UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
November 15, 2022

ImmunityBio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-37507	43-1979754
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3530 John Hopkins Court
San Diego, California 92121
(Address of principal executive offices, including zip code)

(858) 633-0300
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**IBRX**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

Investor Conference

On November 15, 2022, Dr. Patrick Soon-Shiong, the Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio, Inc., a Delaware corporation (the "Company" or "ImmunityBio") will participate in the 2022 Jefferies London Healthcare Conference (the "Conference"), which is taking place in London from November 15-17, 2022. Dr. Soon-Shiong is scheduled to present at the conference on November 15, 2022 at 4:25 P.M. Greenwich Mean Time (GMT). During the Conference, Dr. Soon-Shiong intends to refer to an updated corporate presentation (the "Investor Presentation"), a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference solely for purposes of this Item 7.01 disclosure. Interested parties can access the live audio webcast of this Conference presentation at https://wsw.com/webcast/jeff255/ibrx/1861731 and a replay of the presentation will be available on the Events section of the Investor Relations page on the Company's website.

The information furnished pursuant to this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended (the "Securities Act") or the Exchange Act, except as expressly set forth by specific reference in such a filing. This Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information in the Current Report on Form 8-K that is required to be disclosed solely by Regulation FD.

Item 8.01. Other Events.

The Company is providing updates regarding the registrational development strategy and status for certain of the Company's product candidates. For example, the Company has completed enrollment of the papillary cohort (cohort B) of its QUILT 3.032 clinical trial studying N-803 plus BCG in adults with BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC"), and the Company has a related Type B meeting scheduled with the United States Food and Drug Administration ("FDA") in December 2022. In addition, the Company has completed enrollment in the third-line or greater cohort (cohort C) of its QUILT 88 clinical trial studying low-dose chemotherapy in combination with PD-L1 t-haNK, N-803 and aldoxorubicin in subjects with metastatic pancreatic cancer, and the Company has submitted a related briefing book to the FDA and has a related Type B meeting scheduled with the FDA in December 2022. Further, as previously disclosed, in May 2022, the Company announced the submission of a Biologics License Application ("BLA") to the FDA for N-803 in combination with BCG for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without Ta or T1 disease. In July 2022, the Company announced the FDA had accepted the Company's BLA for review and set a target Prescription Drug User Fee Act ("PDUFA") action date of May 23, 2023. It is unclear when the FDA will approve the Company's BLA, if at all. In anticipation of the PDUFA date and as part of the Company's overall strategy, the Company is exploring to partner with a large biopharmaceutical company for commercialization of N-803 plus BCG for administration intravesically. While the Company is pursuing discussions with multiple prospective global pharmaceutical partners with a view towards completing a transaction by the first quarter of 2023, there can be no assurance that the Company will complete a transaction on acceptable terms in accordance with this timeline or at all.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding clinical trial enrollment and results, the regulatory review process and timing thereof, timing of scheduled meetings with the FDA, the Company's commercialization strategy for N-803 plus BCG for administration intravesically, and potential strategic partnering transactions, 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 execute a partnering relationship with a large biopharmaceutical company for commercialization of N-803 plus BCG for administration intravesically on acceptable terms, if at all, (iii) 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, (iv) ImmunityBio's ability to retain and hire key personnel, (v) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vi) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, (viii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (ix) 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Investor Presentation
104	The cover page of this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMMUNITYBIO, INC.

Date: November 15, 2022

By: /s/ David Sachs
David Sachs
Chief Financial Officer

ImmunityBio

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**

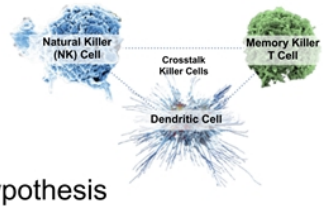
2005 - 2010

Abraxis BioScience (NASDQ: 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+

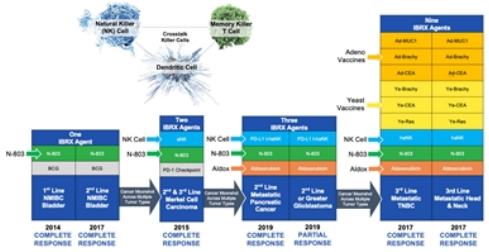
Worldwide Patents Extending to 2035 and Beyond

Biological Manufacturing Scale

*Through Potential Strategic Collaborators

Multiple Tumor Type Scale

Cancer Moonshot 2014 to 2020



ImmunityBio

NASDAQ: IBRX

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

ONCOIMMUNOLOGY
2021, VOL. 10, NO. 1, e1912865 (7 pages)
https://doi.org/10.1080/2162402X.2021.1912865

Taylor & Francis
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ORIGINAL RESEARCH

OPEN ACCESS Check for updates

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

Charles J. Rosser[a], Sergei Tikhomirov[a], Jeffrey W. Nix[a], Owen T.M. Chan[a], Irina Ianculescu[a], Sandeep Reddy[a,b], and Patrick Soon-Shiong[a]

[a]Clinical & Translational Research Program, University of Hawaii Cancer Center,Honolulu, Hawaii; [b]Department of Urology, University of Alabama, Birmingham, Alabama; [c]ImmunityBio, Inc., Culver City, California; [d]NantHealth Inc, Culver City, California

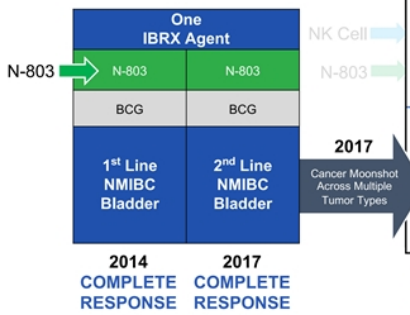
ABSTRACT

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 addition of N-803 to BCG, 9 patients were enrolled in a phase 1b trial. N-803 was administered at 3 × 3 dose-escalation levels. 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/instillation, in combination with increasing doses of N-803 (100, 200, or 400 µg N-803 per instillation). 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 15 March 2021
Accepted 16 March 2021

KEYWORDS
Non-muscle invasive bladder cancer; IL15; BCG

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

2015 COMPLETE RESPONSE

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

**Negative Cystoscopy Inconclusive Cytology

RESPONSE RESPONSE RESPONSE RESPONSE

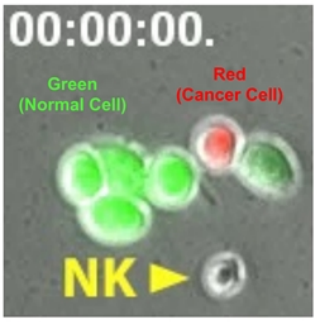
2021

NADAQ: IBRX
NantCell &
NantKwest
Merger

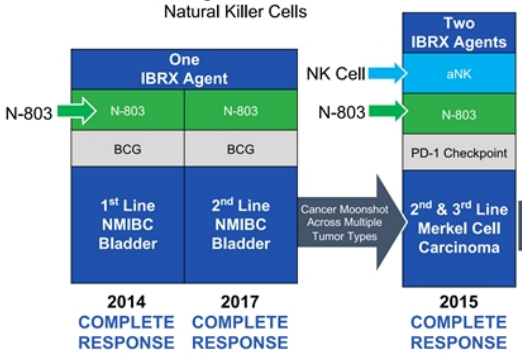
Proof of Concept: Complete Responses Across Multiple Tumor Types

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

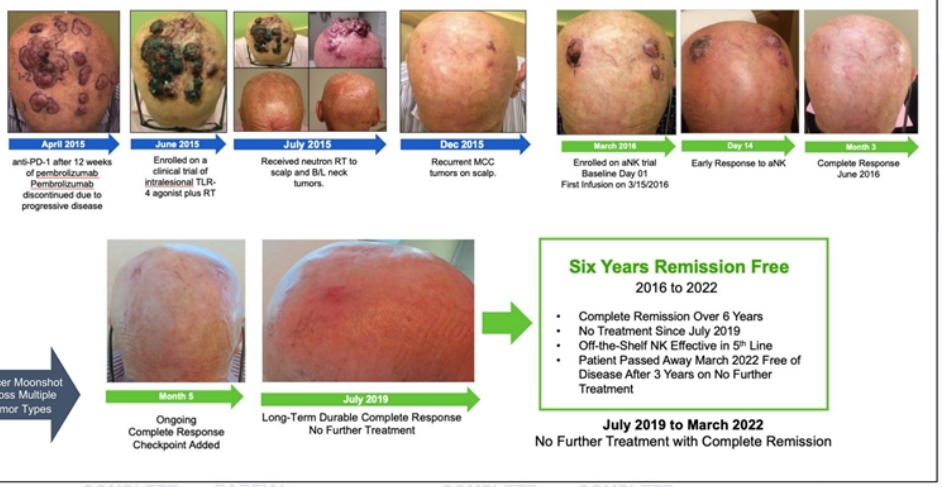
The NANT Cancer Vaccine: QUILT Trials: 2014 - 2020



Tumor Targeted Off-the-Shelf
Natural Killer Cells



Complete Response with Natural Killer Cell Therapy and Long Term Memory



Six Years Remission Free
2016 to 2022

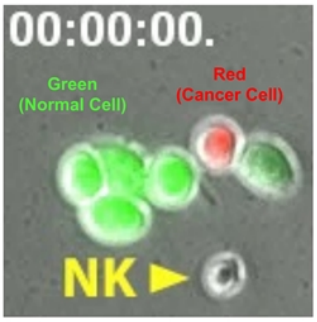
- Complete Remission Over 6 Years
- No Treatment Since July 2019
- Off-the-Shelf NK Effective in 5th Line
- Patient Passed Away March 2022 Free of Disease After 3 Years on No Further Treatment

July 2019 to March 2022
No Further Treatment with Complete Remission

Proof of Concept: Complete Responses Across Multiple Tumor Types

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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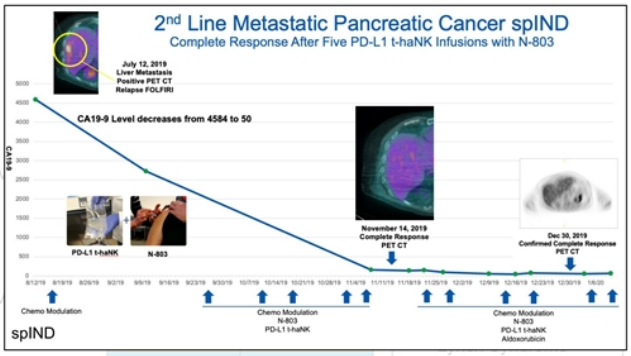

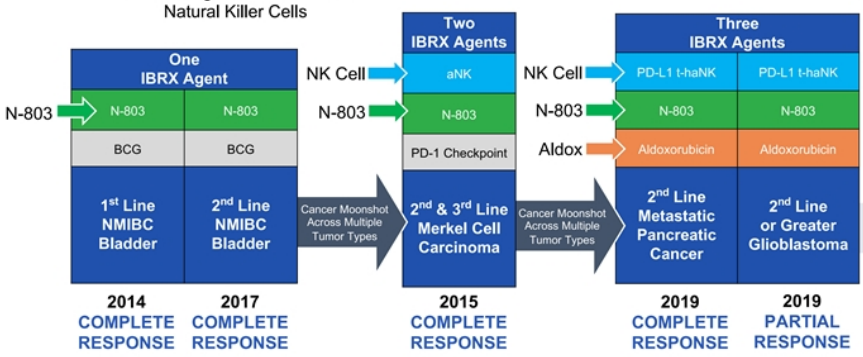

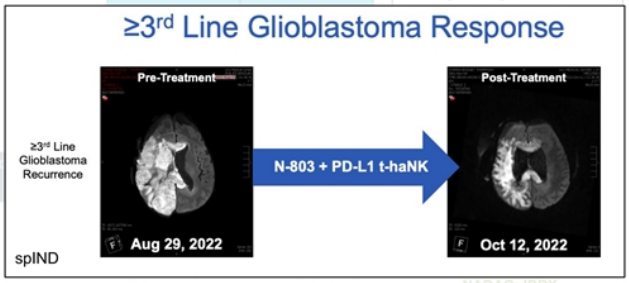

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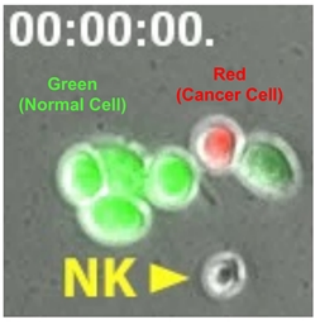

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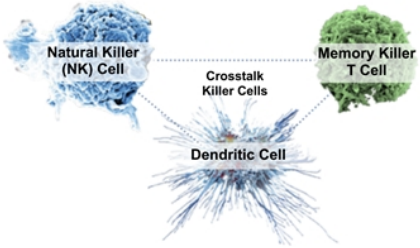
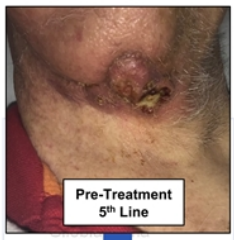


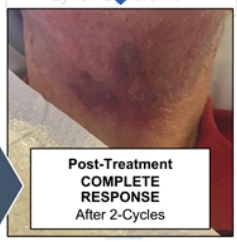
	One IBRX Agent		Two IBRX Agents	Three IBRX Agents		Nine IBRX Agents	
N-803 / NK Cell	N-803	N-803	aNK	PD-L1 t-haNK	PD-L1 t-haNK	haNK	haNK
N-803	N-803	N-803	N-803	N-803	N-803	N-803	N-803
Aldox	BCG	BCG	PD-1 Checkpoint	Aldoxorubicin	Aldoxorubicin	Aldoxorubicin	Aldoxorubicin
Adeno Vaccines						Ad-MUC1	Ad-MUC1
						Ad-Brachy	Ad-Brachy
						Ad-CEA	Ad-CEA
Yeast Vaccines						Ye-Brachy	Ye-Brachy
						Ye-CEA	Ye-CEA
						Ye-Ras	Ye-Ras
	1st Line NMIBC Bladder	2nd Line NMIBC Bladder	2nd & 3rd Line Merkel Cell Carcinoma	2nd Line Metastatic Pancreatic Cancer	2nd Line or Greater Glioblastoma	3rd Line Metastatic TNBC	3rd 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

Cancer Moonshot Across Multiple Tumor Types

>5th Line Metastatic Head & Neck



- Head & Neck Cancer
- Lynch Syndrome



2021

NADAQ: IBRX
NantCell &
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Merger

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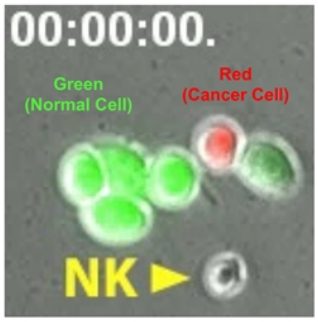

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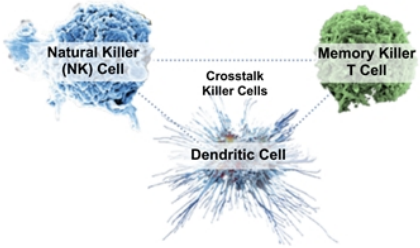

	One IBRX Agent		Two IBRX Agents	Three IBRX Agents		Nine IBRX Agents	
N-803	N-803	N-803					
NK Cell			aNK	PD-L1 t-haNK	PD-L1 t-haNK	haNK	haNK
N-803			N-803	N-803	N-803	N-803	N-803
Aldox				Aldoxorubicin	Aldoxorubicin	Aldoxorubicin	Aldoxorubicin
Adeno Vaccines						Ad-MUC1	Ad-MUC1
						Ad-Brachy	Ad-Brachy
						Ad-CEA	Ad-CEA
Yeast Vaccines						Ye-Brachy	Ye-Brachy
						Ye-CEA	Ye-CEA
						Ye-Ras	Ye-Ras
	BCG	BCG	PD-1 Checkpoint				
	1st Line NMIBC Bladder	2nd Line NMIBC Bladder	2nd & 3rd Line Merkel Cell Carcinoma	2nd Line Metastatic Pancreatic Cancer	2nd Line or Greater Glioblastoma	3rd Line Metastatic TNBC	3rd 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

Cancer Moonshot Across Multiple Tumor Types

Proof of Concept: Complete Responses Across Multiple Tumor Types

2021 - 2025
Registration Strategy

Registration Trials

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

ImmunityBio

2021

NADAQ: IBRX
NantCell & NantKwest Merger

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

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:

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- Pancreatic Cancer
- Lung Cancer
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- Lynch Syndrome

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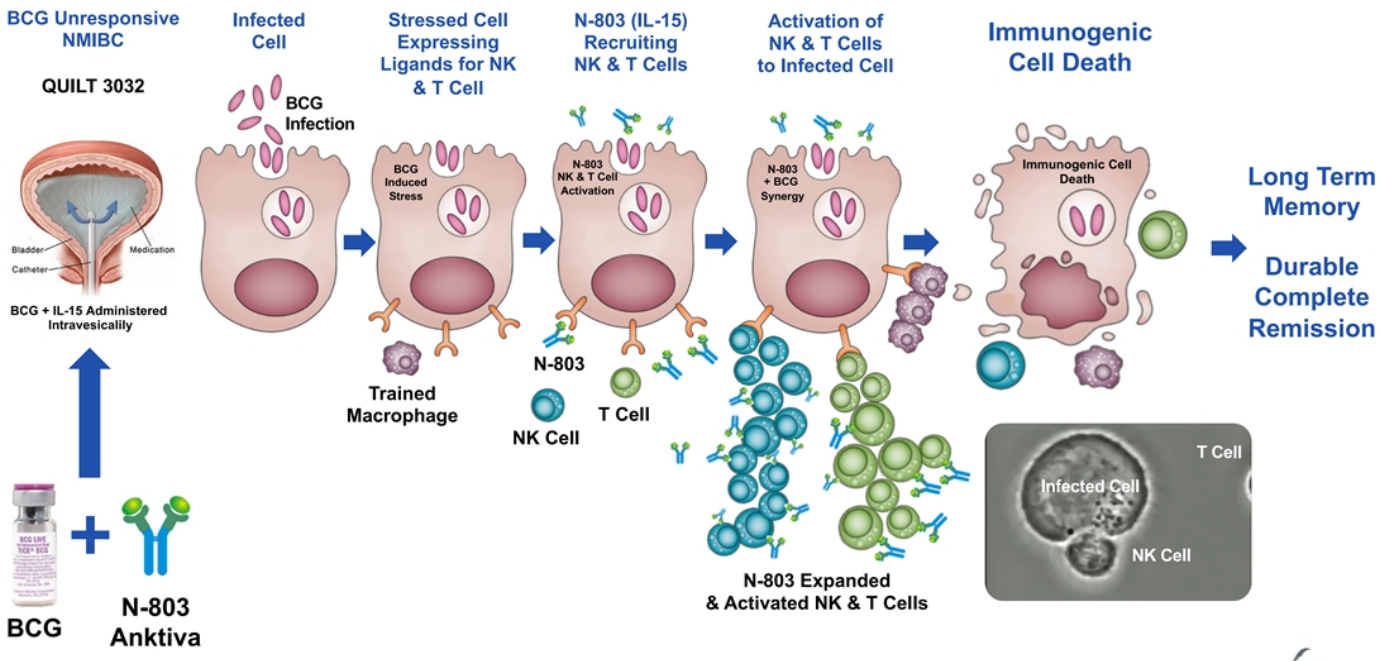
- Pancreatic Cancer
- Lung Cancer
- Head & Neck Cancer
- Lynch Syndrome

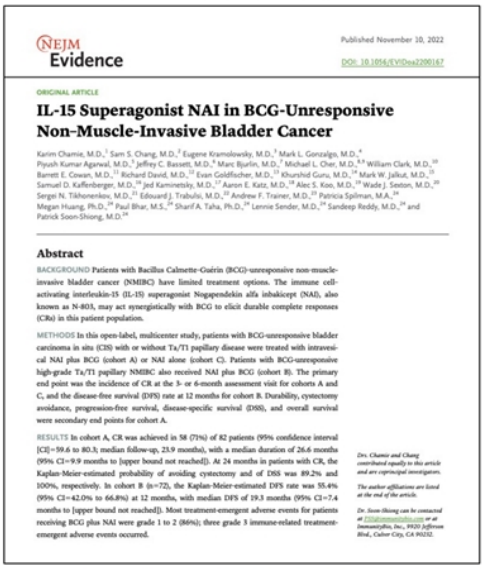
N-803 (Anktiva) Potentiates the NK Cell Induced Immunogenic Cell Death in a BCG Infected Bladder Cancer Cell



N-803 is Investigational: Safety and Efficacy have Not been Established.

Summary of Efficacy of N-803 + BCG

Published November 10, 2022



NEJM Evidence

Published November 10, 2022

DOI: 10.1056/EVIDoa2200167

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.

Drs. Chamie and Chang contributed equally to this article and are coprincipal investigators.

The author affiliations are listed at the end of the article.

Dr. Soon-Shiong can be contacted at CEO@immunitybio.com or at ImmunityBio, Inc., 3930 Jefferson Blvd., Culver City, CA 90232.

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

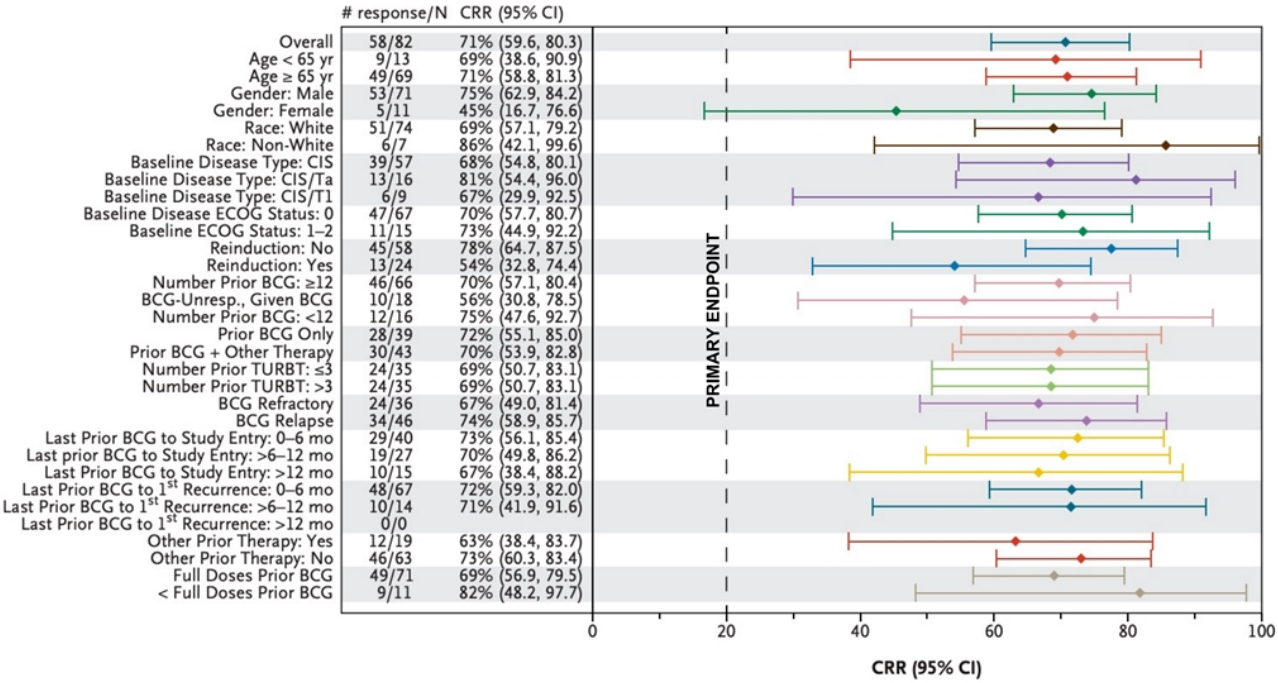
26.6
Months Median Duration of CR

89%
Cystectomy Free At 24 Months

90%
Avoidance of Cystectomy In Responders

N-803 is Investigational: Safety and Efficacy have Not been Established.

Complete Response Rate (CRR) Across Subgroups



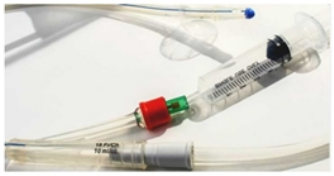
	# response/N	CRR (95% CI)
Overall	58/82	71% (59.6, 80.3)
Age < 65 yr	9/13	69% (38.6, 90.9)
Age ≥ 65 yr	49/69	71% (58.8, 81.3)
Gender: Male	53/71	75% (62.9, 84.2)
Gender: Female	5/11	45% (16.7, 76.6)
Race: White	51/74	69% (57.1, 79.2)
Race: Non-White	6/7	86% (42.1, 99.6)
Baseline Disease Type: CIS	39/57	68% (54.8, 80.1)
Baseline Disease Type: CIS/Ta	13/16	81% (54.4, 96.0)
Baseline Disease Type: CIS/T1	6/9	67% (29.9, 92.5)
Baseline Disease ECOG Status: 0	47/67	70% (57.7, 80.7)
Baseline ECOG Status: 1–2	11/15	73% (44.9, 92.2)
Reinduction: No	45/58	78% (64.7, 87.5)
Reinduction: Yes	13/24	54% (32.8, 74.4)
Number Prior BCG: ≥12	46/66	70% (57.1, 80.4)
BCG-Unresp., Given BCG	10/18	56% (30.8, 78.5)
Number Prior BCG: <12	12/16	75% (47.6, 92.7)
Prior BCG Only	28/39	72% (55.1, 85.0)
Prior BCG + Other Therapy	30/43	70% (53.9, 82.8)
Number Prior TURBT: ≤3	24/35	69% (50.7, 83.1)
Number Prior TURBT: >3	24/35	69% (50.7, 83.1)
BCG Refractory	24/36	67% (49.0, 81.4)
BCG Relapse	34/46	74% (58.9, 85.7)
Last Prior BCG to Study Entry: 0–6 mo	29/40	73% (56.1, 85.4)
Last prior BCG to Study Entry: >6–12 mo	19/27	70% (49.8, 86.2)
Last Prior BCG to Study Entry: >12 mo	10/15	67% (38.4, 88.2)
Last Prior BCG to 1st Recurrence: 0–6 mo	48/67	72% (59.3, 82.0)
Last Prior BCG to 1st Recurrence: >6–12 mo	10/14	71% (41.9, 91.6)
Last Prior BCG to 1st Recurrence: >12 mo	0/0	
Other Prior Therapy: Yes	12/19	63% (38.4, 83.7)
Other Prior Therapy: No	46/63	73% (60.3, 83.4)
Full Doses Prior BCG	49/71	69% (56.9, 79.5)
< Full Doses Prior BCG	9/11	82% (48.2, 97.7)

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)

N-803 is Investigational: Safety and Efficacy have Not been Established.

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

N-803 is Investigational: Safety and Efficacy have Not been Established.

ImmunityBio

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**

N-803, Aldoxorubicin and PD-L1 t-haNK are Investigational: Safety and Efficacy have Not been Established.

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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

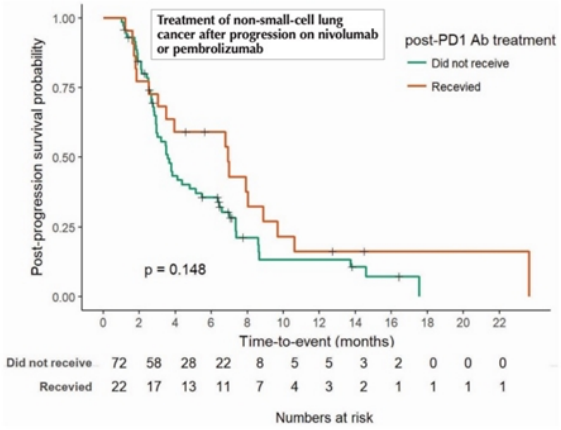


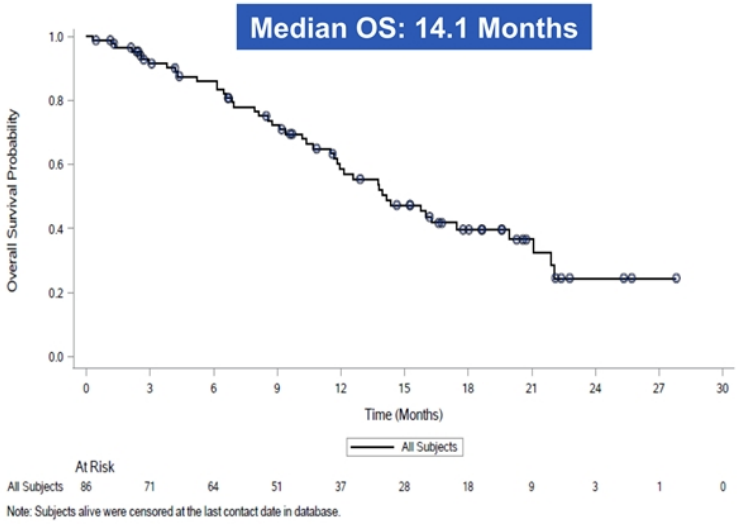
FIGURE 3 Post-progression survival after cessation of PD-1 monoclonal antibody (Ab) in 22 patients who received post-progression therapy and 72 patients who did not within 30 days of PD-1 Ab cessation.

doi: 10.3747/co.27.5495

QUILT 3.055

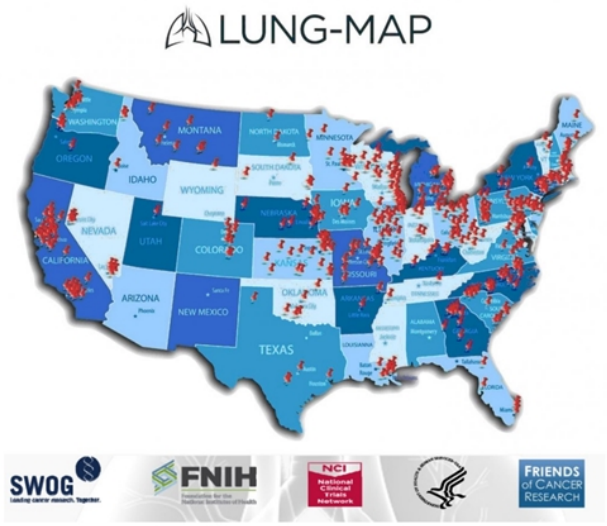
Anktiva IL-15 Therapy Following Checkpoint Inhibitor Progression

Median OS: 14.1 Months



Note: Subjects alive were censored at the last contact date in database.

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



Investigator Initiated Trial - NCT05096663

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.

N-803 is Investigational: Safety and Efficacy have Not been Established.

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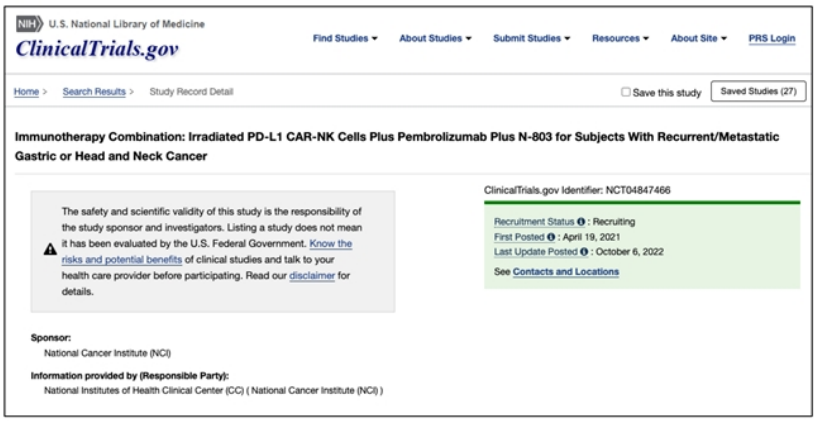
- Head & Neck Cancer
- Lynch Syndrome

Metastatic Head & Neck Cancer

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



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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.

ClinicalTrials.gov Identifier: NCT04847466

Recruitment Status : Recruiting
First Posted : April 19, 2021
Last Update Posted : October 6, 2022

See Contacts and Locations

Sponsor:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
National Institutes of Health Clinical Center (CC) (National Cancer Institute (NCI))

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

NIH NATIONAL CANCER INSTITUTE

Investigator Initiated Trial: NCT04847466

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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- 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 Americans[1]
- Lynch syndrome accounts for approximately 3% of CRCs and 3% of endometrial cancers[2]
- 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 cancers[1]

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.

N-803 and hAd5 CEA, MUC1, and Brachyury are Investigational: Safety and Efficacy have Not been Established.

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

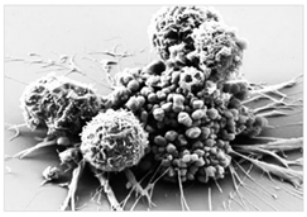
Nov 2022

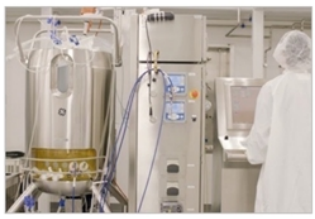
ImmunityBio

NASDAQ: IBRX

>5 Trillion

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





6

Immune Enhancing Platforms

DAMP Inducers	DNA Vaccine	RNA Vaccine	Fusion Proteins & Cytokines	Toll Receptor Activators	NK Cell Therapy
• Aldoxorubicin • Nanatinostat	• hAd5 Adenovirus	• Self-Amplifying RNA (saRNA)	• NK & T Cell Activators • Subunit Protein Antigens	• TLR 4, 7, 8, 9	• 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

ImmunityBio

Outsmart Your Disease

Thank You