



NASDAQ: IBRX

Overview Presentation

November 2022



Forward-Looking Statements

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 from the clinical trials for certain of ImmunityBio's product candidates, clinical trial enrollment and results, the regulatory review process and timing thereof, timing of regulatory submissions, timing of meetings with regulators, potential implications to be drawn from clinical trials, potential commercialization of product candidates, ImmunityBio's product candidates as compared to existing treatment options, and intellectual property protection and patent life, among others. Statements 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 approve ImmunityBio's filed BLA and the risks and uncertainties associated with the regulatory approval process, (ii) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (iii) ImmunityBio's ability to retain and hire key personnel, (iv) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (v) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, (vii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (viii) the unknown future impact of the COVID-19 pandemic on certain clinical trials or their milestones and/or ImmunityBio's business operations or operating expenses. 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 1, 2022 and the Company's Form 10-Q filed with the SEC on November 9, 2022, 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.

Background: History of Driving Shareholder Value in the Biopharmaceutical Industry Through Innovation, Quality and Scale

2001 - 2008



American Pharmaceutical Partners (NASDAQ: APPX)

- One of the nation's largest injectable manufacturing
190 FDA approved dosage forms
- 2001: IPO NASDAQ: APPX, market cap \$769M
- 2008: Safe supply of heparin during the heparin crisis in 2008
- 2008: Fresenius SE acquired APPX for **\$5.6 billion** inclusive of CVRs
- 2009: APPX products approached **\$800 million dollars in sales**



2005 - 2010

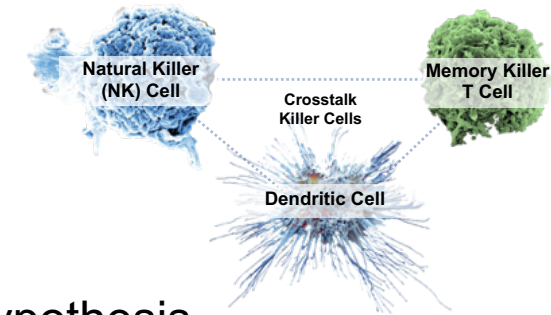


Abraxis BioScience (NASDAQ: ABII)

- 2005: Abraxane - Nation's first protein (albumin) nanoparticle chemotherapy approved
- Abraxane approved for breast cancer, lung cancer and pancreatic cancer with state-of-the-art global manufacturing plant for protein nanoparticles
- 2010: Abraxis acquired by Celgene for **\$3.6 billion**
- 2020: Abraxane achieves **Blockbuster status** of over a \$1 billion dollar in sales
- 2021: Abraxane global sales at Bristol Meyers Squibb reached **\$1.2 billion dollars in sales**

Background: History of Driving Shareholder Value in the Biopharmaceutical Industry Through Innovation, Quality and Scale

- **2000 - 2010: American Pharmaceutical Partners (APP) and Abraxis BioScience (ABII)**
- **2010 - 2020: Cancer Moonshot Initiative (QUILT Trials): The NANT Cancer Vaccine**
 - **Scale in platforms and products** across the immune system
 - **Scale in biological manufacturing** capacity at GMP commercial level
 - **Scale in exploratory clinical trials** across multiple tumor types to validate the hypothesis
- **2021: Launch of ImmunityBio (NASDAQ: IBRX) Through Merger of NantKwest & NantCell**
- **2021 - 2025: Registration Strategy and Anticipated Product Launches**



Indications:

- Bladder Cancer
- Pancreatic Cancer
- Lung Cancer
- Glioblastoma
- Head & Neck Cancer
- Lynch Syndrome (Prevention of Cancer)

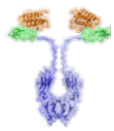
Product Launches

- N-803 (Anktiva)
- PD-L1 t-haNK
- Aldoxorubicin
- hAd5 E6/E7
- hAd5 CEA, MUC1, Brachyury

Multi Billion Dollar Investment in Scale (2010 – 2022)

Immunotherapy Platform Scale

Fusion Proteins & Cytokines



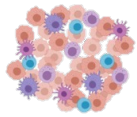
- NK & T Cell Activators
- Subunit Protein Antigens

NK Cell Therapy



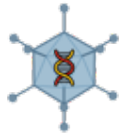
- NK-92
- Memory-Like Cytokine NK

DAMP Inducers



- Aldoxorubicin
- Nanatinostat

DNA Vaccine



- hAd5 Adenovirus

Toll Receptor Activators



- TLR 4, 7, 8, 9

RNA Vaccine



- Self-Amplifying RNA (saRNA)

Patent Terms 2038+

Worldwide Patents Extending to 2035 and Beyond

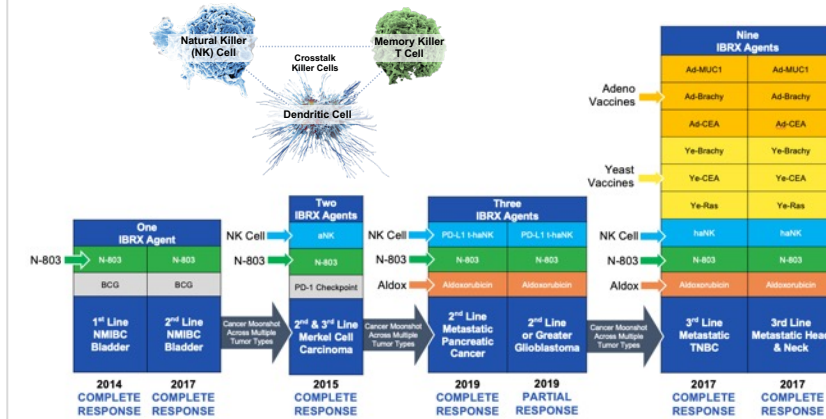
Biological Manufacturing Scale



*Through Potential Strategic Collaborators

Multiple Tumor Type Scale

Cancer Moonshot 2014 to 2020



Registration Strategy
2021 - 2025

Registration Trials

- Bladder Cancer
- Pancreatic Cancer
- Lung Cancer
- Glioblastoma
- Head & Neck Cancer
- Lynch Syndrome

Cancer Moonshot: Tipping the Scales From Immuno-Evasion to Immune Activation Across Multiple Tumor Types

The NANT Cancer Vaccine: QUILT Trials: 2014 - 2020

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ONCOIMMUNOLOGY
2021, VOL. 10, NO. 1, e1912885 (7 pages)
<https://doi.org/10.1080/21624022.2021.1912885>

ORIGINAL RESEARCH

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

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ABSTRACT
Intravesical BCG is active against non-muscle invasive bladder cancer (NMIBC), but bladder cancer will recur and even progress in a significant number of patients. To improve the response rate, N-803, an IL-15 superagonist was administered in combination with BCG. To evaluate the safety and efficacy associated with the use of intravesical N-803 and BCG in patients with BCG-naïve NMIBC. This phase 1b clinical trial used a 3 + 3 dose-escalation design. Participants were enrolled from July 2014 and July 2015, with follow-up and analyses through January 15, 2021. Eligibility criteria included histologically confirmed non-muscle invasive urothelial carcinoma of intermediate or high risk who had not received prior treatment with intravesical BCG (ie, BCG-naïve). All 9 participants met the eligibility criteria, received treatment according to the protocol, and were included in all analyses. Treatment was done once weekly for 6 consecutive weeks with bladder infusion of the standard dose of BCG, 50 mg/institution, in combination with increasing doses of N-803 (100, 200, or 400 µg N-803 per institution). No DLTs were noted in any of the dose cohorts. All adverse events (AEs) were manageable and less than grade 3. During the 2-year follow-up, all 9 participants were disease free. Furthermore, 6 y after treatment, all 9 participants (100%) were disease free with no evidence of disease progression and an intact bladder. This phase 1b trial found the combination of intravesical N-803 and BCG to be associated with modest toxic effects, low immunogenicity, and substantial prolonged antitumoral activity: phase 2 trials are in progress.

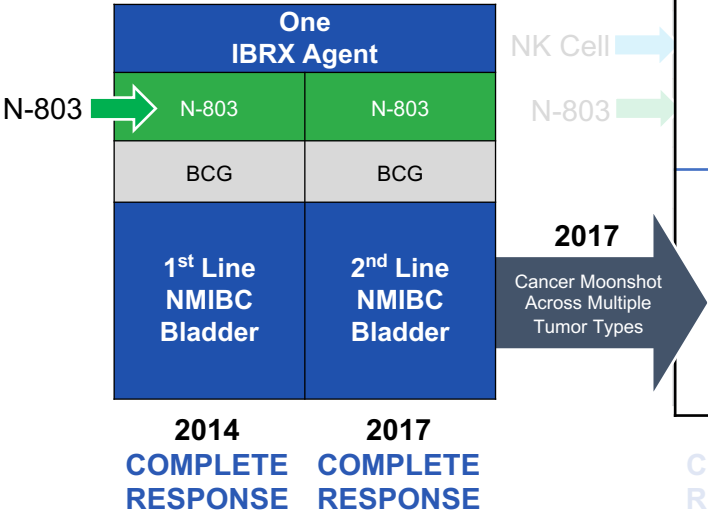
ARTICLE HISTORY
Received 3 March 2021
Revised 31 March 2021
Accepted 31 March 2021

KEYWORDS
Non-muscle invasive bladder cancer; IL-15; BCG

Taylor & Francis
Taylor & Francis Group

OPEN ACCESS

Natural Killer Cells



Dose (intravesicular instillation)	Patient	CIS Papillary	Response Assessments							
			W12	6M	9M	12M	15M	18M	21M	24M
100 µg	1	Pap	CR*	CR	CR	CR	CR	CR	CR	CR
	2	Pap	CR*	CR	CR	CR	CR	CR	CR	CR
	3	Pap	CR*	CR	CR	CR	CR	CR	CR	CR
200 µg	4	Pap	IC	CR*	CR	CR	CR	CR	CR	CR
	5	CIS	IC	IC	IC	CR	CR	CR	CR	CR
	6	Pap	CR*	CR	CR	CR	CR	CR	CR	CR
400 µg	7	Pap	CR*	CR	CR	CR	CR	CR	CR	CR
	8	CIS	CR*	CR	CR	CR	CR	CR	CR	CR**
	9	Pap	CR*	CR	CR	CR	CR	CR	CR	CR

*CR termed as No Recurrence (NR) in Papillary Disease

**Negative Cystoscopy Inconclusive Cytology

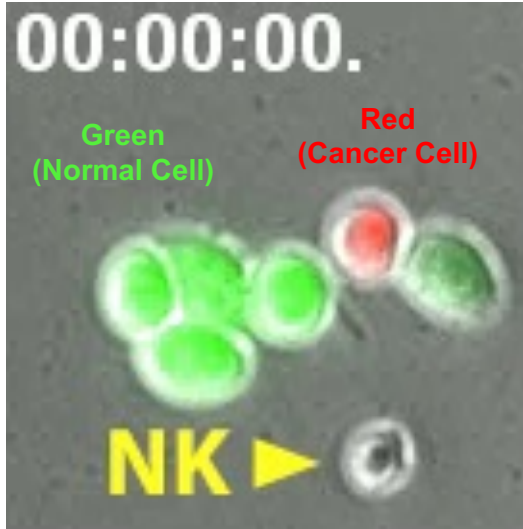
Proof of Concept: Complete Responses Across Multiple Tumor Types

2021

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NantWest
Merger
ImmunityBio

Cancer Moonshot: Tipping the Scales From Immuno-Evasion to Immune Activation Across Multiple Tumor Types

The NANT Cancer Vaccine: QUILT Trials: 2014 - 2020



Tumor Targeted Off-the-Shelf Natural Killer Cells



Natural Killer (NK) Cell

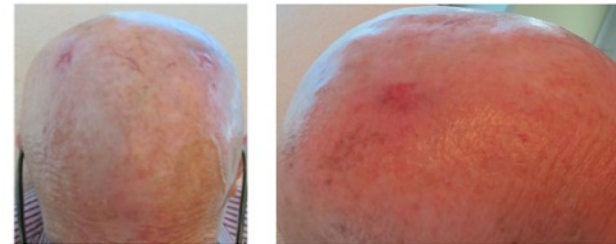
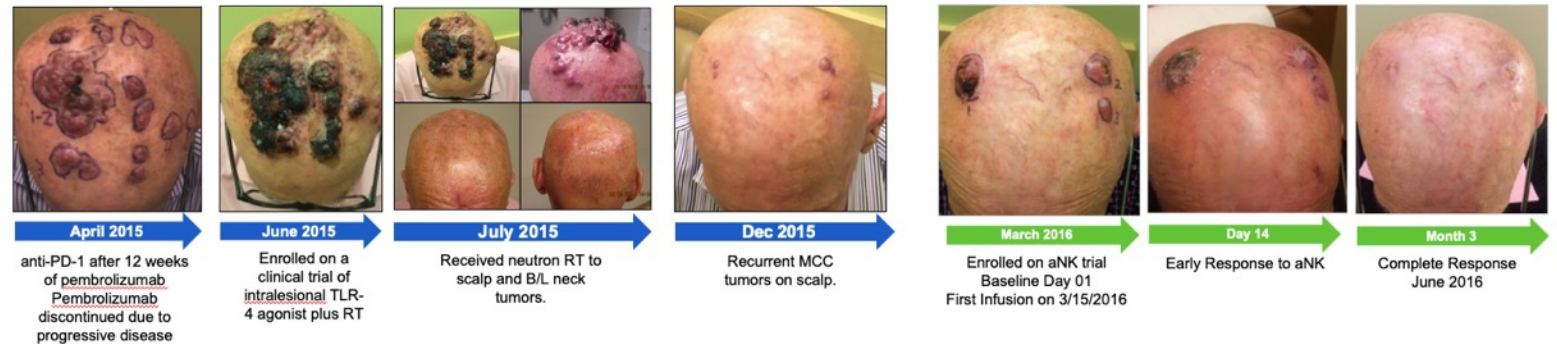
Crosstalk



Memory Killer T Cell

Nine
IBRX Agents

Complete Response with Natural Killer Cell Therapy and Long Term Memory



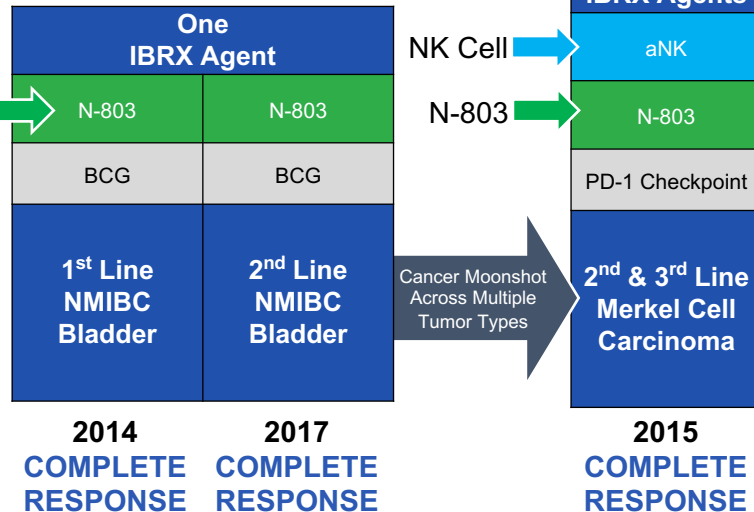
Month 5
Ongoing Complete Response Checkpoint Added

July 2019
Long-Term Durable Complete Response No Further Treatment

Six Years Remission Free
2016 to 2022

- Complete Remission Over 6 Years
- No Treatment Since July 2019
- Off-the-Shelf NK Effective in 5th Line
- Patient Passed Away March 2022 Free of Disease After 3 Years on No Further Treatment

July 2019 to March 2022
No Further Treatment with Complete Remission

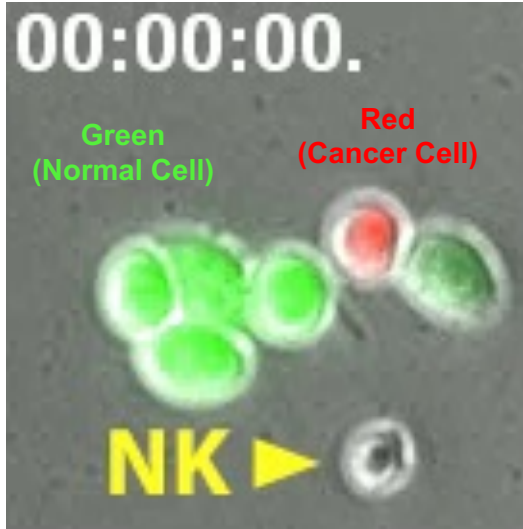


Proof of Concept: Complete Responses Across Multiple Tumor Types

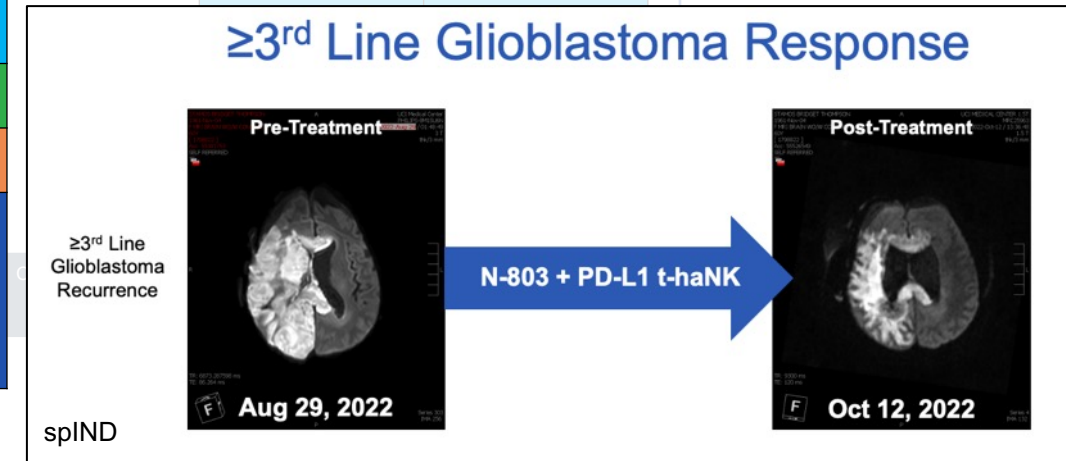
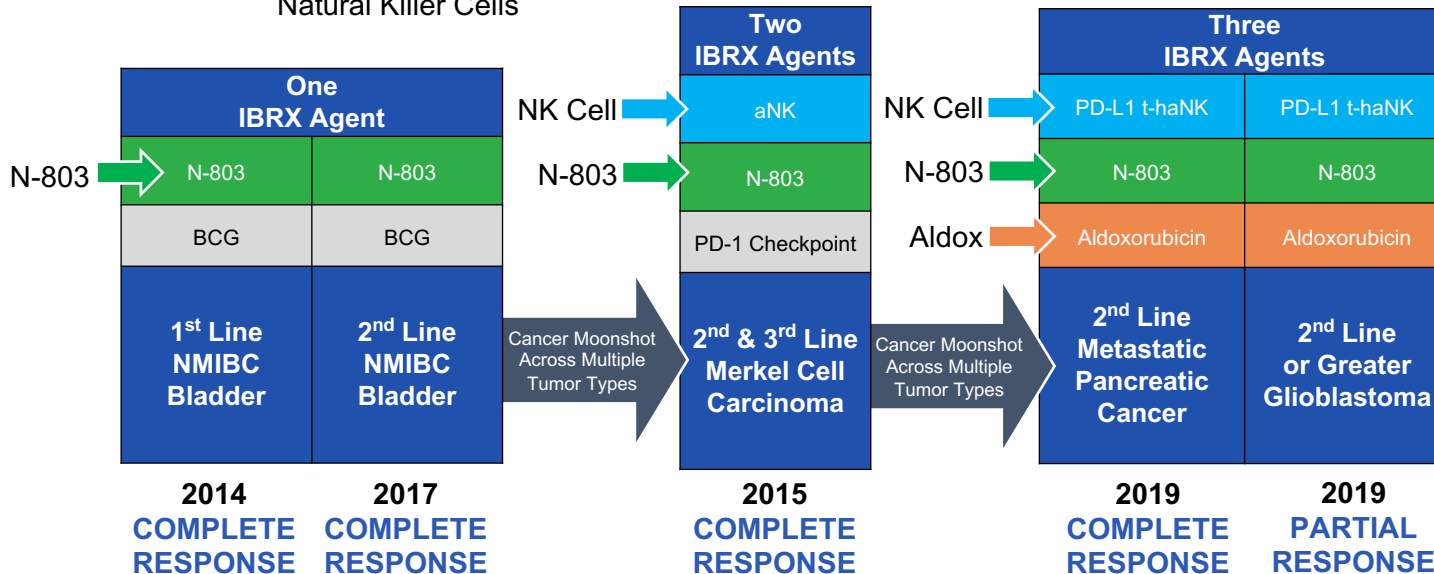
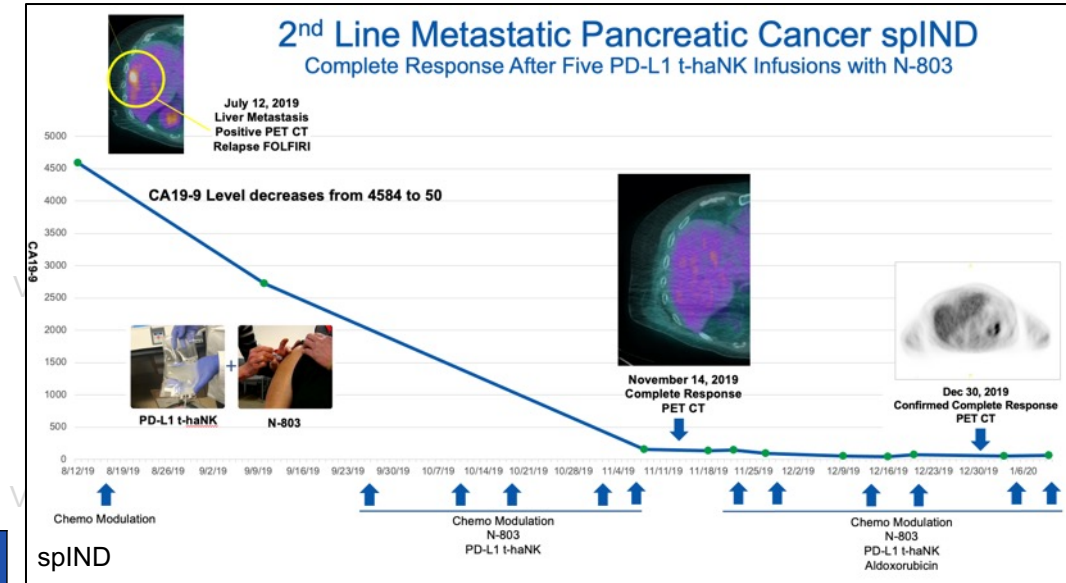
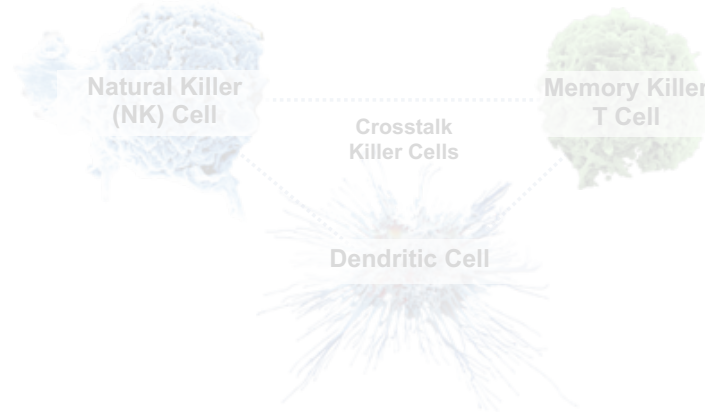
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Cancer Moonshot: Tipping the Scales From Immuno-Evasion to Immune Activation Across Multiple Tumor Types

The NANT Cancer Vaccine: QUILT Trials: 2014 - 2020



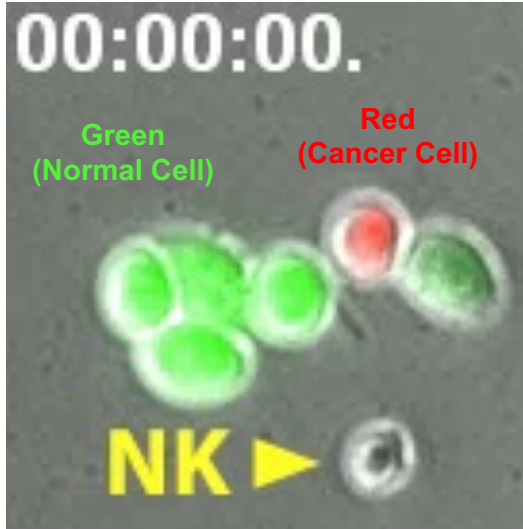
Tumor Targeted Off-the-Shelf Natural Killer Cells



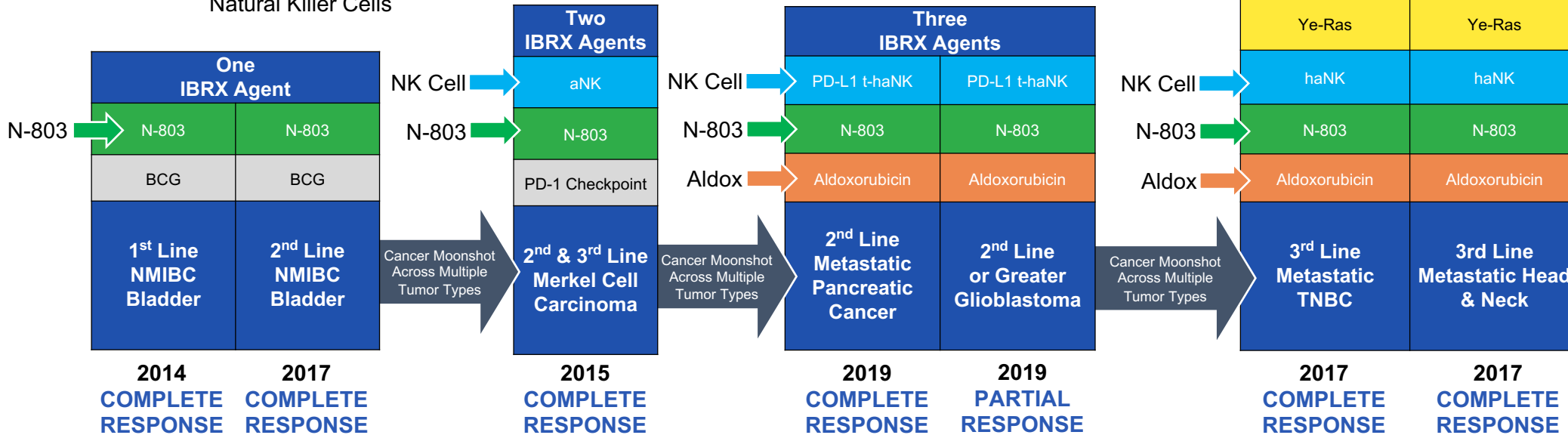
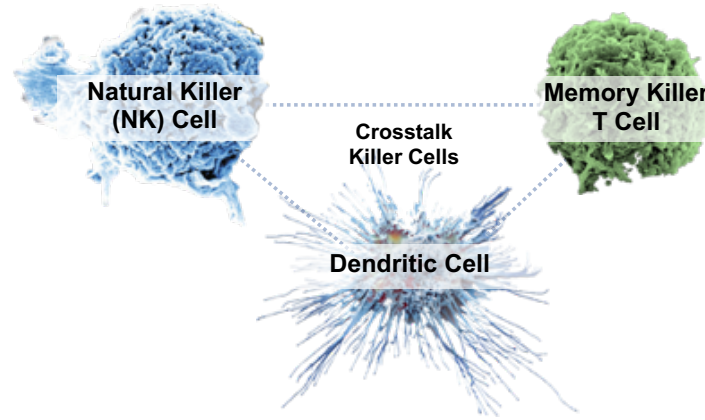
Proof of Concept: Complete Responses Across Multiple Tumor Types

Cancer Moonshot: Tipping the Scales From Immuno-Evasion to Immune Activation Across Multiple Tumor Types

The NANT Cancer Vaccine: QUILT Trials: 2014 - 2020



Tumor Targeted Off-the-Shelf Natural Killer Cells



>5th Line Metastatic Head & Neck



Pre-Treatment 5th Line

- Head & Neck Cancer
- Lynch Syndrome



Post-Treatment **COMPLETE RESPONSE** After 2-Cycles

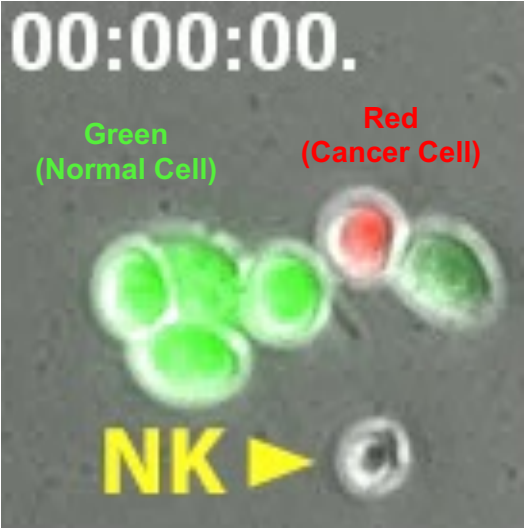
2021

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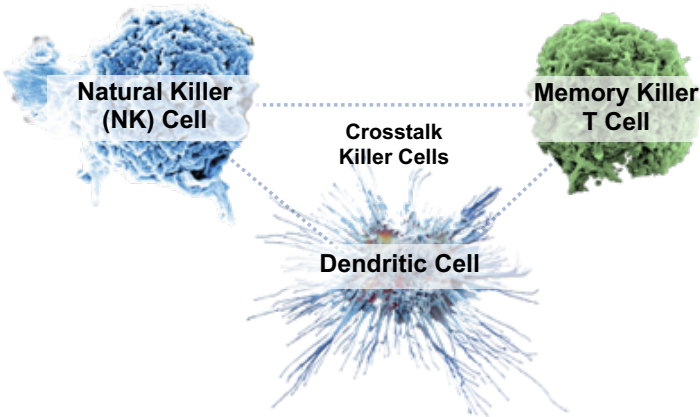
Proof of Concept: Complete Responses Across Multiple Tumor Types

Cancer Moonshot: Tipping the Scales From Immuno-Evasion to Immune Activation Across Multiple Tumor Types

The NANT Cancer Vaccine: QUILT Trials: 2014 - 2020



Tumor Targeted Off-the-Shelf Natural Killer Cells



Adeno Vaccines

Yeast Vaccines

Nine IBRX Agents	
Ad-MUC1	Ad-MUC1
Ad-Brachy	Ad-Brachy
Ad-CEA	Ad-CEA
Ye-Brachy	Ye-Brachy
Ye-CEA	Ye-CEA
Ye-Ras	Ye-Ras
haNK	haNK
N-803	N-803
Aldoxorubicin	Aldoxorubicin

2021 - 2025
Registration Strategy

Registration Trials

- Bladder Cancer
- Pancreatic Cancer
- Lung Cancer
- Glioblastoma
- Head & Neck Cancer
- Lynch Syndrome



2021

NASDAQ: IBRX
NantCell &
NantKwest
Merger

One IBRX Agent	
N-803	N-803
BCG	BCG
1 st Line NMIBC Bladder	2 nd Line NMIBC Bladder

Two IBRX Agents	
aNK	N-803
PD-1 Checkpoint	
2 nd & 3 rd Line Merkel Cell Carcinoma	

Three IBRX Agents	
PD-L1 t-haNK	PD-L1 t-haNK
N-803	N-803
Aldoxorubicin	Aldoxorubicin
2 nd Line Metastatic Pancreatic Cancer	2 nd Line or Greater Glioblastoma

Three IBRX Agents	
haNK	haNK
N-803	N-803
Aldoxorubicin	Aldoxorubicin
3 rd Line Metastatic TNBC	3 rd Line Metastatic Head & Neck

2014
COMPLETE RESPONSE

2017
COMPLETE RESPONSE

2015
COMPLETE RESPONSE

2019
COMPLETE RESPONSE

2019
PARTIAL RESPONSE

2017
COMPLETE RESPONSE

2017
COMPLETE RESPONSE

Proof of Concept: Complete Responses Across Multiple Tumor Types

Registrational Development Strategy & Status

Nov 2022

Investigational Product	Anticipated Registrational Trial Indications (2023 – 2025)	Current Status
IL-15 Superagonist Anktiva, N-803	<ul style="list-style-type: none"> • BCG-Unresponsive Bladder Cancer CIS N-803 + BCG 	<ul style="list-style-type: none"> • BLA Filed, PDUFA May 2023
	<ul style="list-style-type: none"> • BCG-Unresponsive Bladder Cancer Papillary N-803 + BCG 	<ul style="list-style-type: none"> • Enrollment Completed, FDA Type B Meeting Scheduled Dec 2022
	<ul style="list-style-type: none"> • BCG Naïve Bladder Cancer CIS & Papillary N-803 + BCG 	<ul style="list-style-type: none"> • Actively Enrolling
	<ul style="list-style-type: none"> • 2nd Line Lung Cancer N-803 + Checkpoint 	<ul style="list-style-type: none"> • LungMAP Actively Enrolling, Multi-Center Trial
PD-L1 t-haNK	<ul style="list-style-type: none"> • ≥3rd Line Metastatic Pancreatic Cancer N-803 + PD-L1 t-haNK + Aldox 	<ul style="list-style-type: none"> • Enrollment Completed, FDA Type B Meeting Scheduled Dec 2022
	<ul style="list-style-type: none"> • >2nd Line Glioblastoma N-803 + PD-L1 t-haNK + Aldox 	<ul style="list-style-type: none"> • Phase 2 Randomized Trial
Aldoxorubicin	<ul style="list-style-type: none"> • ≥3rd Line Metastatic Pancreatic Cancer N-803 + PD-L1 t-haNK + Aldox 	<ul style="list-style-type: none"> • Enrollment Completed, FDA Type B Meeting Scheduled Dec 2022
Adenovirus Vector hAd5 E6/E7	<ul style="list-style-type: none"> • HPV⁺ Head & Neck Cancer N-803 + hAd5 E6/E7 + PD-L1 t-haNK 	<ul style="list-style-type: none"> • IND Anticipated 1H 2023
Adenovirus Vector hAd5 CEA, MUC1, Brachyury	<ul style="list-style-type: none"> • Lynch Syndrome - Prevention of Colon Cancer N-803 + hAd5 CEA, MUC1, Brachyury 	<ul style="list-style-type: none"> • FDA / IRB Authorized: Initiation of Multi-Center Trial Anticipated Q1 2023. NIH Sponsored Trial

Orchestrating the Immune System

First-in-Class Comprehensive Platforms

NK + T Cells

- Anktiva (N-803)

Natural Killer Cells

- PD-L1 t-haNK

DAMP Inducers

- Aldoxorubicin

Memory B & T Cells

- Adenovirus (hAd5)

Late-Stage U.S. Clinical Trial Updates:

- Bladder Cancer
- Pancreatic Cancer
- Lung Cancer
- Head & Neck Cancer
- Lynch Syndrome

Orchestrating the Immune System

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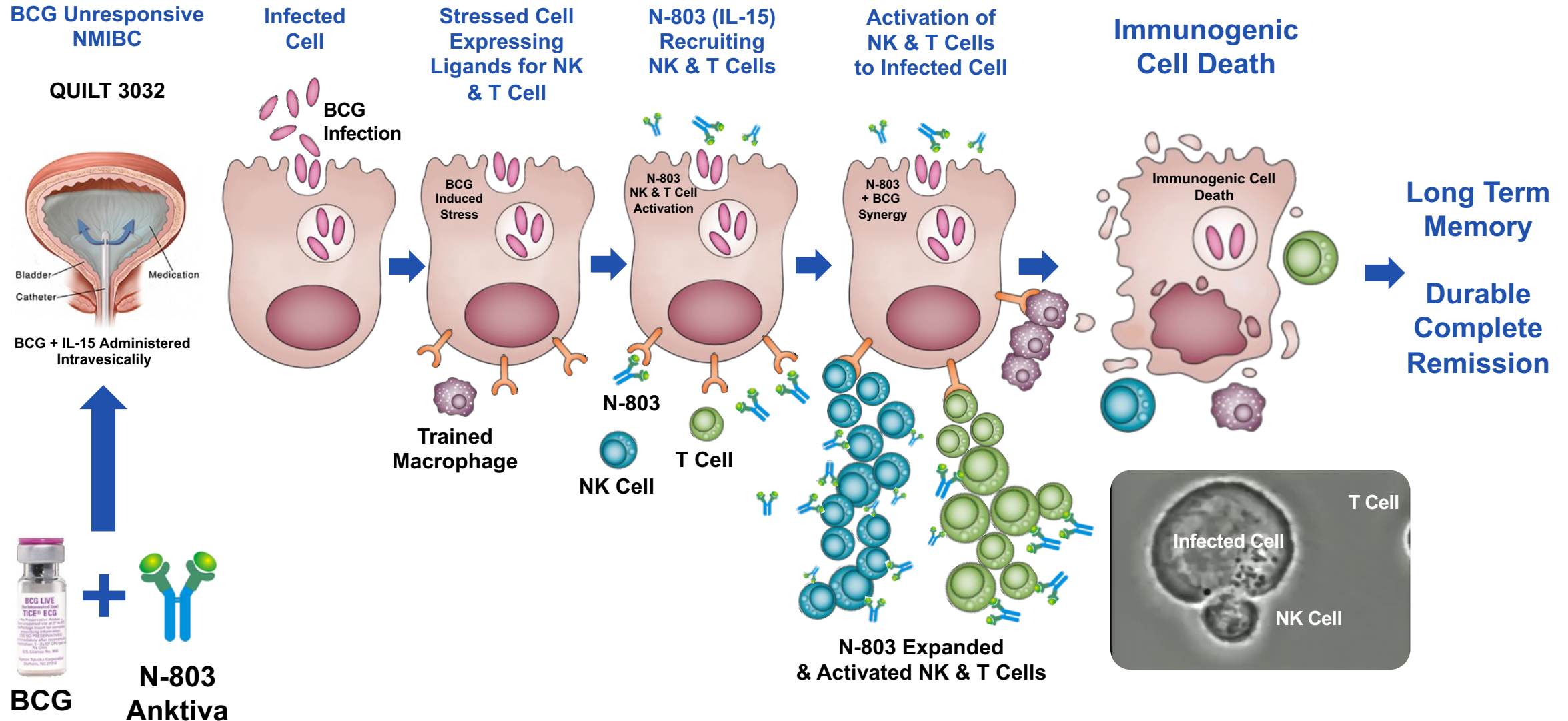
Late-Stage U.S. Clinical Trial Updates:



Bladder Cancer


- Pancreatic Cancer
- Lung Cancer
- Head & Neck Cancer
- Lynch Syndrome

N-803 (Anktiva) Potentiates the NK Cell Induced Immunogenic Cell Death in a BCG Infected Bladder Cancer Cell



Summary of Efficacy of N-803 + BCG

Published November 10, 2022



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ORIGINAL ARTICLE

IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer

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Abstract

BACKGROUND Patients with *Bacillus Calmette-Guérin* (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC) have limited treatment options. The immune cell-activating interleukin-15 (IL-15) superagonist Nogapendekin alfa inbakicept (NAI), also known as N-803, may act synergistically with BCG to elicit durable complete responses (CRs) in this patient population.

METHODS In this open-label, multicenter study, patients with BCG-unresponsive bladder carcinoma in situ (CIS) with or without Ta/T1 papillary disease were treated with intravesical NAI plus BCG (cohort A) or NAI alone (cohort C). Patients with BCG-unresponsive high-grade Ta/T1 papillary NMIBC also received NAI plus BCG (cohort B). The primary end point was the incidence of CR at the 3- or 6-month assessment visit for cohorts A and C, and the disease-free survival (DFS) rate at 12 months for cohort B. Durability, cystectomy avoidance, progression-free survival, disease-specific survival (DSS), and overall survival were secondary end points for cohort A.

RESULTS In cohort A, CR was achieved in 58 (71%) of 82 patients (95% confidence interval [CI]=59.6 to 80.3; median follow-up, 23.9 months), with a median duration of 26.6 months (95% CI=9.9 months to [upper bound not reached]). At 24 months in patients with CR, the Kaplan-Meier-estimated probability of avoiding cystectomy and of DSS was 89.2% and 100%, respectively. In cohort B (n=72), the Kaplan-Meier-estimated DFS rate was 55.4% (95% CI=42.0% to 66.8%) at 12 months, with median DFS of 19.3 months (95% CI=7.4 months to [upper bound not reached]). Most treatment-emergent adverse events for patients receiving BCG plus NAI were grade 1 to 2 (86%); three grade 3 immune-related treatment-emergent adverse events occurred.

Dr. Chamie and Chang contributed equally to this article and are coprincipal investigators.
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DOI: <https://doi.org/10.1056/EVIDoa2200167>

“NEJM Evidence presents innovative original research and fresh, bold ideas in clinical trial design and clinical decision-making.”

71%
CR Rate
At Any Time

62%
12 Months
Complete Response

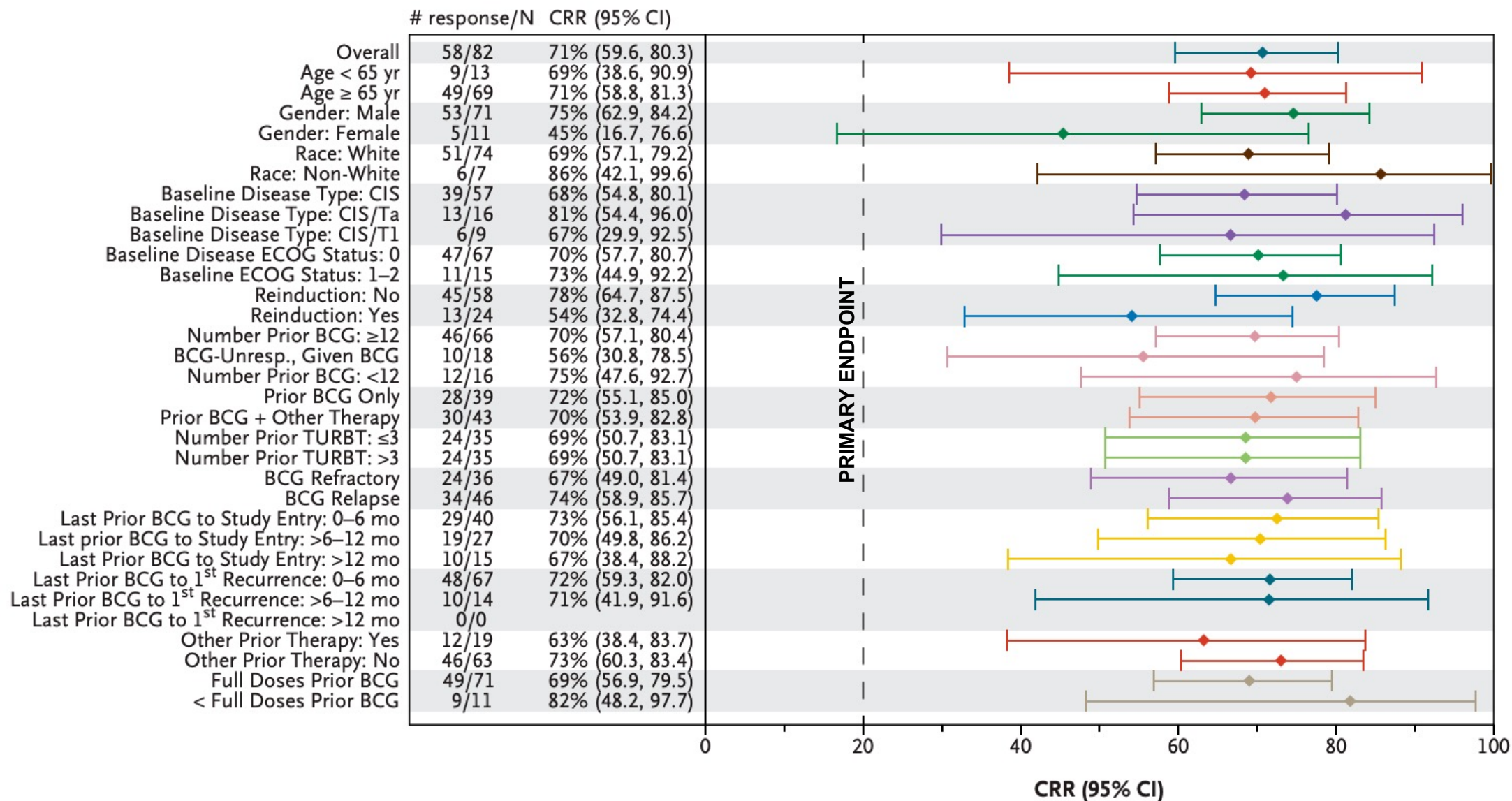
53%
24 Months
Complete Response

26.6
Months Median
Duration of CR

89%
Cystectomy Free
At 24 Months

90%
Avoidance of
Cystectomy
In Responders

Complete Response Rate (CRR) Across Subgroups



Response rates for subgroups are shown. The vertical dashed line represents the threshold required for the lower limit of the 95% confidence interval (CI) to meet the primary end point. 'BCG-unresp. Given BCG' represents patients previously defined as bacillus Calmette–Guerin (BCG) unresponsive who were given additional BCG. CIS denotes carcinoma in situ; ECOG, Eastern Cooperative Oncology Group; and TURBT, transurethral resection of the bladder tumor.

Summary of Safety

Safety and tolerability profile comparable to BCG alone

N-803 (Anktiva)
+
BCG

1%

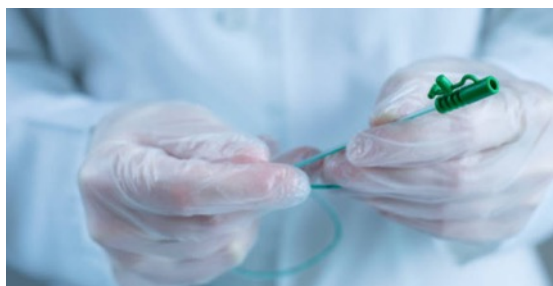
Treatment Related
SAEs

0%

Immune Related
SAEs

0%

Treatment Related
Grade 4 and 5 AEs



2%

Treatment Related
Discontinuation



The AE profile is consistent with PK results showing no systemic distribution

Adverse reactions considered related to treatment leading to interruption of N-803 in combination with BCG occurred in 13% of Patients

Most common treatment related AEs were those expected for intravesical instillation and included dysuria, pollakiuria and hematuria

N-803 Activity is **Local to the Bladder** with **Zero Systemic** IL-15 Levels per PK (Exploratory Endpoint)

Summary: Anktiva + BCG in BCG Unresponsive Bladder Cancer CIS & Papillary

- First-in-class IL-15 superagonist: N-803 (Anktiva) enhances trained immunity and promotes long-term innate immune memory
- **Efficacy: BCG-unresponsive CIS** (median follow-up 23.9 months) Data Cutoff: January 2022
 - 71 % complete response rate (CR) at any time
 - 53% CR at 24 months
 - 26.6 months median duration of CR
 - 90% cystectomy avoidance rate in responders
- **Efficacy: BCG-unresponsive Papillary** (median follow-up 19.3 months) Data Cutoff: January 2022
 - 55% disease free rate at 12 months
 - 48% disease free rate at 24 months
 - 94% radical cystectomy avoidance rate
- **Safety and tolerability** profile analogous to BCG alone
- Familiar and favorable **local intravesical administration** with no special handling or storage requirements

Orchestrating the Immune System

First-in-Class Comprehensive Platforms

NK + T Cells

- Anktiva (N-803)

Natural Killer Cells

- PD-L1 t-haNK

DAMP Inducers

- Aldoxorubicin

Memory B & T Cells

- Adenovirus (hAd5)

Late-Stage U.S. Clinical Trial Updates:

- Bladder Cancer

▶ Pancreatic Cancer

- Lung Cancer
- Head & Neck Cancer
- Lynch Syndrome

Addressing Advanced Pancreatic Cancer with Combination Immunotherapy

N-803



PD-L1 t-haNK



Aldoxorubicin

January 2022

ImmunityBio Announces Results of Phase 2 Metastatic Pancreatic Cancer Trial at ASCO GI with Median Overall Survival of 6.3 Months in Patients with Third-Line Disease, More than Doubling Historical Survival

Jan 18, 2022

- Data show that ImmunityBio's combination immunotherapy, Nant Cancer Vaccine, is potentially effective in pancreatic cancer where very few treatment options exist
- Nant Cancer Vaccine therapy more than doubles median overall survival (OS) versus historical OS in patients who had progressed after two prior lines of therapy (N=30) with median OS of 6.3 months (95% CI: 5.0, 9.8 months)
- When patients with even more advanced disease who failed four to six prior lines of therapy are added, the median OS even with such advanced disease (N=63) is 5.8 months (95% CI: 3.9, 6.9 months)
- Treatment-related serious adverse events were uncommon and no treatment-related deaths were reported
- The company plans to meet with the FDA in 2022 to discuss the path for the approval of combination therapies for pancreatic cancer

November 2022

- Cohort A** 1st Line therapy (Randomized) **Actively Enrolling**
- Cohort B** 2nd Line therapy (Randomized) **Actively Enrolling**
- Cohort C** 3rd Line or greater therapy (Single-Arm) **Fully Enrolled**

- QUILT-88 (Cohort C) 3rd line or Greater, Fully Enrolled, N=80
- Briefing Book Submitted to the FDA
- **Type B Meeting Scheduled December 2022**

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▶ Lung Cancer

- Head & Neck Cancer

- Lynch Syndrome

Median Overall Survival of Anktiva Compared to Any Therapy in Patients Who Progressed on Checkpoint Inhibitor

Additional Therapy Following Checkpoint Inhibitor Progression

Median OS: 6.1 Months

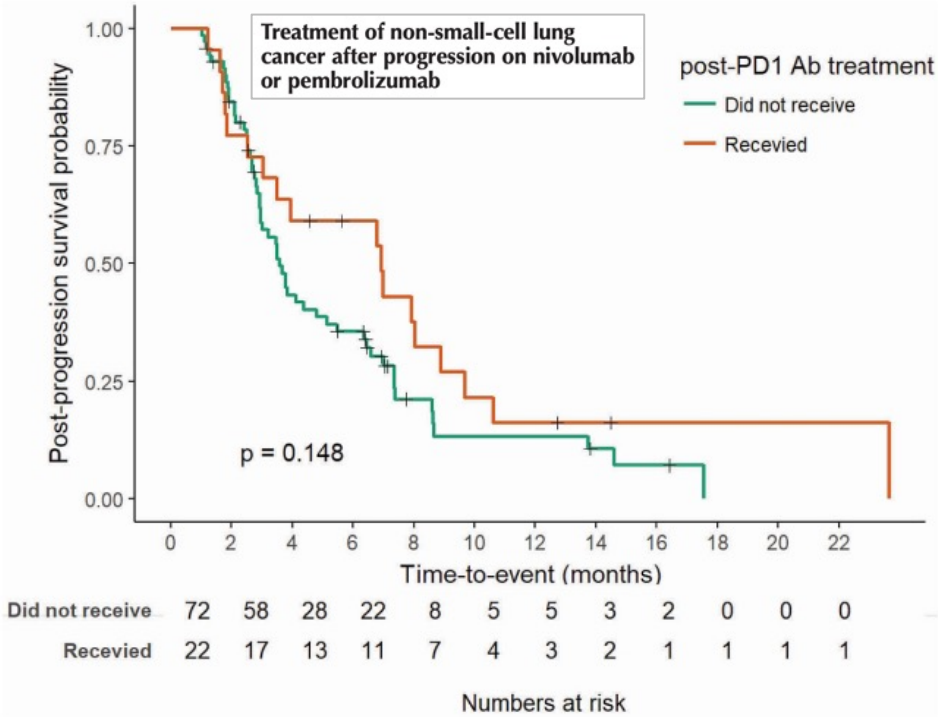


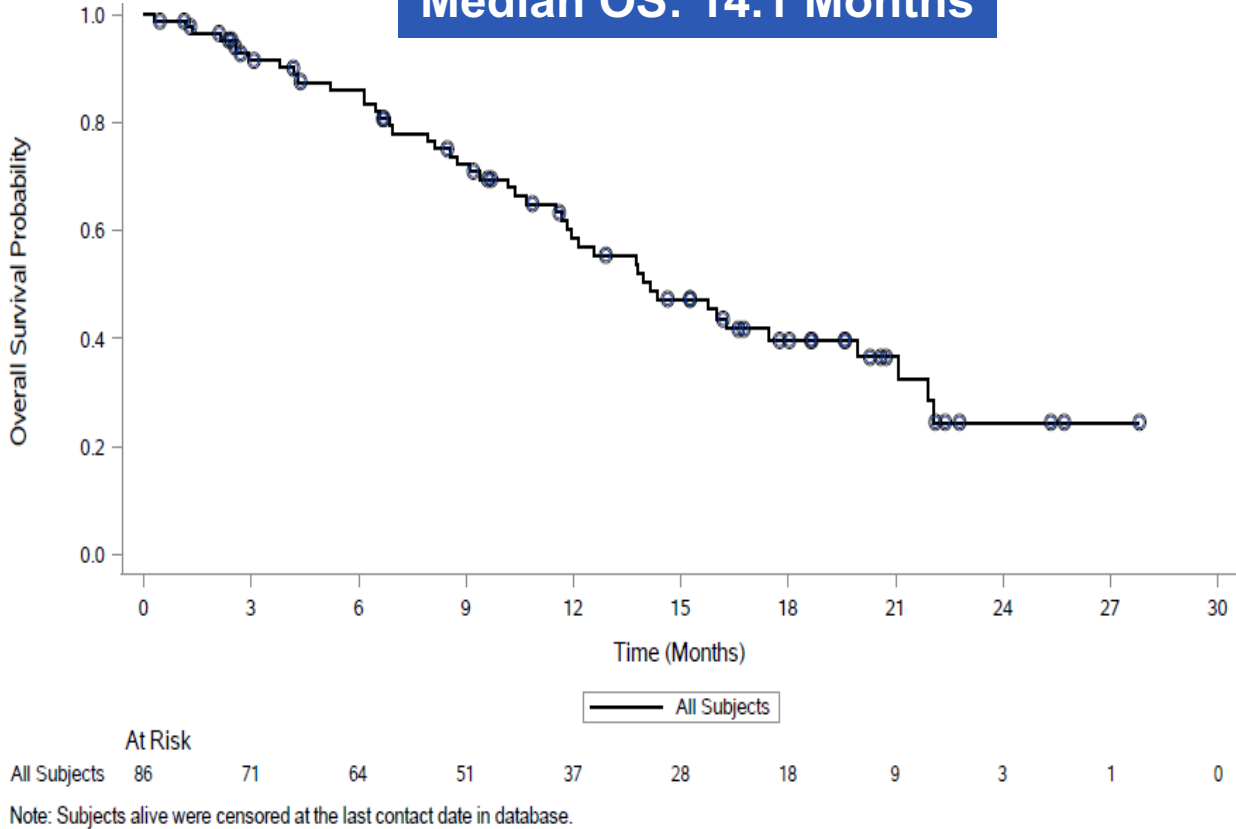
FIGURE 3 Post-progression survival after cessation of PD-1 monoclonal antibody (Ab) in 22 patients who received post-progression therapy and 72 patients who did not within 30 days of PD-1 Ab cessation.

doi: 10.3747/co.27.5495

QUILT 3.055

Anktiva IL-15 Therapy Following Checkpoint Inhibitor Progression

Median OS: 14.1 Months



Anktiva Selected by LUNG-MAP for 2nd Line Patients who Progressed on Checkpoint Therapy Actively Enrolling



ImmunityBio Announces First Participants Have Been Enrolled in Lung-MAP Trial Studying Anktiva to Activate NK and T Cells in Non-Small Cell Lung Cancer

April 25, 2022

- Novel combination therapy of Anktiva, an IL-15 superagonist, and Keytruda targeted at patients with lung cancer who have failed checkpoint inhibitor therapy
- The study currently includes nearly **200 U.S. sites** and will involve 478 patients when fully enrolled
- Nearly 237,000 new cases of lung cancer are estimated to be diagnosed in the U.S. this year, making it the second most common cancer in the U.S.



Investigator Initiated Trial - NCT05096663

Orchestrating the Immune System

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Late-Stage U.S. Clinical Trial Updates:

- Bladder Cancer
- Pancreatic Cancer
- Lung Cancer

▶ Head & Neck Cancer

- Lynch Syndrome

Metastatic Head & Neck Cancer

N-803 + PD-L1 t-haNK + Checkpoint



Investigator Initiated Trial: NCT04847466

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Immunotherapy Combination: Irradiated PD-L1 CAR-NK Cells Plus Pembrolizumab Plus N-803 for Subjects With Recurrent/Metastatic Gastric or Head and Neck Cancer

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Sponsor:

National Cancer Institute (NCI)

Information provided by (Responsible Party):

National Institutes of Health Clinical Center (CC) (National Cancer Institute (NCI))

ClinicalTrials.gov Identifier: NCT04847466

Recruitment Status : Recruiting

First Posted : April 19, 2021

Last Update Posted : October 6, 2022

See [Contacts and Locations](#)

Condition or disease	Intervention/treatment	Phase
Gastroesophageal Junction (GEJ) Cancers	Drug: N-803	Phase 2
Advanced HNSCC	Drug: Pembrolizumab	
	Biological: PD-L1 t-haNK	

Study Design

- Study Type

: Interventional (Clinical Trial)
- Estimated Enrollment

: 55 participants
- Allocation

: N/A
- Intervention Model

: Single Group Assignment
- Masking

: None (Open Label)
- Primary Purpose

: Treatment
- Official Title

: A Phase II Study of Immunotherapy Combination: Irradiated PD-L1 CAR-NK Cells Plus Pembrolizumab Plus N-803 for Subjects With Recurrent/Metastatic Gastric or Head and Neck Cancer
- Actual Study Start Date

: December 14, 2021
- Estimated Primary Completion Date

: January 31, 2025
- Estimated Study Completion Date

: December 31, 2025

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- Pancreatic Cancer
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- Head & Neck Cancer

▶ **Lynch Syndrome**

Lynch Syndrome – Prevention of Colon Cancer and Endometrial Cancer



NATIONAL CANCER INSTITUTE
Division of Cancer Prevention

Investigator Initiated Trial
Clinical Trials: NCT05419011

INT21-05-01

Protocol Version 3.0, 10/04/2021

COVER PAGE

DCP Protocol #: INT21-05-01

Local Protocol #: NWU21-05-01

**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**

- Lynch syndrome (LS) is the most common hereditary colorectal cancer (CRC) syndrome with a population prevalence affecting 1 in 279 Americans¹
- Lynch syndrome accounts for approximately 3% of CRCs and 3% of endometrial cancers²
- First large scale multi-center clinical trial for the prevention of colon cancer by activating innate NK cells (with Anktiva) and inducing tumor specific CD4+, CD8+, and memory T cells (with hAd5 CEA, MUC1, Brachyury).
- Anticipated initiation of trial Q1 2023

Investigational Agents:

N-803 (Anktiva) + hAd5 CEA, MUC1, Brachyury

Lifetime risk and mean age at diagnosis for Lynch syndrome associated cancers¹

Type of cancer	Lifetime risk (%)	Mean age at diagnosis (years)
Colorectal	52-58	44-61
Endometrial	25-60	48-62
Gastric	6-13	56
Ovarian	4-12	42.5

1. Win AK, et al. Prevalence and penetrance of major genes and polygenes for colorectal cancer. *Cancer Epidemiol Biomarkers Prev.* 2017;26:404–12.
2. [Moreira et al 2012](#), [Jiang et al 2019](#), [Kahn et al 2019](#), [Dong et al 2020](#)
3. "Lynch Syndrome". *DynaMed*. February 22, 2019. Retrieved November 18, 2019.

Registrational Development Strategy & Status

Nov 2022

Investigational Product	Anticipated Registrational Trial Indications (2023 – 2025)	Current Status
IL-15 Superagonist Anktiva, N-803	• BCG-Unresponsive Bladder Cancer CIS N-803 + BCG	• BLA Filed, PDUFA May 2023
	• BCG-Unresponsive Bladder Cancer Papillary N-803 + BCG	• Enrollment Completed, FDA Type B Meeting Scheduled Dec 2022
	• BCG Naïve Bladder Cancer CIS & Papillary N-803 + BCG	• Actively Enrolling
	• 2nd Line Lung Cancer N-803 + Checkpoint	• LungMAP Actively Enrolling, Multi-Center Trial
PD-L1 t-haNK	• ≥3rd Line Metastatic Pancreatic Cancer N-803 + PD-L1 t-haNK + Aldox	• Enrollment Completed, FDA Type B Meeting Scheduled Dec 2022
	• >2nd Line Glioblastoma N-803 + PD-L1 t-haNK + Aldox	• Phase 2 Randomized Trial
Aldoxorubicin	• ≥3rd Line Metastatic Pancreatic Cancer N-803 + PD-L1 t-haNK + Aldox	• Enrollment Completed, FDA Type B Meeting Scheduled Dec 2022
Adenovirus Vector hAd5 E6/E7	• HPV⁺ Head & Neck Cancer N-803 + hAd5 E6/E7 + PD-L1 t-haNK	• IND Anticipated 1H 2023
Adenovirus Vector hAd5 CEA, MUC1, Brachyury	• Lynch Syndrome - Prevention of Colon Cancer N-803 + hAd5 CEA, MUC1, Brachyury	• FDA / IRB Authorized: Initiation of Multi-Center Trial Anticipated Q1 2023. NIH Sponsored Trial

ImmunityBio: A Leading Immunotherapy Company

Tipping the Scales from Immune-Evasion to Immune Activation

Nov 2022

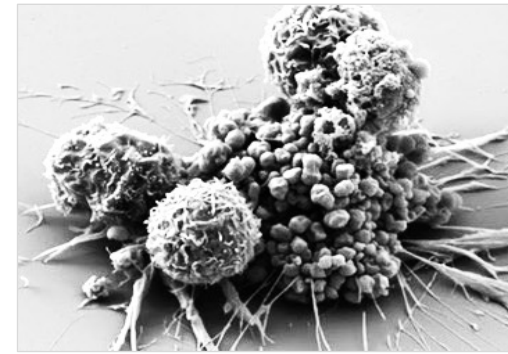


NASDAQ: IBRX



>5 Trillion

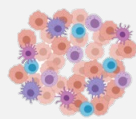
Over 5 Trillion Natural Killer (NK) Cells Manufactured to Date



6

Immune Enhancing Platforms

DAMP Inducers



- Aldoxorubicin
- Nanatinostat

DNA Vaccine



- hAd5 Adenovirus

RNA Vaccine



- Self-Amplifying RNA (saRNA)

Fusion Proteins & Cytokines



- NK & T Cell Activators
- Subunit Protein Antigens

Toll Receptor Activators



- TLR 4, 7, 8, 9

NK Cell Therapy



- NK-92
- Memory-Like Cytokine NK

2038+

Worldwide Patents Extending to 2035 and Beyond



>700,000

Square Feet of Manufacturing R&D, Office and Corporate Facilities



1,800+

Patients Studied



Thank You