



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.

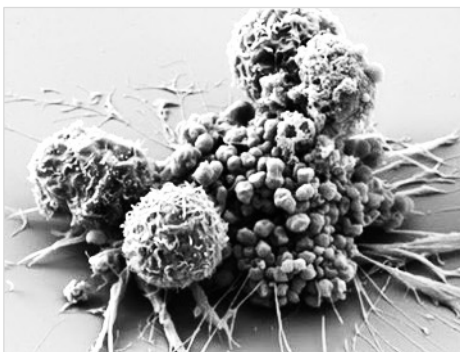
ImmunityBio: A Leading Immunotherapy Company



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



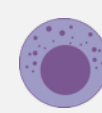
Chemo Immuno
Modulators



Vaccine
Technologies



Natural Killer
Cells



A Leading Immunotherapy Platform in Oncology & Infectious Diseases

600+

Worldwide Patents Extending to
2035 and Beyond

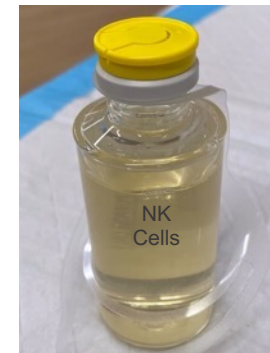
~400,000

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



N=80

FULLY ENROLLED

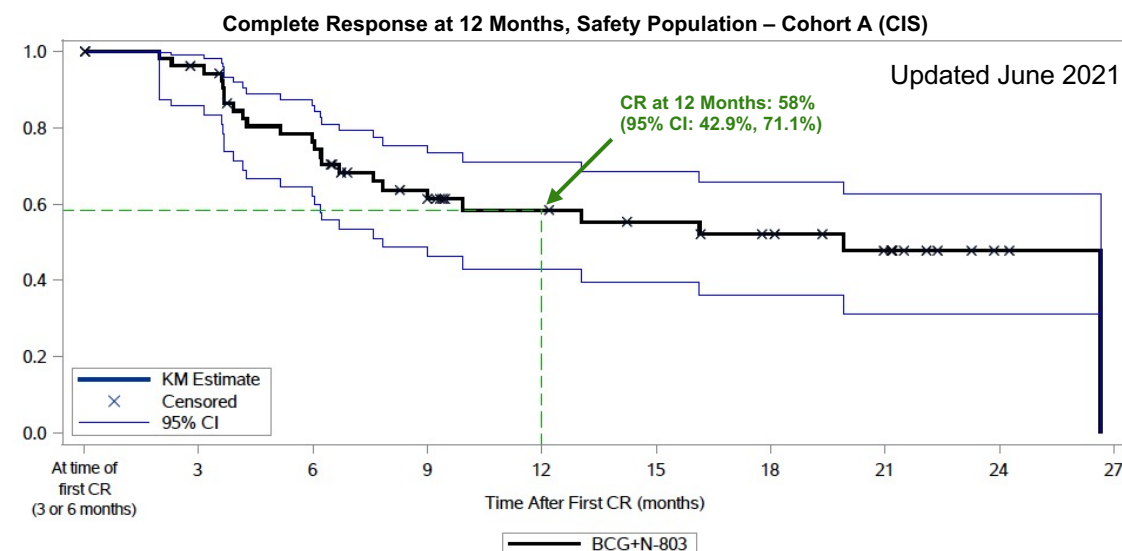
Pivotal Registration Data (QUILT-3.032) in BCG-Unresponsive NMIBC CIS

Primary Endpoint Met

- Primary Endpoint: CR at any time, with lower bound of 95% CI $\geq 20\%$
- To meet the primary endpoint, 24 out of 80 patients must have had a CR at any time
- **56 out of 80 CRs** 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

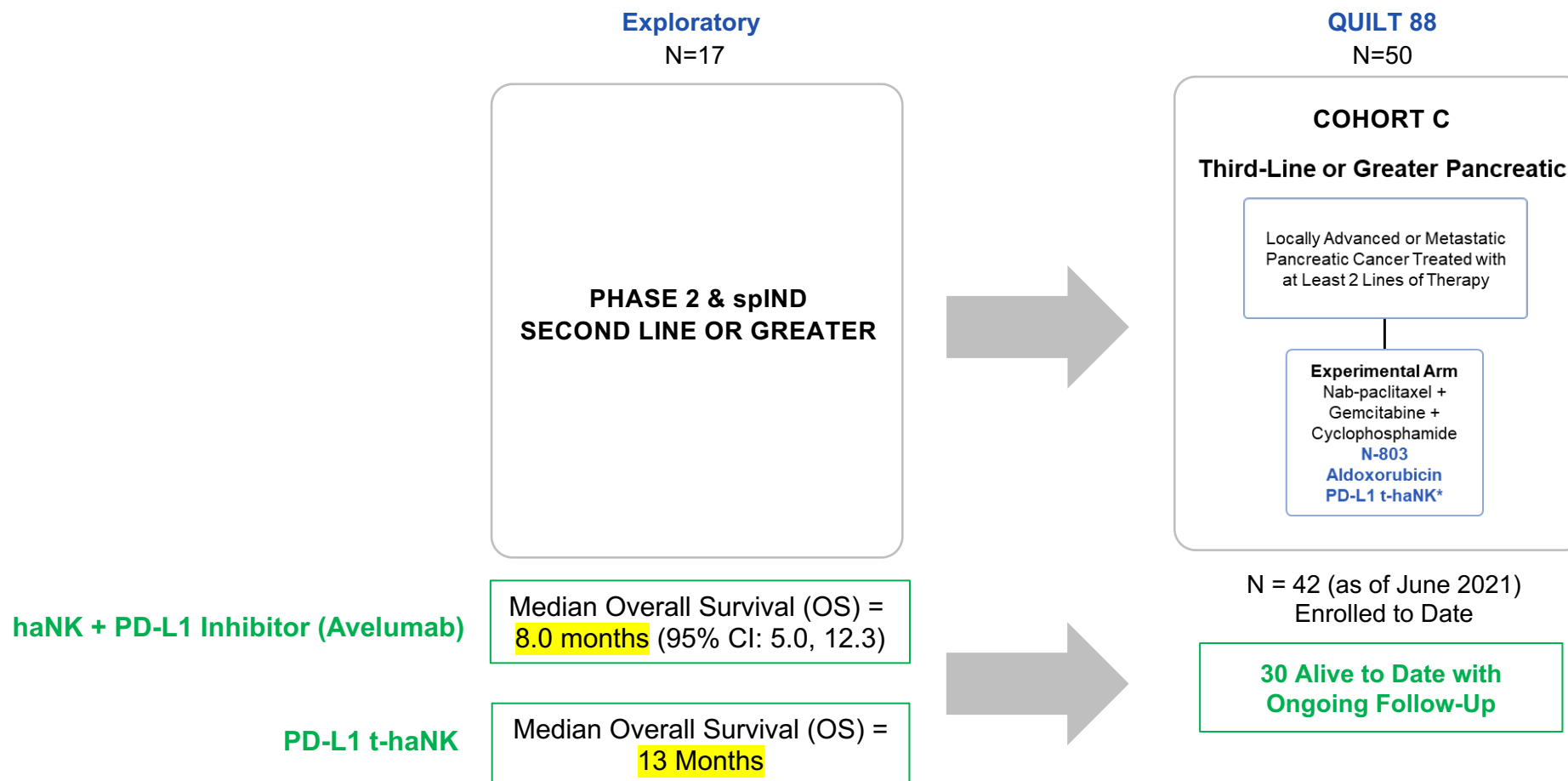
A historical comparison. Not a head to head comparison

Selected Clinical Pipeline Updates for June 2021

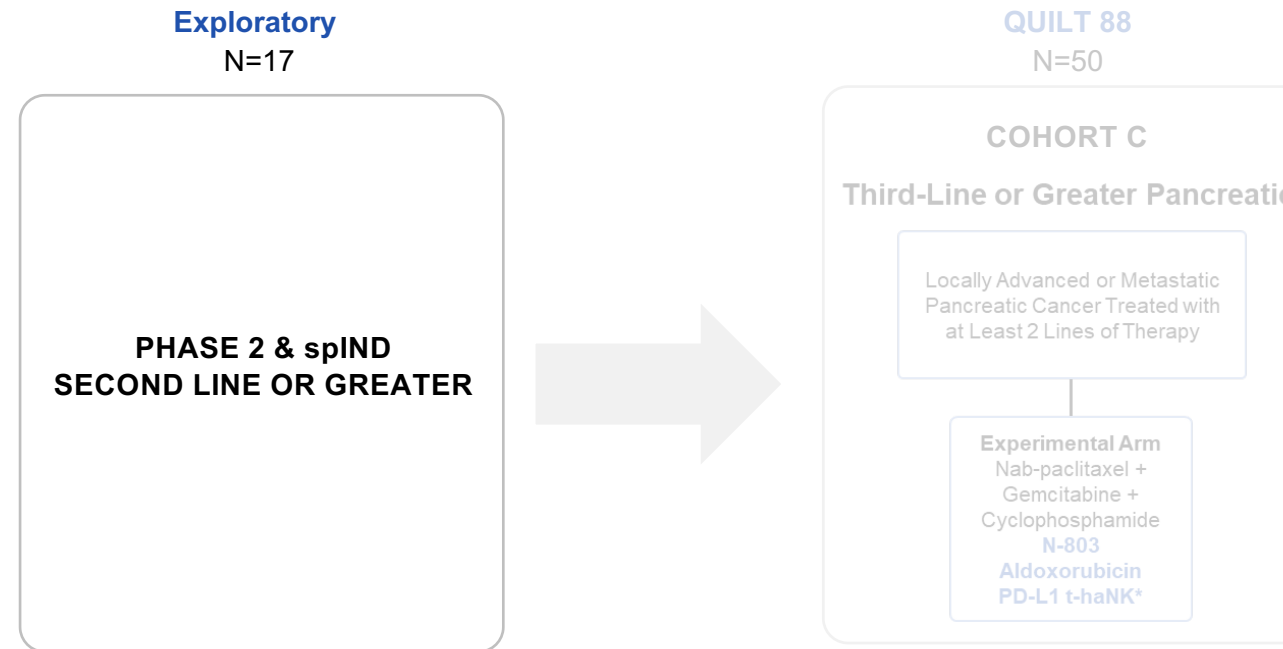
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QUILT 88: 3rd Line or Greater Metastatic Pancreatic Cancer



QUILT 88: 3rd Line or Greater Metastatic Pancreatic Cancer

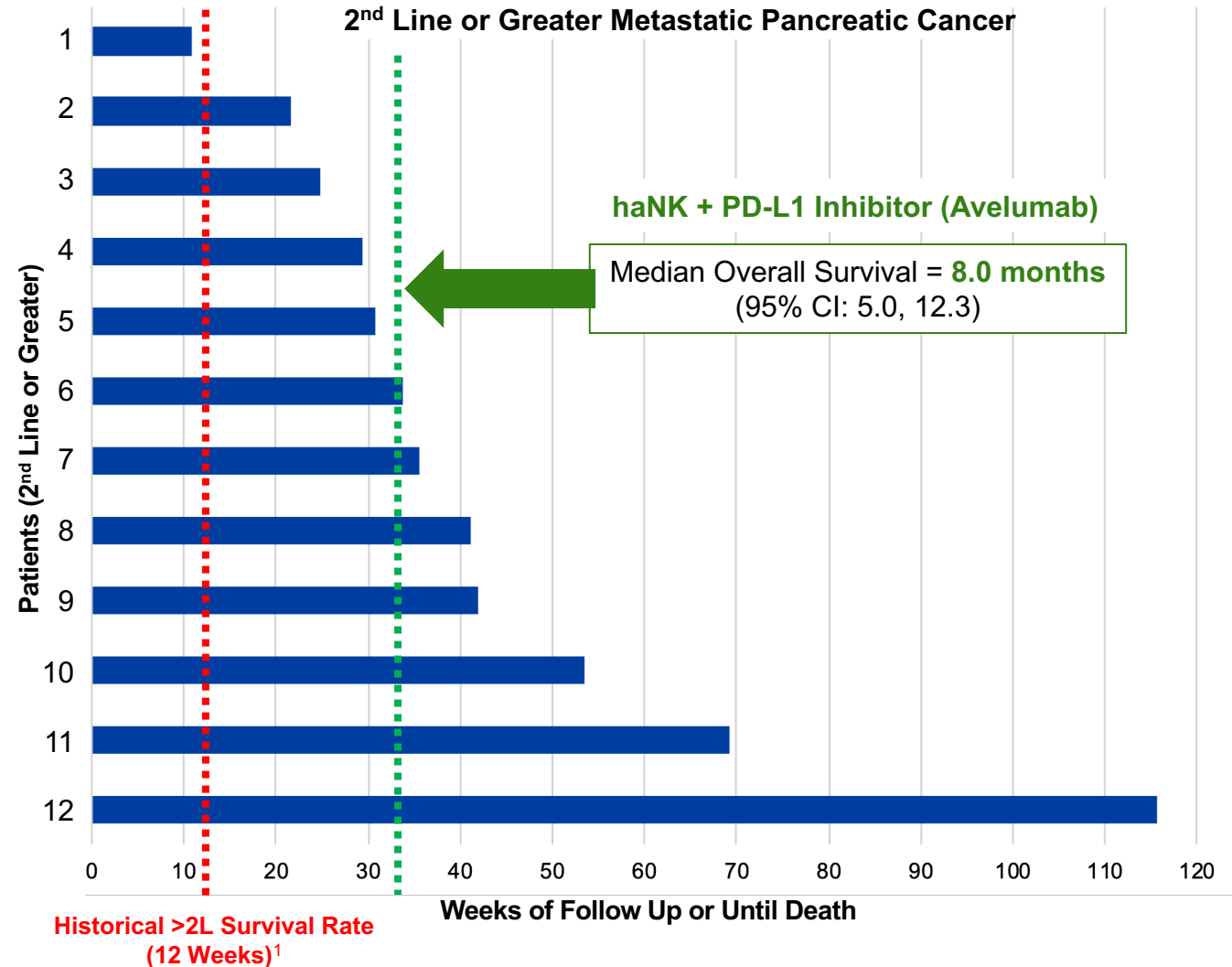


NK Synergy in Pancreatic Cancer

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**

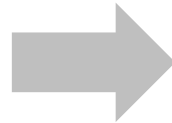
NCT03329248 (Closed)
QUILT 3.039, 3.060, 3.070, 3.080
NANT Cancer Vaccine



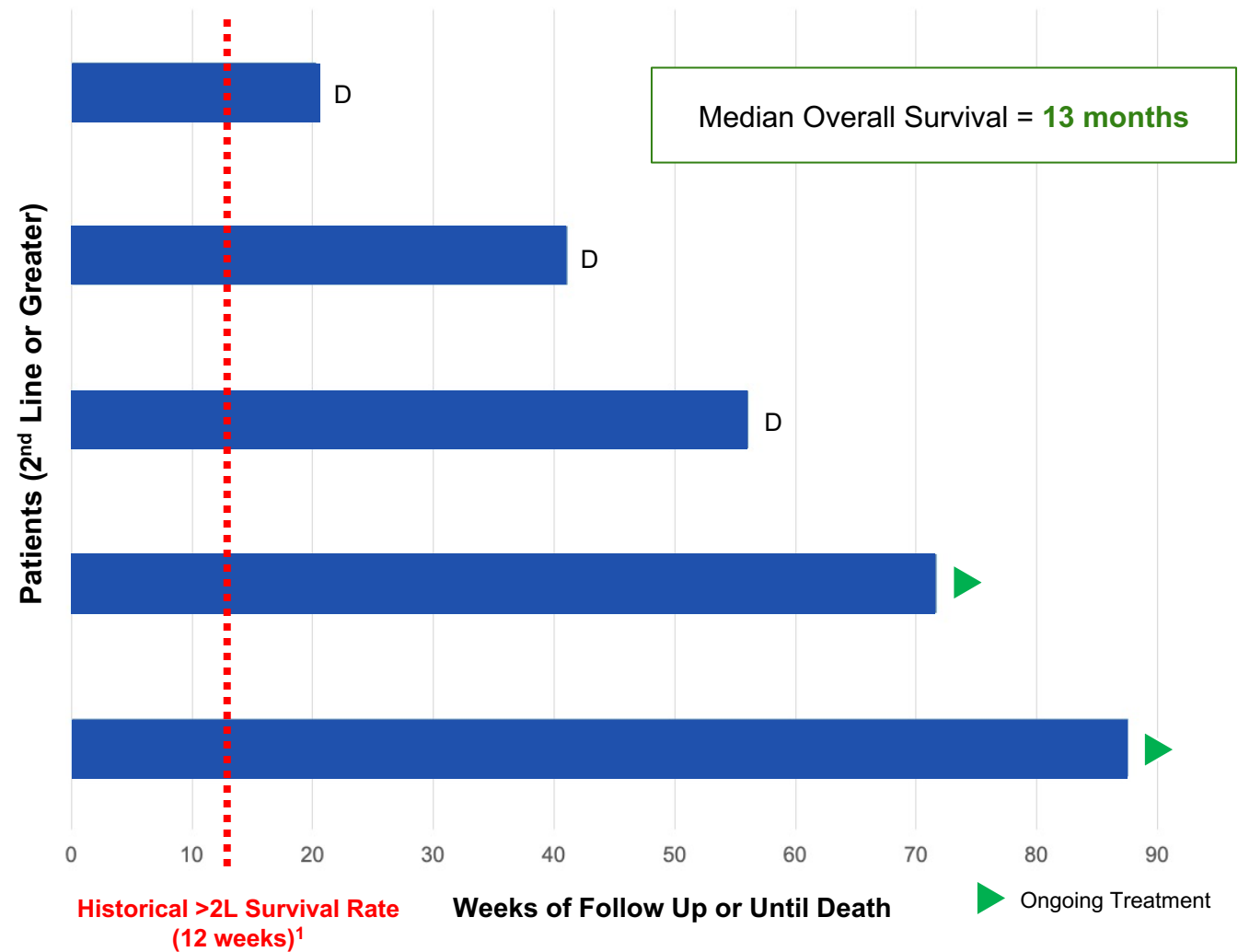
PD-L1 t-haNK in Metastatic Pancreatic Cancer

Median Overall Survival (OS) is 394 Days (13 Months)

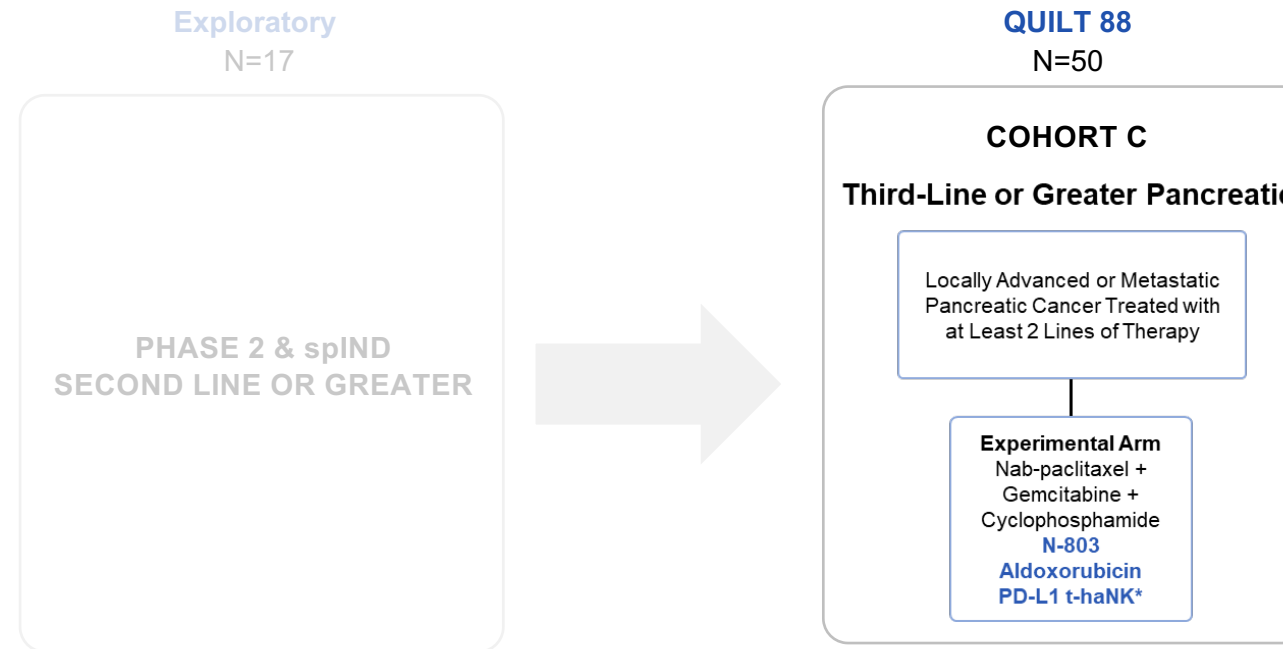
Exploratory Trial of PD-L1 t-haNK
in Combination with Chemo
Immunomodulation in Advanced
Metastatic Pancreatic Cancer



2nd Line or Greater Metastatic Pancreatic Cancer



QUILT 88: 3rd Line or Greater Metastatic Pancreatic Cancer



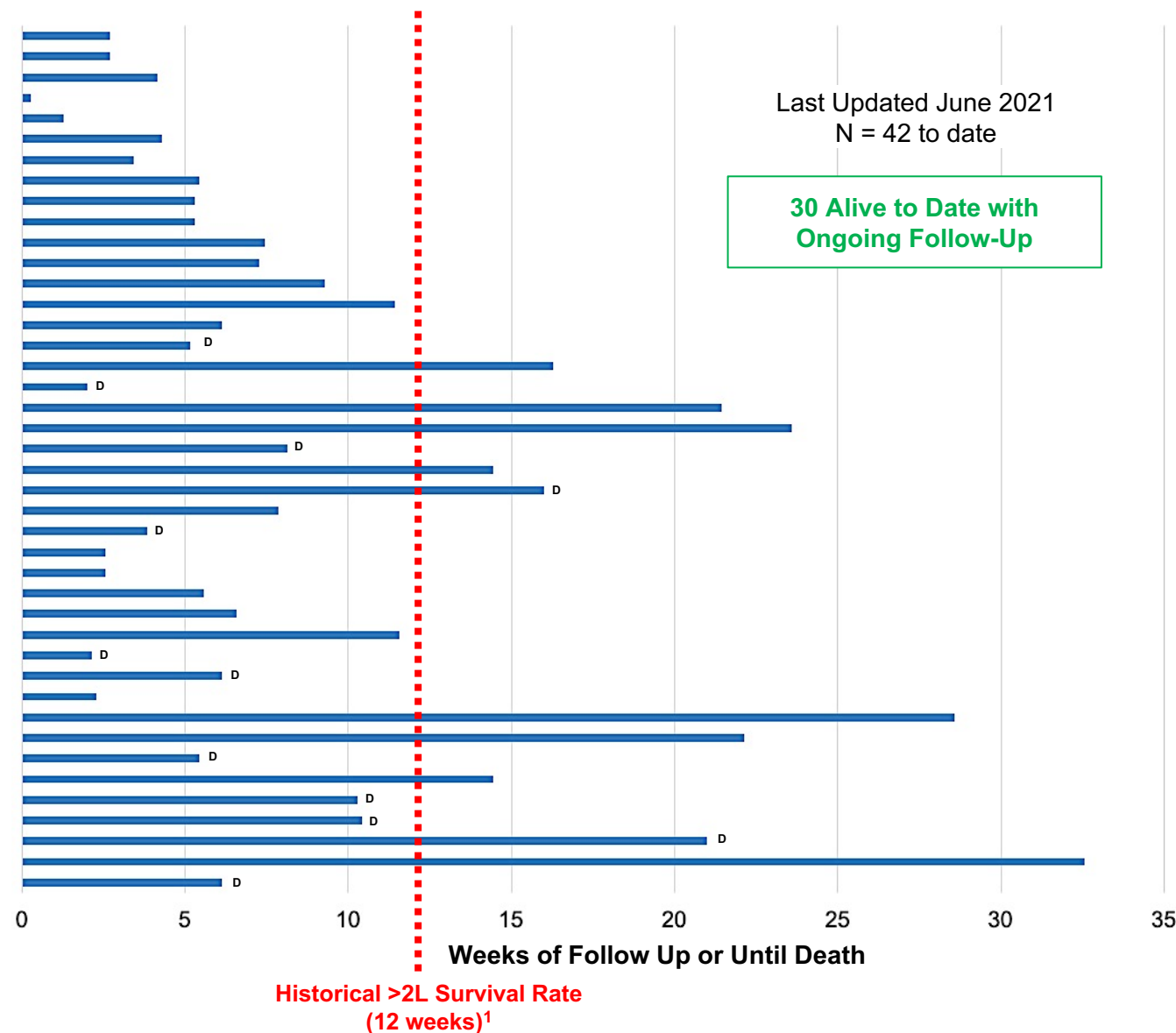
PD-L1 t-haNK + Chemo Immunomodulation in Locally Advanced or Metastatic Pancreatic Cancer (QUILT-88)

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
 Clinical Trial Protocol: QUILT-88 Amendment 3

ImmunityBio, Inc.

**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

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 Seery¹, Chaitali Nangia¹, Leonard Sender², Sandeep Reddy², Patrick Soon-Shiong²¹Hoag 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 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.

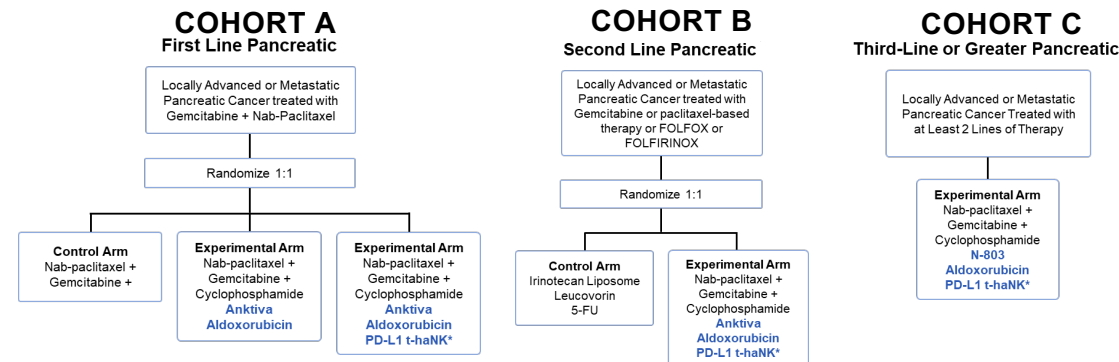
Safety Endpoints:

- 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.

STUDY DESIGN



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.
- 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.
- 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

- Absolute neutrophil count (ANC) < 1000 cells/mm³.
- 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
- Hemoglobin < 9 g/dL.
- Total bilirubin greater than two times the upper limit of normal (ULN); unless the subject has documented Gilbert's syndrome).
- Aspartate aminotransferase (AST [SGOT]) or alanine aminotransferase (ALT [SGPT]) > 2.5 × ULN (> 5 × ULN in subjects with liver metastases).
- Alkaline phosphatase (ALP) levels > 2.5 × ULN (> 5 × ULN in subjects with liver metastases, or > 10 × ULN in subjects with bone metastases).
- Serum creatinine > 2.0 mg/dL or 177 μmol/L.
- Serum anion gap > 16 mEq/L or arterial blood with pH < 7.3.
- Albumin < 3.0.
- Ascites requiring paracentesis.

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)

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 Koo, 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

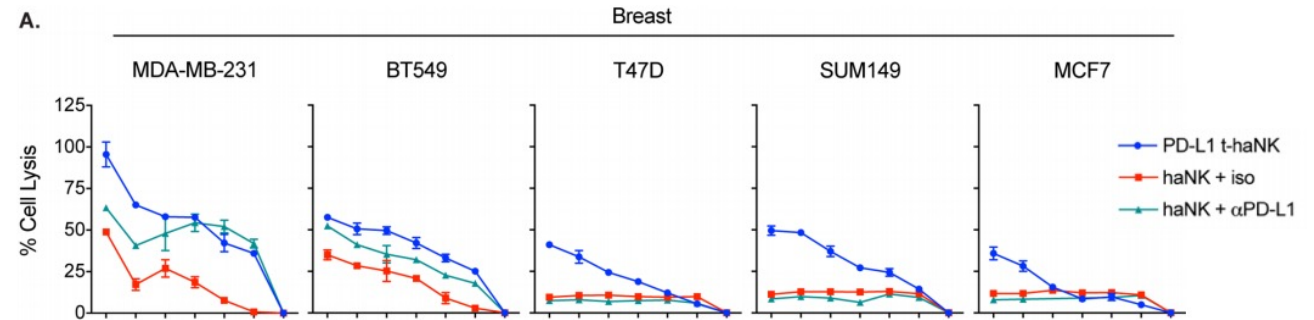
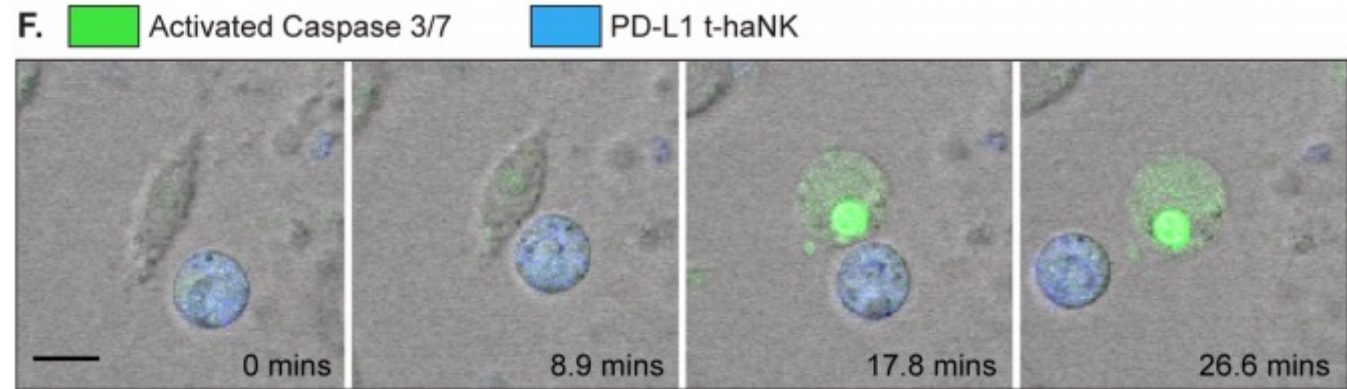
Open access

Original research



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

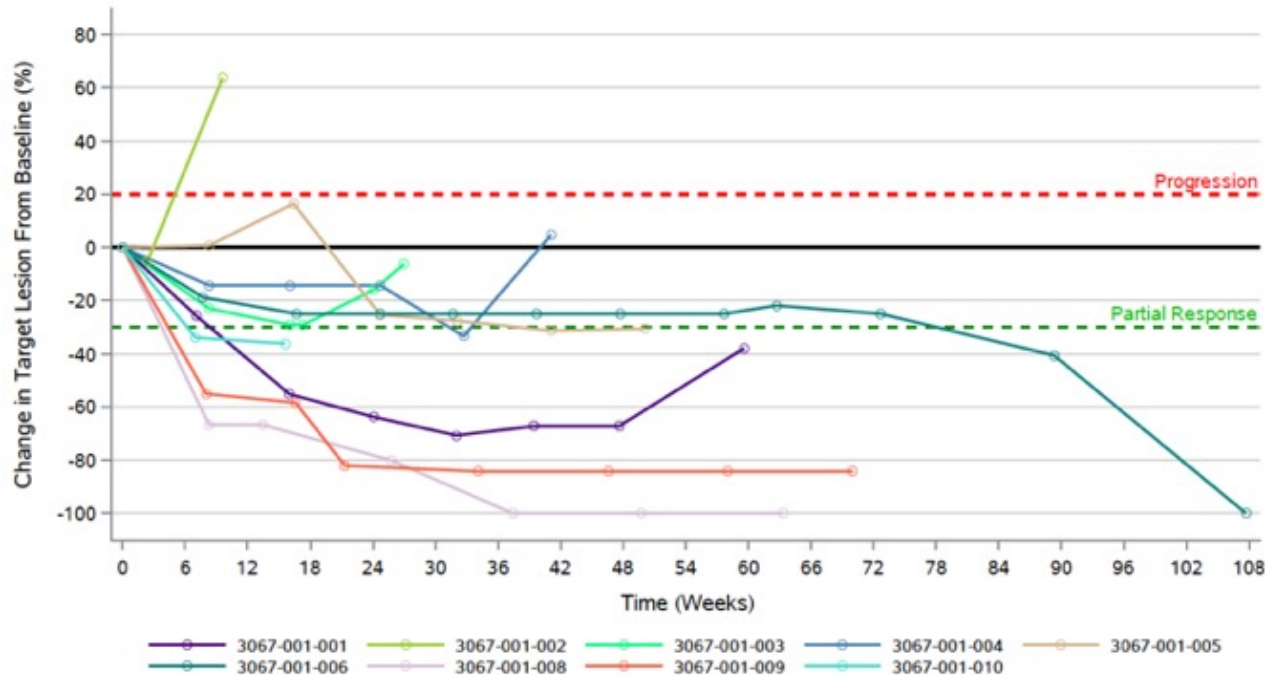
Kellsye P Fabian,¹ Michelle R Padget,¹ Renee N. Donahue,¹ Kristen Solocinski,¹ Yvette Robbins,¹ Clint T. Allen,² John H. Lee,³ Shahrooz Rabizadeh,^{4,5} Patrick Soon-Shiong,^{4,5} Jeffrey Schlom ,¹ James W Hodge ¹



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**

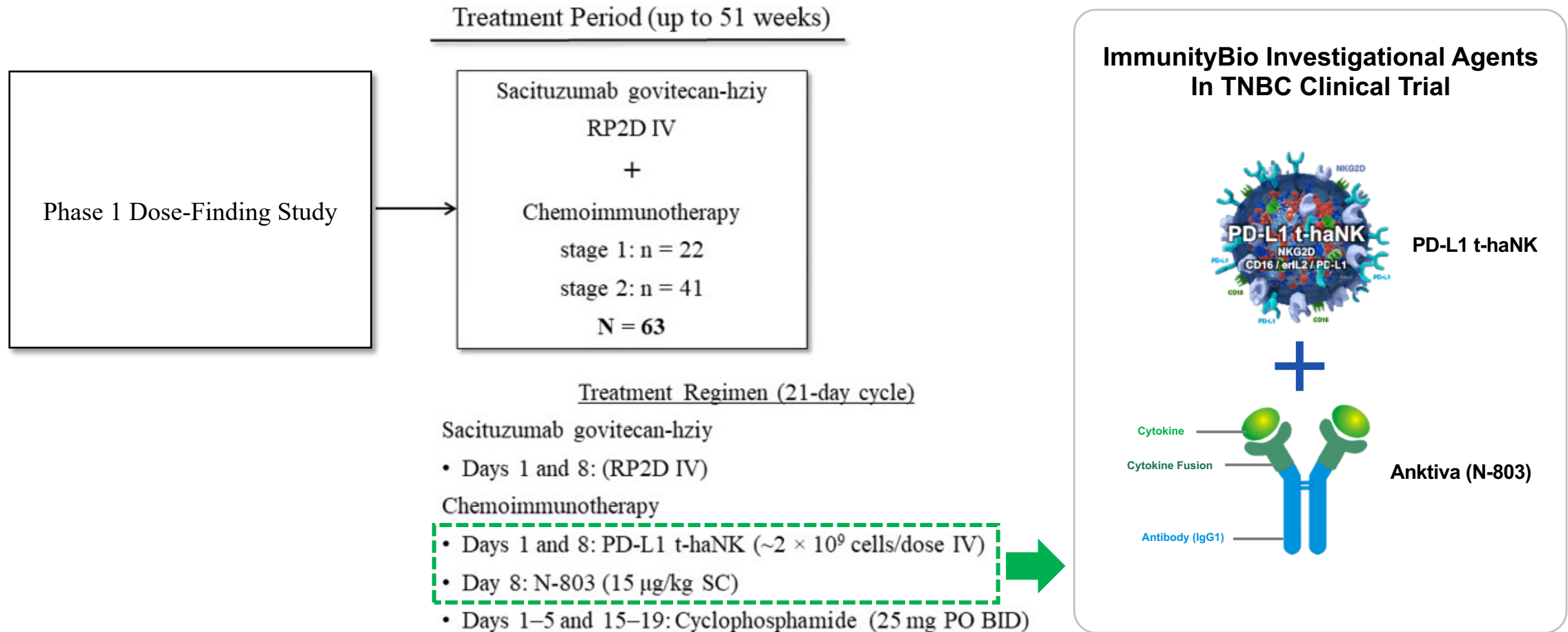
April 2020

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

TNBCC Phase 1 / 2 Treatment Schema



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Liquid & Solid Tumor Cell Therapy Program

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

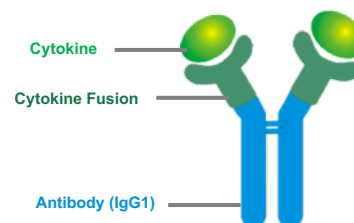
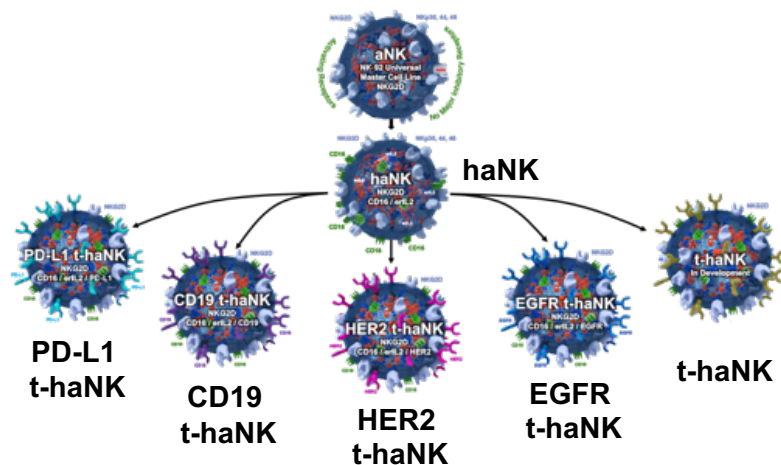
- Pancreatic Cancer (Ph 2/3)
- TNBC (Ph 1/2)
- Lung Cancer (Ph 3)
- Merkel Cell Carcinoma (Ph 2)
- Diffuse Large Cell Lymphoma (Ph 1)
- GBM (Ph 1)

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)

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

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



Anktiva (N-803)



M-ceNK

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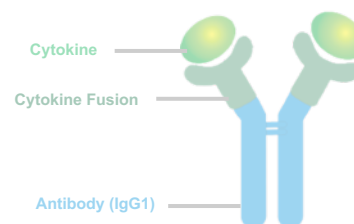
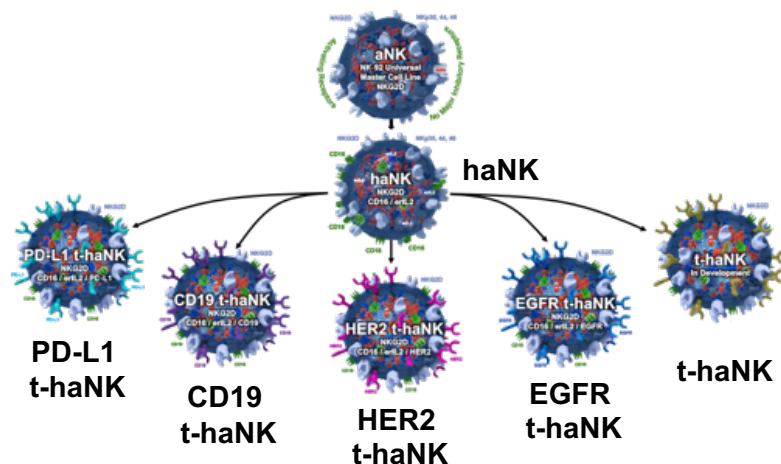
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Anktiva (N-803)



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](#)

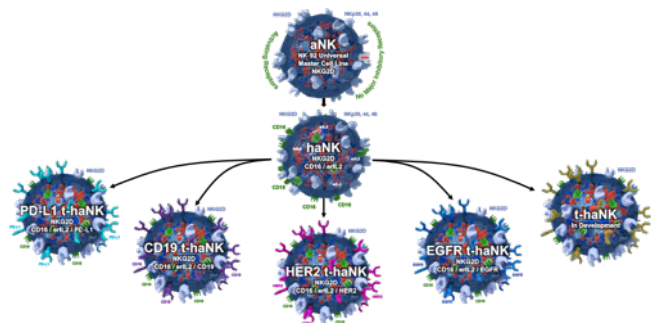
As testing accelerates, company boosts manufacturing speed, output, and quality control with over 2 trillion cryopreserved NK cells ready for off-the-shelf use

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

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

NK-92 Universal NK Cell Line



	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)

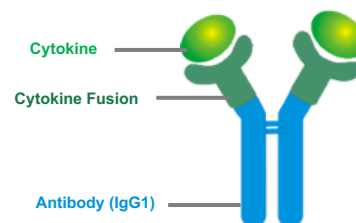
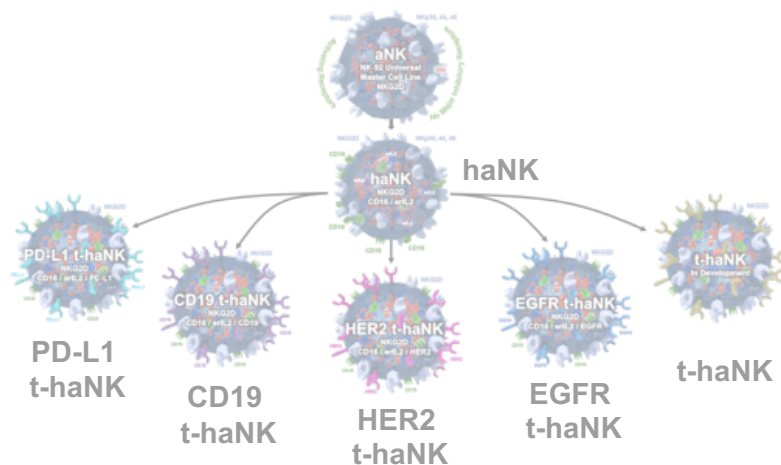
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Anktiva (N-803)



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 Trials: Immunotherapy

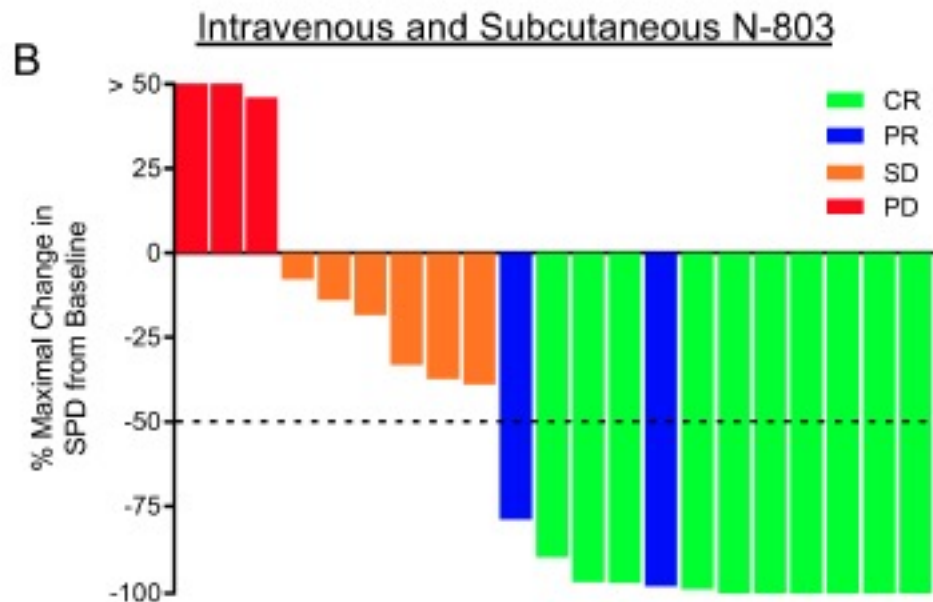
Phase I Trial of N-803, an IL15 Receptor Agonist, with Rituximab in Patients with Indolent Non-Hodgkin Lymphoma

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

[Add to Cart \(\\$50\)](#)

DOI: 10.1158/1078-0432.CCR-20-4575

[Check for updates](#)



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Liquid & Solid Tumor Cell Therapy Program

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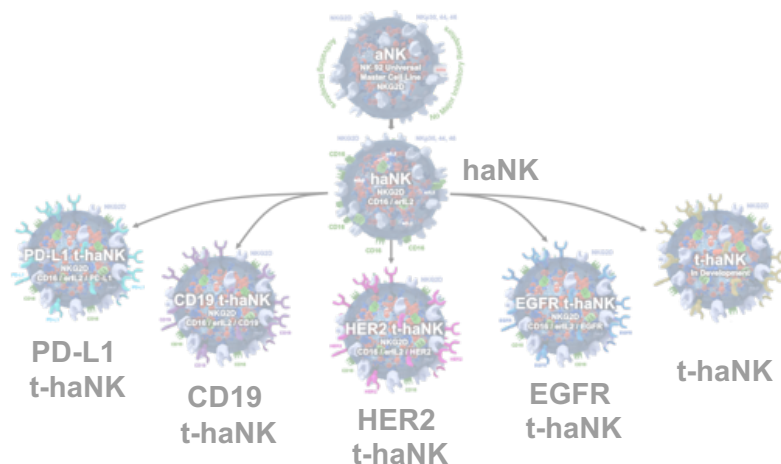
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- Bladder Cancer (Ph 2/3)
- Pancreatic Cancer (Ph 2/3)
- TNBC (Ph 1)
- Lung Cancer (Ph 3)
- Indolent Non-Hodgkin Lymphoma (Ph 1)

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

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



Anktiva (N-803)



M-ceNK

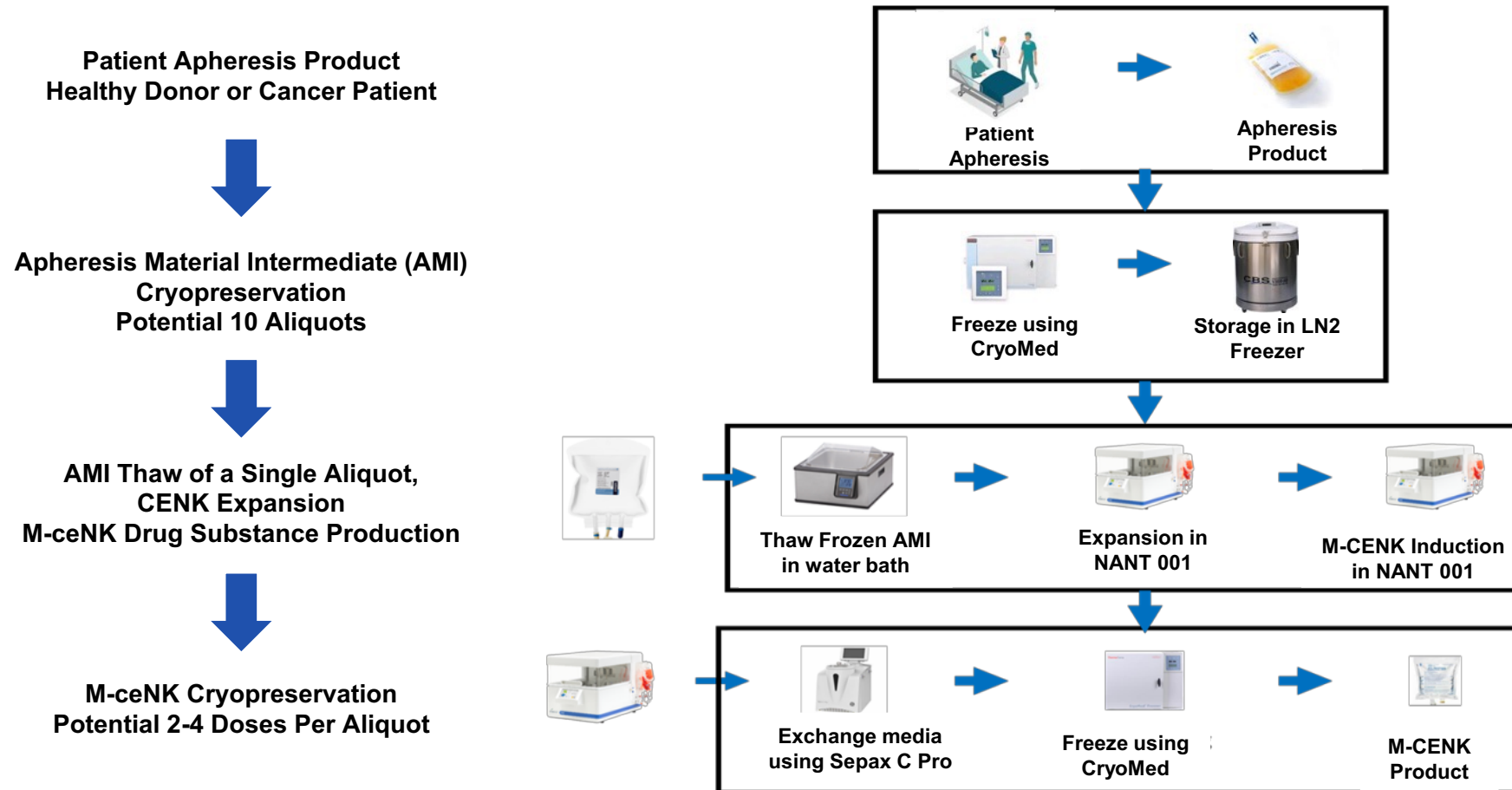
M-ceNK (N=20): 3,000% Cell Expansion with Potent Killing Across Multiple Cell Lines

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

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- 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

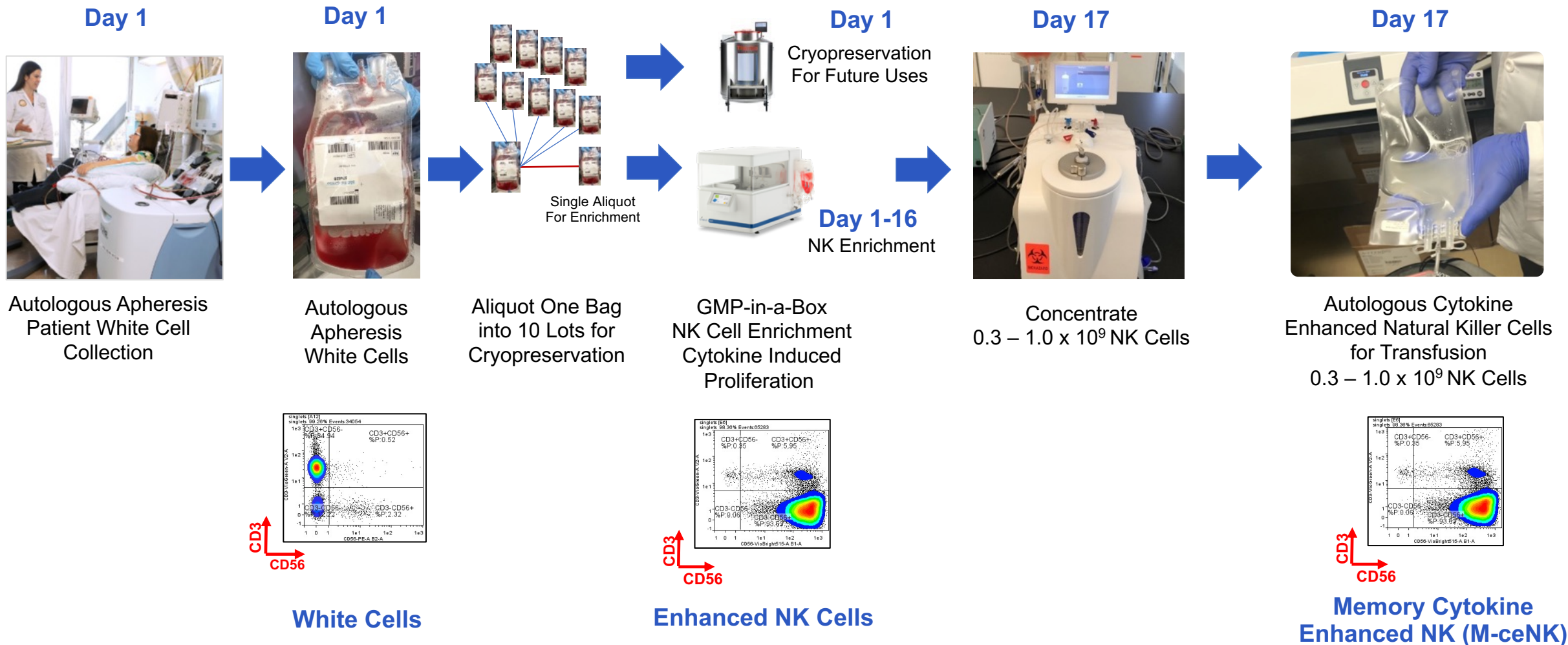


Potential ~20 Doses of Potent M-ceNK Cells Per Single Apheresis

First in Human Autologous NK For Solid Tumors

M-ceNK: Autologous and Allogeneic Proprietary Process

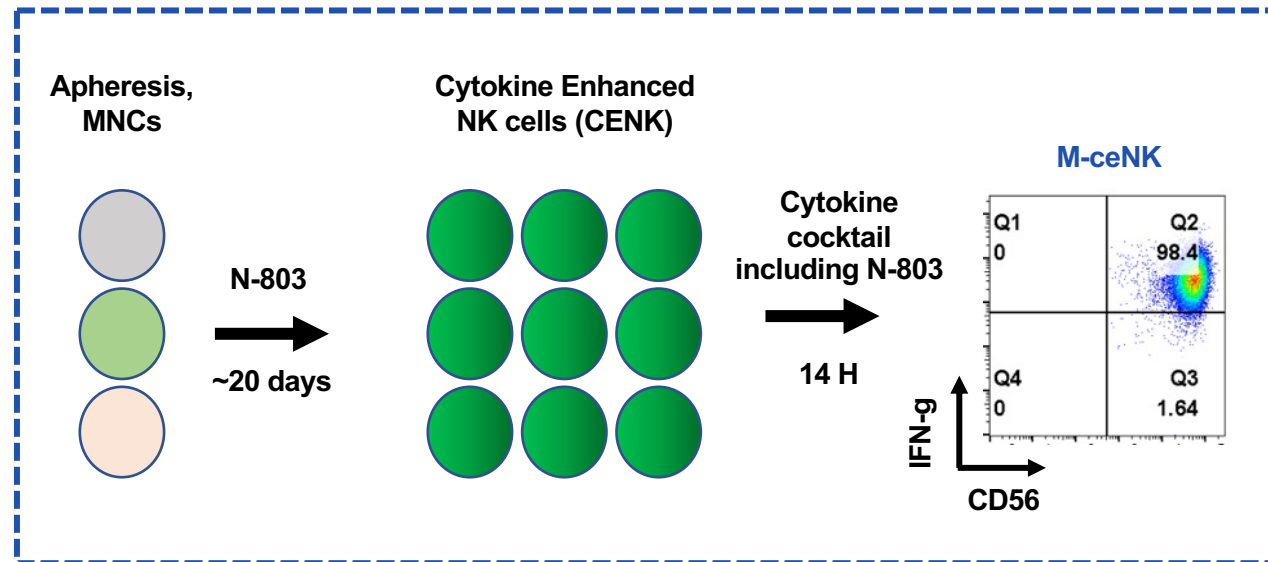
Memory Cytokine Enhanced NK (M-ceNK)



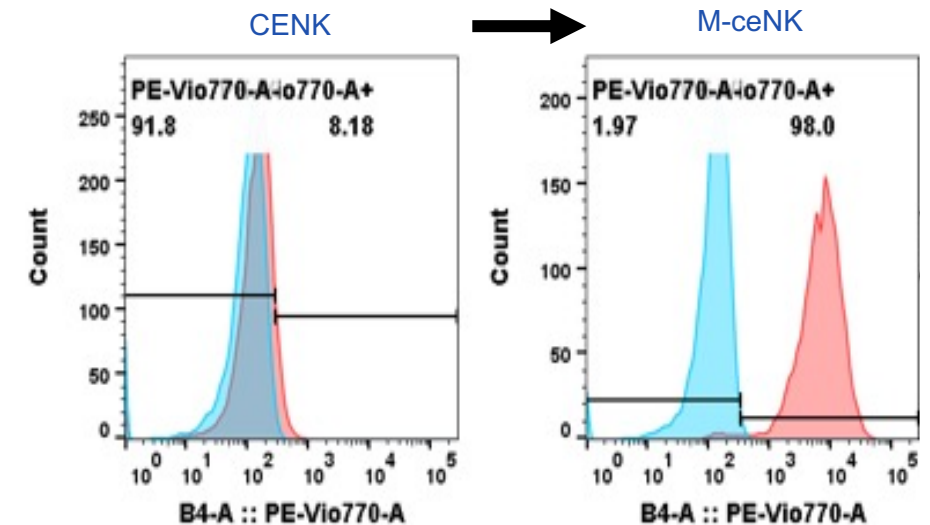
Potential ~20 Doses of Potent M-ceNK Cells Per Single Apheresis

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

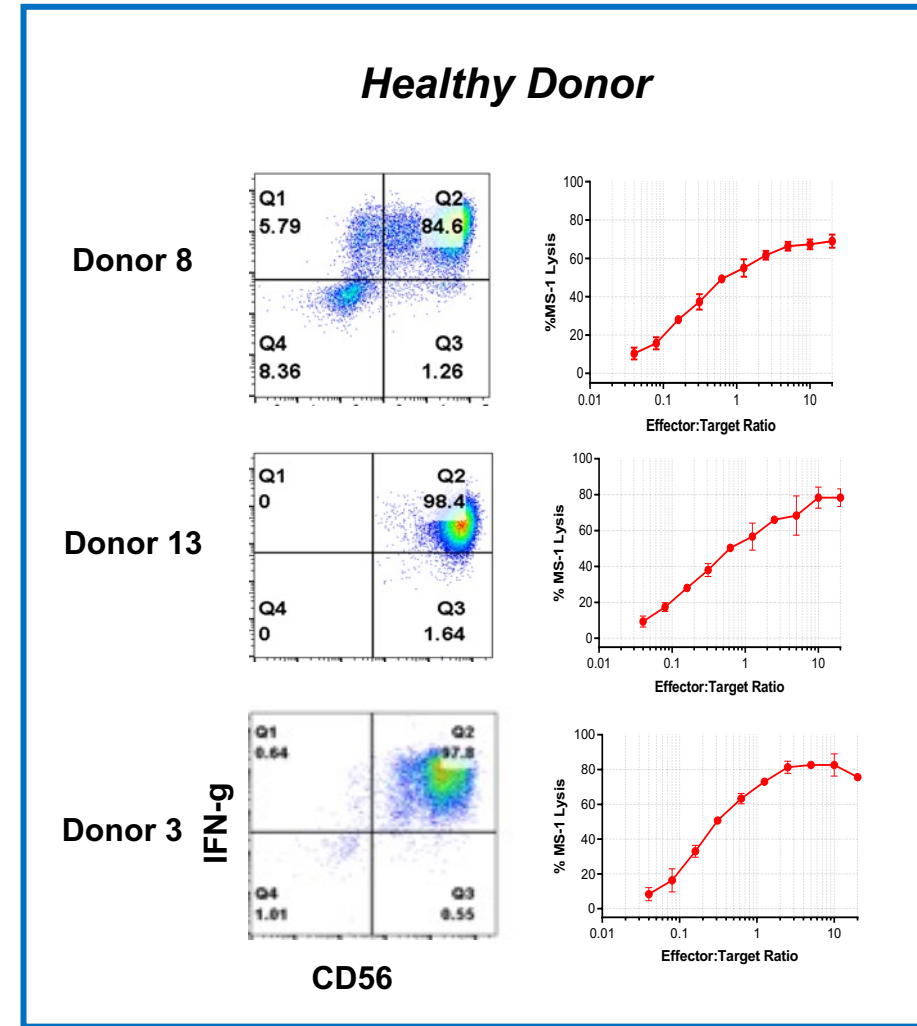
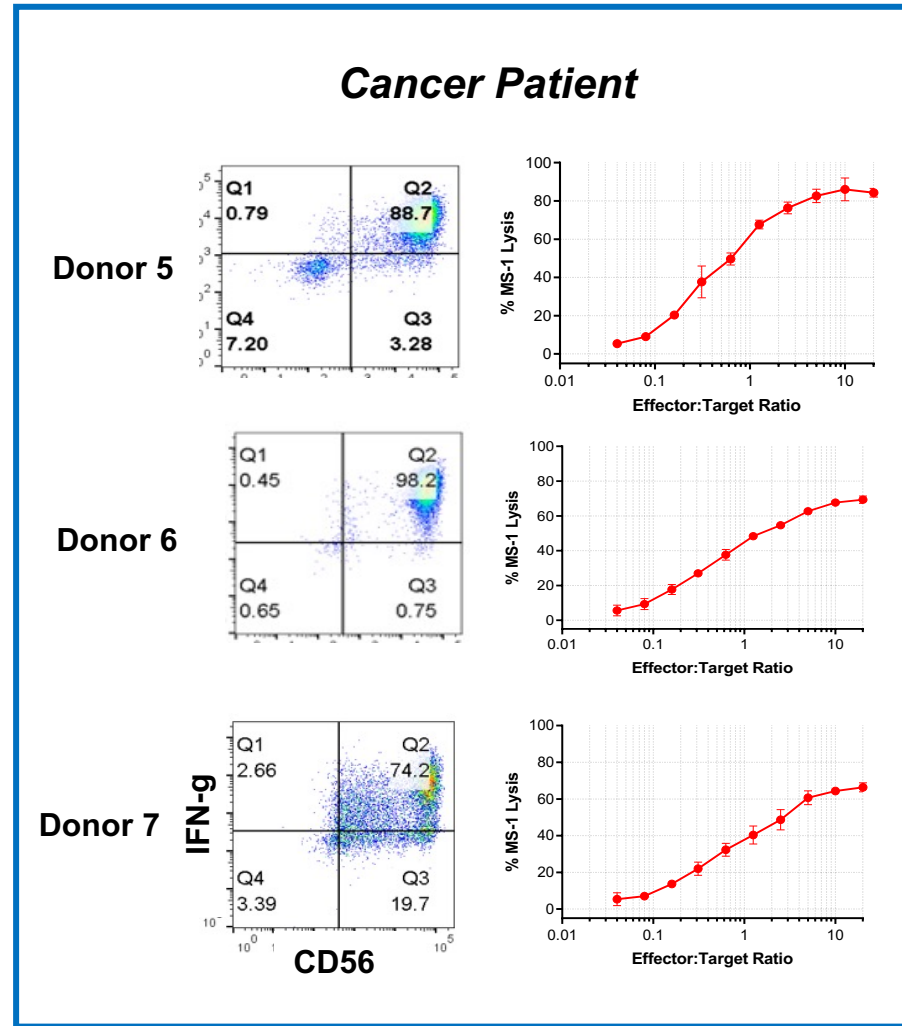
Donors	Apheresis collected	Range of total nucleated cells (TNC) collected	% of NK cells	% of Expansion and Production of M-ceNK cells in 18-20 days	Potential # of Doses Cryopreserved M-ceNK from One Apheresis
Healthy Donor	N = 15	8 - 27 Billion Cells Per Donor	11 - 16 % CD56+ cells	~3,000%	~20 doses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

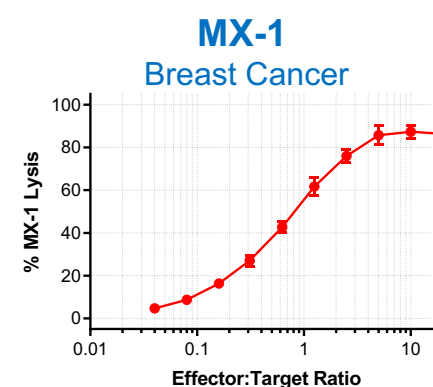
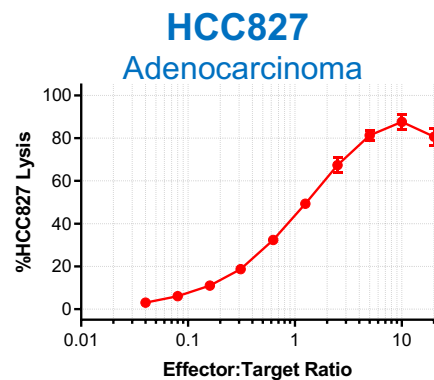
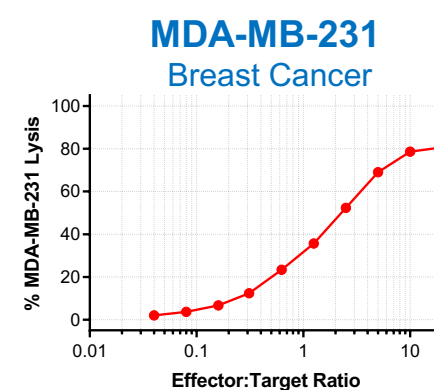
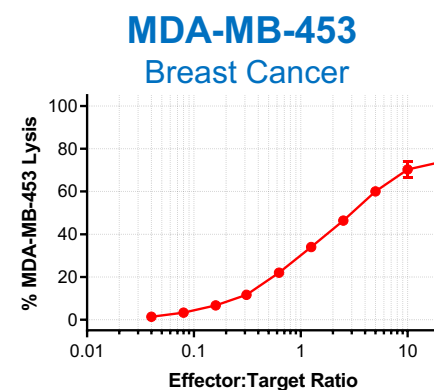
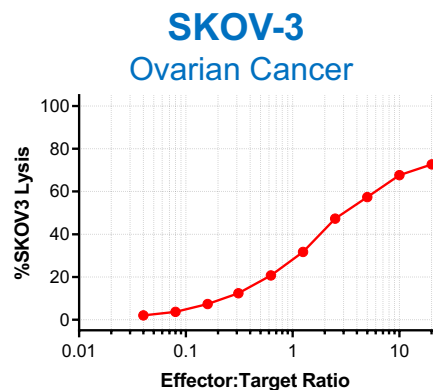
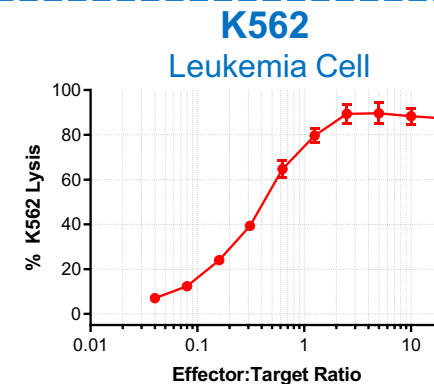
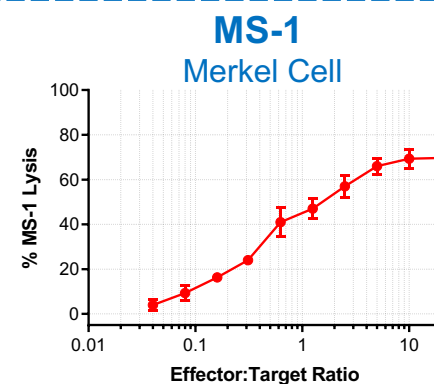
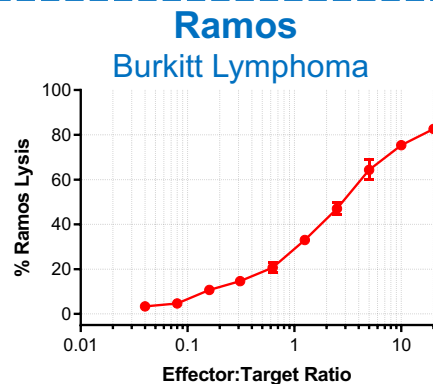


M-ceNK Production from Healthy Donor vs Cancer Patient Are Equally Potent



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

Effector Cell	% Lysis		
	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

Effector Cell	% Lysis		
	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

Effector Cell	% Lysis		
	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

Effector Cell	% Lysis		
	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

Effector Cell	% Lysis		
	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

Effector Cell	% Lysis		
	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

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

Phase 1 – First in Human M-ceNK Trial

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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Home > Search Results > Study Record Detail ☐ Save this study

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

ClinicalTrials.gov Identifier: NCT04898543

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

Sponsor:
ImmunityBio, Inc.

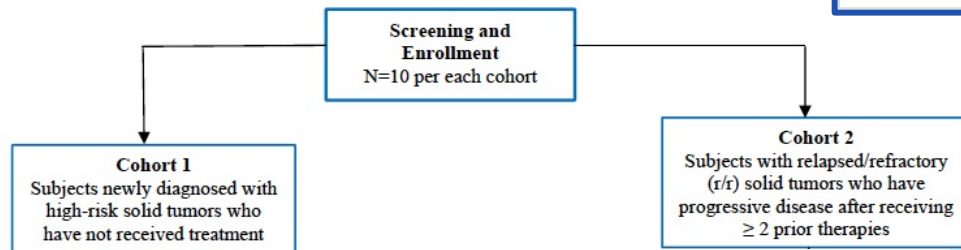
Information provided by (Responsible Party):
ImmunityBio, Inc.

Recruitment Status: Not yet recruiting
First Posted: May 24, 2021
Last Update Posted: May 24, 2021
[See Contacts and Locations](#)

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- 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)



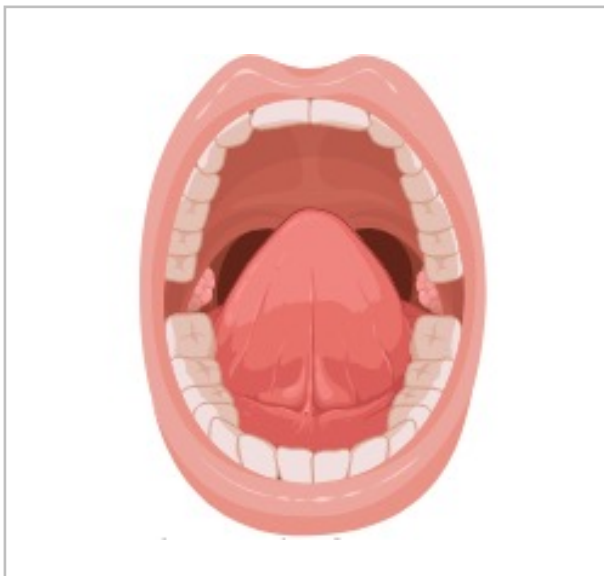
USA & South Africa



Oral Capsule (Room Temp)



South Africa



Sublingual (Room Temp)



USA & South Africa



Intranasal (2-8°C)



South Africa

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South Africa

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

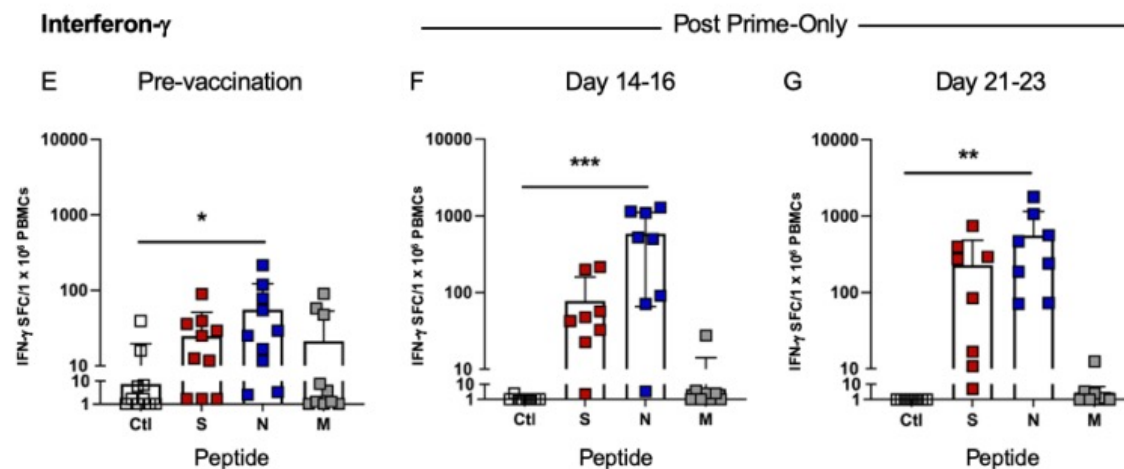
ImmunityBio Announces Single Prime hAd5 COVID-19 Vaccination Induces a 10-Fold Increase in T Cell Response Equivalent to T Cell Responses from Patients Previously Infected with SARS-CoV-2

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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Subcutaneous (2-8°C)



USA & South Africa



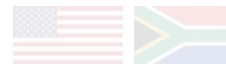
Oral Capsule (Room Temp)



South Africa



Sublingual (Room Temp)



USA & South Africa



Intranasal (2-8°C)



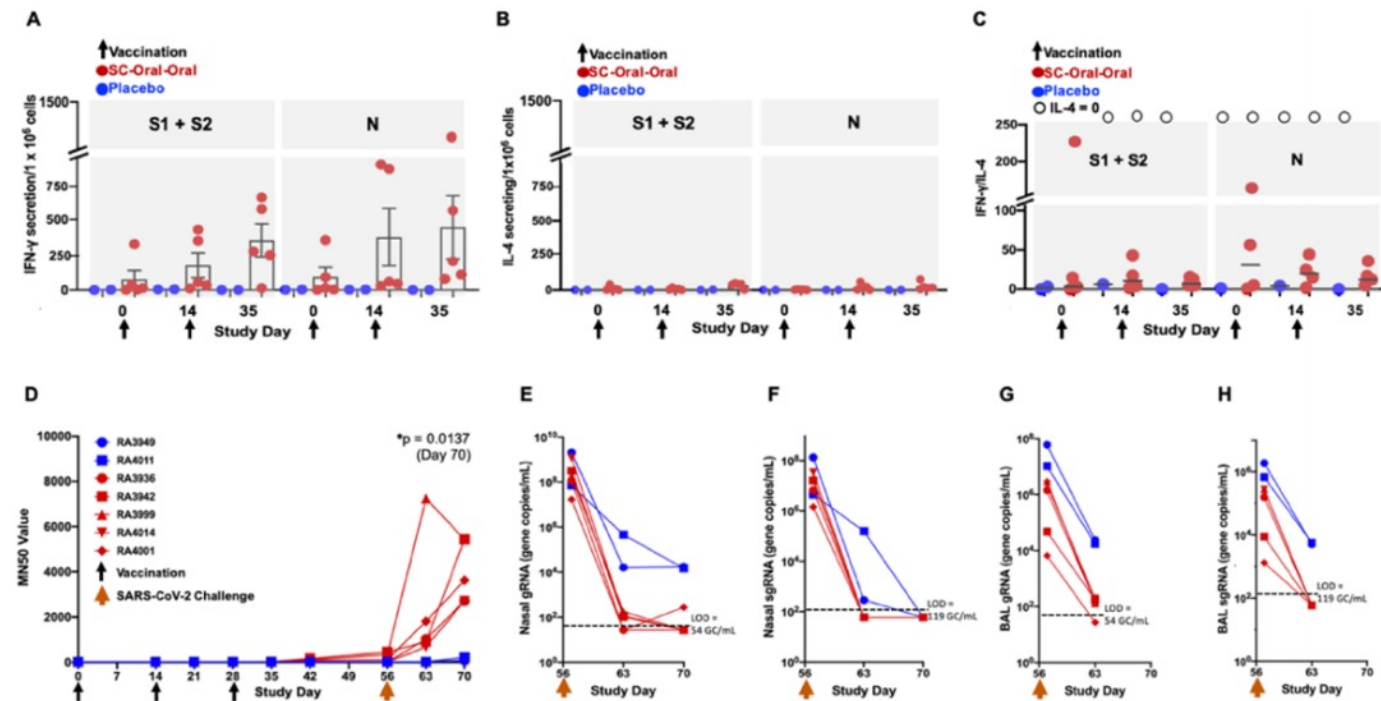
South Africa

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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Subcutaneous (2-8°C)



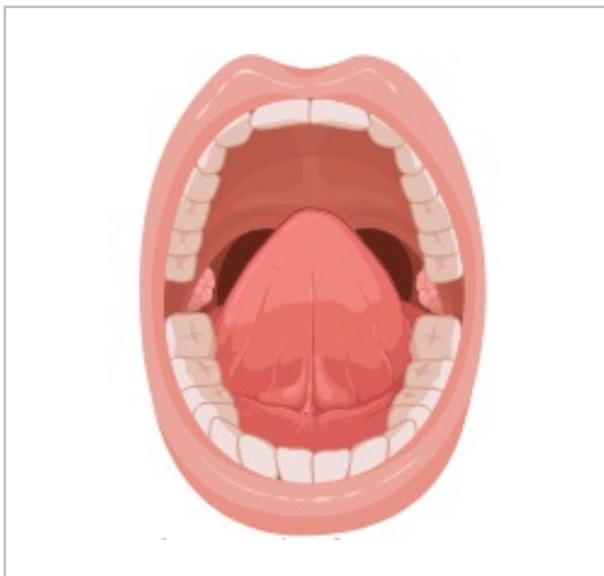
USA & South Africa



Oral Capsule (Room Temp)



South Africa



Sublingual (Room Temp)



USA & South Africa



Intranasal (2-8°C)



South Africa

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

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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

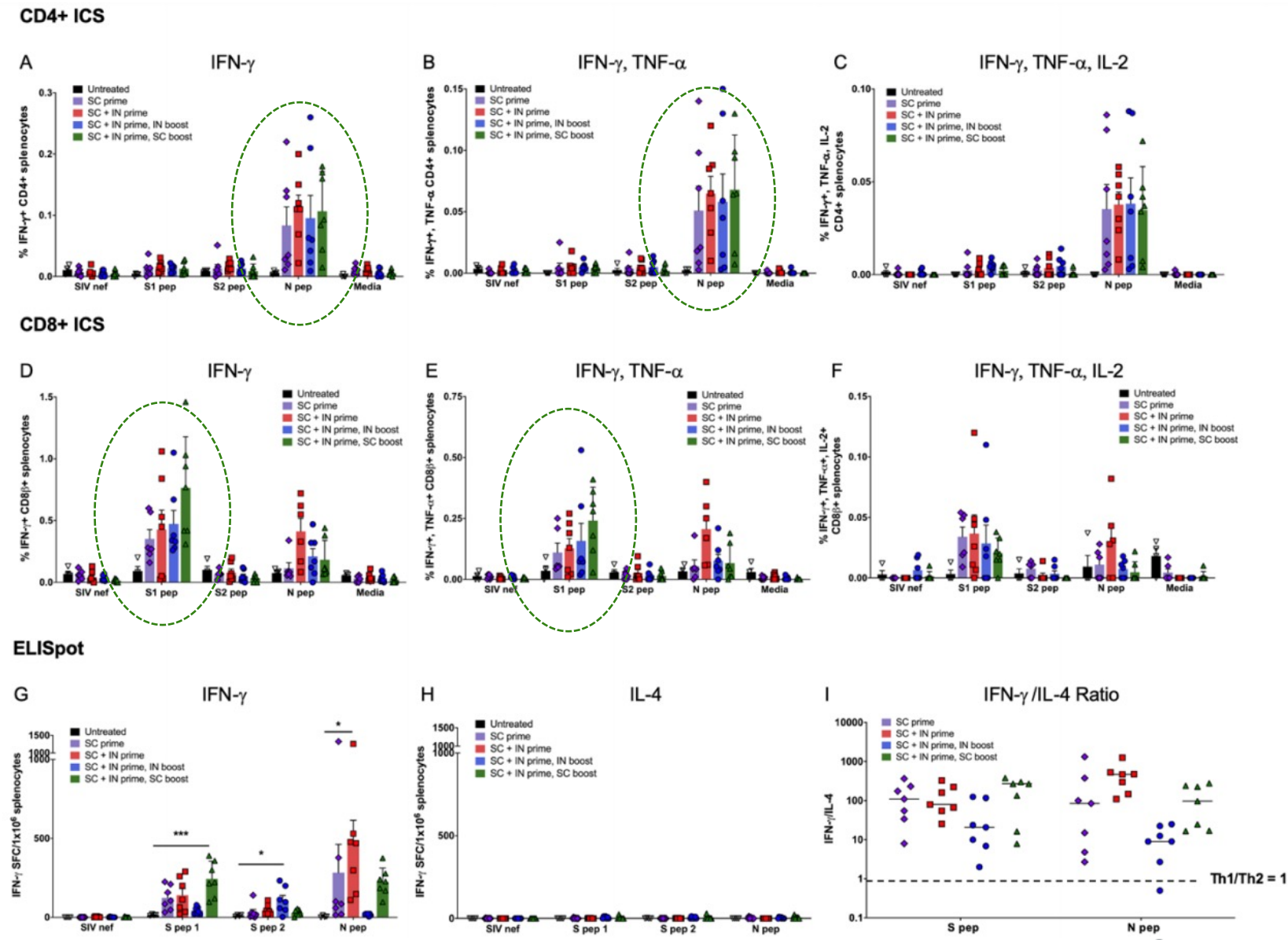
ImmunityBio Expands Trials of T-Cell-Based COVID-19 Vaccine Candidate as a 'Universal Boost' in Vaccinated Subjects and Receives Approval to Test Intranasal Spray in South Africa

Published: May 25, 2021



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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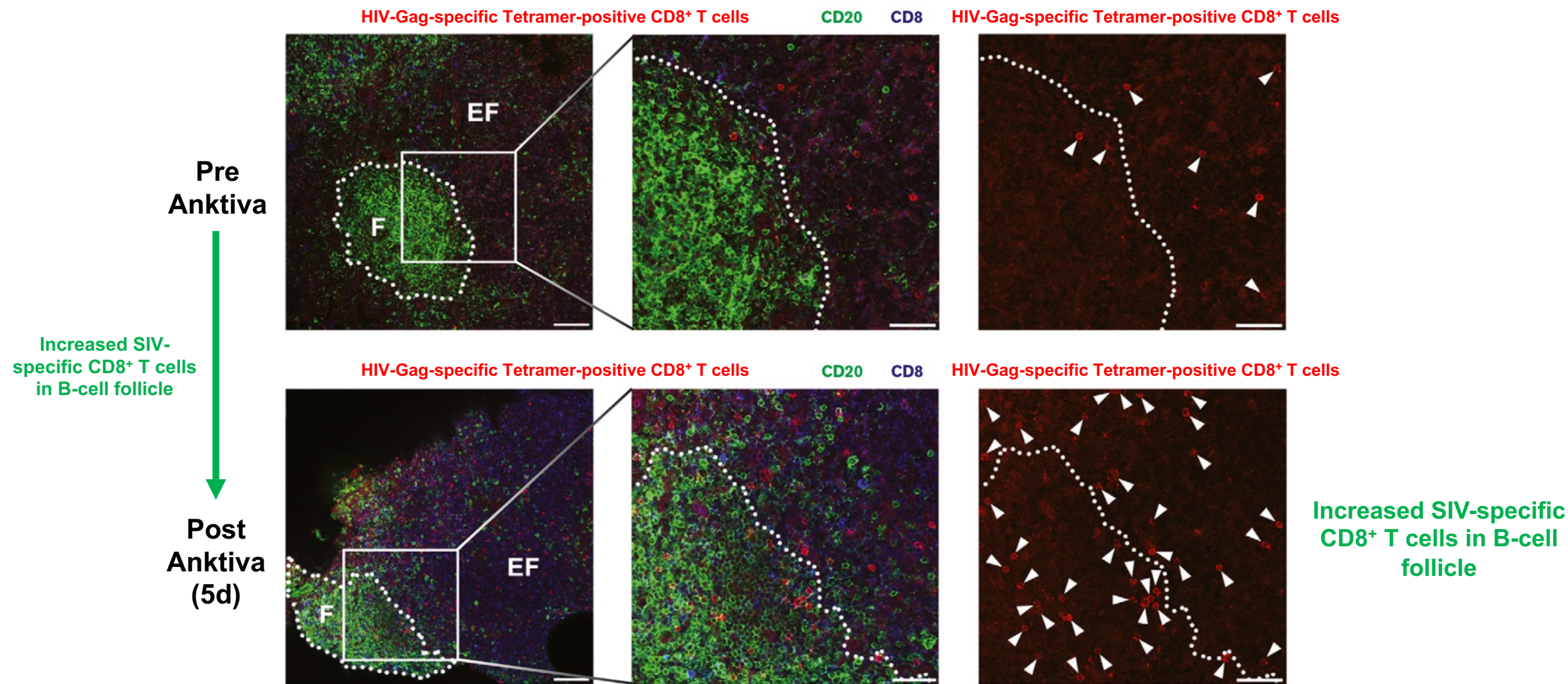
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Rationale for N-803 in HIV

- 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:

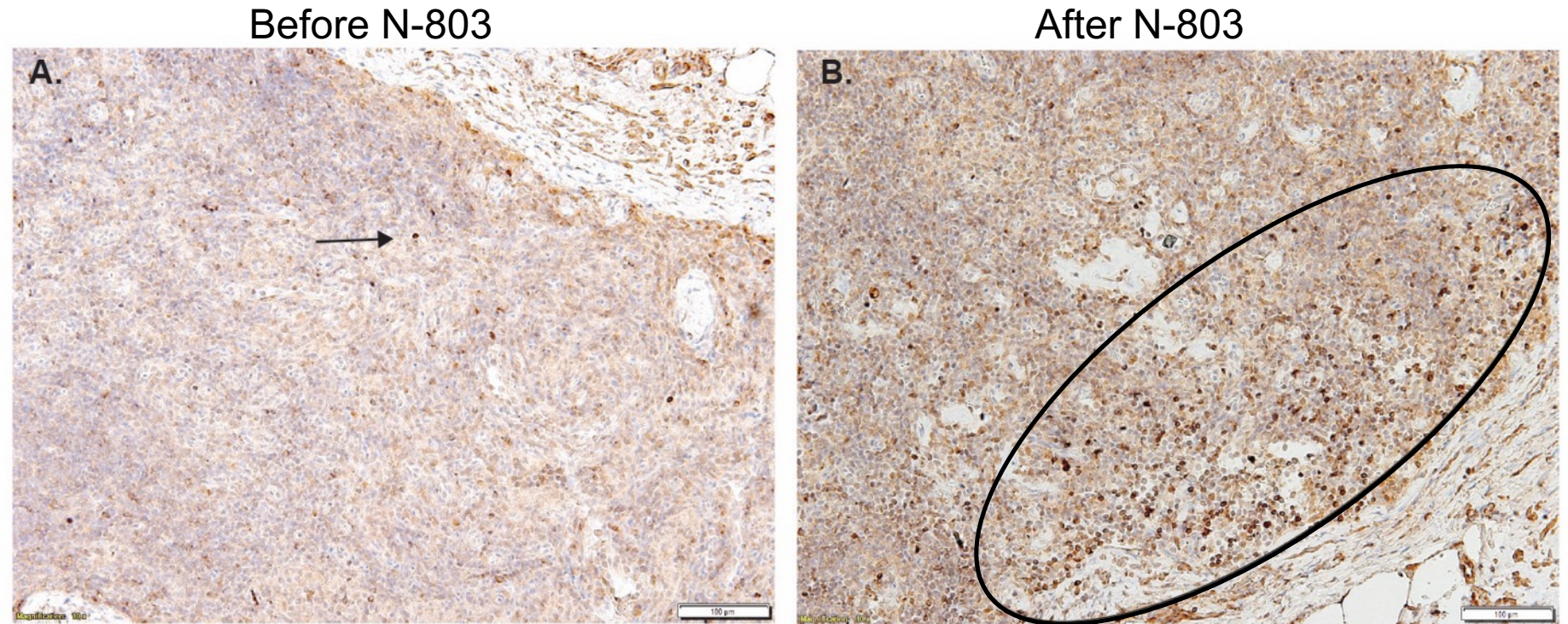
Phase I Study of Anktiva (N-803) in HIV Infected Patients to Clear Latent HIV Reservoirs

Zachary Davis¹, Jodi Anderson¹, Ann Thorkelson¹, Hing C. Wong², Jonathan Karn³, Curtis Dobrowlski³, Jeffrey S. Miller¹, Sarah Cooley¹, Daniel C Douek⁴, Timothy W Schacker¹

¹University of Minnesota, Minneapolis, MN, ²Altor BioScience, a Nantworks company, Miramar, FL, ³Case Western Reserve University, Cleveland, OH, ⁴Vaccine 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

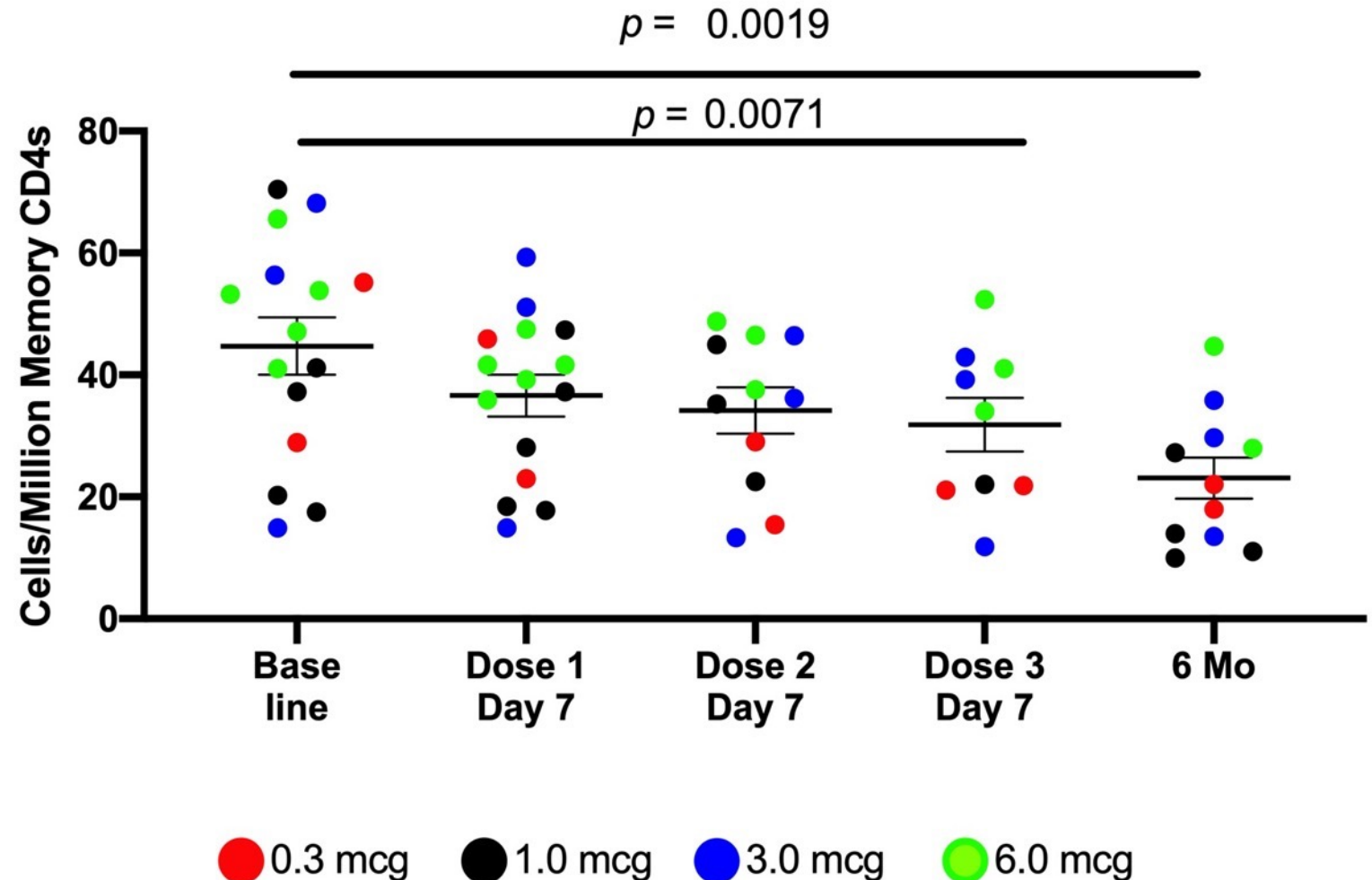


CD56 Staining of LN before (A) and 1 week after (B) the 3rd dose of N-803 in participant 2543 (3.0 mcg/kg SC).

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

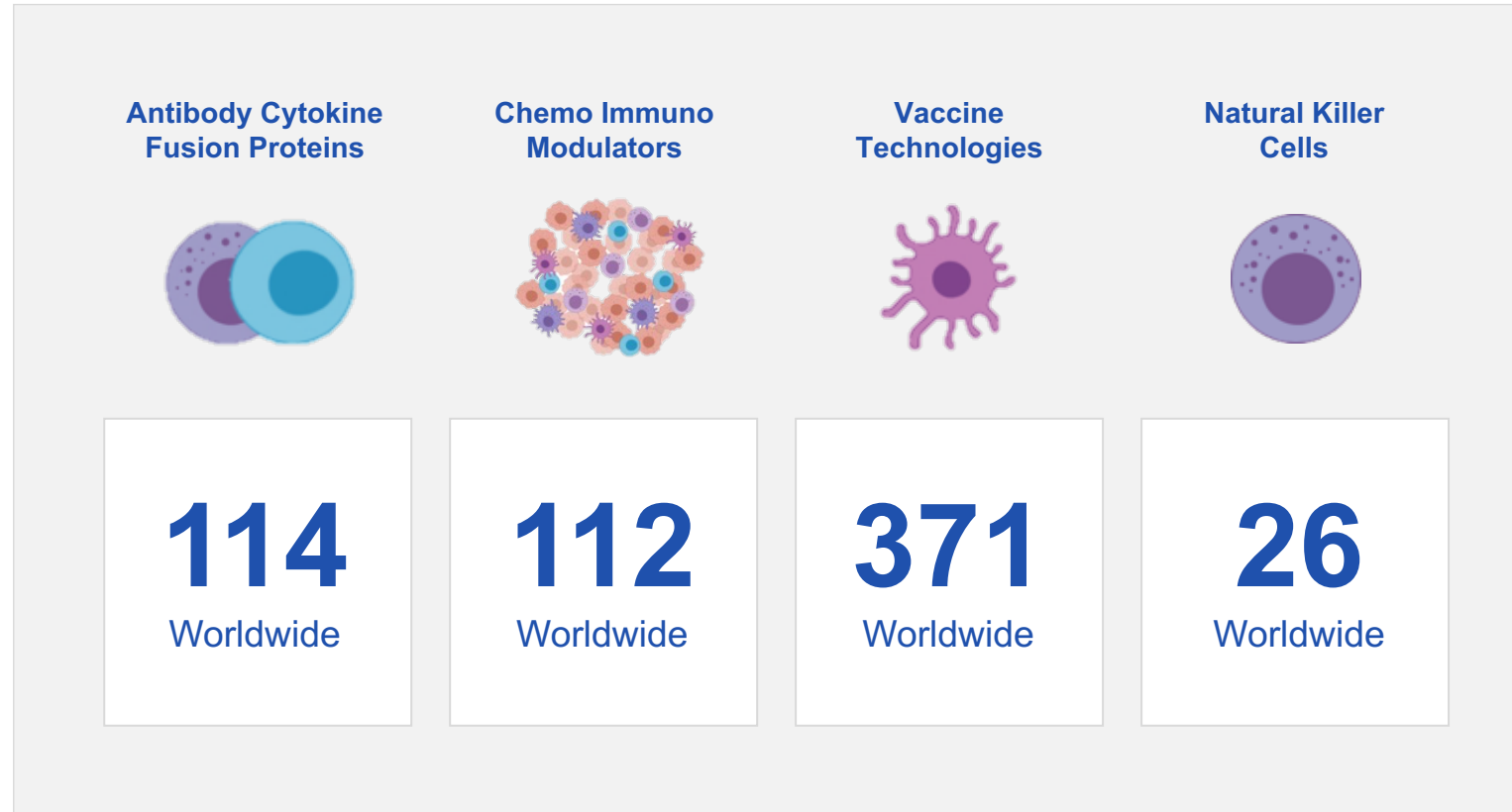
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Seminal Patents: By The Numbers



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

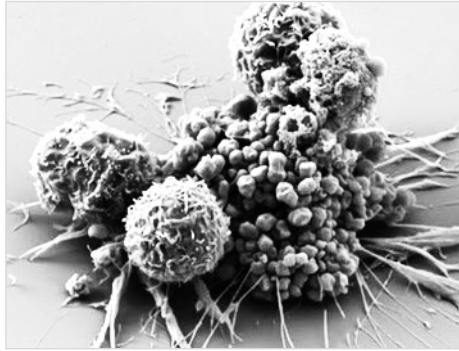
ImmunityBio: A Leading Immunotherapy Company



NASDAQ: IBRX

40

Phase I / II / III
Clinical Trials



1,800+

Patients Studied

25

Phase II / III
Clinical Trials

17

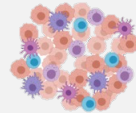
First in Human
Immunotherapy Molecules
and cells



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

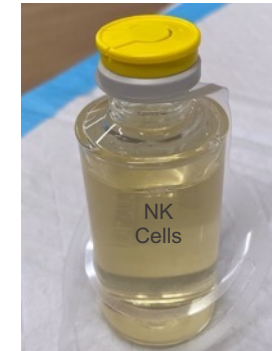
~400,000

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