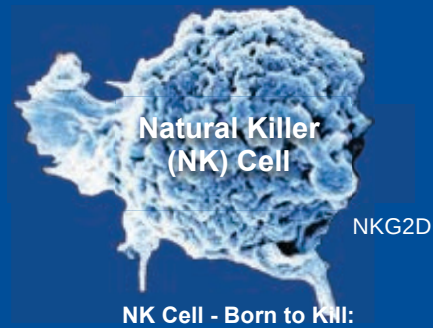
NantKwest

The Leading Late Stage Immunotherapy Companies Harnessing Immunogenic Cell Death

ImmunityBio

JP Morgan Healthcare Conference
January 14, 2020

Off-the-Shelf NK Cell



NK Cell - Born to Kill:
Nature's Killer Cell
Innate Immune System

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E2b Deleted Adenovirus

Dendritic Cell - The Trainer:
Nature's Trainer Cell
The Cross Talk Between
Innate & Adaptive Immune System

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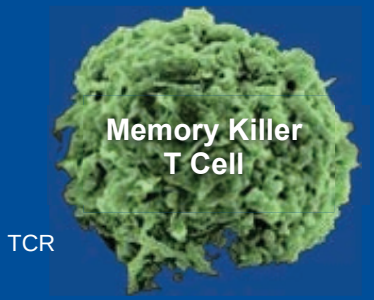
IL-15 Fusion Protein



T Cell - Trained to Kill:
Nature's Targeted Killer
Adaptive Immune System

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FORWARD-LOOKING STATEMENTS

These slides and the accompanying oral presentation contain forward-looking statements within the meaning of the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include, but are not limited to:

- our ability to pioneer immunotherapy, harness the power of the innate immune system, implement precision cancer medicine and change the current paradigm of cancer care;
- our expectations regarding the potential benefits of our strategy and technology;
- our ability to utilize multiple modes to induce cell death;
- our beliefs regarding the benefits and perceived limitations of competing approaches, and the future of competing technologies and our industry;
- our beliefs regarding the success, cost and timing of our product candidate development activities and clinical trials;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including any planned investigational new drug (IND) filings or pursuit of accelerated regulatory approval pathways or orphan drug status and breakthrough therapy designations;
- our ability to implement an integrated discovery ecosystem and the operation of that planned ecosystem;
- our expectations regarding our ability to utilize the Phase I aNK clinical trial data to support the development our other product candidates;
- our ability to produce an "off-the-shelf" therapy;
- our beliefs regarding the potential manufacturing and distribution benefits associated with our product candidates, and our ability to scale up the production of our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidate and not infringe upon the intellectual property of others;
- the ability and willingness of strategic collaborators, including certain of our affiliates, to share our vision and effectively work with us to achieve our goals;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities; and
- regulatory developments in the United States and foreign countries.

Factors that could cause our results to differ materially from those expressed in forward-looking statements include, without limitation:

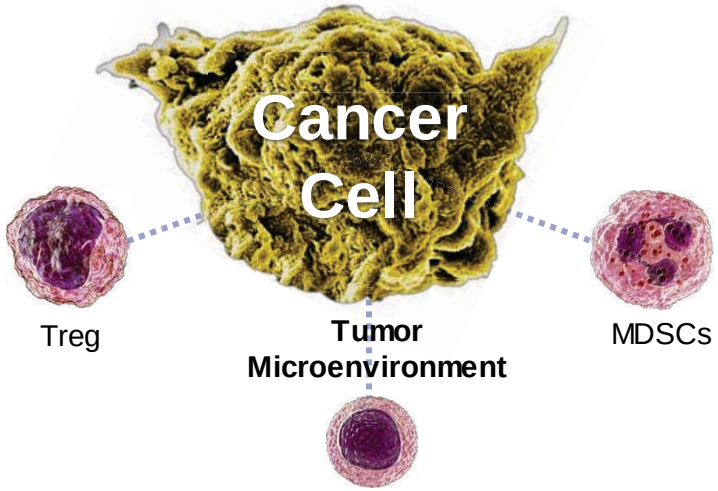
- the fact that our business is based upon the success of aNK cells as a technology platform and the success of N-803 and the other product candidates;
- our aNK platform and other product candidate families, including genetically modified taNK, haNK and t-haNK product candidates, will require significant additional clinical testing;
- even if we successfully develop and commercialize our aNK product candidates or N-803, we may not be successful in developing and commercializing our other product candidates either alone or in combination with other therapeutic agents;
- we may not be able to file INDs, to commence additional clinical trials on timelines we expect;
- we will need to obtain substantial additional financing to complete the development and any commercialization of our product candidates; and
- risks associated with our ability to enforce intellectual property rights.

Forward-looking statements include statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. These and other risks regarding our business are described in detail in NantKwest's Securities and Exchange Commission filings. We encourage you to review NantKwest's SEC filings in order to understand these risks. These forward-looking statements speak only as of the date thereof, and we disclaim any obligation to update these statements except as may be required by law. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this presentation.

Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. No representation or warranty, express or implied, is given as to the completeness or accuracy of the information or opinions contained in this document and we do not accept any liability for any direct, indirect or consequential loss or damage arising from reliance on such information or opinions. Past performance should not be taken as an indication or guarantee of future performance. You should read this presentation completely and with the understanding that our actual future results may be materially different from what we expect.

The Cross Talk of the Immune System in Cancer Inducing Immunogenic Cell Death



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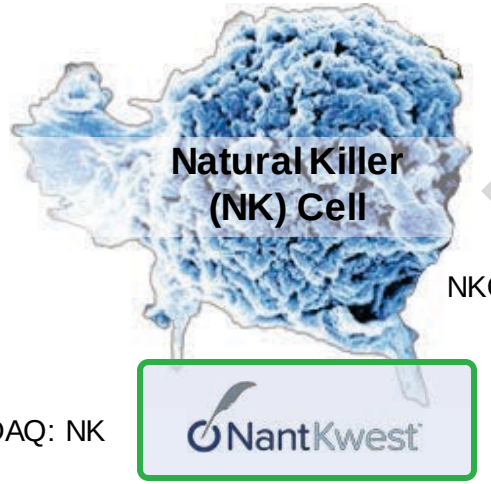

NASDAQ: NK

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Cross Talk

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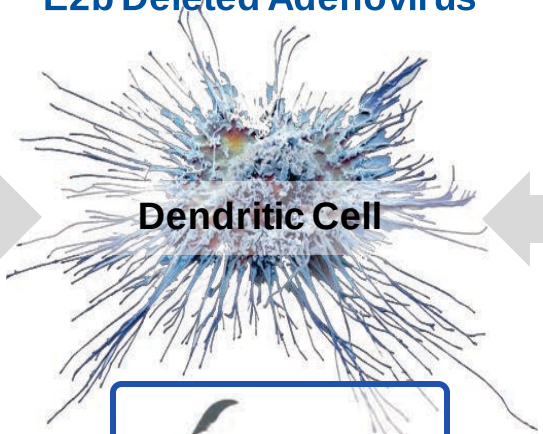

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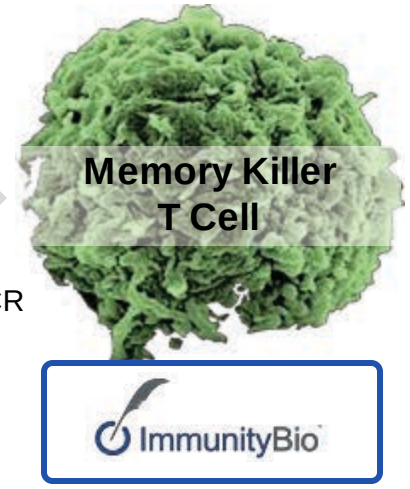

T Cell - Trained to Kill:
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ASCO 2019: Seminal Discovery by NANT of Neoepitope Silencing

Abstract #2591

Evidence for selective silencing of MHC-binding neoepitopes to avoid immune surveillance

Nant

UC San Diego Moores Cancer Center

CONTRIBUTING RESEARCHERS

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BACKGROUND

Overall response rates to immune checkpoint inhibition (ICI) are <50% even in Tumor Mutation Burden (TMB)-high patients (e.g. Checkmate-227), suggesting **other mechanisms of immune escape exist beyond expressing checkpoints**. At least **18% of somatic-specific exonic DNA variants are not expressed** into mRNA (Rabizadeh, 2018), yet the selection criteria for which variants to silence remains unclear. We sought to determine if **immunogenicity of variants factors into their suppression**

METHODS

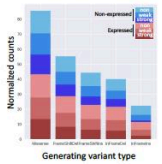
- 1418 clinical cases with paired tumor/normal whole-exome (~150x coverage) and whole-transcriptome (200x10^6 reads) were available from the NantHealth database
- TMB was calculated by counting somatic-specific non-synonymous exonic mutations. High-TMB was defined as >200 exonic mutations as in Rizvi et al 2015
- All possible 9-mer neoepitopes resulting from SNV or INDEL variants were generated and assessed for immunogenicity by NetMHC-4.0. For each variant, the neoepitope with the highest predicted affinity was analyzed further
- Neoepitopes were designated as non-expressed if fewer than 2 RNA reads supported the generating variant
- Immune-cell infiltration was estimated using RNA deconvolution on known immune cell marker genes (Bindea et al. 2013)

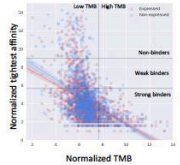
RESULTS

Figure 1. **Clinical cohort description.** Aggregated demographics statistics for 1395 clinical cases with predicted neoepitopes. Cancer types with fewer than 20 cases are grouped as "Other", Unannotated or unknown-primary cases are grouped as "Unreported".

	N	Avg. Age	% Female	Avg. TMB	Avg. #SB
Breast	259	56.1	99.2	126.5	5.3
Colon	137	58.1	55.5	263.6	9.9
Lung	109	63.0	53.2	257.9	11.2
Bone and Soft Tissue Cancers (Including Sarcoma)	107	47.2	45.8	125.6	5.4
Pancreatic	85	63.0	43.5	73.4	1.4
Ovarian	73	59.7	100.0	88.5	2.8
Brain	70	41.9	42.9	96.6	4.7
Prostate	34	63.5	0.0	98.5	5.7
Esophageal	33	64.9	27.3	164.1	6.8
Melanoma	32	63.5	31.3	596.5	28.4
Head and Neck	30	63.8	23.3	97.9	3.7
Gastric (Stomach)	30	58.3	36.7	134.5	2.6
Oral and Throat Cancers (Including Thyroid)	27	63.8	37.0	143.7	4.8
Rectal	27	56.7	29.6	248.3	14.1
Kidney	27	48.6	29.6	83.0	2.4
Liver	25	61.8	32.0	135.3	7.0
Bladder	22	71.3	45.5	255.0	14.9
Soft Tissue	20	32.9	30.0	101.6	3.4
Other (N<20)	129	58.8	57.4	347.5	13.3
Unreported	119	56.4	45.4	311.4	15.3

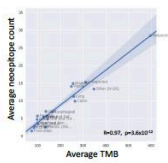
Figure 2. **Presence of strong neoepitopes is not exclusively driven by high TMB or variant type.** There is little difference in the proportion of predicted binders from disparate variant types or their expression rates (left). High-TMB patients almost all express at least one high-affinity neoepitope (middle, right), however so do the majority of low-TMB patients. Over 90% of patients have a non-expressed neoepitope predicted to be a strong binder.

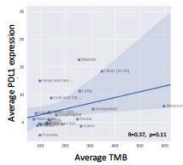




	Low TMB	High TMB
No binding neoepitopes expressed	62 (5.3%)	0 (0%)
≥1 weak binder expressed	1066 (91.9%)	235 (100%)
≥1 strong binder expressed	887 (76.5%)	231 (98.3%)
Total	1160 (83.2%)	235 (16.8%)

Figure 3. **TMB does not drive checkpoint expression.** TMB is highly correlated with neoantigen load when aggregating on a tissue level (left). However TMB and PDL1 expression appear to be independent, both when aggregated on the tissue level (middle) and when observing individual patients (right), as has been previously reported (Goodman, 2017)





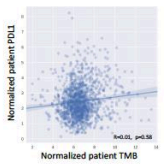
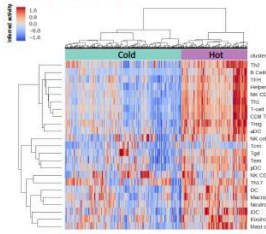


Figure 4. **Immune-deconvolution significantly differentiates expression of multiple checkpoints.** Inferred activity of immune cell types clusters tumors into two subgroups; Hot and Cold (left). These subgroups have highly significant differential expression of 7 key immunoregulatory genes (right).



gene	t	p	adj. p
FOXP3	31.6	8.37E-166	5.86E-165
CTLA4	29.2	6.06E-147	2.12E-146
PDL2	21.2	1.18E-86	2.75E-86
PDL1	20.2	7.72E-80	1.35E-79
LAG3	19.8	3.19E-77	4.47E-77
TIM3	18.3	2.31E-67	2.69E-67
IDO	12.0	1.31E-31	1.31E-31

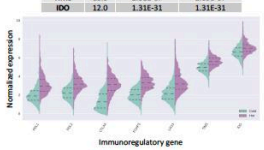
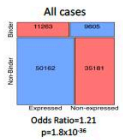


Figure 5. **Evidence for systematic silencing of strong neoepitopes.** Mosaic plots showing significant enrichment for silencing strong-binding neoepitopes across all patients (left), and especially in patients with active immunity but low checkpoint expression (right).



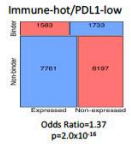


Figure 6. **Proposed immune-evasion mechanism.** Enrichment of silencing in immune-activated low-PDL1 patients suggests neoepitope modulation as an alternative to checkpoint expression to evade immune surveillance.

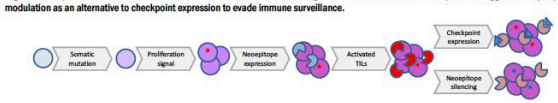
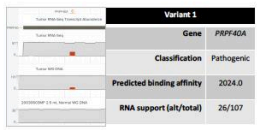
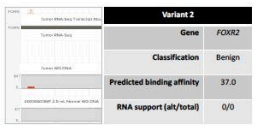


Figure 7. **Patient case study.** Renal medullary carcinoma with a very low TMB (0.9mts/Mb) yet is detected as immune-hot. Expression and binding characteristics are suggestive of selective neoepitope silencing.



Variant 1	
Gene	*PRPF40A*
Classification	Pathogenic
Predicted binding affinity	2024.0
RNA support (alt/total)	26/107



Variant 2	
Gene	*FOXR2*
Classification	Benign
Predicted binding affinity	37.0
RNA support (alt/total)	0/0

KEY FINDINGS

- A total of 147,015 potential neoepitopes were identified from 1,395/1,418 patients (98.4%).
- While high-TMB patients almost all expressed at least one high-affinity neoepitope, strong binders were not exclusively expressed in this group; 80% of all patients (1,116/1,395) expressed at least one high-affinity neoepitope.
- Across all cases a small but significant enrichment was observed for silencing neoepitopes that are predicted to bind strongly to MHC1 (OR = 1.21, p = 1.8x10^{-36})
- Silencing of potential neoepitopes was most prominent in 19% of patients with high inferred immune infiltration but low PDL1 expression (N = 261, OR = 1.37, p = 2.0x10^{-16})
- TMB and neoantigen load are highly similar biomarkers. TMB and PDL1 expression are independent.

CONCLUSIONS:

We observe **significant preferential silencing of MHC binding neoepitopes**. Specifically, **when tumor infiltrating immune cells are activated**, silencing neoepitopes may be an alternative to checkpoint expression for avoiding an immune cascade. Patients with TILs and silenced neoepitopes may benefit from epigenetic priming therapy prior to ICI therapy.

1. Borghaei, Hossein, et al. "Nivolumab (Nivo)+ platinum-doublet chemotherapy (Chemo) vs chemo as first-line (1L) treatment (Tx) for advanced non-small cell lung cancer (NSCLC) with< 1% tumor PD-L1 expression: Results from CheckMate 227." (2018): 9001-9001.
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ASCO ANNUAL MEETING, CHICAGO, IL, MAY31-JUN4 2019

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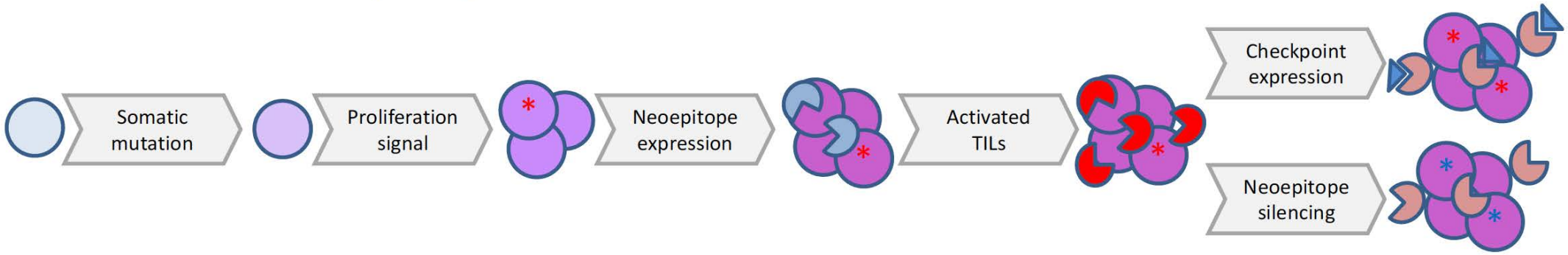

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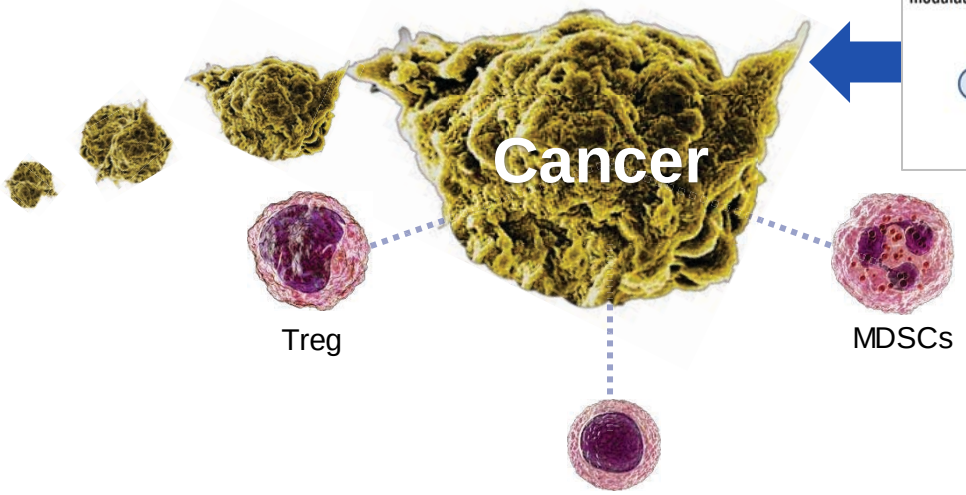
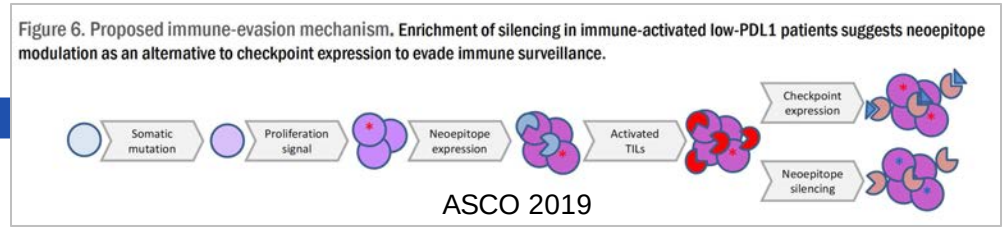
ASCO ANNUAL MEETING, CHICAGO, IL, MAY31-JUN4 2019

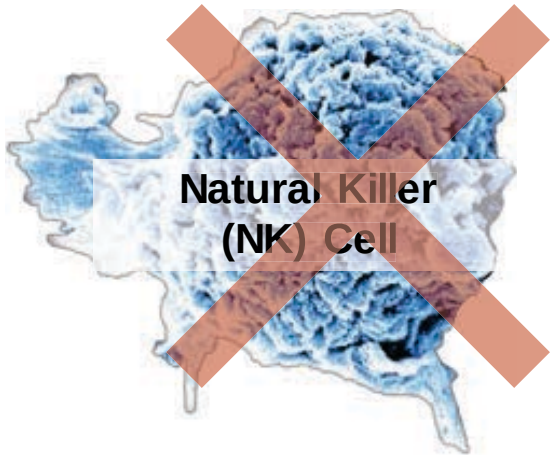
The NANT Discovery of the Tumors Ability to Evade & Silence the Immune System

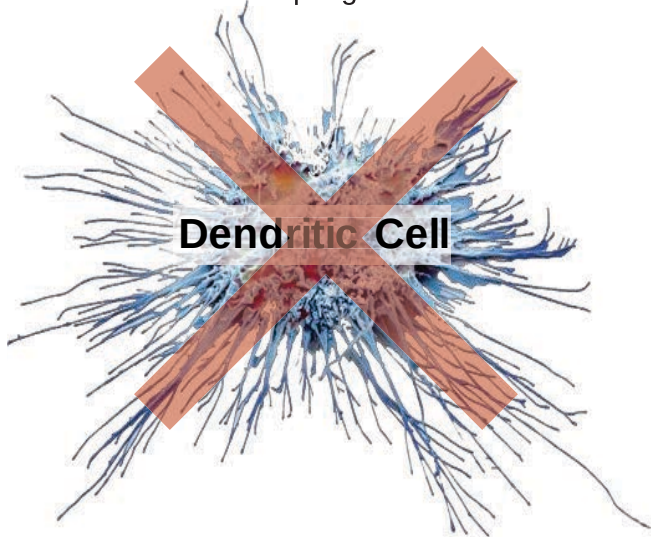
Tumor's Defense

Hide
Suppress
Disable
Metastasize

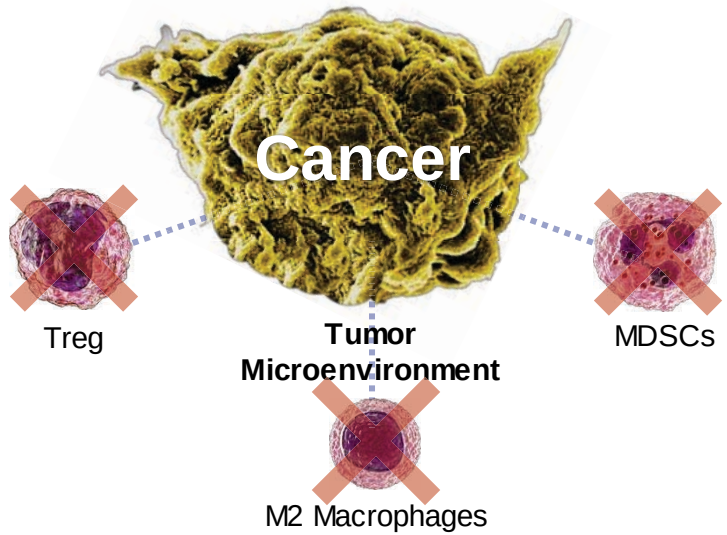








Next Generation Immunotherapy



The NANT Cancer Vaccine

The Path to Complete Remission:
Unleashing the Triangle Offense of Killer Cells

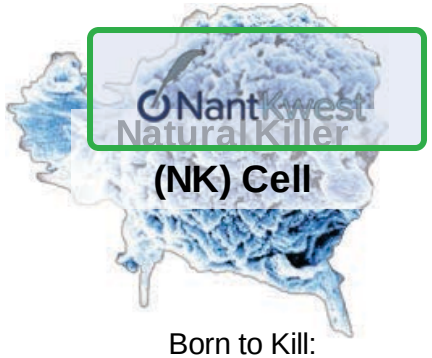
Immunomodulate the Tumor Itself as a Vaccine (DAMPs) and Transform the Microenvironment to Overcome Suppression (Metronomic Therapy)

Triangle Offense

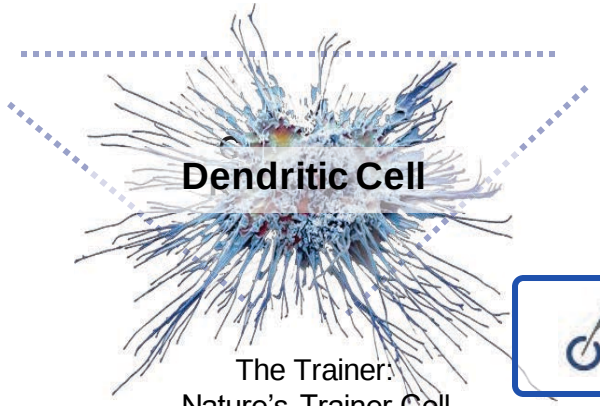
Expose
Unleash
Kill
Complete Remission

Triangle Offense: Simultaneous Activation of NK, Dendritic and T Cells

Temporal Spatial Orchestration of NK & T Cells Towards Immunogenic Cell Death

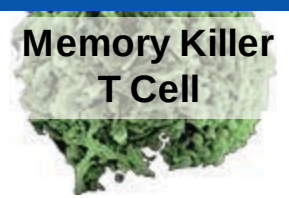


Born to Kill:
Nature's Killer Cell
Innate Immune System



ImmunityBio

The Trainer:
Nature's Trainer Cell
The Cross Talk Between
Innate & Adaptive Immune System

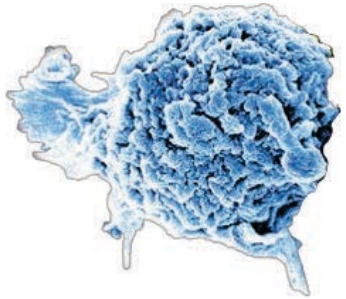


Trained to Kill:
Nature's Targeted Killer
Adaptive Immune System

1990 – 2017: Identified and Developed Key First-in-Class Agents Driving Immunogenic Cell Death

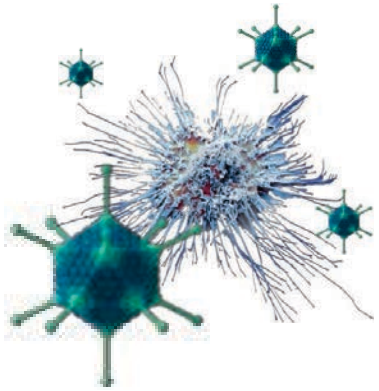
1990
Abraxane (Nab-Paclitaxel)
Transcytosis to the Tumor Microenvironment
Activation of M2 Macrophages

Bristol-Myers Squibb



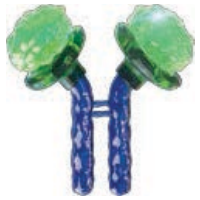
1992
NK-92: Off-The-Shelf NK
Activated NK Cell Line Without Inhibitory Receptors

NantKwest



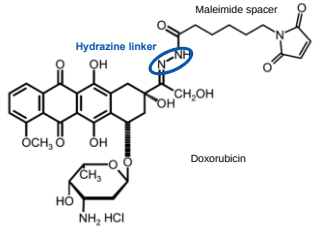
2015
E2b Deleted Adenovirus
Genomically Informed Dendritic Cell

ImmunityBio



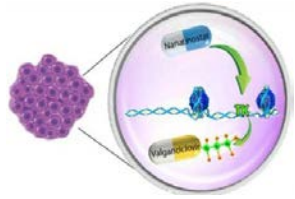
2015
N-803 IL-15 Fusion Protein
Activation of NK & Memory T Cells

ImmunityBio



2017
Aldoxorubicin
Transcytosis to the Tumor Microenvironment
DAMP Activator

ImmunityBio



2017
Nanatinostat
Epigenetic Activation of MHC1

NantKwest

1990 – 2017: Key First-in-Class Immunogenic Cell Death Agents

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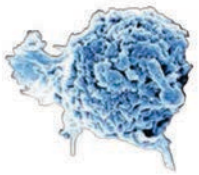

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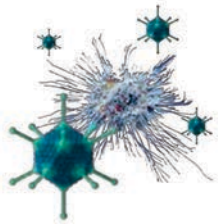

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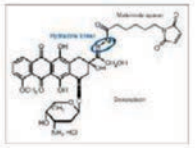

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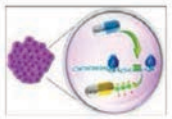

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Nanatinostat
Epigenetic Activation of MHC1

NantKwest

2016: Announce Cancer Breakthroughs 2020

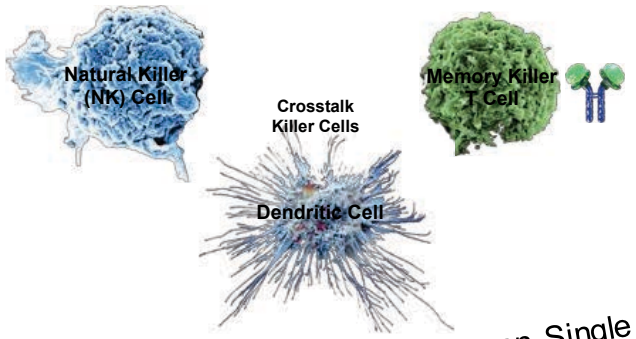
2017: Obtain FDA Authorization to Test Novel-Novel Immunological Combinations – QUILT

The NANT Cancer Vaccine: The Triangle Offense

2017 – 2019: Demonstrate Early Signals of Durable Complete Remission

2020 - 2023: Forecast for FDA Approvals in Multiple Tumor Types

Cancer Breakthroughs 2020:
Phase I / II Trials to Test the Hypothesis of the "Triangle Offense" in Multiple Tumor Types (2014 – 2019)

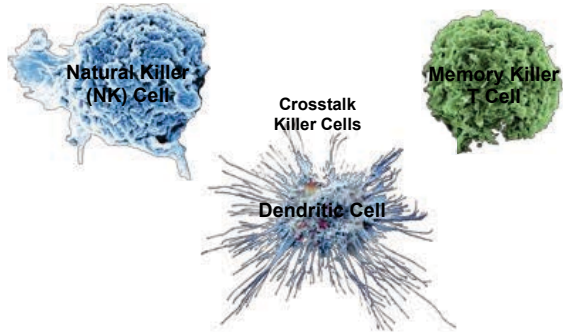


2014 to 2019: From First in Human Single Agent to Two (2) Combinations to Eleven (11) First in Human Combinations of Immunotherapy Agents

	Two (2) I/O Agents						3 I/O Agents		Five (5) I/O Agents		Six (6) I/O Agents	Ten (10) I/O Agents	Eleven (11) I/O Agents		
	N-803	N-803	N-803	N-803	N-803	N-803	haNK	PD-L1 t-haNK	Ad-CEA	Ad-CEA	Aldoxorubicin	Ad-HER2	Ad-HER2	Ad-HER2	Ad-HER2
	BCG	Rituxumab	aNK	BCG	Pembro/Nivo	Pembro	N-803	N-803	Ye-Ras	Ye-Ras	Ad-CEA	Ad-MUC1	Ad-MUC1	Ad-MUC1	Ad-MUC1
	1st Line NMIBC Bladder	2nd & 3rd Line iNHL	2nd & 3rd Line Merkel Cell Carcinoma	2nd Line NMIBC Bladder	3rd Line Checkpoint Relapse NSCLC	1st Line Metastatic NSCLC	Avelumab	Aldoxorubicin	aNK	haNK	Ye-Ras	Ad-Brachy	Ad-Brachy	Ad-Brachy	Ad-Brachy
							2nd & 3rd Line Merkel Cell Carcinoma	2nd Line Metastatic Pancreatic Cancer	N-803	N-803	aNK	Ye-Brachy	Ye-Brachy	Ye-Brachy	Ye-Brachy
									Avelumab	Avelumab	N-803	Ye-CEA	Ye-CEA	Ye-CEA	Ye-CEA
									2nd & 3rd Line Metastatic Pancreatic Cancer	2nd & 3rd Line Metastatic Pancreatic Cancer	Avelumab	Aldoxorubicin	Aldoxorubicin	Aldoxorubicin	Aldoxorubicin
											2nd & 3rd Line Metastatic Pancreatic Cancer	Ad-CEA	Ad-CEA	Ad-CEA	Ad-CEA
												3rd Line Metastatic TNBC	3rd Line Metastatic Head & Neck	3rd Line Metastatic Randomized Colorectal	2nd & 3rd Line Metastatic Pancreatic Cancer
	QUILT-2.005	QUILT-3.002	QUILT-3.009	QUILT-3.032	QUILT-3.055	QUILT-2.023	QUILT-3.063	spIND	QUILT-3.039	QUILT-3.060	QUILT-3.070	QUILT-3.067	QUILT-3.090	QUILT-3.071	QUILT-3.080
	Fast Track Phase 2*	Phase 1 / 2	Phase 2	Breakthrough Phase 2*	Pivotal Phase 2*	Pivotal Phase 2*	Pivotal Phase 2*	spIND	Phase Ib / II	Phase Ib / II	Phase Ib / II	Phase Ib / II	Phase Ib / II	Phase Ib / II	Phase Ib / II
	NCT02138734	NCT02384954	NCT02465957	NCT03022825	NCT03228667	NCT03520686	NCT03853317	spIND	NCT03136406	NCT03329248	NCT03387098	NCT03387085	NCT03387111	NCT03563157	NCT03586869
Initiation Date	May 2014	Mar 2015	Jun 2015	Jan 2017	Jul 2017	May 2018	Feb 2019	Sep 2019	May 2017	Nov 2017	Dec 2017	Dec 2017	Dec 2017	Jun 2018	Jul 2018

Cancer Breakthroughs 2020:
Evidence of Early Signals of Durable Complete Remission in Multiple Tumor Types

59 out of 105 (56%) Complete Responses in 7 Tumor Types
69 out of 161 (41%) Overall Response Rate in 8 Tumor Types



Two (2) I/O Agents					
N-803	N-803	N-803	N-803	N-803	N-803
BCG	Rituxumab	aNK	BCG	Pembro/Nivo	Pembro
1st Line NMIBC Bladder	2nd & 3rd Line iNHL	2nd & 3rd Line Merkel Cell Carcinoma	2nd Line NMIBC Bladder	3rd Line Checkpoint Relapse NSCLC	1st Line Metastatic NSCLC
Complete Response	Complete Response	Complete Response	Complete Response	Durable Response	Durable Response

3 I/O Agents	
haNK	PD-L1 t-haNK
N-803	N-803
Avelumab	Aldoxorubicin
2nd & 3rd Line Merkel Cell Carcinoma	2nd Line Metastatic Pancreatic Cancer
	Complete Response

Five (5) I/O Agents	
Ad-CEA	Ad-CEA
Ye-Ras	Ye-Ras
aNK	haNK
N-803	N-803
Avelumab	Avelumab
2nd & 3rd Line Metastatic Pancreatic Cancer	2nd & 3rd Line Metastatic Pancreatic Cancer

Six (6) I/O Agents
Aldoxorubicin
Ad-CEA
Ye-Ras
aNK
N-803
Avelumab
2nd & 3rd Line Metastatic Pancreatic Cancer

Ten (10) I/O Agents
Ad-MUC1
Ad-Brachy
Ye-Brachy
Ye-CEA
Aldoxorubicin
Ad-CEA
Ye-Ras
haNK
N-803
Avelumab
3rd Line Metastatic TNBC
Complete Response

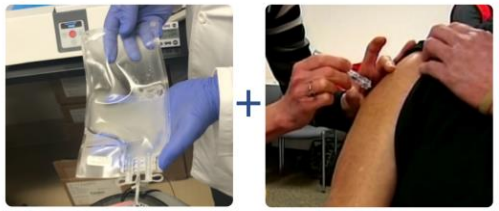
Eleven (11) I/O Agents		
Ad-HER2	Ad-HER2	Ad-HER2
Ad-MUC1	Ad-MUC1	Ad-MUC1
Ad-Brachy	Ad-Brachy	Ad-Brachy
Ye-Brachy	Ye-Brachy	Ye-Brachy
Ye-CEA	Ye-CEA	Ye-CEA
Aldoxorubicin	Aldoxorubicin	Aldoxorubicin
Ad-CEA	Ad-CEA	Ad-CEA
Ye-Ras	Ye-Ras	Ye-Ras
haNK	haNK	haNK
N-803	N-803	N-803
Avelumab	Avelumab	Avelumab
3rd Line Metastatic Head & Neck	3rd Line Metastatic Randomized Colorectal	2nd & 3rd Line Metastatic Pancreatic Cancer
Complete Response	Complete Response	Durable Response

Cancer Breakthroughs 2020:
Evidence of Early Signals of Durable Complete Remission in Multiple Tumor Types

ImmunityBio

NK & T Cell Activator

N-803



NantKwest

Off-the-Shelf Natural Killer Cell Line

haNK
PD-L1 t-haNK

Complete & Durable Responses in Advanced Metastatic Disease Across Multiple Tumor Types

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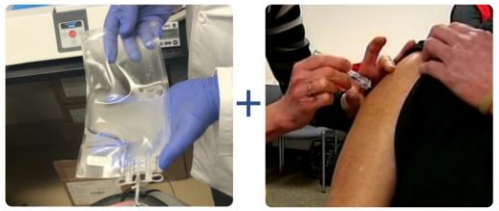

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Bladder Cancer – Complete Response in 9 of 9 Patients

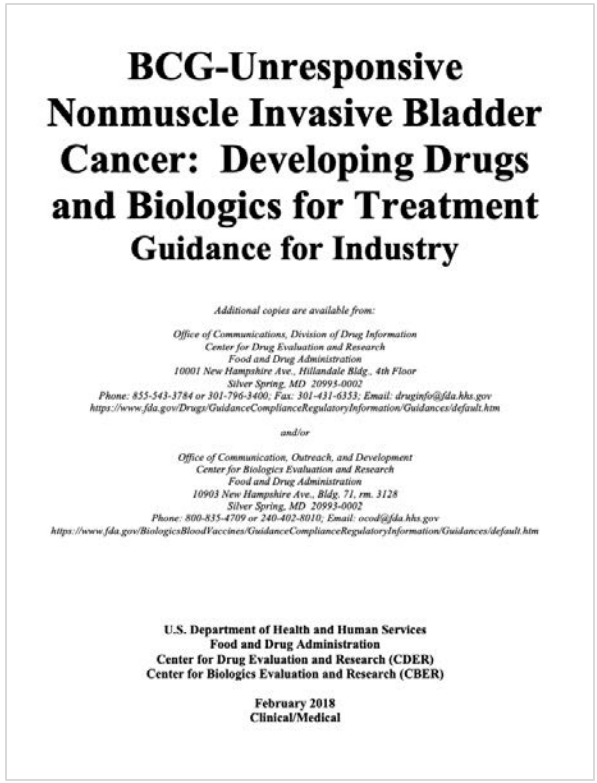
Phase I
NCT02138734
QUILT 2.005

Phase I (N=9)
A Study of Intravesical BCG in Combination With N-803 in Patients With Non-Muscle Invasive Bladder Cancer

N-803 + BCG in High-Risk NMIBC – Phase I Results

Durable Complete Responses (CR) or No Recurrence (NR) in 9 out of 9 Patients

Dose (intravesicular instillation)	Patient	Stage	Response Assessments							
			W12	6M	9M	12M	15M	18M	21M	24M
100 µg	1	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
	2	Pap Ta	CR*	CR	CR	CR	CR	CR	CR	CR
	3	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
200 µg	4	Pap T1	IC	CR*	CR	CR	CR	CR	CR	CR
	5	CIS	IC	IC	IC	CR	CR	CR	CR	CR
	6	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
400 µg	7	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
	8	CIS	CR*	CR	CR	CR	CR	CR	CR	CR**
	9	Pap Ta	CR*	CR	CR	CR	CR	CR	CR	CR



BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment
Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353; Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

and/or

Office of Communication, Outreach, and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, rm. 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010; Email: ocod@fda.hhs.gov
https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2018
Clinical/Medical

9 of 9 (100%) Patients Disease-Free at 24 Months

BCG naïve alone (SoC): Historical response rate is 55-75% at 3-6 months post BCG alone

Based on this data, FDA granted Fast Track Designation to the Pivotal Trial

*CR termed as No Recurrence (NR) in Papillary Disease **Negative Cystoscopy Inconclusive Cytology

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Evidence of Early Signals of Durable Complete Remission in Multiple Tumor Types

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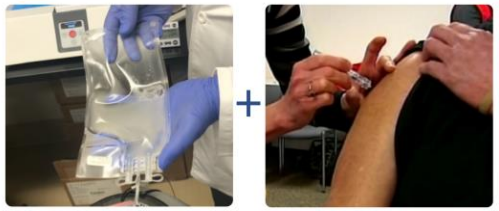
NK & T Cell Activator

N-803



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Breakthrough Designation

Registrational Trial in BCG Unresponsive CIS NMIBC

2nd Line N-803 + BCG

Indication and Tumor Type	Design	Patients Enrolled	CR Rate	Cystectomy Avoidance	Safety & Tolerability
2nd Line BCG Unresponsive CIS	Single Arm: BCG + N-803 N = 80	**55 / 80** to Date	**73%** Complete Response	**89%** Cystectomy Free	**1%** with treatment related SAEs

ImmunityBio Granted FDA Breakthrough Therapy Designation for N-803 IL-15 Superagonist in Non-Muscle Invasive Bladder Cancer

Results of Phase 1 and 2 studies in BCG Unresponsive Non-Muscle Invasive Bladder Cancer in High Risk Carcinoma in Situ Disease Earn FDA Breakthrough Status for ImmunityBio's IL-15 Superagonist Complex

December 04, 2019 08:30 AM Eastern Standard Time

CULVER CITY, Calif.--(BUSINESS WIRE)--ImmunityBio, a privately held immunotherapy company, has received Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration (FDA) for its interleukin-15 (IL-15) agonist complex, N-803, in combination with Bacillus Calmette-Guerin (BCG), for the treatment of patients with BCG-unresponsive non-muscle invasive bladder carcinoma in situ (CIS).

Breakthrough Designation

Registrational Trial in BCG Unresponsive CIS NMIBC

2nd Line N-803 + BCG Compared to Pembro December Approval

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Dec 2019

Local Therapy – 1% Adverse Events

Drug	Patients	CR any time	CR 3 months	CR 6 months	CR 9 months	CR 12 months
N-803 + BCG	**55**	**73%** CI (57%, 85%)	**Ongoing Study**			

Pembrolizumab Granted Priority Review for Treatment of Patients With NMIBC Jan 2020

The FDA has granted priority review to a new supplemental Biologics License Application (sBLA) for pembrolizumab (Keytruda), for which Merck is seeking approval for the treatment of patients with Bacillus Calmette-Guerin (BCG)-

Systemic Therapy - >10% Adverse Events

Pembro *Systemic Therapy*	96	NA	**41%** CI (25%, 51%)	NA	NA	20% CI (16%, 33%)

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Evidence of Early Signals of Durable Complete Remission in Multiple Tumor Types

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NK & T Cell Activator

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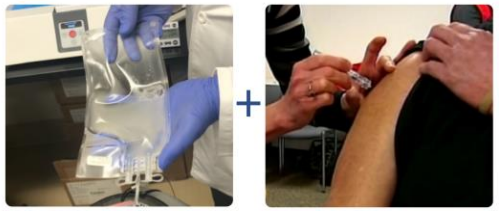

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Metastatic Non-Small Cell Lung Cancer (NSCLC)
N-803 in Combination with Nivolumab in 3rd Line or Greater Patients
Relapsed and Refractory to Nivo or Chemo

Efficacy Endpoint	All Patients Enrolled (n=56)	PD-L1 ≥ 50% (n=16)
Median Progression Free Survival	3.5 Months (2.7, 5.1)	4.5 Months (1.4, 8.5)
Median Overall Survival	13.4 Months (9.6, 19.5)	17.1 Months (4.6, **Ongoing**)
Overall Response Rate	18%	**38%**
Stable Disease	45%	38%
Disease Control Rate	63%	75%

Jan 12, 2020: Presented, Plenary Session: Sixth AACR-IASLC International Joint Conference: Lung Cancer Translational Science from the Bench to the Clinic

N-803 When Combined with Nivo Appears to Reduce AE's Associated with Checkpoint Inhibitors

Comparison of Immune Related AEs in 2nd Line Treatment of NSCLC

Agent	Trial	Immune Related AEs Grade 3 or higher
Nivo + N-803	**NCT02523469**	**7%**
Nivo Alone	Checkmate 57	~14%
Pembro Alone	Keynote 10	~15%

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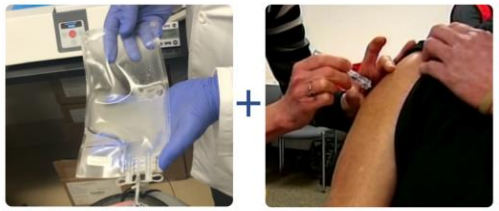

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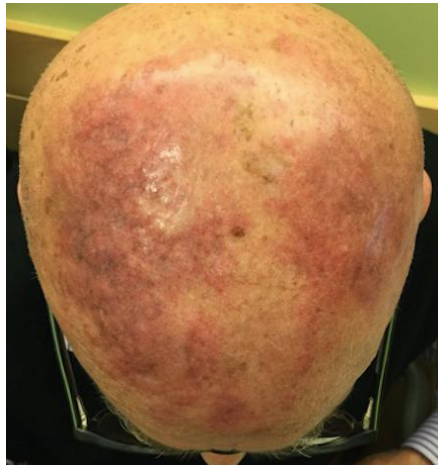
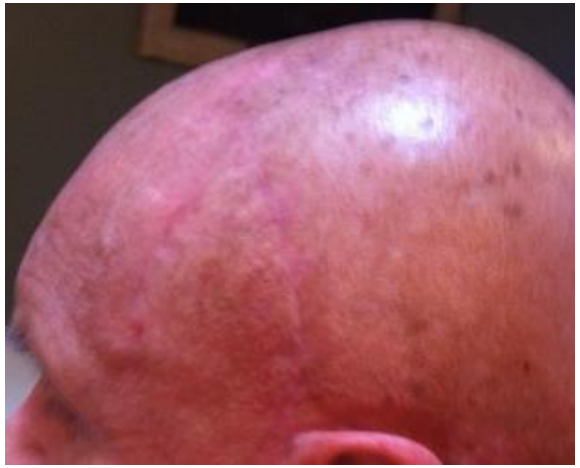
4th Line Head & Neck Cancer	1 / 4 CR	7 Months	Metronomic Low Dose
3rd Line Triple Negative Breast Cancer	2 / 9 CR	9 – 12 Months & Ongoing	Metronomic Low Dose
2nd Line Metastatic Pancreatic Cancer	1 / 9 CR	2 Months & Ongoing	Metronomic Low Dose

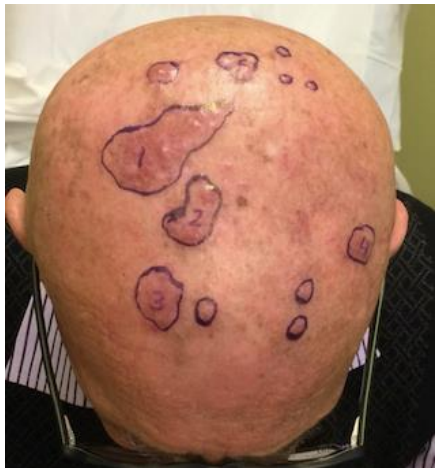
Phase I/II: Complete Response in **Merkel Cell Carcinoma** Who Failed Checkpoints & Previous Chemotherapy



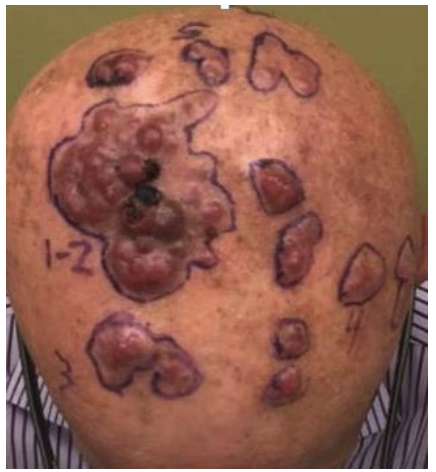
10/2014
First consultation at UW, Seattle



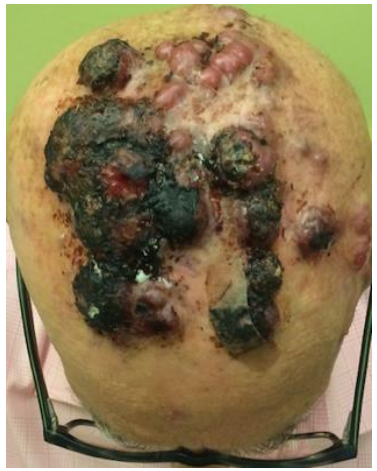
12/2014
After RT plus IFN plus Imiquimod



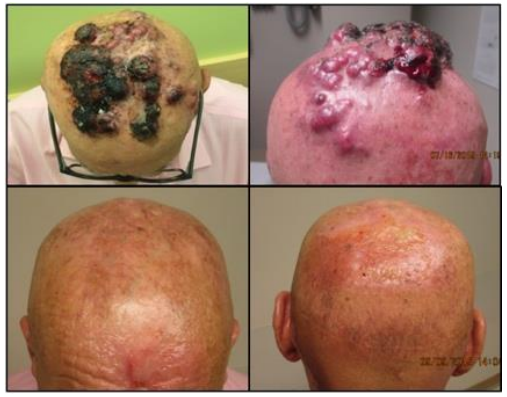
01/2015
Recurrent MCC nodules on scalp in RT fields. Started anti-PD-1 (pembrolizumab) for unresectable MCC



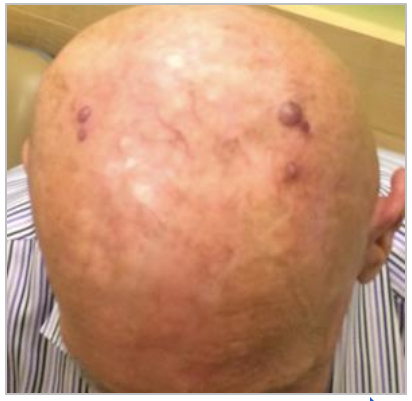
04/2015
anti-PD-1 after 12 weeks of pembrolizumab
Pembrolizumab discontinued due to progressive disease



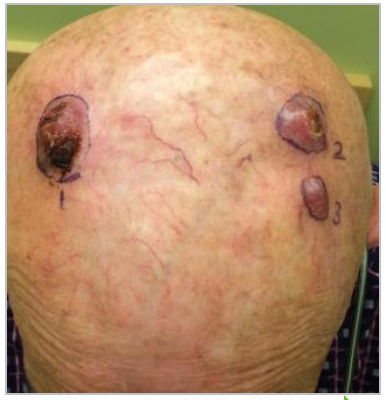
06/2015
Enrolled on a clinical trial of intralesional TLR-4 agonist plus RT



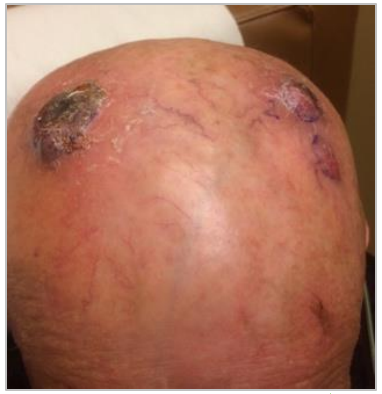
07/2015
Received neutron RT to scalp and B/L neck tumors.



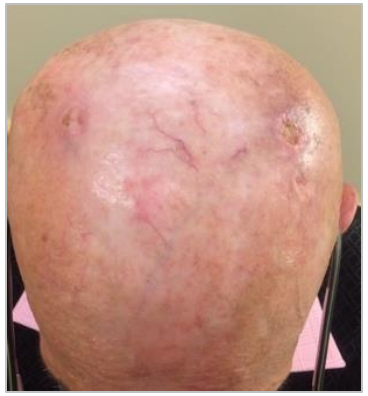
12/2015
Recurrent MCC tumors on scalp.



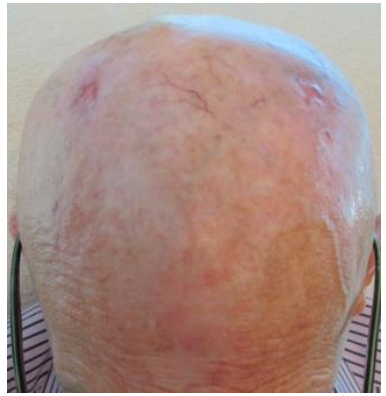
03/14/2016
Enrolled on aNK trial
Baseline Day 01
First Infusion on 03/15/2016



03/30/2016
Day 14



06/21/2016
Day 99
No New Lesions
Since 03/14/2016



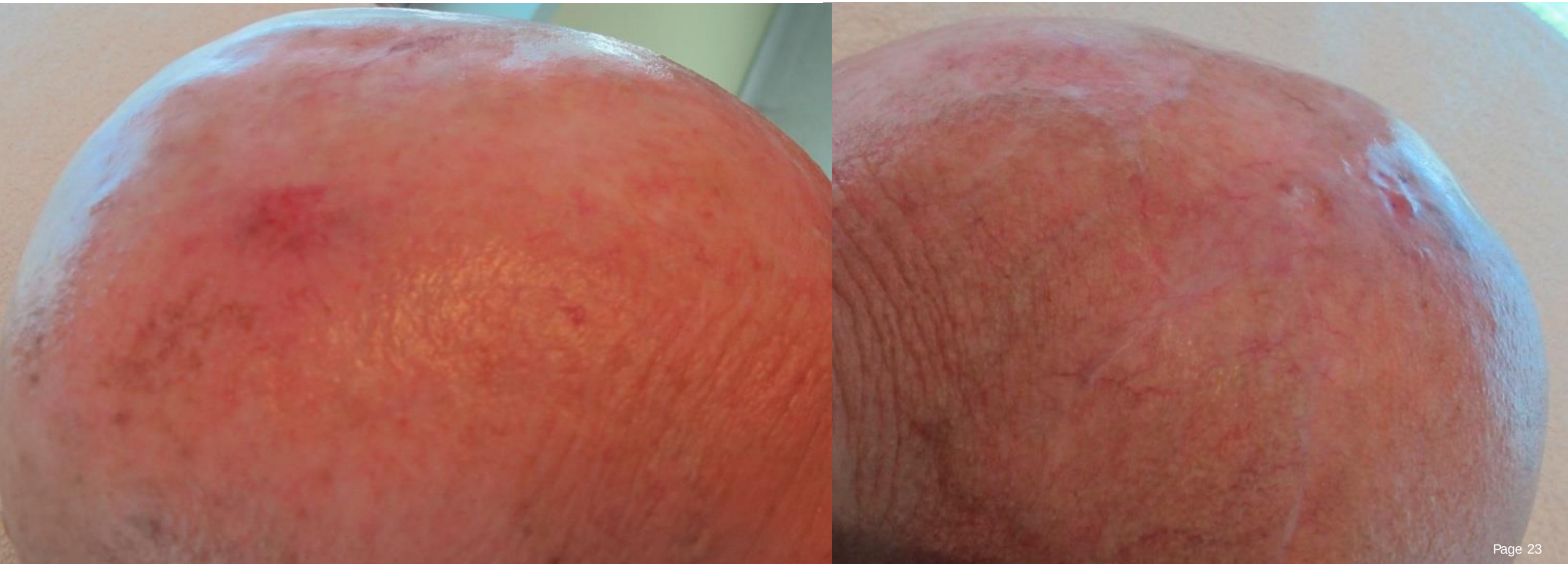
09/01/2016
Day 171
No New Lesions
Since 03/14/2016

Durable Complete Response in Merkel Cell Carcinoma

aNK alone followed by Checkpoint

Treatment Initiation – August 2016
No Treatment Since July 2019
Durable Complete Response 42 Months and Ongoing

Patient alive and disease free to date
(1,258 Days: 3.5 Years – As of Jan 11, 2020)

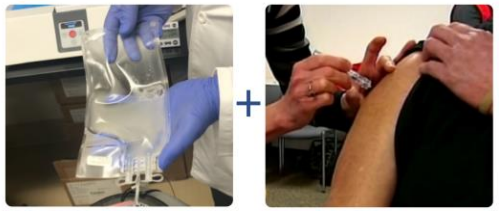


Cancer Breakthroughs 2020:
Evidence of Early Signals of Durable Complete Remission in Multiple Tumor Types

ImmunityBio

NK & T Cell Activator

N-803



NantKwest

Off-the-Shelf Natural Killer Cell Line

haNK
PD-L1 t-haNK

Complete & Durable Responses in Advanced Metastatic Disease Across Multiple Tumor Types

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BCG Unresponsive CIS Bladder Cancer (Phase II)	34 / 46 CR	3 – 29 Months & Ongoing	✓
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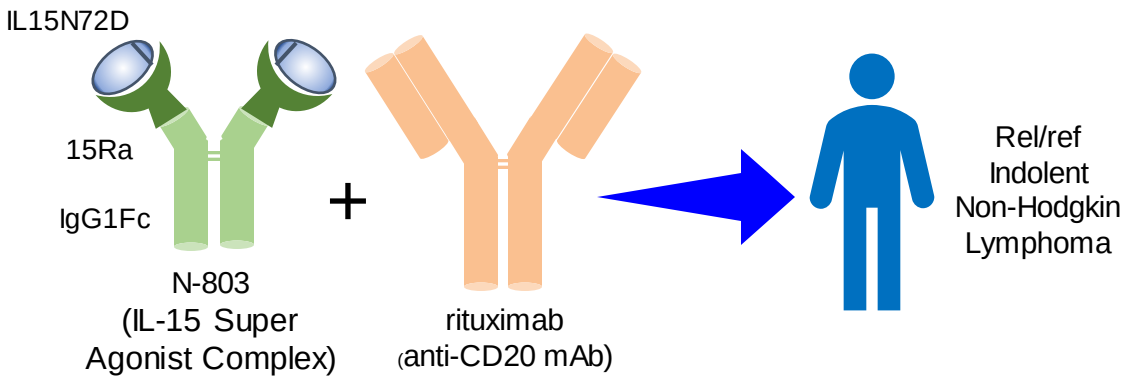
Relapsed Indolent Non-Hodgkin's Lymphoma Phase 1/2 Clinical Trial of N-803 Plus Rituximab



78% CR Rate

Best Response	SubQ (N=9)
CR	**7 (78%)**
PR	0 (0%)
ORR	7 (78%)
SD	2 (22%)
PD	0 (0%)

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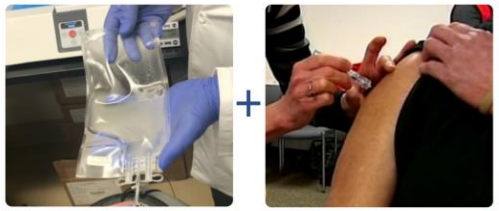

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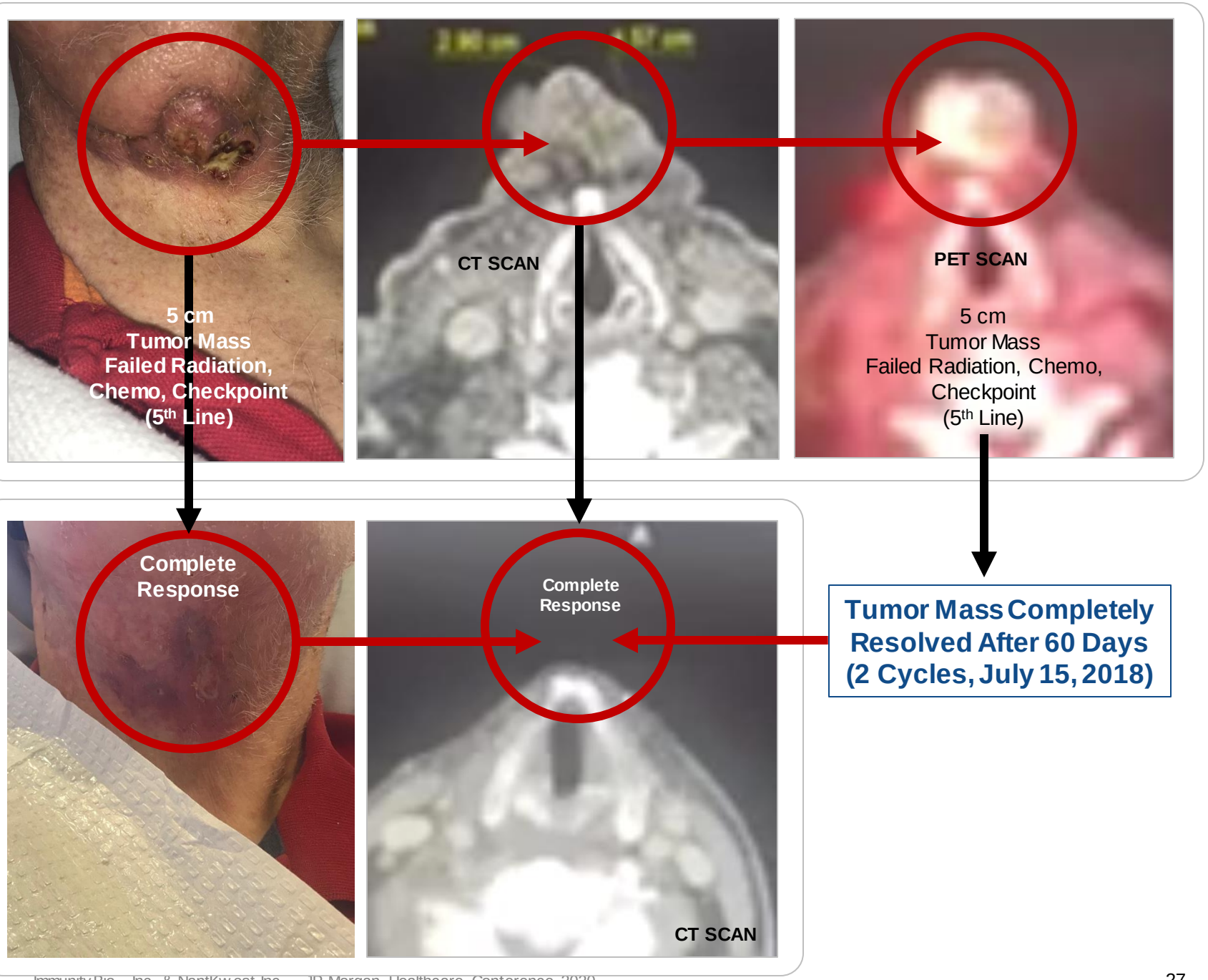
5th Line Relapsed Head and Neck Cancer

Patient: 3090–001-002
Pre-Treatment
5th Line



Complete Response in 5th Line Metastatic Head & Neck Cancer After 2 Cycles

Complete Remission Post Cancer Memory Vaccine Treatment
After 2-Cycles

Unpublished Data

Cancer Breakthroughs 2020:
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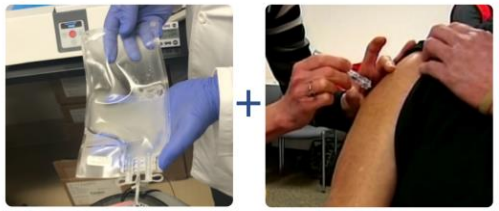

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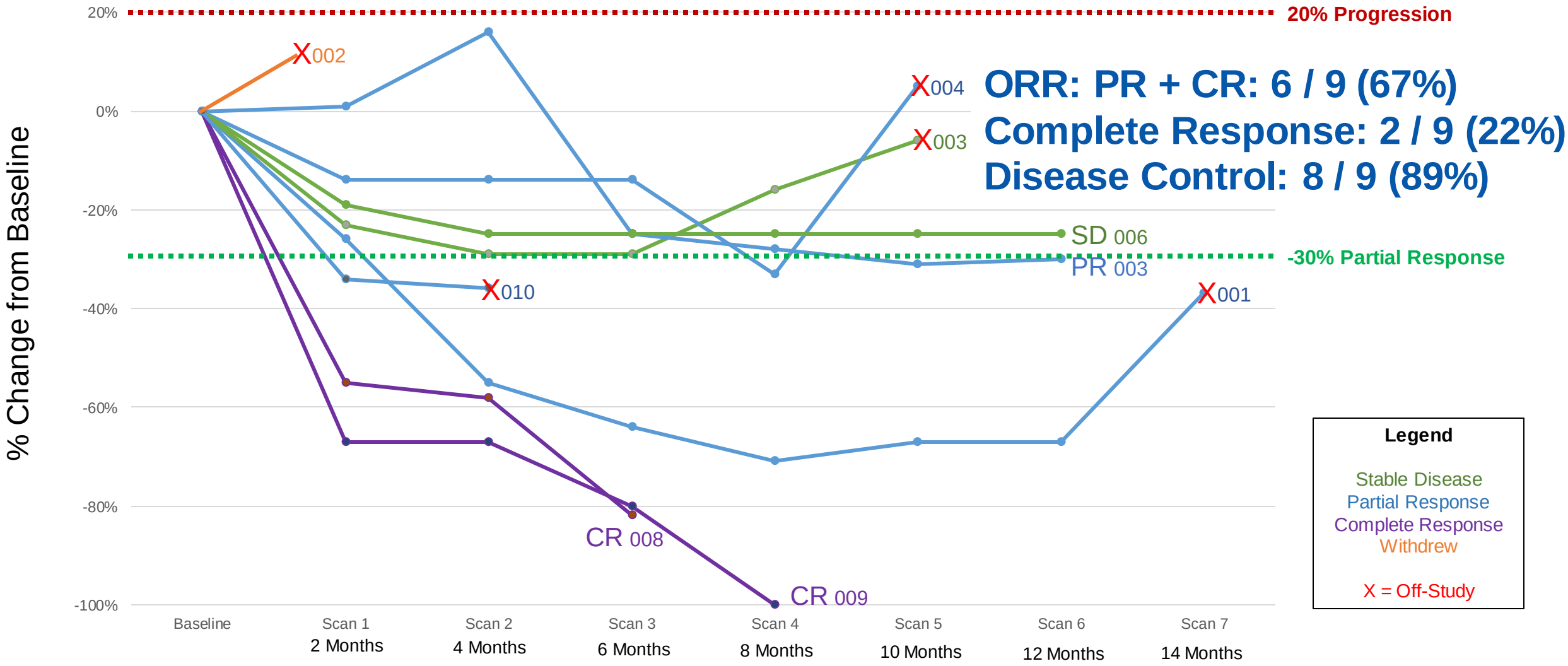
2nd Line Metastatic Pancreatic Cancer	1 / 9 CR	2 Months & Ongoing	Metronomic Low Dose

3rd Line Triple Negative Breast Cancer

Best Response by Resist 1.1



Encouraging Efficacy Signals with Combination Therapy

KEYNOTE-086

ESMO
Annals of Oncology 30: 397–404, 2019
doi:10.1093/annonc/mdy517
Published online 26 November 2018

ORIGINAL ARTICLE

Pembrolizumab monotherapy for previously treated metastatic triple-negative breast cancer: cohort A of the phase II KEYNOTE-086 study

S. Adams[1*], P. Schmid[2], H. S. Rugo[3], E. P. Winer[4], D. Loirat[5], A. Awada[6], D. W. Cescon[7], H. Iwata[8], M. Campone[9], R. Nanda[10], R. Hui[11], G. Curigliano[12,13], D. Toppmeyer[14], J. O'Shaughnessy[15,16,17], S. Loi[18], S. Paluch-Shimon[19], A. R. Tan[20], D. Card[21], J. Zhao[21], V. Karantza[21] & J. Cortés[22,23,24]

[1]Department of Medicine, Perlmutter Cancer Center, New York University School of Medicine, New York, USA; [2]Centre for Experimental Cancer Medicine, Barts Cancer Institute, Queen Mary University London, London, UK; [3]Department of Medicine, University of California San Francisco Helen Diller Family Comprehensive Cancer Center, San Francisco; [4]Medical Oncology, Dana-Farber Cancer Institute, Boston, USA; [5]Institut Curie, Paris, France; [6]Oncology Medicine Department, Institut Jules Bordet, Universite Libre de Bruxelles, Brussels, Belgium; [7]Princess Margaret Cancer Centre, University of Toronto, Toronto, Canada; [8]Aichi Cancer Center Hospital, Nagoya, Japan; [9]Institut de Cancerologie de l'Ouest, Nantes, France; [10]Department of Medicine, Section of Hematology/Oncology, The University of Chicago, Chicago, USA; [11]Westmead Hospital and the University of Sydney, Sydney, Australia; [12]Department of Oncology and Hematology, University of Milano, Milan; [13]IEO, European Institute of Oncology IRCCS, Milano, Milan, Italy; [14]Medical Oncology, Rutgers Cancer Institute of New Jersey, New Brunswick, USA; [15]Baylor University Medical Center, Dallas; [16]Texas Oncology, Dallas; [17]US Oncology, Dallas, USA; [18]Division of Research and Cancer Medicine, Peter MacCallum Cancer Centre, Melbourne, Australia; [19]Breast Cancer Service for Young Women, Sheba Medical Center, Tel Hashomer, Ramat Gan, Israel; [20]Levine Cancer Institute, Atrium Health, Charlotte; [21]Merck & Co., Inc., Kenilworth, USA; [22]Breast Cancer Program, Vall d'Hebron Institute of Oncology, Barcelona; [23]Ramon y Cajal University Hospital, Madrid; [24]IOB Institute of Oncology, Quiron Group, Barcelona, Spain

*Correspondence to: Dr Sylvia Adams, Department of Medicine, Perlmutter Cancer Center, New York University School of Medicine, 160 East 34th Street, 4th Floor, New York, NY 10016, USA. Tel: +1-212-731-5795; Fax: +1-212-731-5342; E-mail: Sylvia.Adams@nyumc.org

Note: This study was previously presented at American Society of Clinical Oncology 2017 Annual Meeting, June 2–6, 2017, Chicago, IL, USA; abstract 1008.

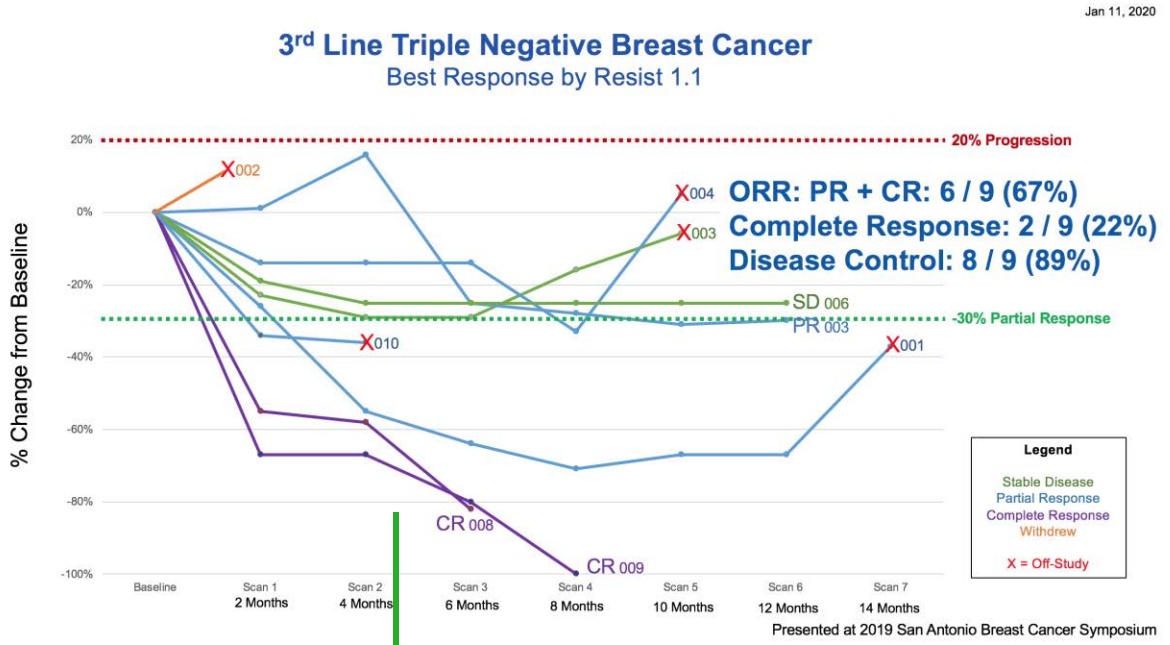
Table 2. Antitumor activity assessed by RECIST v1.1 per independent central review in the total, PD-L1–positive, and PD-L1–negative efficacy populations

Antitumor activity	Total population *N* = 170	PD-L1–positive population *N* = 105	PD-L1–negative population *N* = 64
ORR, *n* (%) [95% CI]	9 (5.3) [2.7–9.9]	6 (5.7) [2.4–12.2]	3 (4.7) [1.1, 13.4]
DCR[a], *n* (%) [95% CI]	13 (7.6) [4.4–12.7]	10 (9.5) [5.1–16.8]	3 (4.7) [1.1–13.4]
Best overall response, *n* (%)			
Complete response	2 (1.2)	2 (1.9)	0 (0.0)
Partial response	7 (4.1)	4 (3.8)	3 (4.7)
Stable disease	34 (20.0)	21 (20.0)	12 (18.8)
Progressive disease	103 (60.6)	66 (62.9)	37 (57.8)

9 out of 170 patients responded (5.3% ORR)
2 out of 170 patients had complete response (1.2% CR)
13 out of 170 patients had disease control (7.6% DCR)

QUILT-3.067

NANT Triple Negative Breast Cancer (TNBC) Vaccine: Molecularly Informed Integrated Immunotherapy in Subjects With TNBC Who Have Progressed on or After Standard-of-care Therapy.



6 (2 CR + 4 PR) out of 9 patients responded (67% ORR)
2 out of 9 patients had complete response (22% CR)
8 out of 9 patients had disease control (89% DCR)

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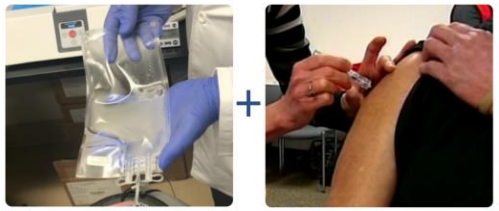
59 out of 105 (56%) Complete Responses in 7 Tumor Types

69 out of 161 (41%) Overall Response Rate in 8 Tumor Types

ImmunityBio

NK & T Cell Activator

N-803



NantKwest

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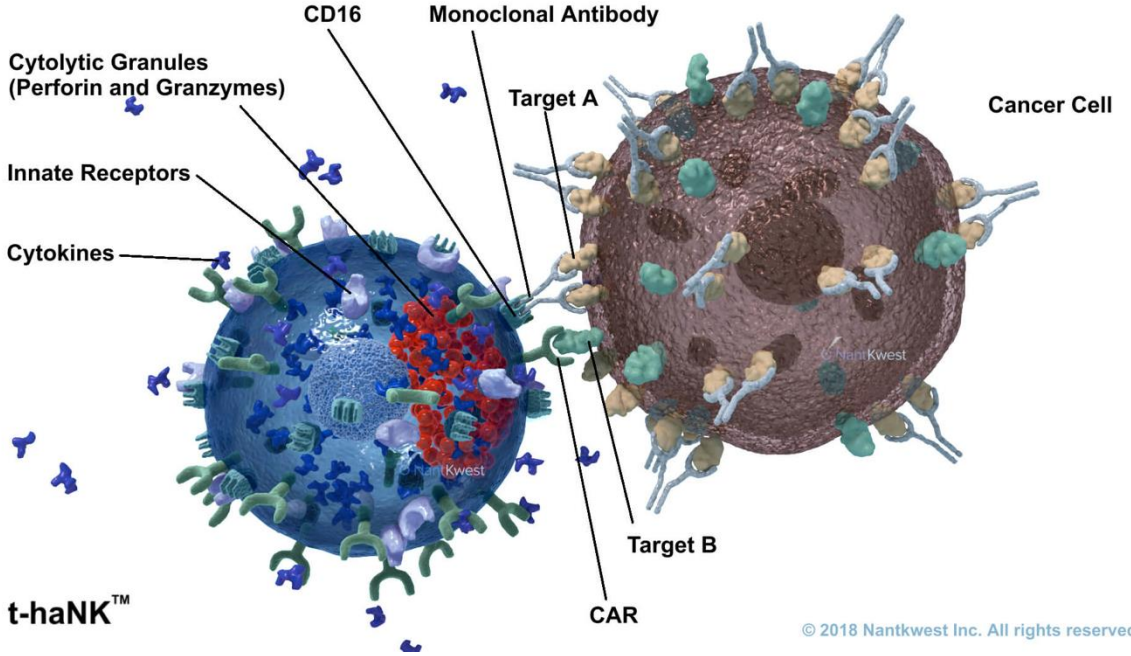
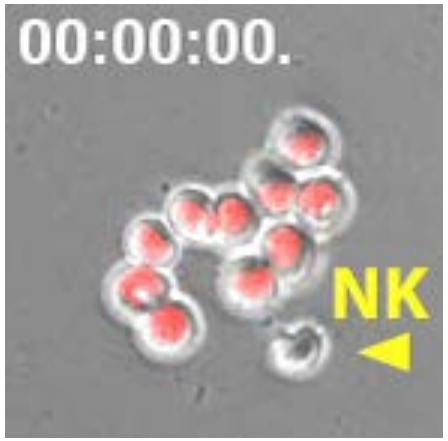
PD-L1 t-haNK (Tumor Targeted High Affinity NK)
First In Human PD-L1 Off-the-Shelf NK

- haNK cells engineered to incorporate CARs to target cancer cells displaying specific surface antigens
- Three modes of killing: via NK receptors, ADCC, and CAR directed killing
- ADCC and CAR-directed cytotoxicity are independent but synergistic
- **Currently in Development:**
  - **PD-L1 t-haNK** **Phase I Complete**
  - **CD19 t-haNK** **IND Approved**
  - **HER2 t-haNK** **IND Ready**

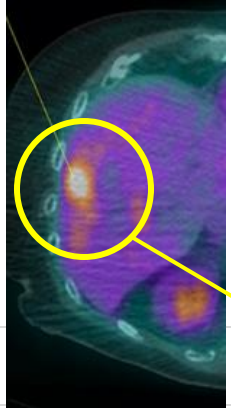




HER2 taNK

NantKwest

2nd Line Metastatic Pancreatic Cancer
Complete Response After Five PD-L1 t-haNK Infusions with N-803

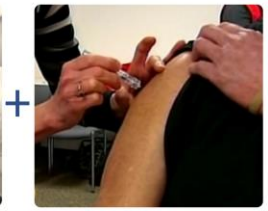


July 12, 2019
Liver Metastasis
Positive PET CT
Relapse FOLFIRI

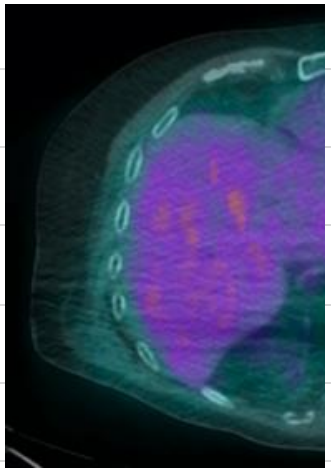
CA19-9 Level decreases from 4584 to 50

PD-L1 t-haNK

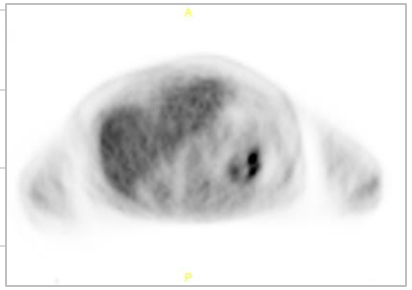
+



N-803



November 14, 2019
Complete Response
PET CT



Dec 30, 2019
Confirmed Complete Response
PET CT

Chemo Modulation

Chemo Modulation
N-803
PD-L1 t-haNK

Chemo Modulation
N-803
PD-L1 t-haNK
Aldoxorubicin

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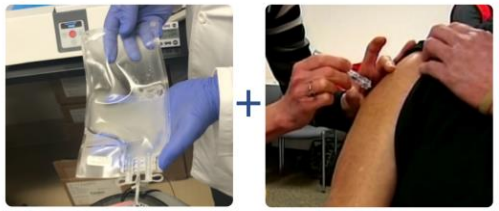

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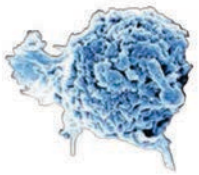
1990 – 2017: Key First-in-Class Immunogenic Cell Death Agents

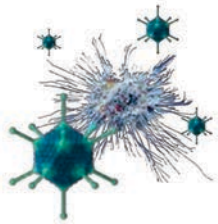
1990
Abraxane (Nab-Paclitaxel)
Transcytosis to the Tumor Microenvironment
Activation of M2 Macrophages

Bristol-Myers Squibb



1992
NK-92: Off-The-Shelf NK
Activated NK Cell Line Without Inhibitory Receptors

NantKwest

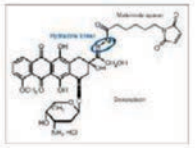


2015
E2b Deleted Adenovirus
Genomically Informed Dendritic Cell

ImmunityBio

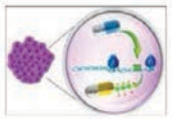
2015
N-803 IL-15 Fusion Protein
Activation of NK & Memory T Cells

ImmunityBio



2017
Aldoxorubicin
Transcytosis to the Tumor Microenvironment
DAMP Activator

ImmunityBio



2017
Nanatinostat
Epigenetic Activation of MHC1

NantKwest

2016: Announce Cancer Breakthroughs 2020

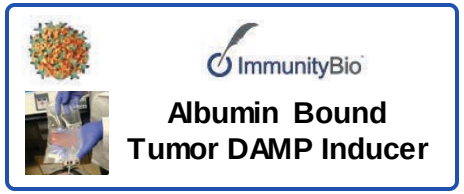
2017: Obtain FDA Authorization to Test Novel-Novel Immunological Combinations – QUILT

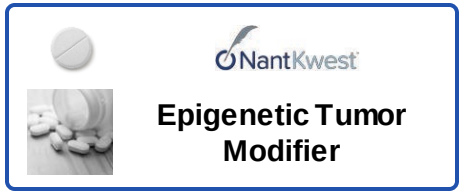
The NANT Cancer Vaccine: The Triangle Offense

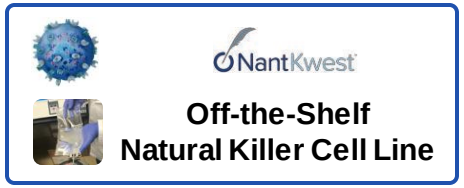
2017 – 2019: Demonstrate Early Signals of Durable Complete Remission

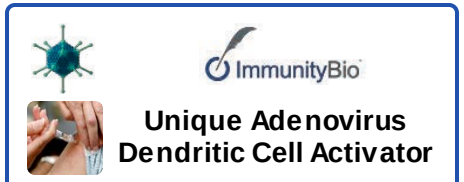
2020 - 2023: Forecast for FDA Approvals in Multiple Tumor Types

Cancer Breakthroughs 2020:
Phase I / II Trials to Test the Hypothesis of the "Triangle Offense" in Multiple Tumor Types





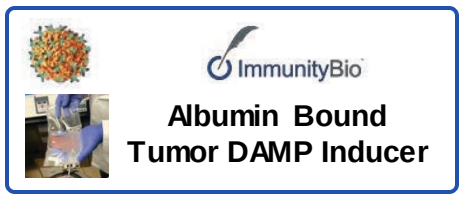


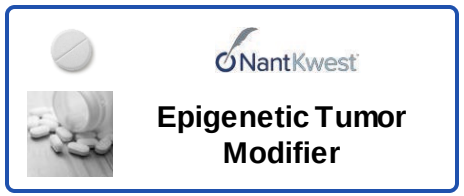


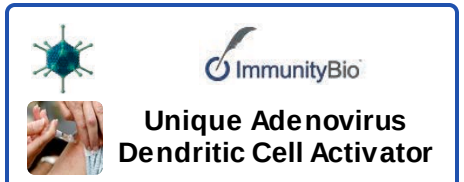
FDA Interactions and Authorizations

	2017	2018	2019	2017-2019
Formal Interactions with FDA	135	268	278	**681**
INDs Authorized by FDA	13	2	3	**18**
Pivotal Studies with Registrational Intent	4	1	2	**7**
spINDs Issued	11	26	38	**75**
Investigator-initiated (II)-INDs Issued	5	2	14	**21**
Fast Track Designations	2	0	1	**3**
Breakthrough Therapy Designation	0	0	1	**1**
FDA Approval	0	0	1	**1**

Tumor Types and Indications Treated







Tumor Types & Indications Studied (2017 – 2020)

Number of Tumor Types	**36**
Number of Indications	**48**

Tumor Type	Number of Indications
Non-Small Cell Lung Cancer (NSCLC)	4
Colon	2
Head & Neck Squamous Cell Carcinoma	2
Indolent Non-Hodgkin's Lymphoma	2
Merkel Cell Carcinoma (MCC)	2
Non-Muscle Invasive Bladder Cancer (NMIBC)	2
Ovarian	2
Pancreatic	2
Prostate	2
Triple Negative Breast Cancer (TNBC)	2
Acute Myeloid Leukemia (AML)	1
Adenoid Cystic Carcinoma	1
Burkitt Lymphoma	1
Carcinosarcoma	1
Cervical	1
Cholangiocarcinoma	1
Chordoma	1
Clear Cell Sarcoma	1
Esophageal	1
Ewing Sarcoma	1
Gastric	1
Glioblastoma	1
Inflammatory Breast Cancer	1
Intravascular Angiosarcoma	1
Laryngeal Squamous Cell Carcinoma	1
Medullary Carcinoma	1
Melanoma	1
Mesothelioma	1
Myelodysplastic Syndrome (MDS)	1
Osteosarcoma	1
Progressive Multifocal Leukoencephalopathy (PML)	1
Rectal	1
Renal Cell Carcinoma (RCC)	1
Rhabdomyosarcoma	1
Small Cell Lung Cancer (SCLC)	1
Spindle Cell Sarcoma	1
36 Total Tumor Types	**48 Total Indications**

Cancer Breakthroughs 2020:
Phase I / II Trials to Test the Hypothesis of the "Triangle Offense" in Multiple Tumor Types

ImmunityBio
Albumin Bound Tumor DAMP Inducer

NantKwest
Epigenetic Tumor Modifier

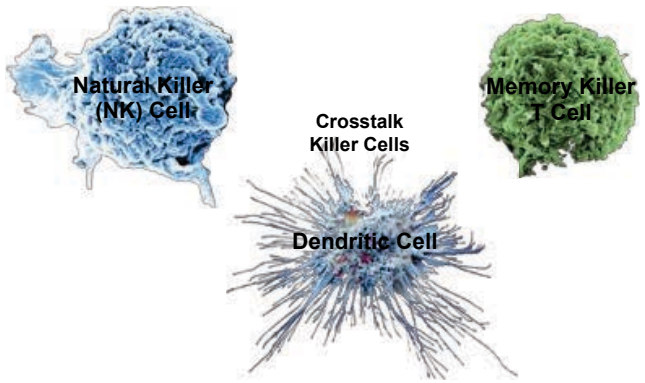
ImmunityBio
NK & T Cell Activator

NantKwest
Off-the-Shelf Natural Killer Cell Line

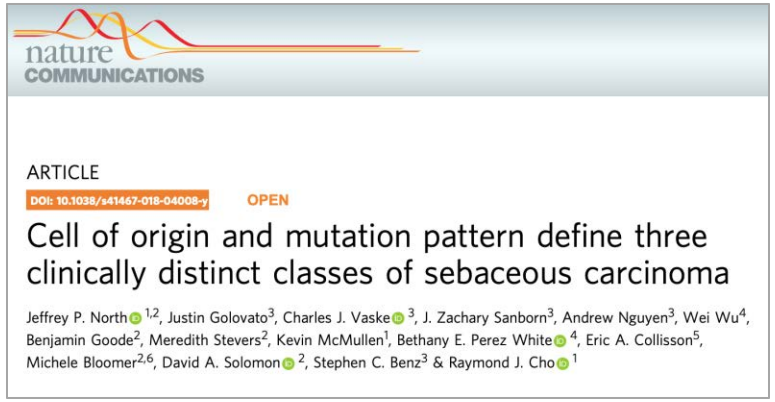
ImmunityBio
Unique Adenovirus Dendritic Cell Activator

Peer Review Publications 2017 - 2019

	Publications
Aldoxorubicin	**15**
Nanatinostat	**1**
N-803	**23**
Natural Killer Cells (aNK, haNK, PD-L1 t-haNK)	**15**
Adenovirus	**4**
GPS Cancer & Neoepitope	**39**
Total	**94**



Selected Key Publications



nature COMMUNICATIONS

ARTICLE

DOI: 10.1038/s41467-018-04008-y OPEN

Cell of origin and mutation pattern define three clinically distinct classes of sebaceous carcinoma

Jeffrey P. North[1,2], Justin Golovato[3], Charles J. Vaske[3], J. Zachary Sanborn[3], Andrew Nguyen[3], Wei Wu[4], Benjamin Goode[2], Meredith Stevers[2], Kevin McMullen[1], Bethany E. Perez White[4], Eric A. Collisson[5], Michele Bloomer[2,6], David A. Solomon[2], Stephen C. Benz[3] & Raymond J. Cho[1]

Oncotarget — Oncotarget, 2018, Vol. 9, (No. 27), pp: 19223-19232

Research Paper

Comprehensive genomic transcriptomic tumor-normal gene panel analysis for enhanced precision in patients with lung cancer

Shahrooz Rabizadeh[1], Chad Garner[1], John Zachary Sanborn[1], Stephen C. Benz[1], Sandeep Reddy[2] and Patrick Soon-Shiong[1,2]

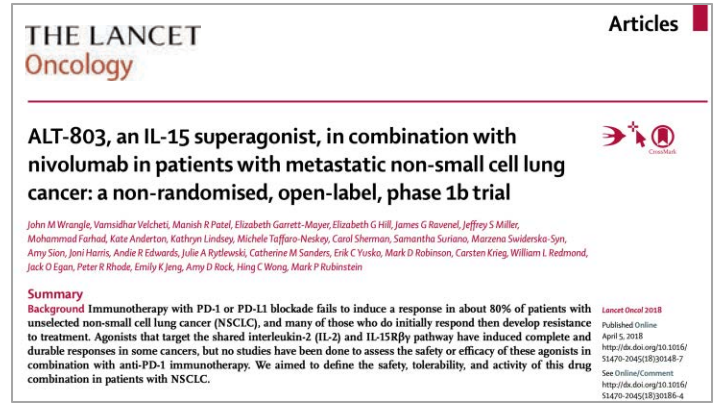
[1]NantOmics, LLC, Culver City, CA, USA

[2]NantHealth, Inc., Culver City, CA, USA

Correspondence to: Shahrooz Rabizadeh, *email:* sr@nantomics.com

Keywords: precision medicine; tumor-normal sequencing; lung cancer; somatic variants; tumor sequencing

Received: November 30, 2017 *Accepted:* March 15, 2018 *Published:* April 10, 2018



THE LANCET Oncology — Articles

ALT-803, an IL-15 superagonist, in combination with nivolumab in patients with metastatic non-small cell lung cancer: a non-randomised, open-label, phase 1b trial

John M Wrangle, Vamsidhar Velcheti, Manish R Patel, Elizabeth Garrett-Mayer, Elizabeth G Hill, James G Ravenel, Jeffrey S Miller, Mohammad Farhad, Kate Anderton, Kathryn Lindsey, Michele Taffaro-Neskey, Carol Sherman, Samantha Suriano, Marzena Swiderska-Syn, Amy Sion, Joni Harris, Andie R Edwards, Julie A Rytlewski, Catherine M Sanders, Erik C Yusko, Mark D Robinson, Carsten Krieg, William I. Redmond, Jack O Egan, Peter R Rhode, Emily K Jeng, Amy D Rock, Hing C Wong, Mark P Rubinstein

Summary

Background Immunotherapy with PD-1 or PD-L1 blockade fails to induce a response in about 80% of patients with unselected non-small cell lung cancer (NSCLC), and many of those who do initially respond then develop resistance to treatment. Agonists that target the shared interleukin-2 (IL-2) and IL-15Rβγ pathway have induced complete and durable responses in some cancers, but no studies have been done to assess the safety or efficacy of these agonists in combination with anti-PD-1 immunotherapy. We aimed to define the safety, tolerability, and activity of this drug combination in patients with NSCLC.

Lancet Oncol 2018 Published Online April 5, 2018 http://dx.doi.org/10.1016/S1470-2045(18)30148-7 See Online/Comment http://dx.doi.org/10.1016/S1470-2045(18)30186-4

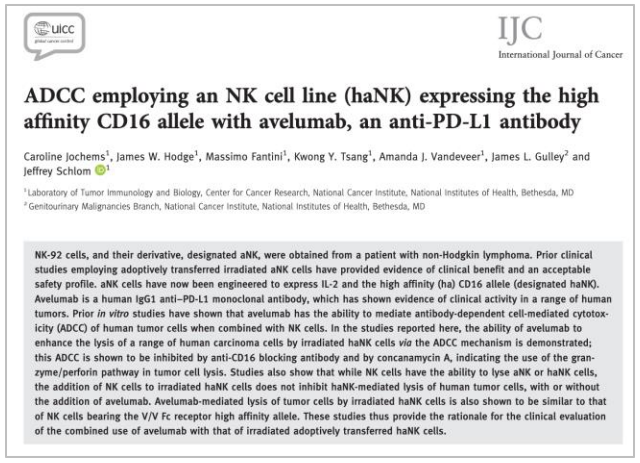
blood — Plenary Paper

TRANSPLANTATION

First-in-human phase 1 clinical study of the IL-15 superagonist complex ALT-803 to treat relapse after transplantation

Rizwan Romee,[1,*] Sarah Cooley,[2,*] Melissa M. Berrien-Elliott,[1] Peter Westervelt,[1] Michael R. Verneris,[2] John E. Wagner,[2] Daniel J. Weisdorf,[2] Bruce R. Blazar,[2] Celalettin Ustun,[2] Todd E. DeFor,[2] Sithara Vivek,[3] Lindsey Peck,[1] John F. DiPersio,[1] Amanda F. Cashen,[1] Rachel Kyllo,[4] Amy Musiek,[4,5] András Schaffer,[4] Milan J. Anadkat,[4,5] Ilana Rosman,[4] Daniel Miller,[6] Jack O. Egan,[7] Emily K. Jeng,[7] Amy Rock,[7] Hing C. Wong,[7] Todd A. Fehniger,[1,†] and Jeffrey S. Miller[2,†]

[1]Division of Oncology, Department of Medicine, Washington University School of Medicine, St. Louis, MO, [2]Blood and Marrow Transplant Program and [3]Masonic Cancer Center, University of Minnesota, Minneapolis, MN; [4]Division of Dermatology, Department of Medicine, and [5]Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, MO; [6]Department of Dermatology, University of Minnesota, Minneapolis, MN; and [7]Altor BioScience, a Nantworks company, Miramar, FL



UICC

IJC International Journal of Cancer

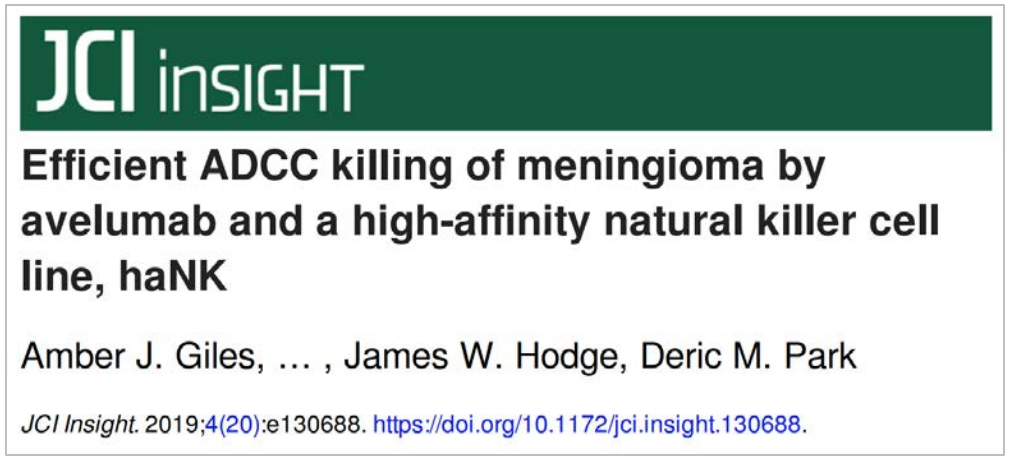
ADCC employing an NK cell line (haNK) expressing the high affinity CD16 allele with avelumab, an anti-PD-L1 antibody

Caroline Jochems[1], James W. Hodge[1], Massimo Fantini[1], Kwong Y. Tsang[1], Amanda J. Vandeveer[1], James L. Gulley[2] and Jeffrey Schlom[1]

[1]Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, MD

[2]Genitourinary Malignancies Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD

NK-92 cells, and their derivative, designated aNK, were obtained from a patient with non-Hodgkin lymphoma. Prior clinical studies employing adoptively transferred irradiated aNK cells have provided evidence of clinical benefit and an acceptable safety profile. aNK cells have now been engineered to express IL-2 and the high affinity (ha) CD16 allele (designated haNK). Avelumab is a human IgG1 anti–PD-L1 monoclonal antibody, which has shown evidence of clinical activity in a range of human tumors. Prior *in vitro* studies have shown that avelumab has the ability to mediate antibody-dependent cell-mediated cytotoxicity (ADCC) of human tumor cells when combined with NK cells. In the studies reported here, the ability of avelumab to enhance the lysis of a range of human carcinoma cells by irradiated haNK cells *via* the ADCC mechanism is demonstrated; this ADCC is shown to be inhibited by anti-CD16 blocking antibody and by concanamycin A, indicating the use of the granzyme/perforin pathway in tumor cell lysis. Studies also show that while NK cells have the ability to lyse aNK or haNK cells, the addition of NK cells to irradiated haNK cells does not inhibit haNK-mediated lysis of human tumor cells, with or without the addition of avelumab. Avelumab-mediated lysis of tumor cells by irradiated haNK cells is also shown to be similar to that of NK cells bearing the V/V Fc receptor high affinity allele. These studies thus provide the rationale for the clinical evaluation of the combined use of avelumab with that of irradiated adoptively transferred haNK cells.

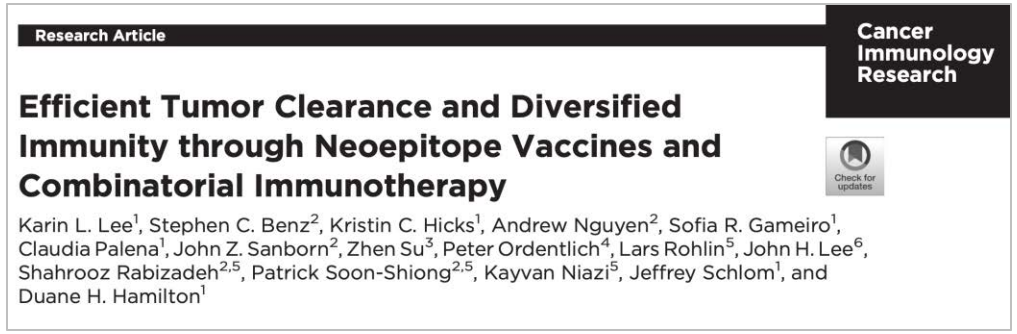


JCI insight

Efficient ADCC killing of meningioma by avelumab and a high-affinity natural killer cell line, haNK

Amber J. Giles, … , James W. Hodge, Deric M. Park

JCI Insight. 2019;4(20):e130688. https://doi.org/10.1172/jci.insight.130688.



Research Article

Cancer Immunology Research

Efficient Tumor Clearance and Diversified Immunity through Neoepitope Vaccines and Combinatorial Immunotherapy

Karin L. Lee[1], Stephen C. Benz[2], Kristin C. Hicks[1], Andrew Nguyen[2], Sofia R. Gameiro[1], Claudia Palena[1], John Z. Sanborn[2], Zhen Su[3], Peter Ordentlich[4], Lars Rohlin[5], John H. Lee[6], Shahrooz Rabizadeh[2,5], Patrick Soon-Shiong[2,5], Kayvan Niazi[5], Jeffrey Schlom[1], and Duane H. Hamilton[1]

Cancer Research

Abstract CT146: First-in-human phase I combination of the IL-15 receptor super agonist complex ALT-803 with a therapeutic (anti-CD20) monoclonal antibody (mAb) for patients with relapsed or refractory indolent non-Hodgkin lymphoma (iNHL)

Todd A. Fehniger, Brian T. Hess, Veronika Bachanova, Michelle Becker-Hapak, Ethan McClain, Melissa Berrien-Elliott, Julia Wagner, Nancy L. Bartlett, Brad Kahl, Neha Mehta-Shah, Amanda F. Cashen, Feng Gao, Kyle Conradi, Amy D. Rock, Emily K. Jeng, Liza Hernandez, Jack O. Egan, Peter R. Rhode, and Hing C. Wong

DOI: 10.1158/1538-7445.AM2018-CT146 Published July 2018

The Oncologist

Clinical Trial Results

A Phase I Trial Using a Multitargeted Recombinant Adenovirus 5 (CEA/MUC1/Brachyury)-Based Immunotherapy Vaccine Regimen in Patients with Advanced Cancer

Margaret E. Gatti-Mays,[a,†] Jason M. Redman,[b,†] Renee N. Donahue,[a] Claudia Palena,[a] Ravi A. Madan,[b] Fatima Karzai,[b] Mario Bilusic,[b] Houssein Abdul Sater,[b] Jennifer L. Marte,[b] Lisa M. Cordes,[b] Sheri McMahon,[b] Seth M. Steinberg,[c] Alanvin Ogpia,[d] Andrea Burmeister,[d] Jeffrey Schlom,[a,*] James L. Gulley,[a,*] Julius Strauss[a]

[a]Laboratory of Tumor Immunology and Biology and [b]Genitourinary Malignancies Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, USA; [c]Biostatistics and Data Management Section, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, USA; [d]Leidos Biomedical Research, Inc., Frederick, Maryland, USA

[†]Contributed equally as first authors.

[*]Contributed equally as senior authors.

Cancer Breakthroughs 2020:
Phase I / II Trials to Test the Hypothesis of the "Triangle Offense" in Multiple Tumor Types

ImmunityBio

Albumin Bound Tumor DAMP Inducer

NantKwest

Epigenetic Tumor Modifier

ImmunityBio

NK & T Cell Activator

NantKwest

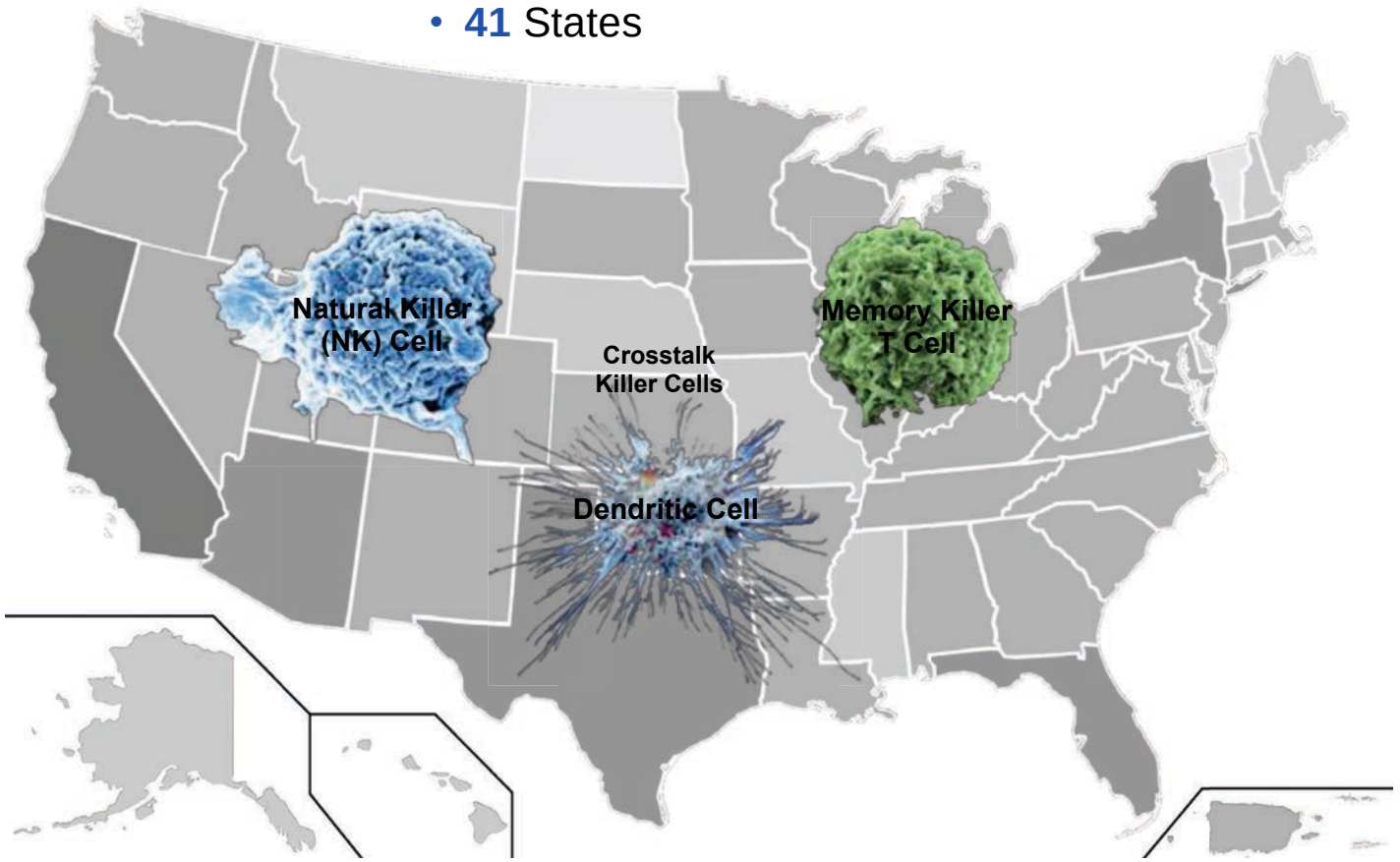
Off-the-Shelf Natural Killer Cell Line

ImmunityBio

Unique Adenovirus Dendritic Cell Activator

Clinical Trial Sites & Investigators Activated (2016 – 2019)

- **206** Clinical Trial Sites Activated
- **206** Investigators
- **20** Clinical Trials Actively Enrolling
- **41** States



Off the Shelf Natural Killer Cells as a Product: World's Largest Production and Clinical Infusion of Natural Killer Cells

3.3 Trillion Cells Manufactured

NantKwest

Off-the-Shelf Natural Killer Cell Line

1.6 Trillion Cells in Storage

Off-the-Shelf Natural Killer Cells Linearly Scalable By the Numbers:

aNK / haNK / PD-L1 t-haNK	2017 – 2019
Number of Cells Manufactured in GMP Facility to Date	**3.3 Trillion Cells**
Number of Patients Dosed as Outpatient	**53**
Number of Doses Administered (>2 Billion Cells Per Dose)	**719**
Number of Cells Administered to 53 Patients Since 2017	**1.5 Trillion Cells**
Number of Cells in Storage	**1.6 Trillion Cells**
NK Treatment Related Cytokine Storm	**Zero**

Off-the-Shelf Engineered NK-92 aNK, haNK, PD-L1 t-haNK Ready for Transfusion

Cryopreserved Off-the-Shelf NK Product

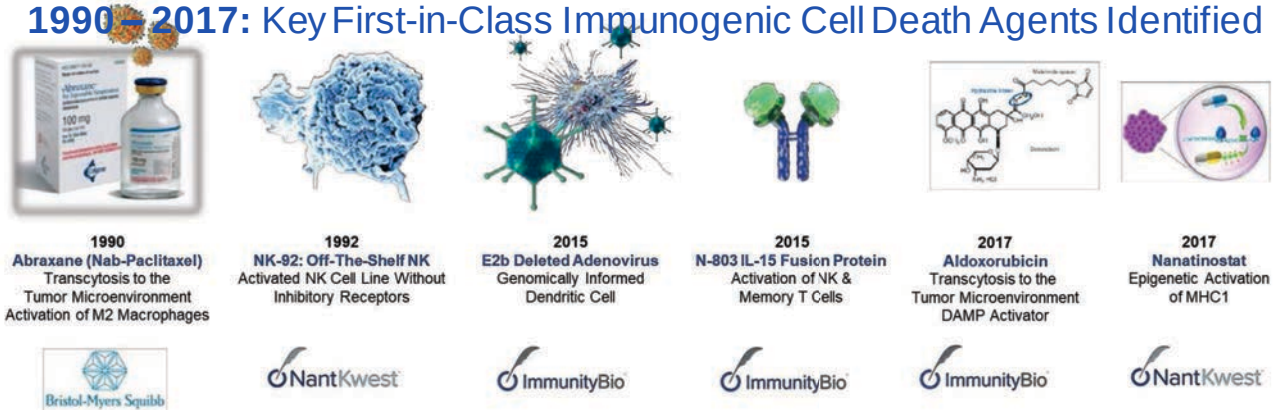
Cancer Breakthroughs Forecast for Next Four Years

Anticipated BLA Registration Filings 2020 - 2024

	Tumor Types & Indications	Filing Date Forecast	NANT Agents ImmunityBio	NANT Agents ImmunityBio	NANT Agents NantKwest	# of Sites	# of Patients Accrued to Date
Bladder	Complete Response **Bladder Cancer:** BCG Unresponsive NMIBC CIS	2020	ImmunityBio N-803			35 Active Sites	FDA Breakthrough 55 / 80
	Bladder Cancer: BCG Unresponsive NMIBC Papillary	2021	ImmunityBio N-803			35 Active Sites	FDA Fast Track 40 / 80
	Bladder Cancer: BCG Naive NMIBC CIS	2023	ImmunityBio N-803			32 Active Sites	FDA Fast Track 49 / 366
Lung	Durable Response **Non-Small Cell Lung Cancer:** Checkpoint Relapsed 2nd Line	2021	ImmunityBio N-803			25 Active Sites	19 / 55
	Non-Small Cell Lung Cancer: Checkpoint Relapsed 3rd Line	2021	ImmunityBio N-803			25 Active Sites	8 / 43
	Durable Response Non-Small Cell Lung Cancer: PD-L1 Expression Second Line	2021	ImmunityBio N-803		NantKwest PD-L1 t-haNK	To Be Opened	0 / 55
	Non-Small Cell Lung Cancer: PD-L1 Expression 1st Line	2023	ImmunityBio N-803			28 Active Sites	11 / 388
TNBC	Complete Response **Triple Negative Breast Cancer** 3rd Line	2022	ImmunityBio N-803	ImmunityBio Aldox	NantKwest PD-L1 t-haNK	To Be Opened	0 / 43
MCC	Complete Response **Merkel Cell Carcinoma:** Checkpoint Relapsed, 2nd Line	2023	ImmunityBio N-803		NantKwest haNK	3 Active Sites	1 / 43
Panc	Complete Response **Metastatic Pancreatic Cancer** 2nd Line	2024	ImmunityBio N-803	ImmunityBio Aldox	NantKwest PD-L1 t-haNK	To Be Opened	0 / 188

Total Patients Accrued To Date = 183 / 1341

1990 – 2017: Key First-in-Class Immunogenic Cell Death Agents Identified



1990
Abraxane (Nab-Paclitaxel)
Transcytosis to the Tumor Microenvironment
Activation of M2 Macrophages
Bristol-Myers Squibb

1992
NK-92: Off-The-Shelf NK
Activated NK Cell Line Without Inhibitory Receptors
NantKwest

2015
E2b Deleted Adenovirus
Genomically Informed Dendritic Cell
ImmunityBio

2015
N-803 IL-15 Fusion Protein
Activation of NK & Memory T Cells
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2017
Aldoxorubicin
Transcytosis to the Tumor Microenvironment
DAMP Activator
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Epigenetic Activation of MHC1
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2016: Announced Cancer Breakthroughs 2020

2017: Obtained FDA Authorization to Test Novel-Novel-Novel Immunological Combinations

2017 – 2019: 39 INDs Authorized with >200 Investigator Sites in 41 States

94 Peer Reviewed Scientific Publications

The Triangle Offense, QUILT Trials Completed with Over 1 Trillion NK Cells Infused

Combination Therapy Tested in 36 Tumor Types in 48 Indications

Tumor Mutation Burden for Tumor-Normal Tissue: First FDA Approval in US – Omics Core

Demonstrated Early Signals of Durable 59 Complete Remissions out of 105 Solid Tumors in Multiple Diseases

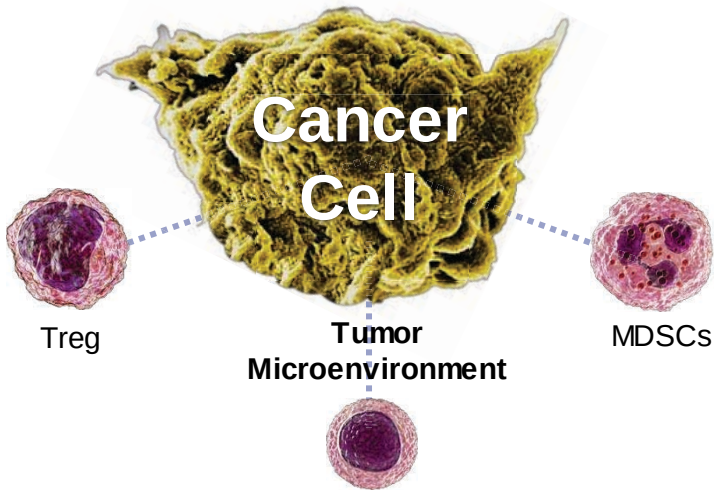
2020 - 2023: Forecast for FDA Approvals in Multiple Tumor Types

Breakthrough Status Achieved for Bladder Cancer

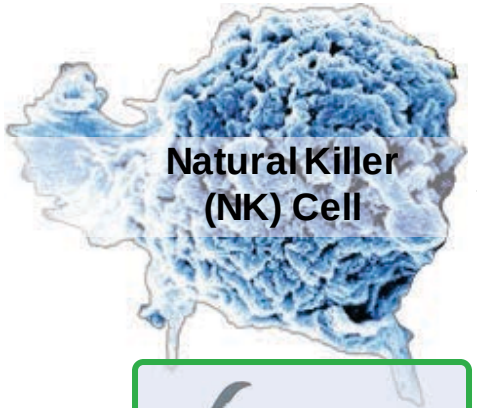
7 Active Registration Trials in Bladder, Lung, and Merkel Cell Cancer

NantKwest & ImmunityBio to Integrate Platforms of NK Cells, N-803 and Aldoxorubicin

The Cross Talk of the Immune System in Cancer Inducing Immunogenic Cell Death



Off-the-Shelf NK Cell



NASDAQ: NK

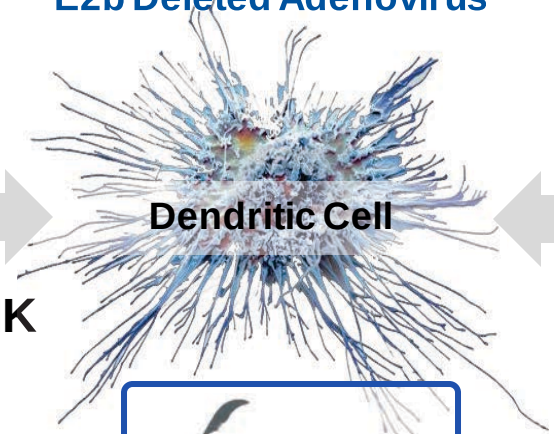
NantKwest

NK Cell - Born to Kill:
Nature's Killer Cell
Innate Immune System

Cross Talk

PD-L1 t-haNK

E2b Deleted Adenovirus



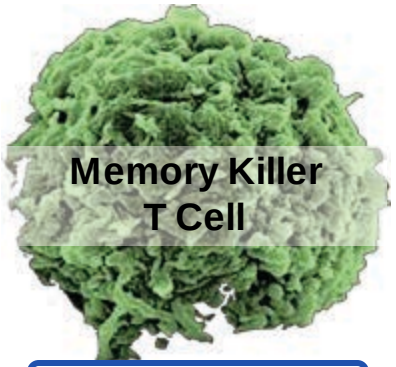
ImmunityBio

Dendritic Cell - The Trainer:
Nature's Trainer Cell
The Cross Talk Between
Innate & Adaptive Immune System

Cross Talk

N-803

IL-15 Fusion Protein



ImmunityBio

T Cell - Trained to Kill:
Nature's Targeted Killer
Adaptive Immune System