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):
June 4, 2021

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.

On June 4, 2021, at 8:30 a.m. PT, ImmunityBio, Inc., a Delaware corporation (the "Company") will present at the Jefferies Virtual Healthcare Conference (the "Conference"). Dr. Patrick Soon-Shiong, the Company's Founder and Executive Chairman, will deliver the presentation, and following the presentation, a replay of the live video webcast may be accessed through the "Investor Relations" section of the Company's website. In addition to Dr. Soon-Shiong, senior management of the Company will be available to discuss the presentation with participants of the Conference after the presentation concludes.

A copy of the slide presentation the Company intends to present at the Conference is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information referenced under Item 7.01 (including Exhibit 99.1 referenced in Item 9.01 below) of this Current Report on Form 8-K is being furnished and shall not be deemed to be "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 in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ImmunityBio, Inc. Presentation on June 4, 2021
104	Cover page interactive data file (embedded within the Inline XBRL document).

SIGNATURES

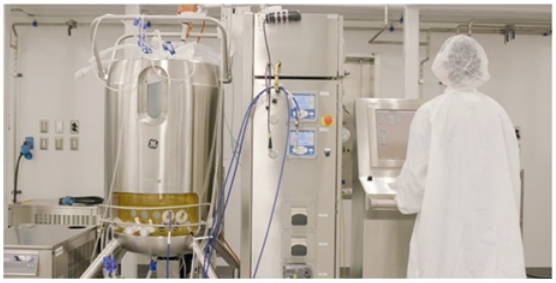
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMMUNITYBIO, INC.

Date: June 4, 2021

By: /s/ David Sachs
Chief Financial Officer

Exhibit 99.1



ImmunityBio

NASDAQ:IBRX

A Leading Immunotherapy Biotech Company

Broad Late-Stage Clinical Platform of Antibody Cytokine Fusion Proteins, Albumin-Linked Chemo-Immunomodulators, Vaccine Vectors and Natural Killer cells

June 4, 2021

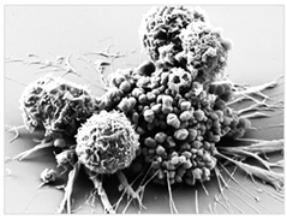
Forward Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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”, “could”, “estimates,” “expects,” “intends,” “may,” “plans,” “potential”, “predicts”, “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions. Statements of past performance, efforts, or results of our clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performances 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 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 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, (ii) whether interim, initial, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, (iii) our ability to obtain additional financing to fund our operations and complete the development and commercialization of our various product candidates, (iv) uncertainty of the expected financial performance and successful integration of the combined company following completion of the merger, including the possibility that the expected synergies and value creation from the merger will not be realized or will not be realized within the expected period, (v) inability to retain and hire key personnel, and (vi) the unknown future impact of the COVID-19 pandemic delay on certain clinical trials or their milestones and/or ImmunityBio’s 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 8-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 10, 2021 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 presentation, except to the extent required by law.

ImmunityBio: A Leading Immunotherapy Company

ImmunityBio
NASDAQ: IBRX

40
Phase I / II / III
Clinical Trials



1,800+
Patients Studied

25
Phase II / III
Clinical Trials

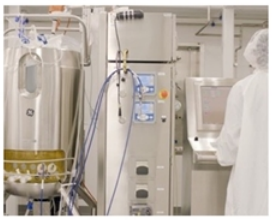
17
First in Human
Immunotherapy Molecules
and cells

Antibody Cytokine Fusion Proteins | **Chemo Immuno Modulators** | **Vaccine Technologies** | **Natural Killer Cells**

A Leading Immunotherapy Platform in Oncology & Infectious Diseases

600+
Worldwide Patents Extending to
2035 and Beyond

~400,000
Square Feet of Manufacturing
and R&D Facilities



100+
Patients Dosed with
Off-the-Shelf
Natural Killer Cells

>5 Trillion
Over 5 Trillion Natural Killer Cells
Manufactured to Date

Selected Clinical Pipeline Updates for June 2021

I. Non-Muscle Invasive Bladder Cancer (NMIBC)

II. Pancreatic Cancer

III. Triple Negative Breast Cancer (TNBC)

IV. M-ceNK

V. COVID-19

VI. HIV

VII. Seminal Worldwide Patents

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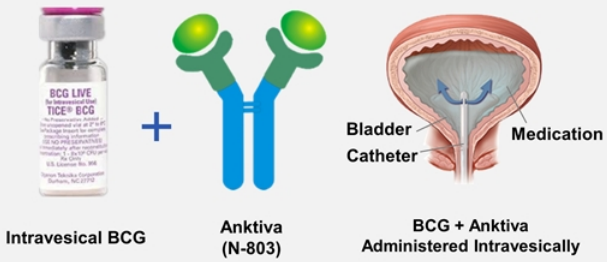
BCG Unresponsive NMIBC CIS Registration Trial
FDA Breakthrough Designation



Intravesical BCG | Anktiva (N-803) | BCG + Anktiva Administered Intravesically

FDA BREAKTHROUGH THERAPY DESIGNATION
for BCG-Unresponsive NMIBC CIS

N=80

FULLY ENROLLED

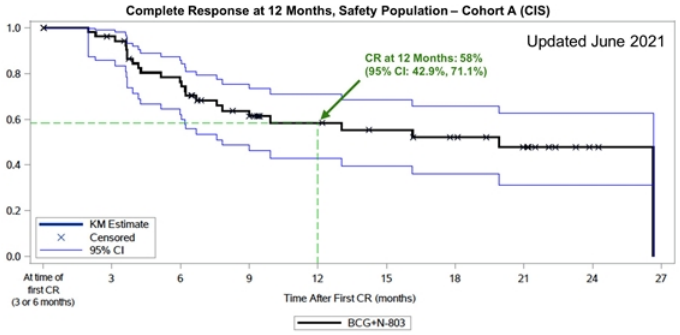
Pivotal Registration Data (QUILT-3.032) in BCG-Unresponsive NMIBC CIS

Primary Endpoint Met

- Primary Endpoint: CR at any time, with lower bound of 95% CI ≥ 20%
- To meet the primary endpoint, 24 out of 80 patients must have had a CR at any time
- **56 out of 80 CR's** have been reached
- **CR rate at any time 70%** (95% CI: 59%, 80%)
- **CR rate confirmed** by central review

Secondary Endpoint

- **CR at 12 months: 58%** (95% CI: 42.9%, 71.1%)
  Probability of patients maintaining CR for 12 months
- **Median Follow-Up Time**: **16.1 Months**



Efficacy & Safety in Patients with BCG-Unresponsive NMIBC CIS in QUILT-3.032 and Historical Comparison to Keytruda

Approved Jan 2020

Efficacy Endpoints	KEYNOTE-057 Keytruda	QUILT-3.032 Anktiva + BCG
CR Rate (95% CI)		
At any time or 3 months	**41%** (31%, 52%)	**70%** (59%, 80%)
Duration of Response in Responding Patients		
Median Duration of CR in Months (range)	**16.2** (0.0+ – 26.8)	**19.9** (0.0+ – 26.6)
Cystectomy Free Rate		
% Cystectomy Free	**63%**	**86%**

Immune-Mediated Adverse Event	KEYNOTE-057 Keytruda	QUILT-3.032 Anktiva + BCG
Any Immune-Mediated AE	**21%**	**0**
Grade 3-5 Immune-Mediated AEs	**3%**	**0**
Any Immune-Mediated SAE	**5%**	**0**
Discontinuation due to Immune-Mediated AEs	**4%**	**0**
Discontinuation due to Immune-Mediated SAEs	**2%**	**0**

A historical comparison. Not a head to head comparison

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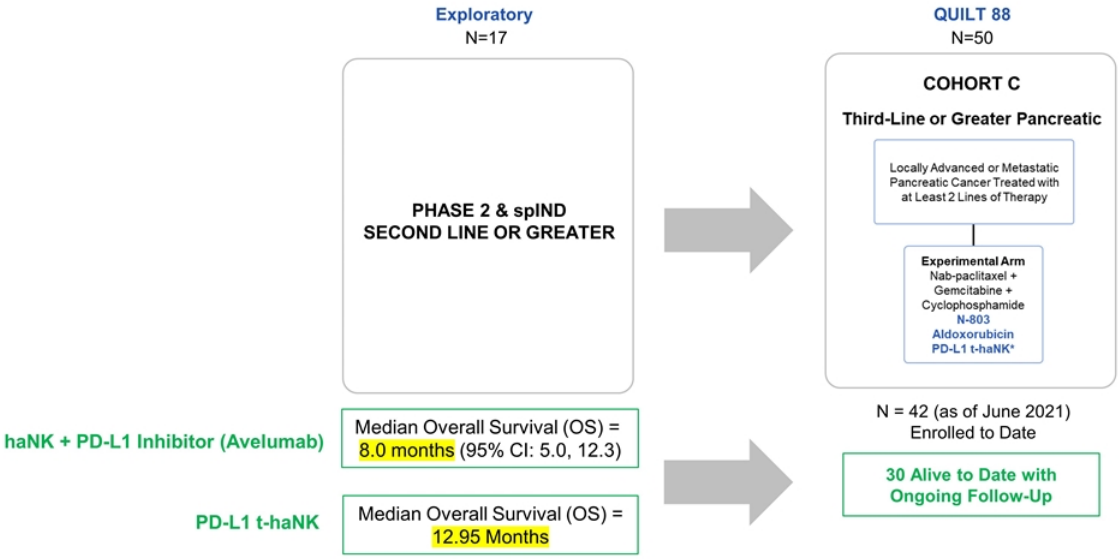
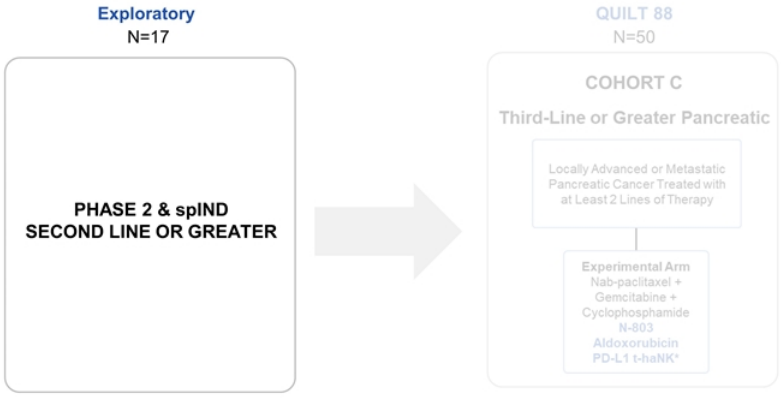
QUILT 88: 3rd Line or Greater Metastatic Pancreatic Cancer



QUILT 88: 3rd Line or Greater Metastatic Pancreatic Cancer



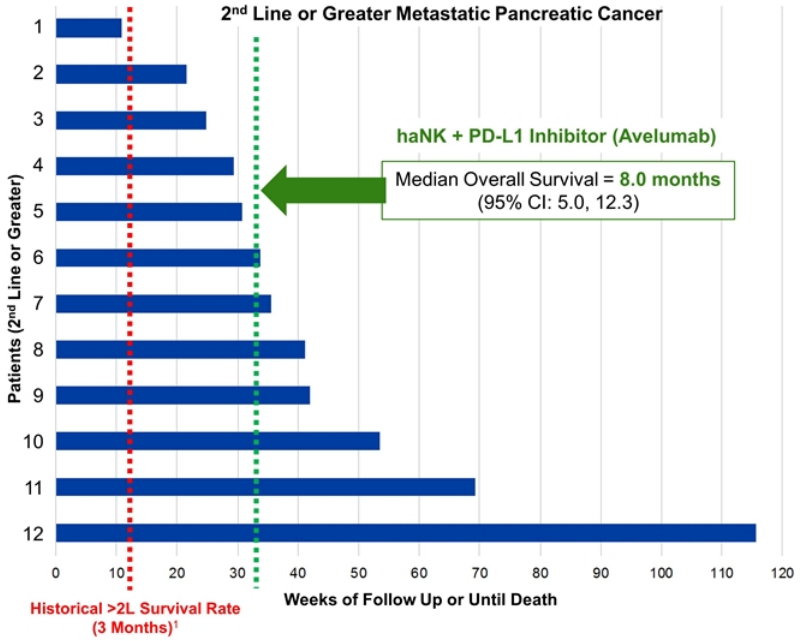
NK Synergy in Pancreatic Cancer

haNK + PD-L1 inhibitor (Avelumab) in Metastatic Pancreatic Cancer
Median Overall Survival 8.0 Months, Doubling Historical Survival Rates

Preliminary Data Lock

Phase 1/2 Trial of haNK + PD-L1 in Combination with Chemo Immunomodulation in Advanced Metastatic Pancreatic Cancer

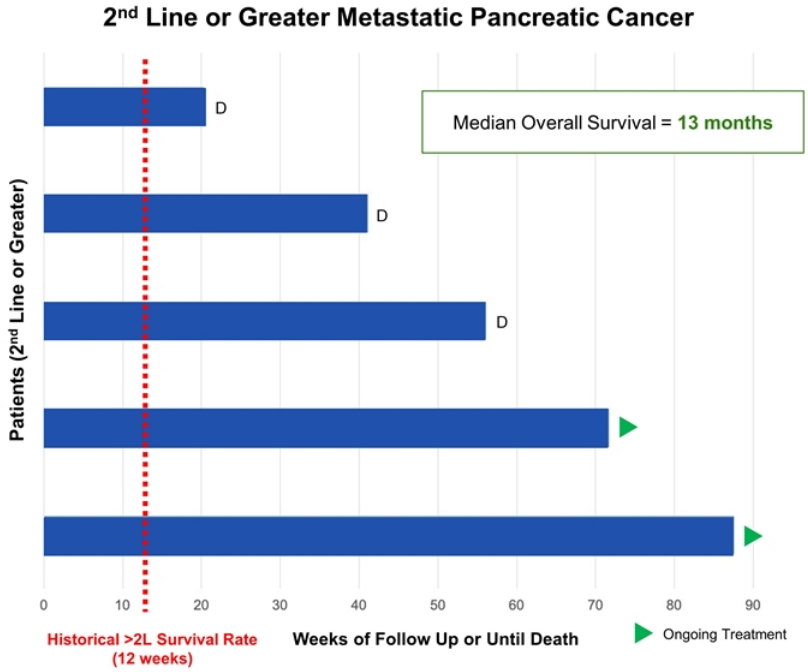
NCT03329248 (Closed)
QUILT 3.039, 3.060, 3.070, 3.080
NANT Cancer Vaccine



1. Accessed Jan 2020 - Taylor et al. Designing Clinical Trials in 3rd Line or Greater Pancreatic Cancer
DOI: 10.1200/JCO.2019.37.4_suppl.226

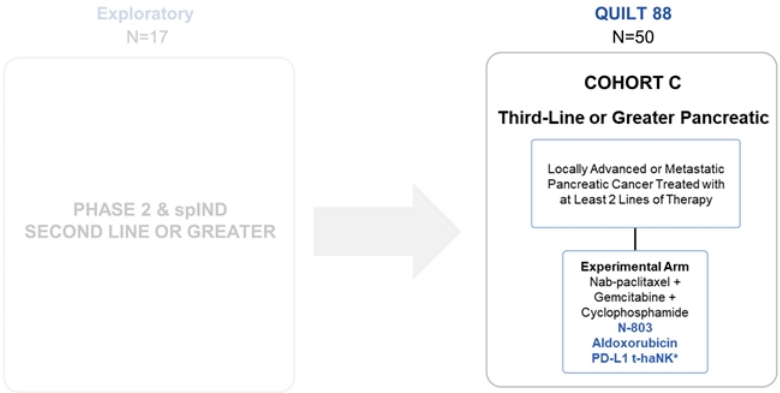
PD-L1 t-haNK in Metastatic Pancreatic Cancer
Median Overall Survival (OS) is 394 Days (13 Months)

Exploratory Trial of PD-L1 t-haNK in Combination with Chemo Immunomodulation in Advanced Metastatic Pancreatic Cancer



1. Accessed Jan 2020 - Taylor et al. Designing Clinical Trials in 3rd Line or Greater Pancreatic Cancer DOI: 10.1200/JCO.2019.37.4_suppl.226

QUILT 88: 3rd Line or Greater Metastatic Pancreatic Cancer



PD-L1 t-haNK + Chemo Immunomodulation in Locally Advanced or Metastatic Pancreatic Cancer (QUILT-88)

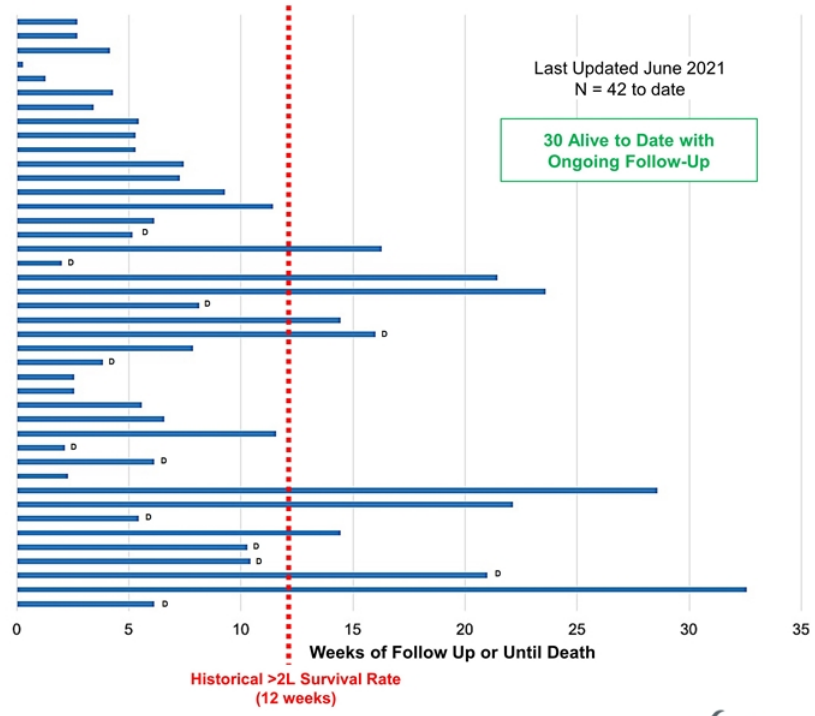
Actively Enrolling

Phase 2 Trial of PD-L1 t-haNK in Combination with Chemo Immunomodulation in Advanced Metastatic Pancreatic Cancer

NCT04390399 (QUILT-88) N=248

Aldoxorubicin HCl, N-803 and PD-L1 t-haNK — ImmunityBio, Inc.
Clinical Trial Protocol: QUILT-88 Amendment 3

OPEN-LABEL, RANDOMIZED, COMPARATIVE PHASE 2 STUDY OF COMBINATION IMMUNOTHERAPY PLUS STANDARD-OF-CARE CHEMOTHERAPY VERSUS STANDARD-OF-CARE CHEMOTHERAPY FOR THE TREATMENT OF LOCALLY ADVANCED OR METASTATIC PANCREATIC CANCER



1. Accessed Jan 2020 - Taylor et al. Designing Clinical Trials in 3rd Line or Greater Pancreatic Cancer DOI: 10.1200/JCO.2019.37.4_suppl.226

Abstract # 343497

Presenting at ASCO 2021

QUILT-88: NANT Pancreatic Cancer Vaccine – Trial in Progress

Open-label, randomized, comparative phase 2/3 study of combination immunotherapy plus standard-of-care chemotherapy and SBRT versus standard-of-care chemotherapy for the treatment of locally advanced or metastatic pancreatic cancer

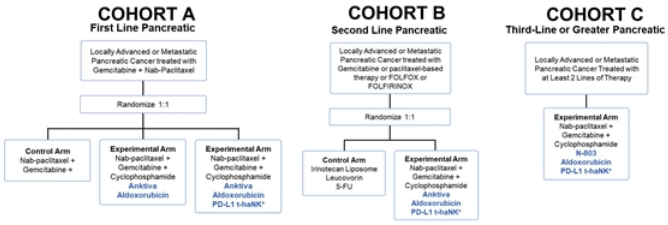
Tara Seery[1], Chaitali Nangia[1], Leonard Sender[2], Sandeep Reddy[2], Patrick Soon-Shiong[2]

[1]Hoag Cancer Center, Newport Beach, CA; [2], ImmunityBio Inc. Culver City, CA.

BACKGROUND

Pancreatic cancer will claim an estimated 47,050 lives in the USA in 2020, with an expected 5 year survival of 10%. Thus there is an urgent need for novel treatment options in this disease. We hypothesize that effective response against pancreatic cancer requires a coordinated approach that orchestrates both the innate and adaptive immune system. We further hypothesize that by orchestrating the activation of the entire immune system, we could accomplish immunogenic cell death with durable responses in this disease. We describe a novel combination immunotherapy protocol of low-dose chemoradiation, cytokine-induced NK and T cell activation via N-803 (Anktiva, IL-15 cytokine fusion protein), and off-the-shelf PDL1-targeted high-affinity NK cell (PDL1 t-haNK) infusion.

STUDY DESIGN



STUDY EXPERIMENTAL TREATMENT

Days 1 and 15, every 4 weeks:
- Nab-paclitaxel
- Gemcitabine

Days 1–5 and 15–19, every 4 weeks:
- Cyclophosphamide

Days 1, 8, 15, and 22; for first cycle only:
- SBRT (not to exceed 8 Gy, exact dose to be determined by the radiation oncologist)

Day 8, every 4 weeks:
- Aldoxorubicin HCl
- N-803 (15 µg/kg SC)

Days 1, 8, and 15; every 4 weeks:
- PD-L1 t-haNK (~2 × 109 cells/dose IV)

STUDY ENDPOINTS

Primary Efficacy Endpoints:
- PFS per RECIST V1.1 (Cohorts A and B).
- OS (Cohort C).

Secondary Efficacy Endpoints:
- ORR, CR rate, DoR, and DCR (confirmed CR or PR, or SD for at least 2 months) by RECIST V1.1
- OS (Cohorts A and B).
- PFS per RECIST V1.1 (Cohort C).
- QoL by PROs.

Safety Endpoints:
- Incidence of treatment-emergent adverse events (AEs) and serious AEs (SAEs), graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.
- Safety laboratory tests.
- Vital signs.

Exploratory Endpoints:
- PFS, ORR, CR rate, DoR, and DCR per iRECIST.
- CA 19-9 levels and correlations with subject outcomes.

MAJOR INCLUSION CRITERIA

For Cohort A, subjects must have initially received, or are currently receiving, continuous treatment with gemcitabine plus nab-paclitaxel for at least 16 weeks and have confirmed PR, CR, or SD prior to receiving first-line maintenance therapy on this study. Duration of actual initial treatment may be unlimited as long as no evidence of disease progression is noted by the Investigator at the time of randomization.

b. For Cohort B, subjects must have PD after receiving initial treatment with FOLFOX, FOLFIRINOX, or a gemcitabine- or paclitaxel-based therapy for pancreatic cancer. Subjects who discontinued prior therapy due to toxicity, intolerance, or available therapy was clinically contraindicated are allowed.

c. For Cohort C, subjects must have PD after receiving at least 2 lines of therapy for pancreatic cancer, including but not limited to neoadjuvant, adjuvant, and/or metastatic settings.

MAJOR EXCLUSION CRITERIA

a. Absolute neutrophil count (ANC) < 1000 cells/mm3.
b. Platelet count < 100,000 cells/mm3.
Aldoxorubicin HCl, N-803 and PD-L1 t-haNK ImmunityBio, Inc.
Clinical Trial Protocol: QUILT-88 Amendment 5
Confidential and Proprietary 10
c. Hemoglobin < 9 g/dL.
d. Total bilirubin greater than two times the upper limit of normal (ULN; unless the subject has documented Gilbert's syndrome).
e. Aspartate aminotransferase (AST [SGOT]) or alanine aminotransferase (ALT [SGPT]) > 2.5 × ULN (> 5 × ULN in subjects with liver metastases).
f. Alkaline phosphatase (ALP) levels > 2.5 × ULN (> 5 × ULN in subjects with liver metastases, or > 10 × ULN in subjects with bone metastases).
g. Serum creatinine > 2.0 mg/dL or 177 µmol/L.
h. Serum anion gap > 16 mEq/L or arterial blood with pH < 7.3.
i. Albumin < 3.0.
j. Ascites requiring paracentesis.

CONTACT

info@immunitybio.com
310-883-1300 Main

REFERENCES

1. An Antibody Designed to Improve Adoptive NK-Cell Therapy Inhibits Pancreatic Cancer Progression in a Murine Model
Jaemin Lee, Tae Heung Kang, Wonbeak Yoo, Hyunji Choi, Seongyea Jo, Kyungsu Kong, Sang-Rae Lee, Sun-Uk Kim, Ji-Su Kim, Duck Cho, Janghwan Kim, Jeong-Yoon Kim, Eun-Soo Kwon and Seokho Kim
DOI: 10.1158/2326-6066.CIR-18-0317 Published February 2019
2. Oh E, Min B, Li Y, Lian C, Hong J, Park GM, Yang B, Cho SY, Hwang YK, Yun CO. Cryopreserved Human Natural Killer Cells Exhibit Potent Antitumor Efficacy against Orthotopic Pancreatic Cancer through Efficient Tumor-Homing and Cytolytic Ability (Running Title: Cryopreserved NK Cells Exhibit Antitumor Effect). Cancers (Basel). 2019 Jul 9;11(7):966. doi: 10.3390/cancers11070966.

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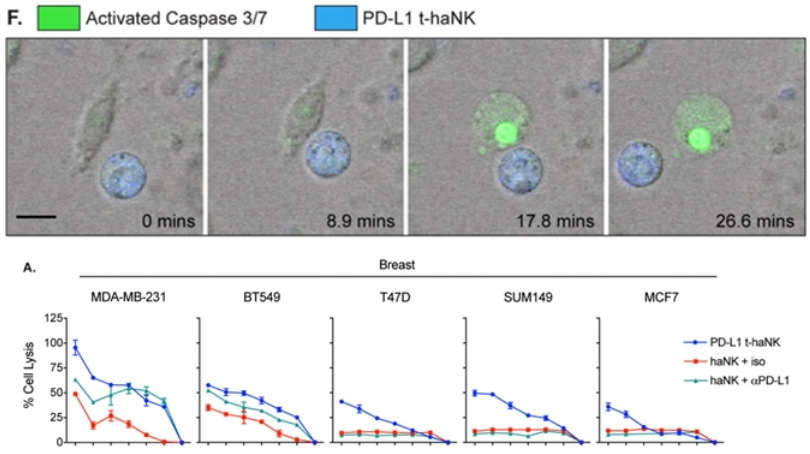
PD-L1 t-haNK Activity in Triple Negative Breast Cancer

Open access Original research

Journal for ImmunoTherapy of Cancer

PD-L1 targeting high-affinity NK (t-haNK) cells induce direct antitumor effects and target suppressive MDSC populations

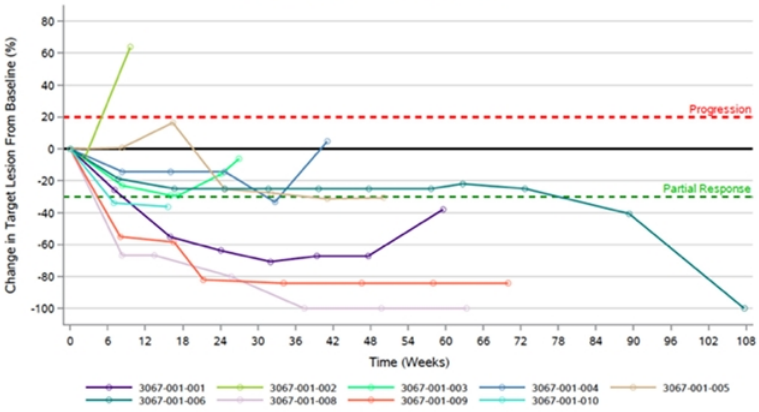
Kellsye P Fabian,[1] Michelle R Padget,[1] Renee N. Donahue,[1] Kristen Solocinski,[1] Yvette Robbins,[1] Clint T. Allen,[2] John H. Lee,[3] Shahrooz Rabizadeh,[4,5] Patrick Soon-Shiong,[4,5] Jeffrey Schlom ,[1] James W Hodge [1]



PD-L1 t-haNK Activity in Triple Negative Breast Cancer

ImmunityBio Phase 1b / 2 TNBC Data (2nd Line or Greater)

ORR: 67%
Median PFS: 14.3 months
Median OS: 20.2 months



FDA grants accelerated approval to sacituzumab govitecan-hziy for metastatic triple negative breast cancer

April 2020

ORR was 33.3% (95% CI: 24.6, 43.1)
Median response duration was 7.7 months (95% CI: 4.9, 10.8)

A historical comparison. Not a head to head comparison

Phase 1/2: Open-label, Phase 1/2 trial of sacituzumab plus **Anktiva** and **PD-L1 t-haNK** for the treatment of subjects with advanced triple-negative breast cancer after prior therapy.
TNBC >2 Prior Treatments for Metastatic Disease

TNBC Phase 1 / 2 Treatment Schema

Treatment Period (up to 51 weeks)

Phase 1 Dose Finding Study → Sacituzumab govitecan-hziy
RP2D IV
+
Chemoimmunotherapy
stage 1: n = 22
stage 2: n = 41
N = 63

Treatment Regimen (21-day cycle)

Sacituzumab govitecan-hziy
- Days 1 and 8: (RP2D IV)

Chemoimmunotherapy
- Days 1 and 8: PD-L1 t-haNK (~2 × 10^9 cells/dose IV)
- Day 8: N-803 (15 µg/kg SC)
- Days 1–5 and 15–19: Cyclophosphamide (25 mg PO BID)

ImmunityBio Investigational Agents In TNBC Clinical Trial

PD-L1 t-haNK

+

Anktiva (N-803)

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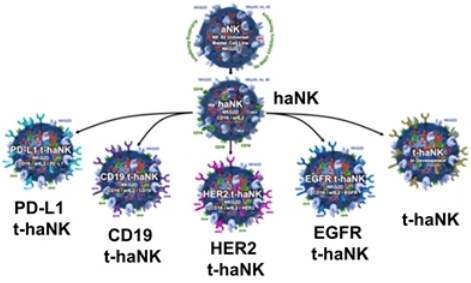
VII. Patents

Liquid & Solid Tumor Cell Therapy Program

Off-the-Shelf Natural Killer Cells (NK-92)

- Pancreatic Cancer (Ph 2/3)
- TNBC (Ph 1/2)
- Lung Cancer (Ph 3)
- Merkel Cell Carcinoma (Ph 2)
- Diffuse Large Cell Lymphoma (Ph 1)
- GBM (Ph 1)



PD-L1 t-haNK | CD19 t-haNK | HER2 t-haNK | EGFR t-haNK | t-haNK

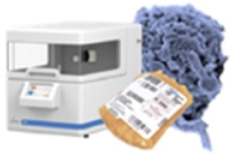
In-Vivo NK and T Cell Activation (Anktiva)

- Bladder Cancer (Ph 2/3)
- Pancreatic Cancer (Ph 2/3)
- TNBC (Ph 1)
- Lung Cancer (Ph 3)
- Indolent Non-Hodgkin Lymphoma (Ph 1)

Anktiva (N-803)

Memory Cytokine Enriched Natural Killer Cells
(M-ceNK: Autologous/Allogeneic)

- Solid Tumors (Ph 1)
- Liquid Tumors (Ph 1)



M-ceNK

Liquid & Solid Tumor Cell Therapy Program

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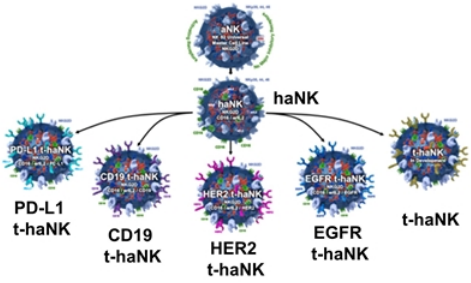
- Diffuse Large Cell Lymphoma (Ph 1)
- GBM (Ph 1)



PD-L1 t-haNK | CD19 t-haNK | HER2 t-haNK | EGFR t-haNK | t-haNK

In-Vivo NK and T Cell Activation (Anktiva)

- Bladder Cancer (Ph 2/3)
- Pancreatic Cancer (Ph 2/3)
- TNBC (Ph 1)
- Lung Cancer (Ph 3)
- Indolent Non-Hodgkin Lymphoma (Ph 1)

Anktiva (N-803)

Memory Cytokine Enriched Natural Killer Cells

(M-ceNK: Autologous/Allogeneic)

- Solid Tumors (Ph 1)
- Liquid Tumors (Ph 1)

M-ceNK

Most Clinically Developed Off-the-Shelf NK Cell Therapy:

More Patients Dosed with Longer Follow-up in NK Cell Therapy

ImmunityBio Announces 100th Patient Dosed with Proprietary Natural Killer Cells; NK Trials Cover Multiple Indications

APRIL 22, 2021

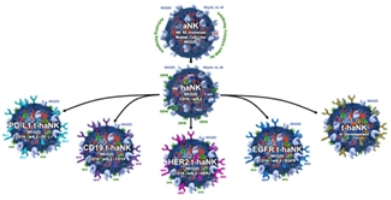
PDF Version

As testing accelerates, company boosts manufacturing speed, output, and quality control with over 2 trillion cryopreserved NK cells ready for off-the-shelf use

CULVER CITY, Calif.--(BUSINESS WIRE)--Apr. 22, 2021-- ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has administered its proprietary Natural Killer cells to more than 100 patients. The cells were administered as part of combination therapies in trials across multiple indications, including pancreatic, triple-negative breast, and Merkel Cell Carcinoma cancers. The 100th patient to receive ImmunityBio's NK cells is participating in the company's QUILT 88 trial for pancreatic cancer (NCT04390399).

NK-92 Universal Cell Line, Off-the-Shelf NK

NK-92 Universal NK Cell Line



First-ever Cell Therapy Engineered with **Four** Active Anti-tumor Modalities Cleared for U.S. Clinical Investigation

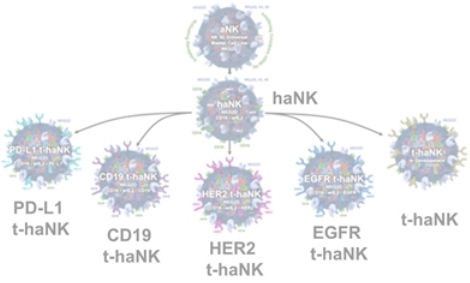
	aNK (NK-92)	haNK	PD-L1 t-haNK	CD-19 t-haNK	HER2 t-haNK	EGFR t-haNK
Innate Immunity Without Major Inhibitory Receptors	NKG2D	NKG2D	NKG2D	NKG2D	NKG2D	NKG2D
High-Affinity CD16	X	CD16	CD16	CD16	CD16	CD16
erIL2	X	erIL2	erIL2	erIL2	erIL2	erIL2
CAR Insertion(s)	X	CD16	PD-L1	CD19	HER2	EGFR
Clinical Indication	Core Cell Line	Registrational Merkel Cell*	Pancreatic* NSCLC	Lymphoma	Breast	Head & Neck
Current Status	Universal NK Cell Line	**Phase II Jan 2019**	**Phase II June 2020**	**IND Authorized**	**IND Planned Q4 2021**	**IND Planned Q3 2021**

*Registrational Intent *Registrational Intent

Liquid & Solid Tumor Cell Therapy Program

Off-the-Shelf Natural Killer Cells (NK-92)

- Pancreatic Cancer (Ph 2/3)
- TNBC (Ph 1/2)
- Lung Cancer (Ph 3)
- Merkel Cell Carcinoma (Ph 2)
- Diffuse Large Cell Lymphoma (Ph 1)
- GBM (Ph 1)



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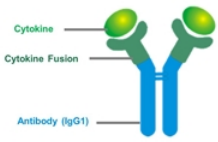

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(M-ceNK: Autologous/Allogeneic)

- Solid Tumors (Ph 1)
- Liquid Tumors (Ph 1)

M-ceNK

Liquid Tumors: Indolent Non-Hodgkin Lymphoma (iNHL)

ImmunityBio Announces 78 Percent Complete Response Following Chemotherapy-Free Combination of IL-15 Superagonist Anktiva with Rituxan in Relapsed Non-Hodgkin Lymphoma Patients

MAY 4, 2021

PDF Version

- Durable complete response achieved in 7 of 9 (78%) CD20 sensitive patients who failed Rituxan® therapy in Phase 1 liquid tumor trial
- Of those patients who responded to the combination therapy of Anktiva™ plus Rituxan, 7 out of 7 (100%) achieved a complete response
- Chemotherapy-free regimen with minimal toxicity potentially enhances Rituxan mAb therapy with potential for broad application across liquid tumor indications
- Prolonged duration of disease without progression ranging from 18 to 24 months

CLINICAL CANCER RESEARCH

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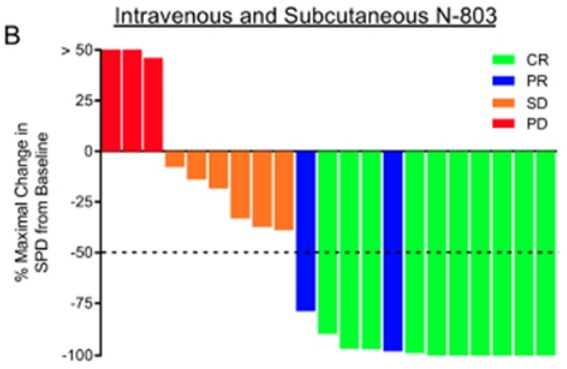
Clinical Trials: Immunotherapy

Phase I Trial of N-803, an IL15 Receptor Agonist, with Rituximab in Patients with Indolent Non-Hodgkin Lymphoma

Jennifer A. Foltz, Brian T. Hess, Veronika Bachanova, Nancy L. Bartlett, Melissa M. Berrien-Elliott, Ethan McClain, Michelle Becker-Hapak, Mark Foster, Timothy Schappe, Brad Kahl, Neha Mehta-Shah, Amanda F. Cashen, Nancy D. Marin, Kristen McDaniels, Chaz Moreno, Matthew Mosior, Feng Gao, Obi L. Griffith, Malachi Griffith, Julia A. Wagner, Narendranath Epperla, Amy D. Rock, John Lee, Allegra A. Petti, Patrick Soon-Shiong, and Todd A. Fehniger

DOI: 10.1158/1078-0432.CCR-20-4575 Check for updates



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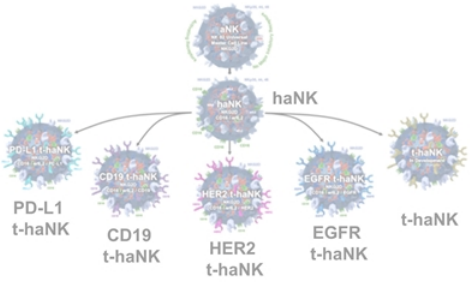

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Anktiva (N-803)

Memory Cytokine Enriched Natural Killer Cells
(M-ceNK: Autologous/Allogeneic)

- Solid Tumors (Ph 1)
- Liquid Tumors (Ph 1)

M-ceNK

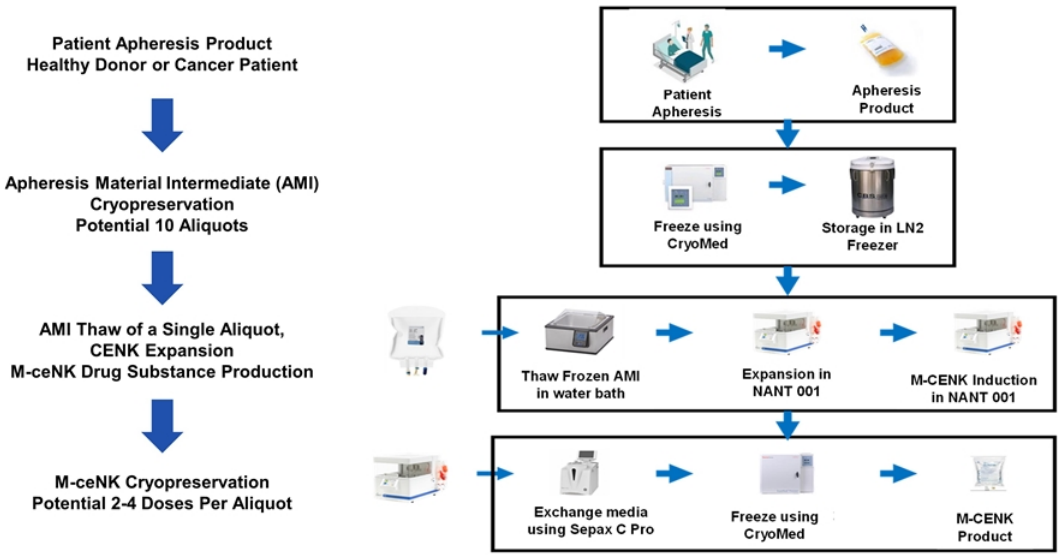
M-ceNK (N=20): 3,000% Cell Expansion with Potent Killing Across Multiple Cell Lines

FDA Authorizes ImmunityBio to Conduct a Trial of its First-in-Human, Cryopreserved, Memory Cytokine-Enriched NK Cell (m-ceNK) Platform in Solid Tumors

May 17, 2021

- The first-in-class, memory cytokine-enriched Natural Killer (m-ceNKÔ) cells are the patient's own NK cells that have been enriched with cytokines, including ImmunityBio's IL-15 superagonist Anktiva (N-803)
- The resulting cryopreserved m-ceNK cells have an enhanced ability to recognize and kill cancer targets with longer persistence
- An initial study inolving 20 subjects (15 healthy donors and five cancer patients) showed that healthy and patient-derived m-ceNK cells killed NK-resistant tumor cells with equal potency in preclinical models
- Over 3000 percent m-ceNK cell expansion was achieved from a single blood draw enabling the potential for 10 to 20 infusions of a billion cells per dose
- The Phase 1 open-label study authorized by the FDA will begin enrolling participants with metastatic solid tumors in Q2 2021.

Introducing ImmunityBio's Proprietary Method of First in Human First in Class M-ceNK Generation From Autologous and Allogeneic Apheresis



Potential ~20 Doses of Potent M-ceNK Cells Per Single Apheresis

First in Human Autologous NK For Solid Tumors

M-ceNK: Autologous and Allogeneic Proprietary Process

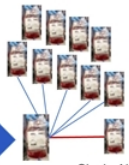
Memory Cytokine Enhanced NK (M-ceNK)

Day 1

Autologous Apheresis Patient White Cell Collection

Day 1

Autologous Apheresis White Cells



Single Aliquot For Enrichment

Aliquot One Bag into 10 Lots for Cryopreservation

Day 1

Cryopreservation For Future Uses

Day 1-16
NK Enrichment

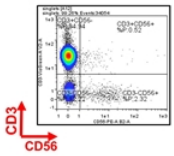
GMP-in-a-Box NK Cell Enrichment Cytokine Induced Proliferation

Day 17

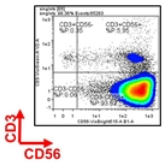
Concentrate
$0.3 – 1.0 \times 10^9$ NK Cells

Day 17

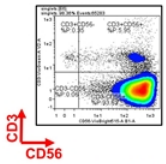
Autologous Cytokine Enhanced Natural Killer Cells for Transfusion
$0.3 – 1.0 \times 10^9$ NK Cells



White Cells



Enhanced NK Cells

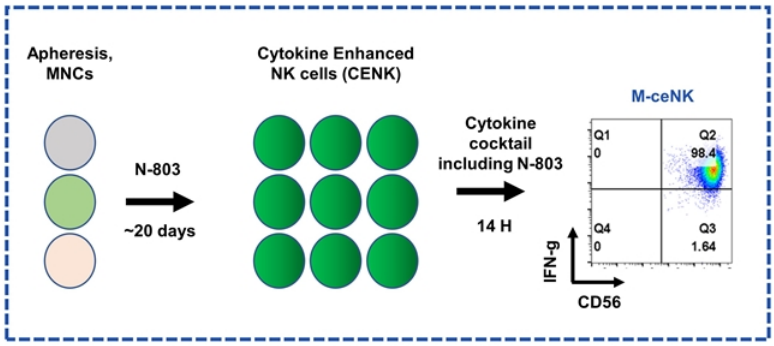


Memory Cytokine Enhanced NK (M-ceNK)

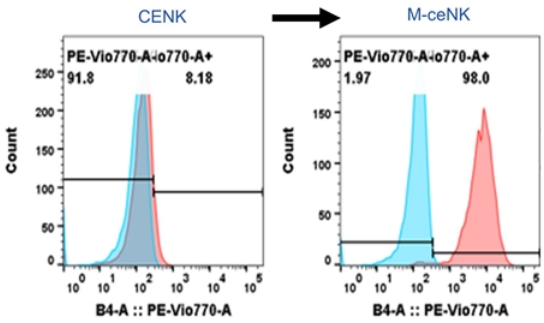
Potential ~20 Doses of Potent M-ceNK Cells Per Single Apheresis

M-ceNK Cell Production From Twenty Donors: Healthy Donors (N=15) and Cancer Patients (N=5)

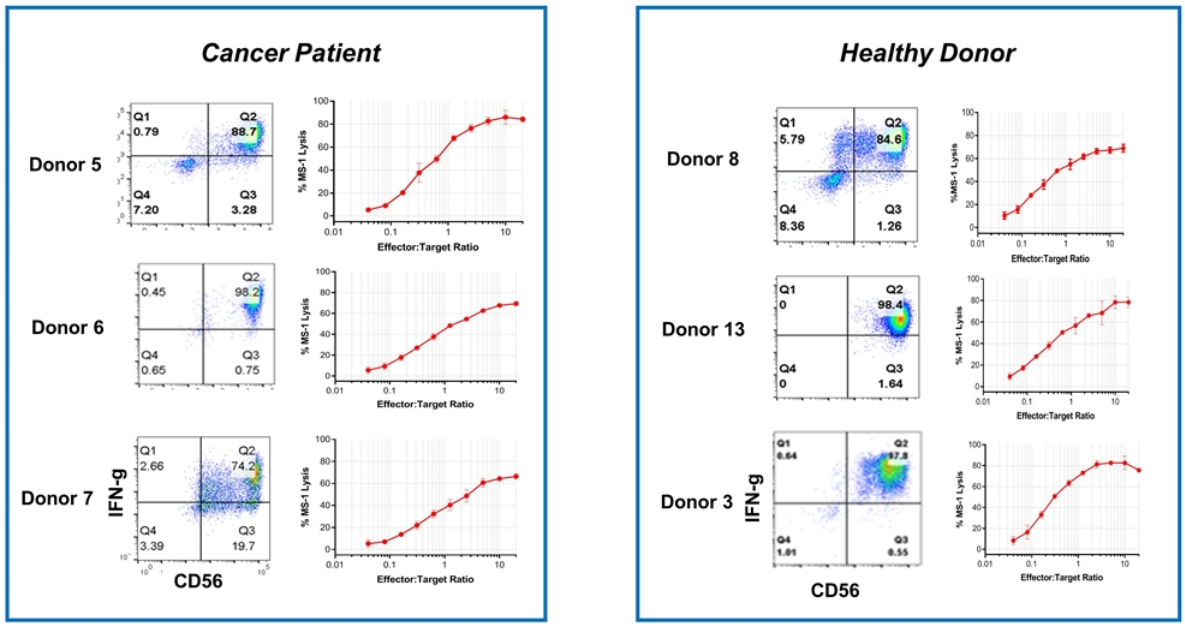
Donors	Apheresis collected	Range of total nucleated cells (TNC) collected	% of NK cells	% of Expansion and Production of M-ceNK cells in 18-20 days	Potential # of Doses Cryopreserved M-ceNK from One Apheresis
Healthy Donor	N = 15	8 - 27 Billion Cells Per Donor	11 - 16 % CD56+ cells	~3,000%	~20 doses
Cancer Patient	N = 5	1.4 - 9.9 Billion Cells Per Donor	13 - 49 % CD56+ cells	~300 to ~6,000%	~15 doses



Intracellular Staining for IFN-γ in CD56+ cells

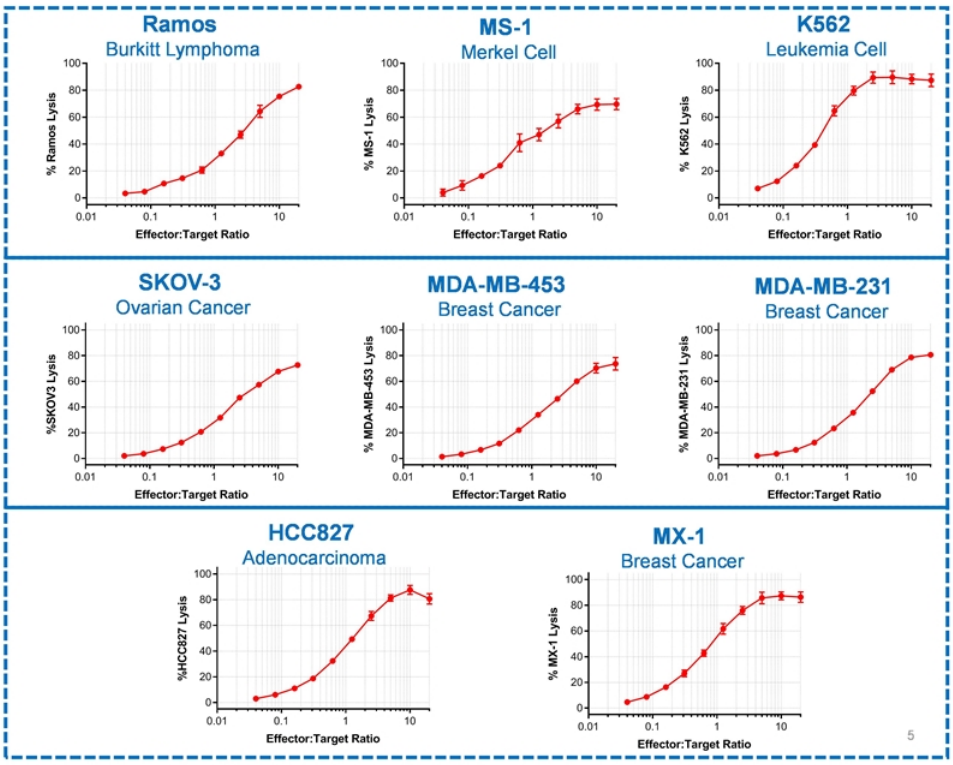


M-ceNK Production from Healthy Donor vs Cancer Patient Are Equally Potent



M-ceNK

a potent killer of cancer cells across multiple solid and liquid tumor types



Confirmation by NCI Researchers: M-ceNK Potent Activity Across Multiple Cell Types

Lysis by NK Cells: Small Cell Lung Cancer

Neuroendocrine, Epithelial

H69 Tumor Cells

	% Lysis		
Effector Cell	E:T 20:1	E:T 10:1	E:T 5:1
DN 1 NK	39.48	27.41	10.36
DN1 NK + N-803	93.35	90.41	76.76
DN 2 NK	4.71	2.59	0.49
DN 2 NK + N-803	83.89	71.51	51.10
ceNK	**85.38**	**82.87**	**76.67**
M-ceNK	**90.94**	**87.88**	**80.95**

Non-neuroendocrine, Mesenchymal

H841 Tumor Cells

	% Lysis		
Effector Cell	E:T 20:1	E:T 10:1	E:T 5:1
DN 1 NK	0.52	0.02	0
DN1 NK + N-803	83.89	69.92	41.20
DN 2 NK	0	0	0
DN 2 NK + N-803	42.08	24.10	10.70
ceNK	**89.07**	**86.11**	**73.61**
M-ceNK	**90.81**	**87.87**	**76.56**

Lysis by NK Cells: Ovarian Cancer

Epithelial

OVCAR3 Tumor Cells

	% Lysis		
Effector Cell	E:T 20:1	E:T 10:1	E:T 5:1
DN 1 NK	0	0	0.24
DN1 NK + N-803	62.91	52.03	31.71
DN 2 NK	1.01	1.38	6.93
DN 2 NK + N-803	44.25	40.12	33.32
ceNK	**68.02**	**57.96**	**48.02**
M-ceNK	**58.00**	**51.54**	**39.25**

Mesenchymal

SK-OV-3 Tumor Cells

	% Lysis		
Effector Cell	E:T 20:1	E:T 10:1	E:T 5:1
DN 1 NK	0.63	0	0
DN1 NK + N-803	32.93	15.64	1.64
DN 2 NK	0	0	0
DN 2 NK + N-803	4.41	0.46	0.27
ceNK	**30.32**	**24.99**	**26.76**
M-ceNK	**35.08**	**29.40**	**20.97**

Lysis by NK Cells: Breast Cancer & NSCLC

Breast Cancer

MDA-MB-231 Tumor Cells

	% Lysis		
Effector Cell	E:T 20:1	E:T 10:1	E:T 5:1
DN 1 NK	0	0	0.24
DN1 NK + N-803	46.9	36.2	19.3
DN 2 NK	0	0	0
DN 2 NK + N-803	19.1	7.7	4.5
ceNK	**48.4**	**43.5**	**38.2**
M-ceNK	**52.0**	**43.5**	**39.4**

NSCLC

H441 Tumor Cells

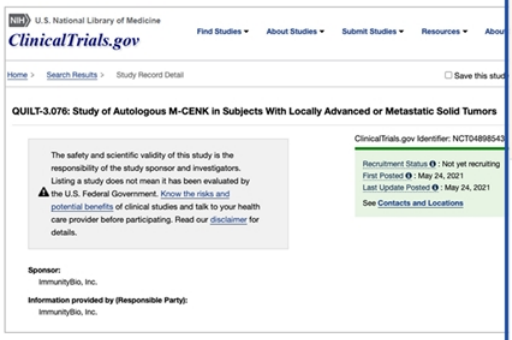
	% Lysis		
Effector Cell	E:T 20:1	E:T 10:1	E:T 5:1
DN 1 NK	0	0	0
DN1 NK + N-803	33.7	24.5	13.8
DN 2 NK	0	0	0
DN 2 NK + N-803	11.7	4.6	2.8
ceNK	**27.6**	**24.8**	**23.7**
M-ceNK	**37.1**	**30.7**	**25.3**

NIH NATIONAL CANCER INSTITUTE

Provided under CRADA: Fousek/Palena Data, LTIB, NCI (National Cancer Institute)

M-ceNK Clinical Trial Authorized – NCT04898543 (QUILT 3.076)

Phase 1 – First in Human M-ceNK Trial


U.S. National Library of Medicine
ClinicalTrials.gov

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QUILT-3.076: Study of Autologous M-CENK in Subjects With Locally Advanced or Metastatic Solid Tumors

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: NCT04898543

Recruitment Status : Not yet recruiting
First Posted : May 24, 2021
Last Update Posted : May 24, 2021
See Contacts and Locations

Sponsor:
ImmunityBio, Inc.

Information provided by (Responsible Party):
ImmunityBio, Inc.

FDA Authorizes ImmunityBio to Conduct a Trial of its First-in-Human, Cryopreserved, Memory Cytokine-Enriched NK Cell (m-ceNK) Platform in Solid Tumors

May 17, 2021

- The first-in-class, memory cytokine-enriched Natural Killer (m-ceNKÔ) cells are the patient's own NK cells that have been enriched with cytokines, including ImmunityBio's IL-15 superagonist Anktiva (N-803)
- The resulting cryopreserved m-ceNK cells have an enhanced ability to recognize and kill cancer targets with longer persistence
- An initial study inolving 20 subjects (15 healthy donors and five cancer patients) showed that healthy and patient-derived m-ceNK cells killed NK-resistant tumor cells with equal potency in preclinical models
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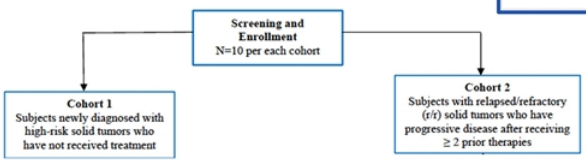
- The Phase 1 open-label study authorized by the FDA will begin enrolling participants with metastatic solid tumors in Q2 2021.



Selected Clinical Pipeline Updates for June 2021

I. Non-Muscle Invasive Bladder Cancer (NMIBC)

II. Pancreatic Cancer

III. Triple Negative Breast Cancer (TNBC)

IV. M-ceNK

V. COVID-19

VI. HIV

VII. Patents

Routes of Administration Being Investigated

hAd5 S-Fusion + N-ETSD COVID Vaccine

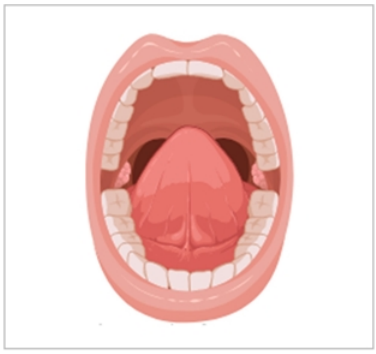
Multiple Routes of Administration of Same Vaccine Construct to Achieve T Cell Mediated & Mucosal Immunity

Subcutaneous (2-8°C)

USA & South Africa

Oral Capsule (Room Temp)

South Africa



Sublingual (Room Temp)

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Single Prime hAd5 Spike (S) + Nucleocapsid (N) Dual Antigen Vaccination of Healthy Volunteers Induces a Ten-Fold Increase in Mean S- and N- T-Cell Responses Equivalent to T-Cell Responses from Patients Previously Infected with SARS-CoV-2

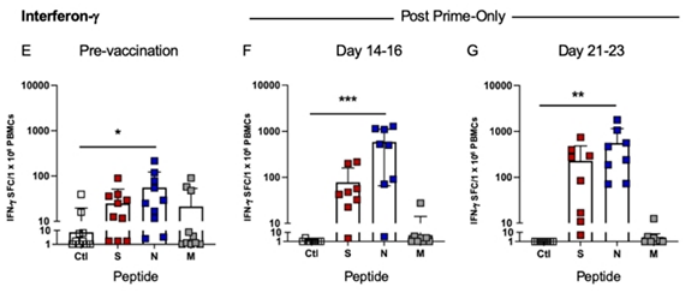
ImmunityBio Announces Single Prime hAd5 COVID-19 Vaccination Induces a 10-Fold Increase in T Cell Response Equivalent to T Cell Responses from Patients Previously Infected with SARS-CoV-2

PRESS RELEASES

Apr 8, 2021

- Preliminary Phase 1b findings in participants receiving the dual antigen hAd5 S + N vaccine generated Th1 dominant S and N specific T cells after a single prime subcutaneous injection
- The magnitude of this T cell response was equivalent to those seen for S & N T cell responses from previously infected convalescent SARS-CoV-2 patients
- These findings provide the potential of the hAd5 S + N T cell vaccine for use as a "Universal T Cell Booster" to enhance T cell immunity in healthy recipients of current vaccines or in previously infected convalescent subjects
- Phase 1b study ongoing to explore the safety and immunogenicity of subcutaneous, oral and sublingual prime boost combinations of hAd5 S+N vaccine

CULVER CITY, Calif., April 8, 2021 – ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today reported initial data indicating that a *single subcutaneous injection* of the company's COVID-19 vaccine candidate in healthy Phase 1 clinical study participants stimulates the generation of T cells that are reactive to the spike (S) and nucleocapsid (N) protein antigens delivered by the vaccine. Just 14-16 days after the single dose, the mean level of T cells generated in response to the hAd5 S+N T cell vaccine were ten times higher for



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USA & South Africa

Oral Capsule (Room Temp)

South Africa

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Intranasal (2-8°C)

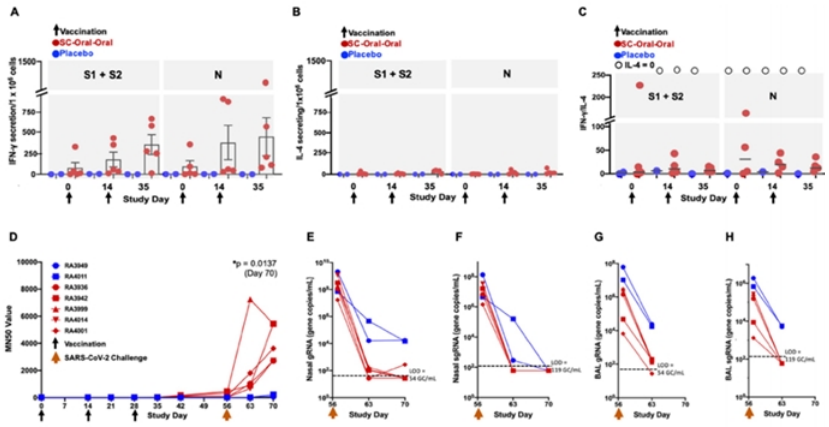
South Africa

Complete Protection of Nasal and Lung Airways Against SARS-CoV-2 Challenge by Antibody Plus Th1 Dominant N- and S-Specific T-Cell Responses to Subcutaneous Prime and Thermally-Stable Oral Boost Bivalent hAd5 Vaccination in an NHP Study

ImmunityBio's hAd5 T-Cell COVID-19 Vaccine Candidate Shows Complete Protection of Airways in Non-Human Primates

BARDA-sponsored study shows second-generation hAd5 vaccine candidate in both subcutaneous and room temperature oral formulations inhibits SARS-CoV-2 virus replication to undetectable levels and clears infection within days in 100% of vaccinated non-human primates

- The second-generation human adenovirus vector hAd5, which delivers both outer spike (S) and inner nucleocapsid (N) antigens, induced T cells and antibodies leading to reduction of SARS-CoV-2 viruses in both lungs and nasal passages within seven days
- The hAd5-COVID-19 oral capsule vaccine candidate was effective at room temperature in non-human primates suggesting that it may not require cold chain logistics that can impede global distribution
- The hAd5-COVID-19 oral vaccine candidate will enter Phase 1 human trials as a prime and a boost and, pending discussions with the FDA, will be explored to provide a boost to subcutaneous vaccinations
- Twenty participants have completed testing in the Phase 1 trial at Hoag Hospital Newport Beach, Calif., which evaluated both low and high doses of subcutaneous hAd5, with zero grade 3/4 adverse events reported. The Phase 2 trial is now actively recruiting.



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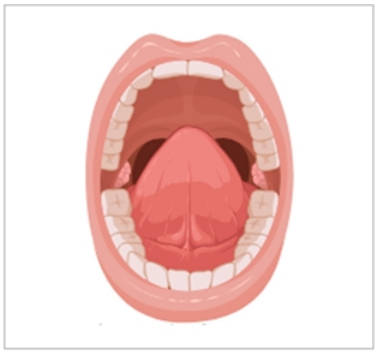

Sublingual (Room Temp)

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Intranasal (2-8°C)

South Africa

ImmunityBio Announces Positive Interim Phase I Safety Data of hAd5 T-Cell COVID-19 Vaccine Candidate in Oral and Sublingual Formulations

PRESS RELEASES

Mar 15, 2021

- Safety assessments completed for first 12 participants and no serious adverse events (SAEs) reported; trials expected to be fully enrolled in Q2
- First COVID-19 vaccine trials designed to deliver both S and N SARS-CoV-2 viral proteins via multiple routes—subcutaneous, sublingual, and oral
- Pre-clinical data from SARS-CoV-2 challenge study involving subcutaneous and oral immunization shows ImmunityBio's lead hAd5-COVID-19 T-cell vaccine candidate is protective in non-human primates (NHP) against high SARS-CoV-2 titer exposures
- Robust T cell and Memory B cell response to virus challenge results in inhibition of virus growth in nose and lungs with subcutaneous/oral vaccine combination in NHP study

CULVER CITY, Calif., March 15, 2021 — ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has met the safety requirements for the first 12 participants in its Phase Ib human adenovirus (hAd5)-based T-cell COVID-19 vaccine trials in sublingual and oral formulations. The independent Safety Review Committee recommended the study continue with no modifications to the trial design. The trials, which will involve 80 participants, are expected to be fully enrolled in Q2.

Routes of Administration Being Investigated

hAd5 S-Fusion + N-ETSD COVID Vaccine

Multiple Routes of Administration of Same Vaccine Construct to Achieve T Cell Mediated & Mucosal Immunity

Subcutaneous (2-8°C)

USA & South Africa

Oral Capsule (Room Temp)

South Africa

Sublingual (Room Temp)

USA & South Africa

Intranasal (2-8°C)

South Africa

The Dual-Antigen Ad5 COVID-19 Vaccine Delivered as an Intranasal Plus Subcutaneous Prime Elicits Th1 Dominant T-Cell and Humoral Responses in CD-1 Mice

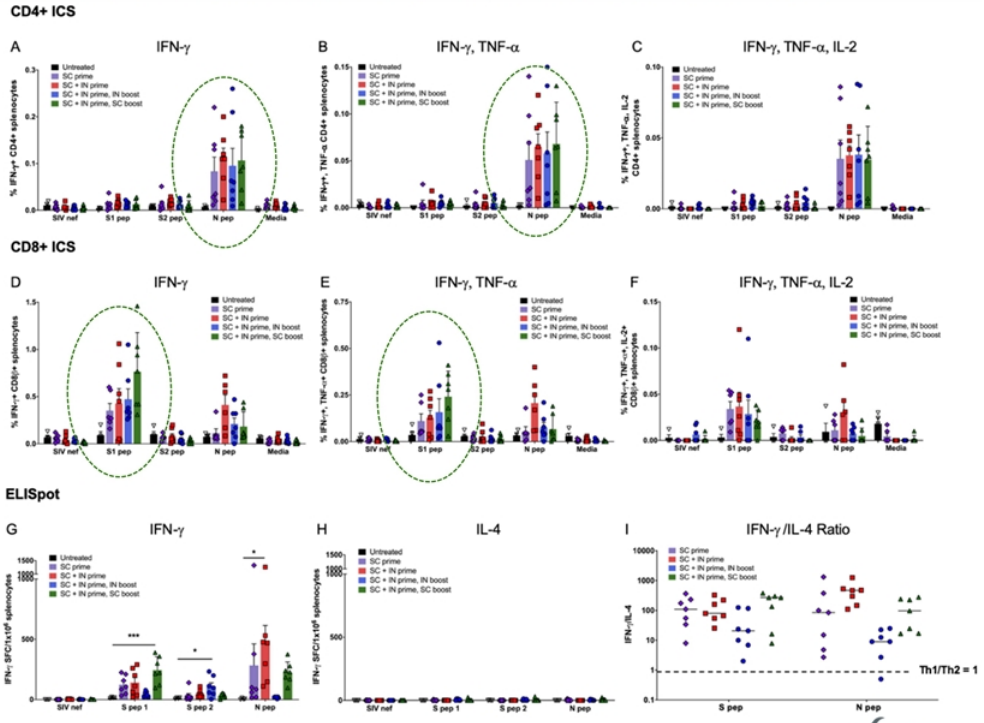
ImmunityBio Expands Trials of T-Cell-Based COVID-19 Vaccine Candidate as a 'Universal Boost' in Vaccinated Subjects and Receives Approval to Test Intranasal Spray in South Africa

Published: May 25, 2021

ImmunityBio

May 25, 2021 13:00 UTC

- Studies will provide data on T-cell-based COVID-19 vaccine candidate as a universal boost with four potential routes of administration (subcutaneous shot, sublingual droplet, oral capsule, and intranasal spray)
- The goal of the vaccine is to activate the entire immune system and potentially provide longer-lasting immune response and head off future variants
- South African Health Products Regulatory Authority (SAHPRA) has approved an expanded study to test intranasal administration of ImmunityBio's T-cell-based COVID-19 vaccine candidate hAd5 S+N in subjects previously infected with SARS-CoV-2
- Phase 1/2/3 Universal Boost trial is designed to evaluate hAd5 S+N as a boost for South African healthcare workers previously vaccinated with a currently available spike-only antibody-based vaccine
- In preclinical studies, hAd5 administered subcutaneously plus intranasally (SC + IN) as a dual prime without a boost was as effective in generating humoral and T-cell responses as the SC + IN prime with a boost



Sisonke Universal Boost Trial in South Africa (Phase 1/2) Prime (Ad26) + Boost (hAd5 S-Fusion + N-ETSD)

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Selected Clinical Pipeline Updates for June 2021

I. Non-Muscle Invasive Bladder Cancer (NMIBC)

II. Pancreatic Cancer

III. Triple Negative Breast Cancer (TNBC)

IV. M-ceNK

V. COVID-19

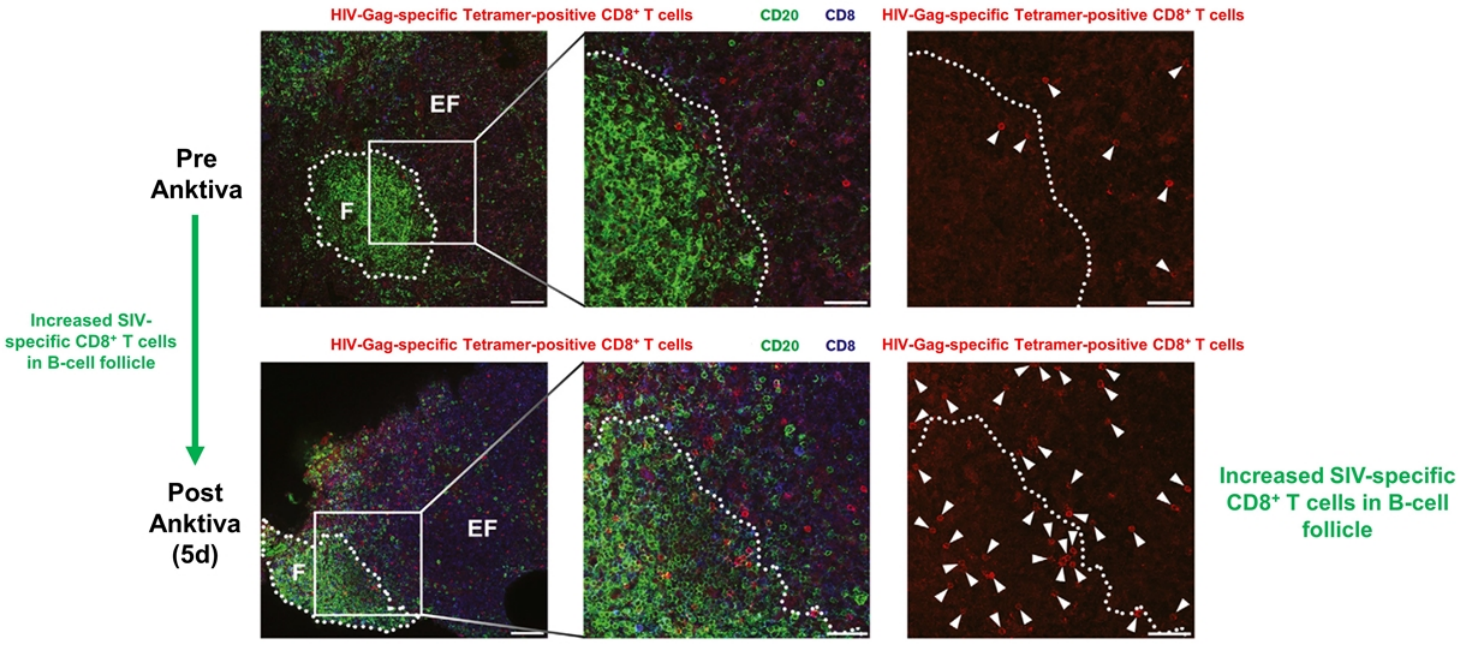
VI. HIV

VII. Patents

Rationale for N-803 in HIV

- Activates CD4 T cells and induces virus from latency
- Causes activation and proliferation of NKs and CD8s which may have direct antiviral activity
- Concentrates in LN where the reservoir is
- Long half-life (physiologic levels 3-5 days after s.q. dose)
- No apparent anti-IL-15 antibodies in monkeys
- Drives immune cells into B cell follicles

Anktiva Sends SIV-Specific CD8⁺ T Cells to B-Cell Follicles



Webb GM, et al. Blood Adv. 2018 Jan 23;2(2):76-84.

F:EF = Follicular:Extra-Follicular

ANKTIVA Clinical HIV Experience:

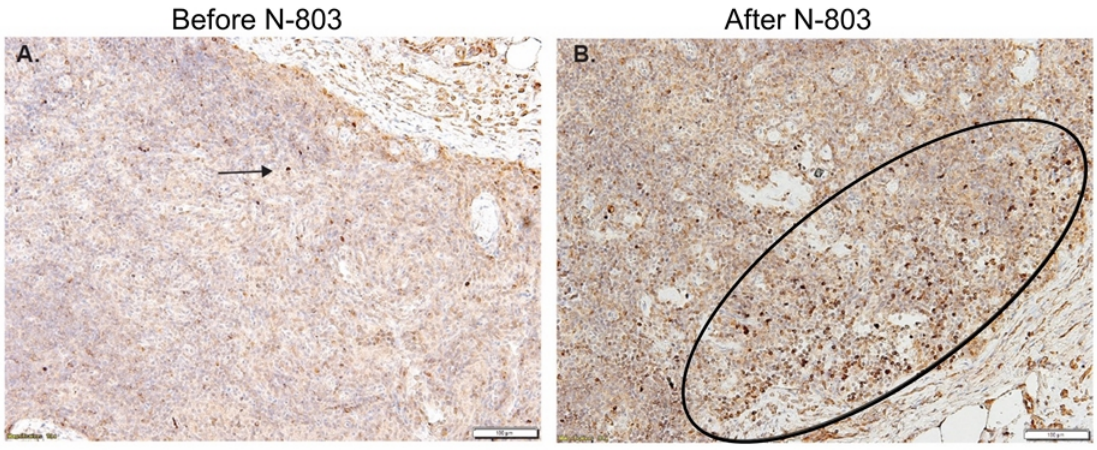
Phase I Study of Anktiva (N-803) in HIV Infected Patients to Clear Latent HIV Reservoirs

Zachary Davis[1], Jodi Anderson[1], Ann Thorkelson[1], Hing C. Wong[2], Jonathan Karn[3], Curtis Dobrowlski[3], Jeffrey S. Miller[1], Sarah Cooley[1], Daniel C Douek[4], Timothy W Schacker[1]

[1]University of Minnesota, Minneapolis, MN, [2]Altor BioScience, a Nantworks company, Miramar, FL, [3]Case Western Reserve University, Cleveland, OH, [4]Vaccine Research Center, National Institutes of Health, Bethesda, MD

N-803 Increases Homing of NK Cells to Lymph Node

Administration of N-803 results in accumulation of NK cells in lymph nodes where latently infected cells reside



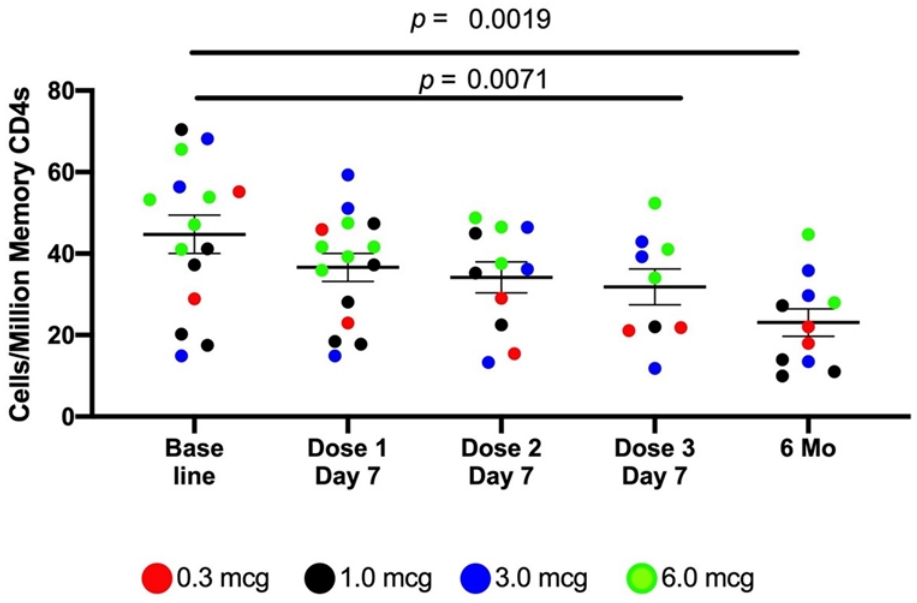
CD56 Staining of LN before (A) and 1 week after (B) the 3rd dose of N-803 in participant 2543 (3.0 mcg/kg SC).

Davis et al., CROI 2018. Abstr 356

N-803 Decreased Detectable HIV Reservoir in Lymphocytes

With ConA Stimulation

- Measure of the overall size of the inducible reservoir



ImmunityBio HIV Clinical Programs: Active Phase 1/2 Clinical Trials in Progress

Phase 1 B Cell Follicle Study
Principle Investigator: Tim Schacker, UMinn
NCT04808908
10 HIV+ patients txt 3x N-803
2 enrolled to date

Phase 1 ACTG 5386: N-803 +/- 2 bNABs in HIV+ subjects
Principle Investigator: Tim Wilken, Weill Cornell Medicine
NCT04340596
46 HIV+ patients randomized to Arm A or B
- Arm A: N-803 alone txt 8x N-803
- Arm B: 2 bNAbs (2x) + N-803 (8x)

Trial opened for enrollment (May, 2021)

Phase II Thailand Trial: N-803 in Acute HIV Infection
Study Chair: Denise C Hsu, MD PhD – Henry M. Jackson Foundation
NCT04505501
15 patients: 10 N-803 txt 3x, 5 Placebo
2 enrolled to date

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II. Pancreatic Cancer

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V. COVID-19

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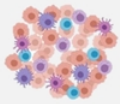
Seminal Patents: By The Numbers

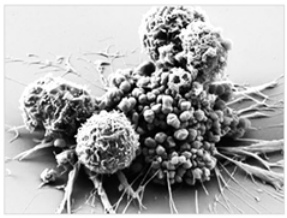
Antibody Cytokine Fusion Proteins	Chemo Immuno Modulators	Vaccine Technologies	Natural Killer Cells
			
114 Worldwide	**112** Worldwide	**371** Worldwide	**26** Worldwide

ImmunityBio patent portfolio extends to 2040
Over 600 Issued Patents Worldwide Covering ImmunityBio Immunotherapy Portfolio

ImmunityBio: A Leading Immunotherapy Company

ImmunityBio
NASDAQ: IBRX

40
Phase I / II / III Clinical Trials



1,800+
Patients Studied

25
Phase II / III Clinical Trials

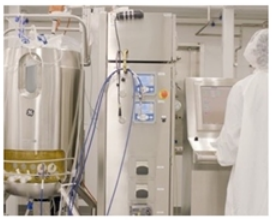
17
First in Human Immunotherapy Molecules and cells

Antibody Cytokine Fusion Proteins | **Chemo Immuno Modulators** | **Vaccine Technologies** | **Natural Killer Cells**

A Leading Immunotherapy Platform in Oncology & Infectious Diseases

600+
Worldwide Patents Extending to 2035 and Beyond

~400,000
Square Feet of Manufacturing and R&D Facilities



100+
Patients Dosed with Off-the-Shelf Natural Killer Cells

>5 Trillion
Over 5 Trillion Natural Killer Cells Manufactured to Date