to 2010 National Health and Nutrition Examination Survey, lymphopenia was associated with shortened survival independently of clinical variables, and this risk was further heightened when accompanied by abnormal hematologic (red blood cell distribution width) and/or inflammatory (C-reactive protein) parameters.

Meaning Based on these findings, patients with lymphopenia, especially those with other immunohematologic abnormalities, may have excess mortality risk; these patients are readily identifiable because tests of lymphocyte levels often occur during routine medical encounters.

2019 JAMA: Lymphopenia Consequences in US General Population







JAMA Network | Open

Original Investigation | Immunology

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OBJECTIVE To determine whether lymphopenia is associated with reduced survival in outpatients.

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2025-2026 ANKTIVA Growth*

	Indication	Agent	Progress	Status
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Cancer Vaccine	**Lynch Syndrome**	**ANKTIVA + Ad CEA, MUC1, Brachyury**	• Phase 2b Randomized • Fully Enrolled	✅ ✅

The Potential for IL-15 to Rescue Sepsis Induced Immunoparalysis

frontiers in Immunology

TYPE Review
PUBLISHED 16 October 2026
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Check for updates

OPEN ACCESS

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Dynamic trajectories of sepsis-induced immunoparalysis: from biological mechanisms to precision monitoring and targeted intervention

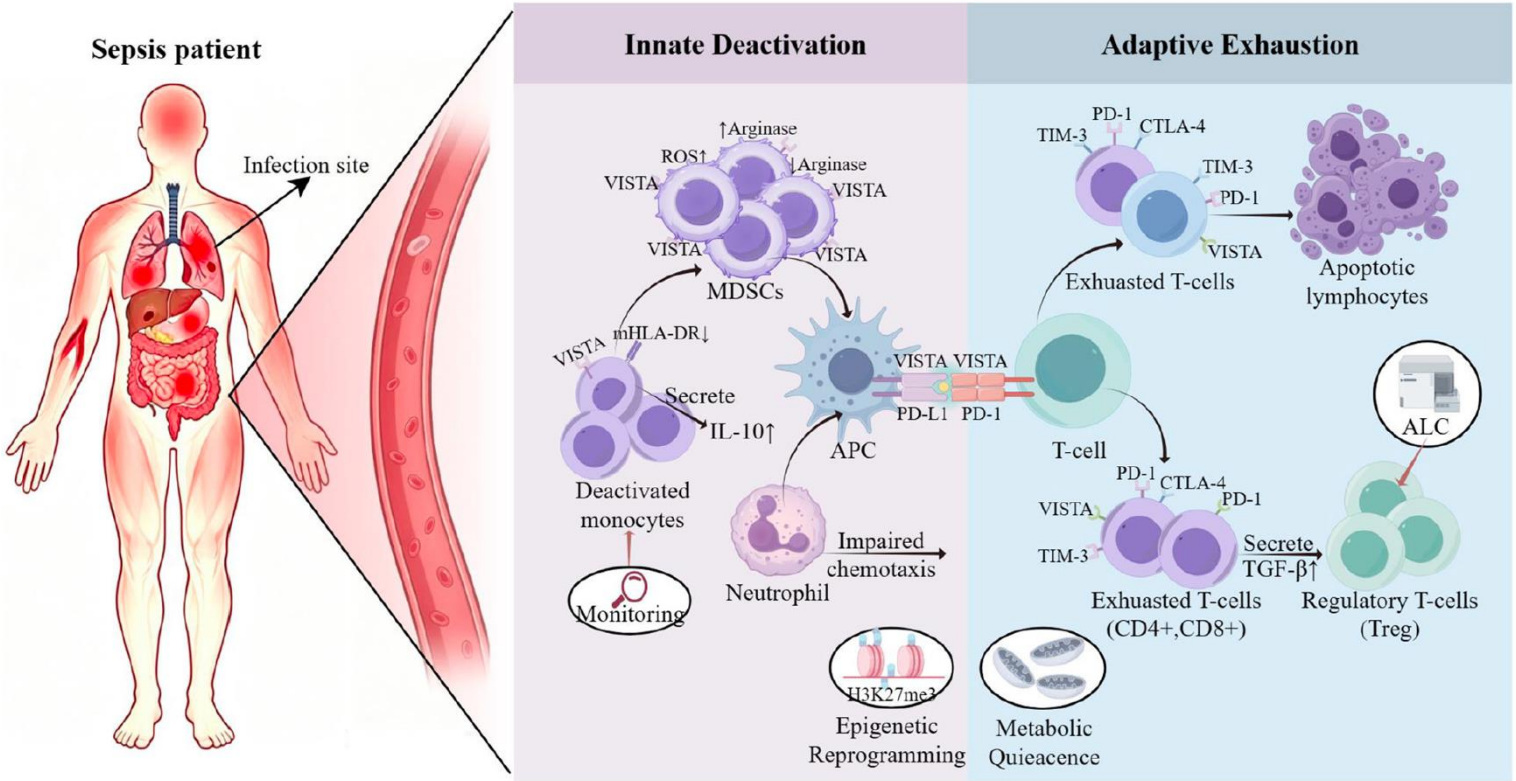
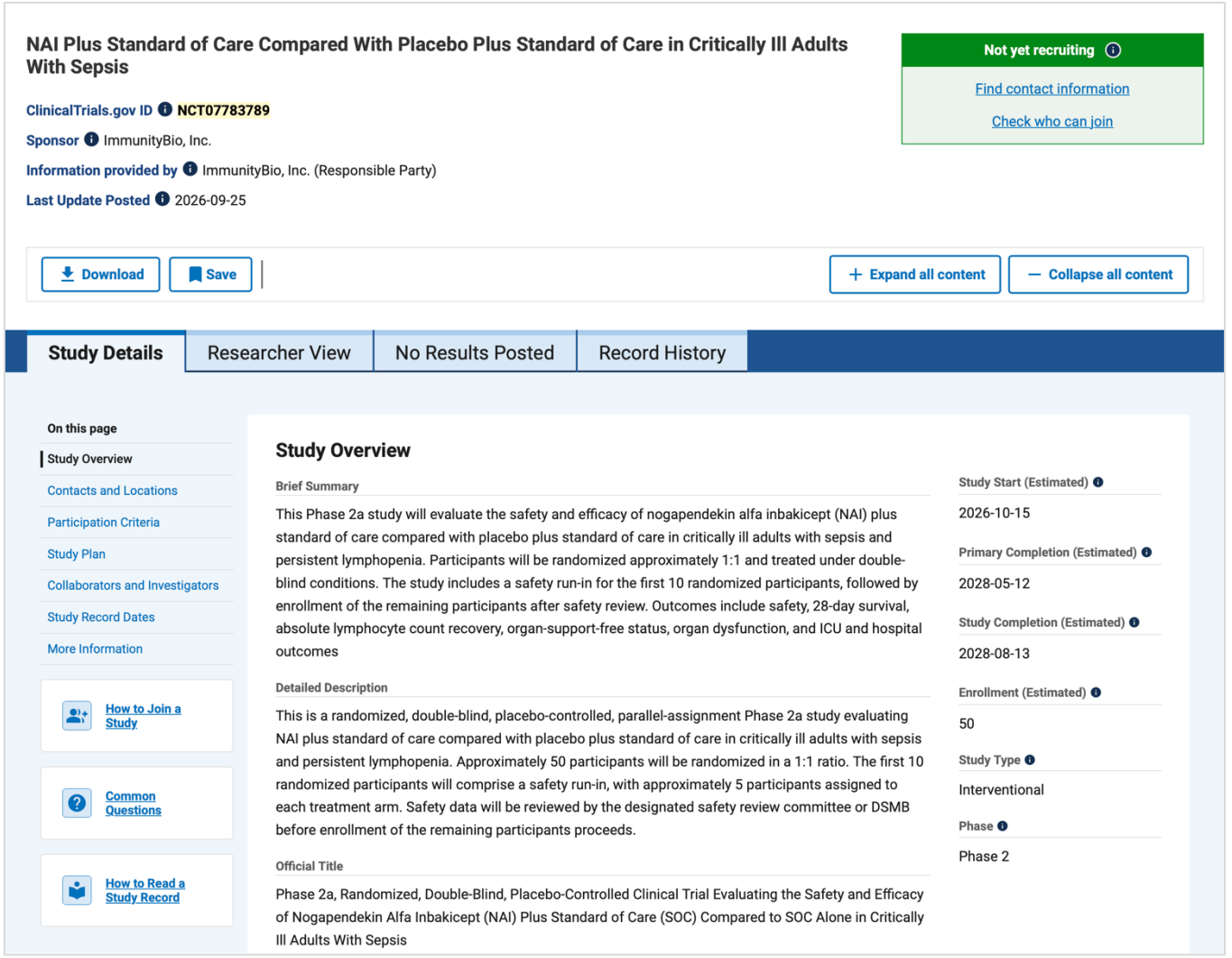


FIGURE 1
The dynamic evolution and biological mechanisms of sepsis-induced immunoparalysis. (By Figdraw).

Sepsis Clinical Trial Initiated in Sepsis (NAI)



NAI Plus Standard of Care Compared With Placebo Plus Standard of Care in Critically Ill Adults With Sepsis

ClinicalTrials.gov ID NCT07783789

Sponsor ImmunityBio, Inc.

Information provided by ImmunityBio, Inc. (Responsible Party)

Last Update Posted 2026-09-25

Not yet recruiting

Find contact information

Check who can join

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Study Details | Researcher View | No Results Posted | Record History

On this page

- Study Overview
- Contacts and Locations
- Participation Criteria
- Study Plan
- Collaborators and Investigators
- Study Record Dates
- More Information

How to Join a Study

Common Questions

How to Read a Study Record

Study Overview

Brief Summary

This Phase 2a study will evaluate the safety and efficacy of nogapendekin alfa inbakicept (NAI) plus standard of care compared with placebo plus standard of care in critically ill adults with sepsis and persistent lymphopenia. Participants will be randomized approximately 1:1 and treated under double-blind conditions. The study includes a safety run-in for the first 10 randomized participants, followed by enrollment of the remaining participants after safety review. Outcomes include safety, 28-day survival, absolute lymphocyte count recovery, organ-support-free status, organ dysfunction, and ICU and hospital outcomes

Detailed Description

This is a randomized, double-blind, placebo-controlled, parallel-assignment Phase 2a study evaluating NAI plus standard of care compared with placebo plus standard of care in critically ill adults with sepsis and persistent lymphopenia. Approximately 50 participants will be randomized in a 1:1 ratio. The first 10 randomized participants will comprise a safety run-in, with approximately 5 participants assigned to each treatment arm. Safety data will be reviewed by the designated safety review committee or DSMB before enrollment of the remaining participants proceeds.

Official Title

Phase 2a, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Evaluating the Safety and Efficacy of Nogapendekin Alfa Inbakicept (NAI) Plus Standard of Care (SOC) Compared to SOC Alone in Critically Ill Adults With Sepsis

Study Start (Estimated) 2026-10-15

Primary Completion (Estimated) 2028-05-12

Study Completion (Estimated) 2028-08-13

Enrollment (Estimated) 50

Study Type Interventional

Phase Phase 2

https://clinicaltrials.gov/study/NCT07783789

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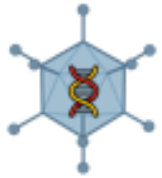
Cancer Vaccine	**Lynch Syndrome**	**ANKTIVA + Ad CEA, MUC1, Brachyury**	• Phase 2b Randomized • Fully Enrolled	✅ ✅

NCI Sponsored, Phase 2b Randomized Preventative Cancer Vaccine for Lynch Syndrome

N-803 + Ad5 CEA/MUC1/Brachyury Cancer Vaccine (Tri-Ad5)

Enrollment Completed 2025

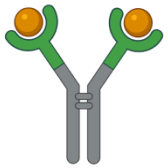


Second Generation Adenovirus (Ad5)

Ad5 CEA, MUC1, Brachyury

+

ANKTIVA (IL-15)



N-803

NIH NATIONAL CANCER INSTITUTE
Division of Cancer Prevention

NCI Sponsored Trial
Clinical Trials: NCT05419011

INT21-05-01
Protocol Version 7.0, 02/09/2023

COVER PAGE
DCP Protocol #: INT21-05-01

Local Protocol #: NCI21-05-01

A PHASE IIB CLINICAL TRIAL OF THE MULTITARGETED RECOMBINANT ADENOVIRUS 5 (CEA/MUC1/BRACHYURY) VACCINES (TRI-AD5) AND IL-15 SUPERAGONIST N-803 IN LYNCH SYNDROME

Northwestern University · KU Medical Center, The University of Kansas · The University of Texas MD Anderson Cancer Center · Mayo Clinic · University of Michigan · UCSF · University of Colorado Anschutz Medical Campus · Cleveland Clinic · The University of Arizona Cancer Center · Universidad de Puerto Rico · Fox Chase Cancer Center, Temple Health · Dana-Farber Cancer Institute · City of Hope · Carbone Cancer Center, University of Wisconsin School of Medicine and Public Health · The Ohio State University Wexner Medical Center · The University of Chicago

- Lynch syndrome affects approximately **1 in 279 individuals** in the general US population based on large unselected sequencing cohorts, making it far more common than previously recognized.
- A global analysis suggesting a worldwide prevalence of **2 to 3 million people** living with Lynch syndrome. 80% increased risk of colon cancer.
- Approximately **3 to 5 percent** of all colorectal cancers and **2 to 6 percent** of endometrial cancers arise from Lynch syndrome, making it a major contributor to preventable malignancy.

In Summary:
Finding the Next Blockbuster in Immunotherapy Beyond Checkpoints

IL-15 Ranked #1 "*Immunotherapy Drug that Could Cure Cancer*", *Mac Cheever 2008*

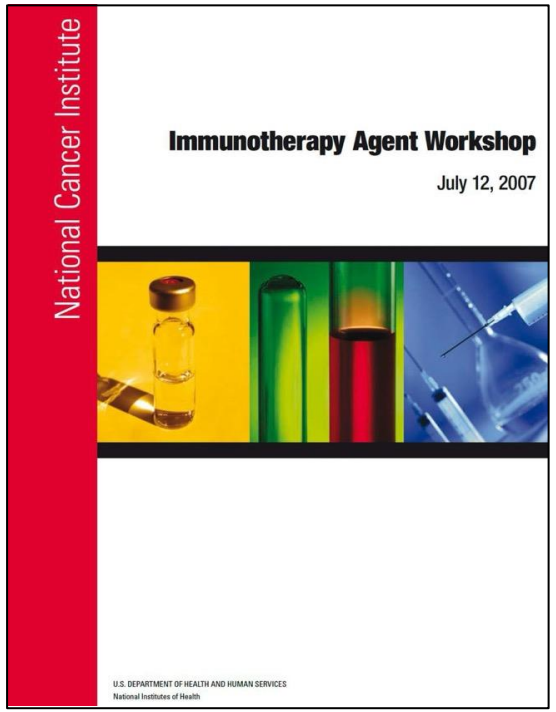
2008

Martin A. 'Mac' Cheever



Twelve immunotherapy drugs that could cure cancers

Finding the Next Blockbuster in Immunotherapy Beyond Checkpoints



ANKTIVA

KEYTRUDA

2007 NCI Workshop

Table 1. **Rankings of agents with high potential for use in treating cancer**

Rank*	Agent	Agent category
1	IL-15	T-cell growth factor
2	Anti-PD1 and/or anti-B7-H1 (PD-1L)	*T-cell checkpoint blockade inhibitor
3	IL-12	Vaccine adjuvant
4	Anti-CD40 and/or CD40L	Antigen presenting cell stimulator
5	IL-7	T-cell growth factor

Keytruda: 19 Tumor Types With FDA Approval

Future Potential Immunotherapy Paths Beyond Checkpoint

Finding the Next Blockbuster in Immunotherapy Beyond Checkpoints

Year of first FDA approval, by tumor type, for indications on the current US label of Keytruda

Head and Neck	2016	2018	Mediastinal B-Cell Lymphoma
Classical Hodgkin Lymphoma	2017	2020	Triple-Negative Breast
Melanoma	2014	2020	Cutaneous Squamous Cell
Esophageal	2019	2021	Gastric and GEJ
Non-Small Cell Lung	2015	2019	Renal Cell (Kidney)
Pleural Mesothelioma	2024	2018	Merkel Cell
Hepatocellular (Liver)	2018	2019	Endometrial
Biliary Tract	2023	2018	Cervical
Colorectal (MSI-H/dMMR)	2020	2017	Bladder and Urothelial
Ovarian	2026		



Tumor-agnostic **MSI-H/dMMR 2017 TMB-H 2020**

Sources: US FDA approval announcements and Keytruda US prescribing information, as compiled by Drugs.com, November 2026.

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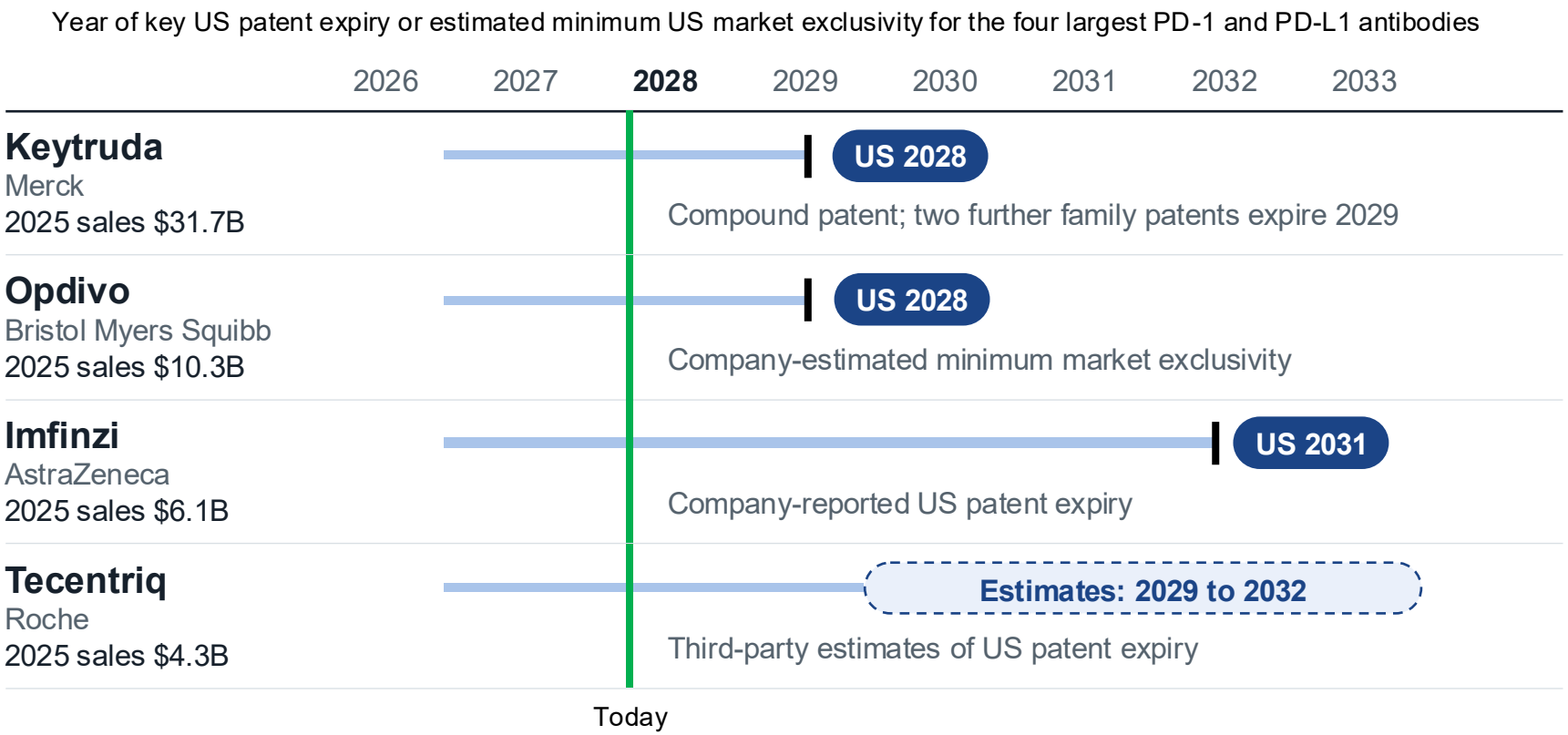
The Opportunity Beyond Checkpoints: IL-15 Rescue of Checkpoint Failures

The Checkpoint Patent Cliff



Finding the Next Blockbuster in Immunotherapy Beyond Checkpoints

ANKTIVA + Checkpoint Inhibitor Combination. Issued Patent Term 2035

Sources: Merck and Bristol Myers Squibb Forms 10-K (FY2025); AstraZeneca patent expiries supplement (Feb 2026); ApexOnco; GlobalData.

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IL-15: Immunotherapy 2.0: The Potential Next Blockbuster From Treating Cancer Across Multiple Tumor Types to Lymphopenia to Sepsis to Cancer Vaccine

IL-15 Backbone to Checkpoint Inhibitors

19

Tumor Types Approved for Keytruda

Keytruda is FDA-approved in 19 tumor types across 44 indications, yet only about 1 in 5 patients with advanced cancer responds to a checkpoint inhibitor. ANKTIVA + CPI patent term 2035 / 2037

Keytruda (pembrolizumab) US Prescribing Information, Merck, 2026; Haslam et al., Int J Cancer, 2025 ImmunityBio US Patent Nos. 9,925,247, 11,071,774, 12,318,432, 11,992,516

Lymphopenia

1 in 5

US Adults ~54 million

1 in 5 U.S. adults has a low lymphocyte count (ALC ≤1,500/μL), and it is associated with a 30% higher risk of death.

Zidar et al., JAMA Network Open, 2019

Sepsis

1.7 Million

Sepsis Annually 350,000 Deaths

At least 1.7 million U.S. adults develop sepsis each year, and at least 350,000 die in hospital or are discharged to hospice.

Centers for Disease Control and Prevention, About Sepsis; underlying data from Rhee C, et al. JAMA. 2017;318(13):1241-1249.

Cancer Vaccine

1 in 279

US Adults w/ Lynch Syndrome 1.2 million Americans

1 in 279 people carries a Lynch syndrome mutation, roughly 1.2 million Americans with lynch syndrome.

Win et al., Cancer Epidemiology, Biomarkers & Prevention, 2017

IL-15, a NK and T Cell Growth Factor

Indication and Important Safety Information

Indication and Important Safety Information

INDICATION AND USAGE
ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC).

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 BCG-unresponsive NMIBC have evidence of high-grade disease after a second induction course of ANKTIVA with BCG, reconsider cystectomy.

CONTRAINDICATIONS: None

DOSAGE AND ADMINISTRATION
For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes. Instill intravesically only after dilution. Total time from vial puncture to the completion of the intravesical instillation should not exceed 2 hours.

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.

ADVERSE REACTIONS
The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

For more information about ANKTIVA, please see the Full Prescribing Information at www.anktiva.com. You are encouraged to report negative side effects of prescription drugs to 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).