



BEYOND
CANCER™

Next level immuNO-oncology

Corporate Presentation

April 2024

Ultra-High Concentration Nitric Oxide (UNO) as a Potent Immunotherapy

Upregulates Immune Activity

Utilizing **U**ltra-high concentration **N**itric **O**xide (**UNO**) to upregulate immune activity to treat solid tumors and distant metastases

Promising Early Phase 1a Results

First in human, Phase 1 clinical trial ongoing in unresectable, relapsed or refractory solid tumors

Combination Therapy

Combination therapy with immune checkpoint inhibitors (ICIs) to improve patient outcomes

Patented Delivery Approach

Differentiated MOA with 2 U.S. issued patents (expiry 2040) involving a novel delivery system

Beyond Cancer Leadership Expertise in Emerging Healthcare Companies and Clinical Oncology



Selena Chaisson, MD
Chief Executive Officer



- 16 years as Head of Healthcare Investments at Bailard managing the Emerging Life Science strategy
- Over 25 years of experience as a healthcare investor
- Stanford MD/MBA



Jedd Monson, MD
Chief Medical Officer



- Founding partner of cCARE
- Practiced at City of Hope, Valley Radiotherapy Associates, and 21st Century Oncology
- Stanford MD, a member of American College of Radiology and American Society of Therapeutic Radiology & Oncology



Gavin Choy, PharmD
Chief Operating Officer



- 20+ years of biopharmaceutical operating experience
- Integral member of four New Drug Applications (NDA) and seven Investigational New Drug (IND) filings
- PharmD from University of Southern California and MBA from University of California, Irvine

Board of Directors with Proven Business Record and Development Experience



Gregory Berk, MD

- Independent oncology drug development consultant
- Over 30 years of experience. Served as interim CEO, CMO at GT Biopharma, Inc.
- Weill Medical College of Cornell University, New York Presbyterian Hospital, Case Western Reserve University



David Dvorak

- Chairman and CEO of DeepThink Health, Inc.
- Served as President & CEO of Zimmer Biomet Holdings, Inc.
- Over 20 years of global executive-level leadership and operating experience



Robert Carey

- Board member at Beyond Air (XAIR) since February 2019
- Co-Founder, President & COO of ACELYRIN
- Served as Executive VP and CBO at Horizon
- Previously Managing Director & Head of Healthcare Investment Banking at JMP Securities



**Steve Lisi
Chairman**

- CEO & Chairman of Beyond Air (XAIR) since 2017
- 18 years experience as a healthcare investor
- 3 years as SVP Head of Strategy and BD at Avadel (AVDL)



**Amir Avniel
Executive Director**

- CBO and Co-Founder of Beyond Air (XAIR)
- Over 20 years of executive-level experience in finance, business development and operations, including M&A

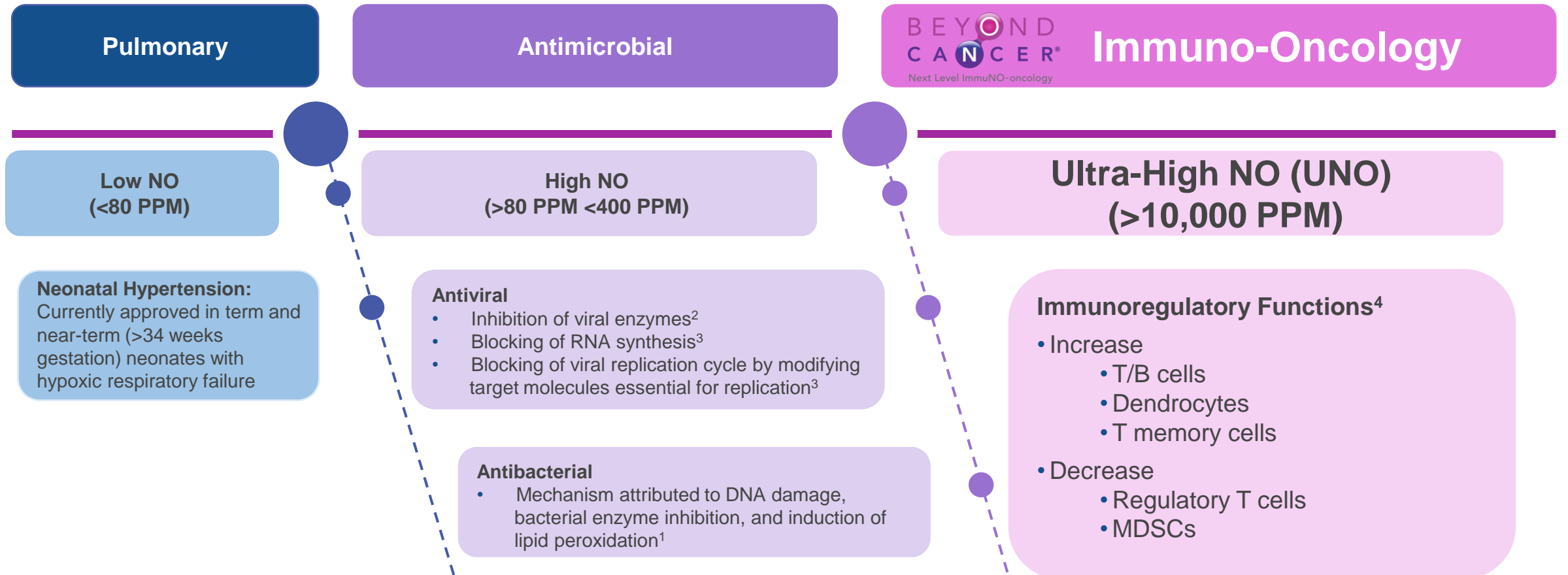


**Selena Chaisson, M.D.
CEO**

- 16 years as Head of Healthcare Investments at Bailard managing the Emerging Life Science strategy
- Over 25 years of experience as a healthcare investor
- Stanford MD/MBA



Therapeutic Concentrations of Nitric Oxide (NO)



1) Wink DA et al., Chemical biology of nitric oxide: Insights into regulatory, cytotoxic, and cytoprotective mechanisms of nitric oxide. Free Rad Biol Med 1998; (4-5): 434-56.

2) Saura, M., et al., An antiviral mechanism of nitric oxide: inhibition of a viral protease. Immunity, 1999. 10(1): p. 21-8

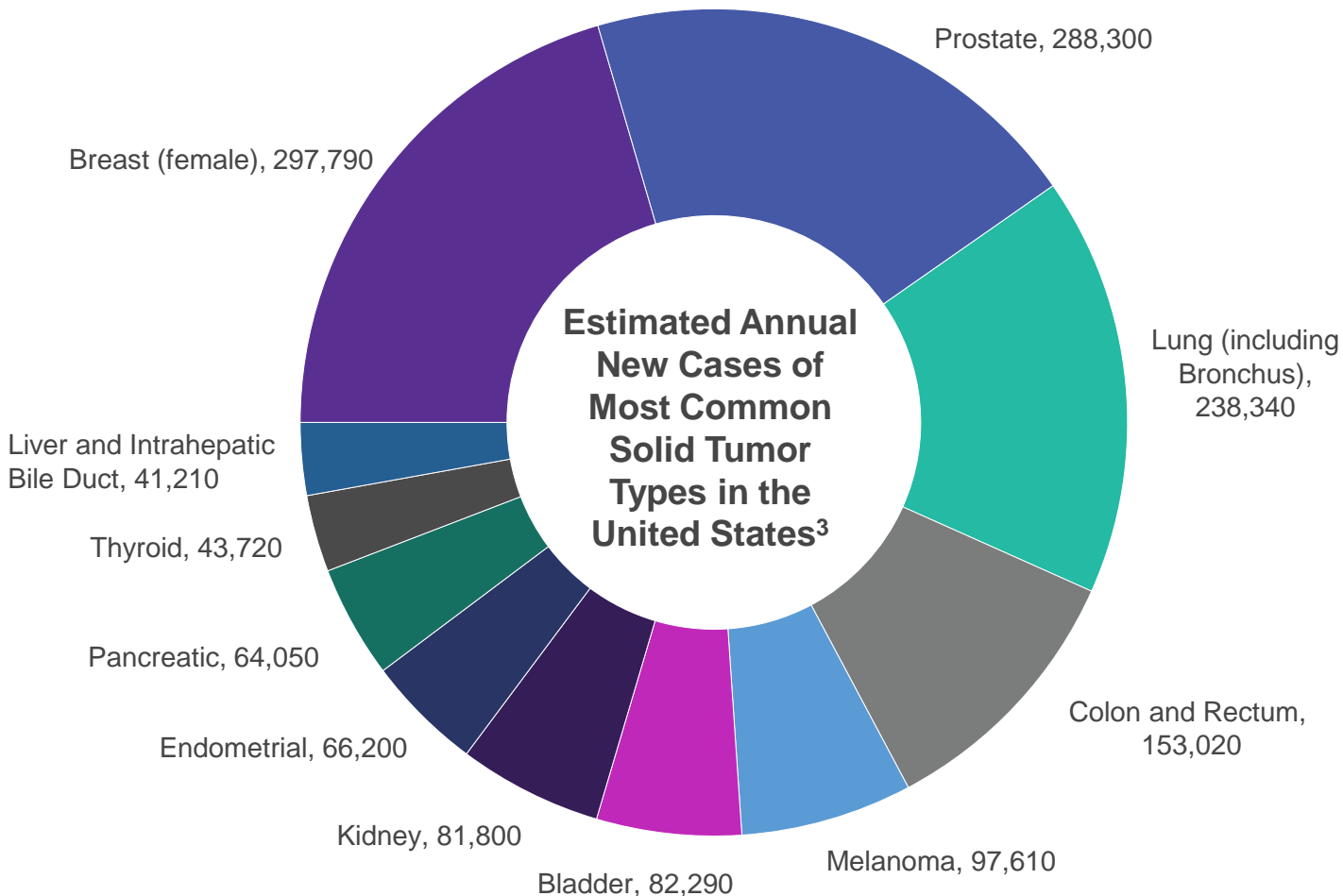
3) Akerström S et al. Nitric oxide inhibits the replication cycle of severe acute respiratory syndrome coronavirus. J Virol. 2005; 79(3):1966-9

4) 2023-10-30-SITC_Poster_Final.pdf (beyondcancer.com)

Immunotherapy has Emerged as a Cornerstone Treatment for Solid Tumors

Solid Tumors represent approximately 90% of adult human cancers¹, accounting for approximately 1.5 million annual new cases of most common cancer types in the United States³

Metastatic Disease is responsible for 90% of solid tumor deaths²



1) Cooper GM. The Cell: A Molecular Approach. 2nd edition. Sunderland (MA): Sinauer Associates; 2000. The Development and Causes of Cancer. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK9963/>
2) Fontebasso Y, Dubinett SM. Drug Development for Metastasis Prevention. Crit Rev Oncog. 2015;20(5-6):449-473. doi:10.1615/CritRevOncog.v20.i5-6.150
3) According to the National Cancer Institute: <https://www.cancer.gov/types/common-cancers>. Accessed: April 15, 2024. Data as of March 7, 2023

The Majority of Immunotherapies are Checkpoint Inhibitors

Company	Drug Name	First FDA Approval	2023 Revenue
Bristol-Myers Squibb	Yervoy	March 2011	\$2.2 Billion
Merck	Keytruda	Sept 2014	\$25.0 Billion
Bristol-Myers Squibb	Opdivo	Dec 2014	\$9.0 Billion
Roche	Tecentriq	May 2016	\$3.4 Billion
AstraZeneca	Imfinzi	May 2017	\$4.2 Billion

Despite a >\$40B Market, Most Cancer Patients are Either Ineligible, Do Not Respond, or Develop Resistance

Proprietary UNO Delivery System Directly Targets the Tumor

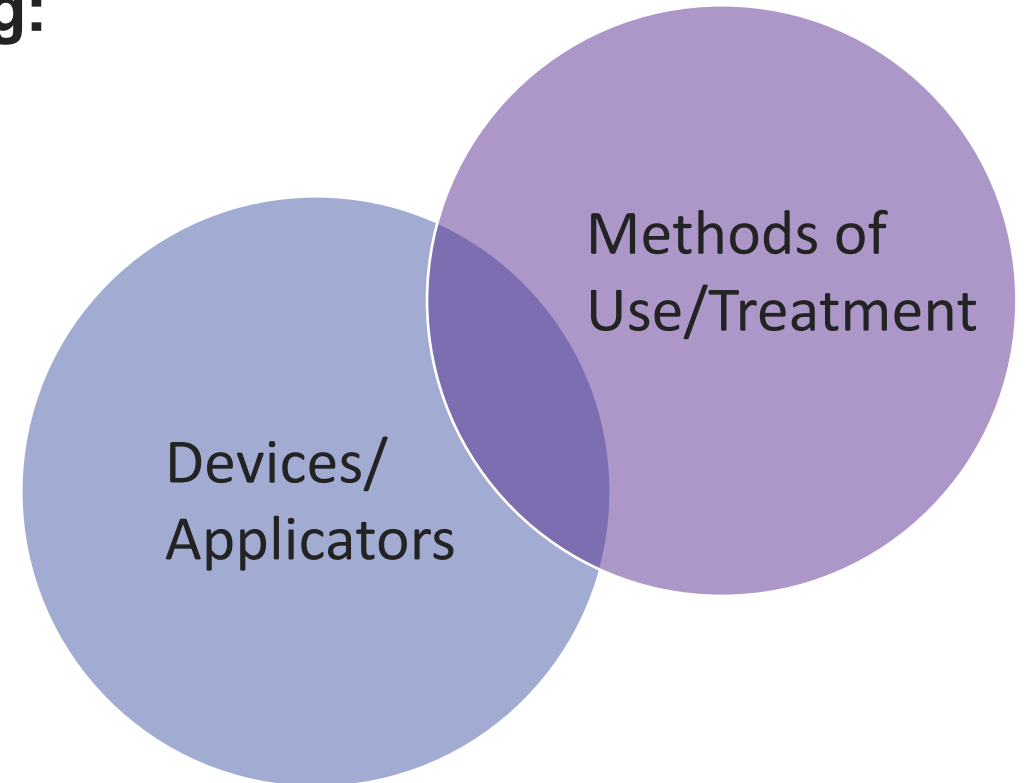
Novel system to deliver Ultra-high concentration Nitric Oxide (UNO)

- Advantages
 - Ability to obtain significantly higher intra-tumoral NO concentrations than endogenous or NO donor systems
 - Quick and simple procedure
- Optimizing delivery to meaningfully improve ease of use
 - Current high-volume system has produced promising results both preclinically and in Phase 1a
 - Low volume system expected for use in Phase 1b trial
- Encouraging toxicity profile allows for potential combination with approved therapies to enhance clinical outcomes






Two issued U.S. patents (expiry 2040), with more pending from patent families including:

- UNO monotherapy for the treatment of solid tumors
- UNO in combination with checkpoint therapies and other anti-cancer agents
- Delivery systems
- Delivery applicators



Platform Technology Targeting Multiple Solid Tumors

Program	Initial Indication	Discovery	Pre-Clinical	Phase 1a	Phase 1b
Monotherapy					
UNO101	Cutaneous / near cutaneous tumors				
Combination Therapy					
UNO201 + anti-PD-1	PD-1 Resistant or Refractory Patients with Cutaneous / near cutaneous tumors				
UNO201 + other agents	Multiple solid tumors				

UNO101: High Volume

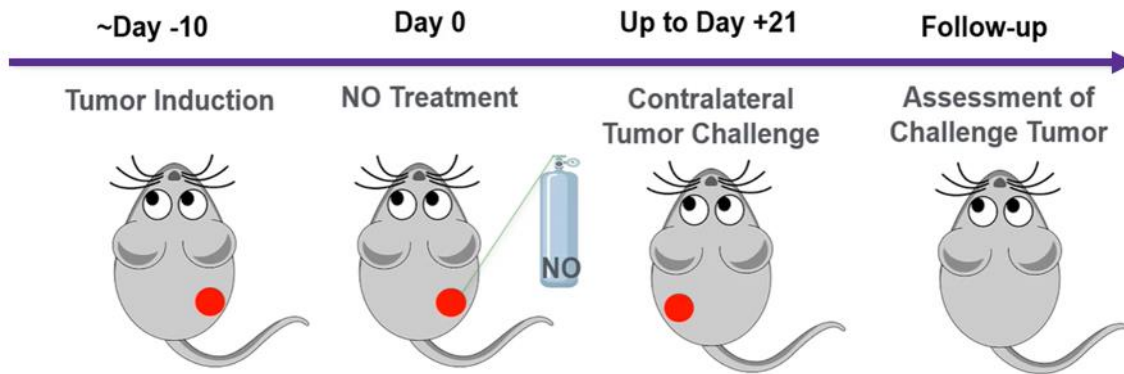
UNO201: Low Volume

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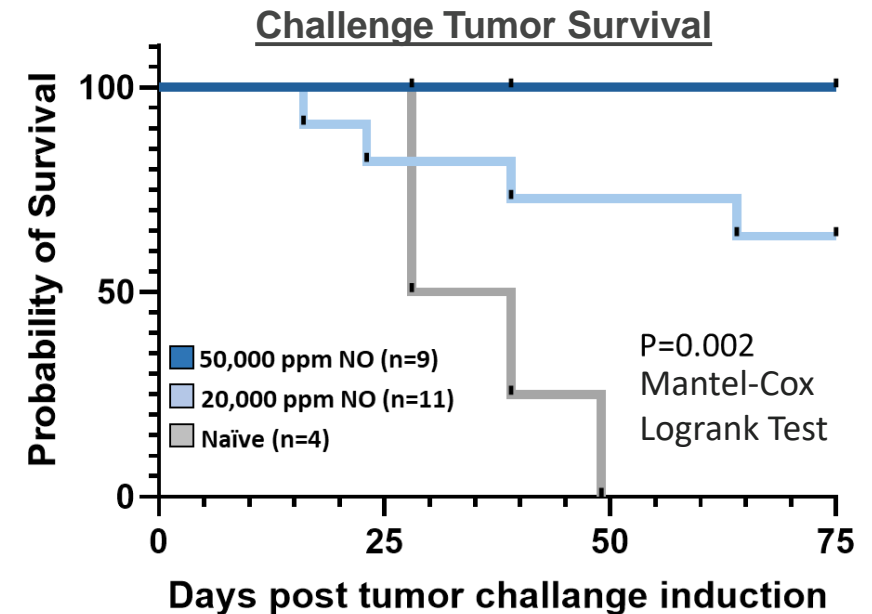
UNO Preclinical Data Demonstrates Immune Response

UNO in CT26 Challenge Tumors In Vivo Showed Evidence of Dose-Dependent Effects on Survival



Challenge assay:

- CT26 study mice treated with 20,000 or 50,000 ppm NO for 5 minutes.
- Naïve mice inoculated with the same cancer cells served as an internal control.
- Up to 21 days post NO treatment, all mice were re-inoculated with colon cancer cells (CT26 cells) as a challenge tumor and survival was monitored.

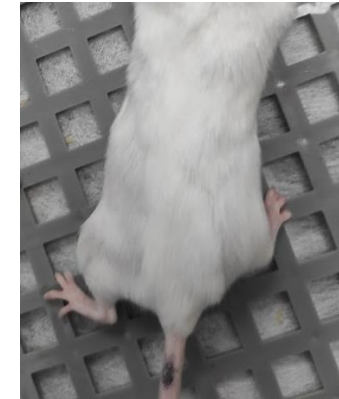
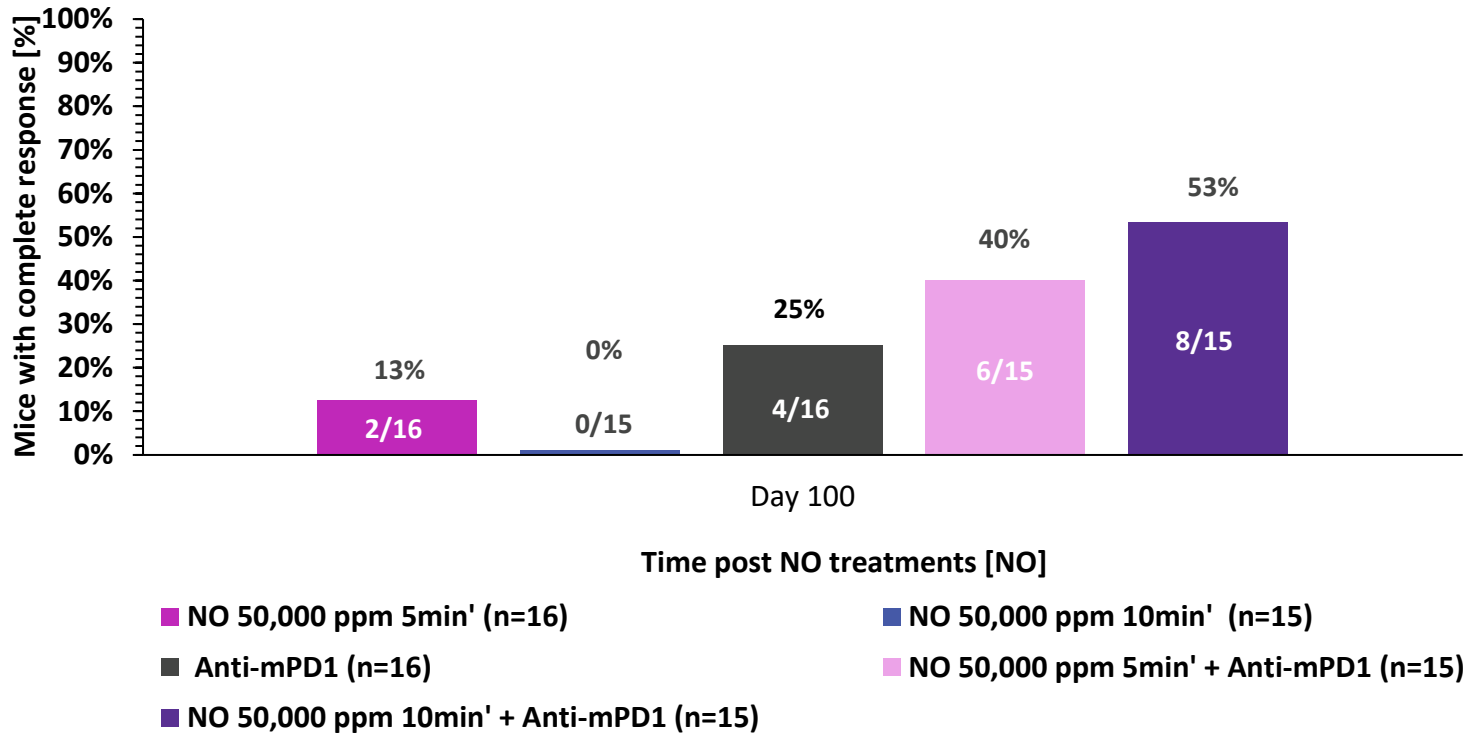


Survival Results at Day 75:

- 100% of 50,000 ppm NO mice alive
- 64% of 20,000 ppm NO mice alive
- 0% of naïve mice alive

UNO in Combination with Anti-mPD-1 Showed a Doubling of Tumor-Free Mice

CT26 Primary and Secondary Tumor-free Mice



UNO+anti-PD-1
Complete Response

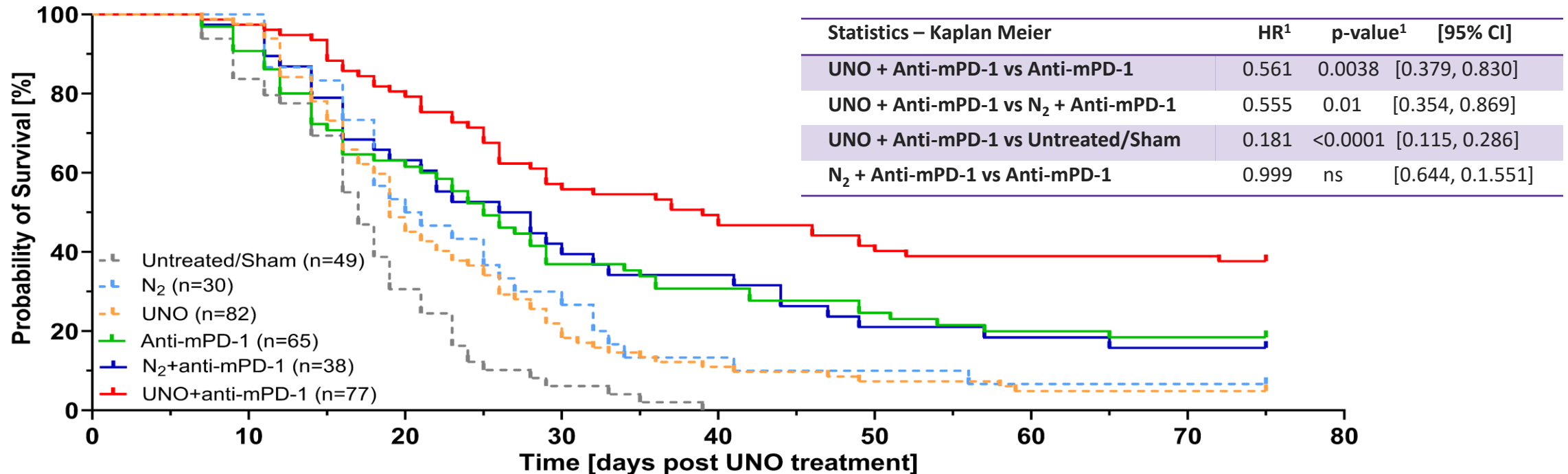


Control
Primary &
Secondary tumors

Statistical analysis: Fisher's Exact Test: P-value = 0.1489,
Pairwise Treatment Group Comparison - 50,000 10 min + Anti-mPD1 vs Anti-mPD1

Effect of a Single UNO Treatment and Anti-mPD-1 on Mice Survival

The combination of Ultra-high concentration NO with anti-mPD-1 improved outcomes and mice survival compared to UNO or anti-mPD-1 alone, as UNO assists the immune system in overcoming anti-mPD-1 resistance.



Pooled data across studies of 5 or 10-min UNO and anti-mPD-1 (5 or 10 mg/kg) treatment – survival data.

¹Hazard ratio and p-value derived from Cox proportional hazard model.

Experimental model: CT26; Mouse model: Balb/c mice.

UNO treatment regimen: 50,000 or 100,000 ppm injected for 5 or 10 minutes, at 0.2 LPM.

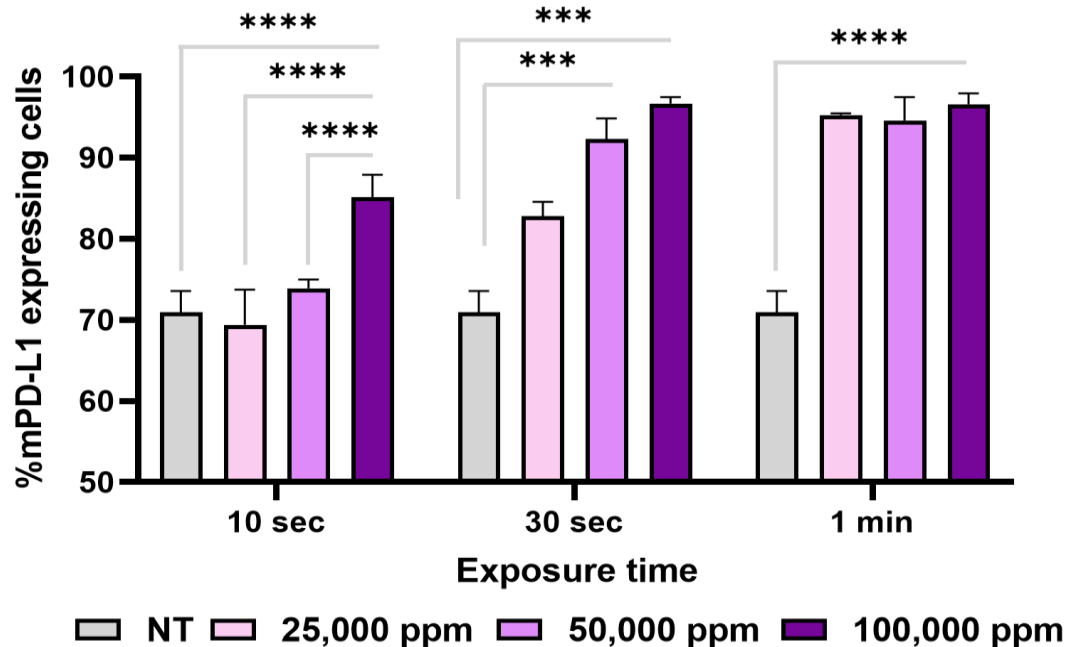
Anti-mPD-1 dosing started at days (-2) to (+2). 5 or 10 mg/kg doses injected every 2-3 days, 4-5 doses in total.

All studies were conducted under approved IACUC protocols.

Data presented at the EORTC-NCI-AACR
Annual Meeting, October 2023

UNO Upregulates mPD-L1 Expression at Day 5

mPD-L1 expression in PI-negative CT26 tumor cells



- mPD-L1 expression 5 days after exposure to UNO
- Two-way ANOVA, multiple comparison test, *** $P < 0.001$, **** $P < 0.0001$.

Dose-Dependent Effects of NO in Cancer

	Tumor Response/Survival	Intra-Tumoral Effects	Systemic Effects	Source
UNO 1,000,000's	Prevents challenge tumors ² +ICI: Complete tumor regression/ survival in >50% (Day 100) ³	↑ Central Memory T cells ↓ T regs	↑ Central Memory T cells ↑ Tumor Antigen Specific T cells ↓ M-MDSCs ↓ T regs ¹	Mouse colon, CT26 + Clinical data
	Hydrogel + ICI: Survival in B16 (Day 35) and 4T1 (DAY 55) ⁷ + ICI: ↓ Primary & secondary tumor volume ⁷		± ICI: Unchanged ⁷ ↑ T regs ⁷	4T1 & B16.F10-OVA
NO Donors 1,000's	Tumor growth inhibition ^{5,8}	↓ Antigen presentation by Dendritic cells (<i>in vitro</i>) ⁴		OT-II mouse model (4) & SCC VII (5)
	Tumor growth inhibition ⁶ ± Chemo: ↓ tumor volume/ Up to 20% survival (Day 60)	↓ Central memory T cells ⁶ ↑ T regs ⁶		LLC1, CT26 & B16F1

* Estimated ratio of maximum NO delivered intratumorally

1. [2023-10-30-SITC_Poster_Final.pdf \(beyondcancer.com\)](#)
2. Confino, H., Cancer Cell International: Gaseous nitric oxide tumor ablation. BMC; (2022) 22:405
3. Confino, H., Cells: Intratumoral Administration of High-Concentration Nitric Oxide. MDPI; 2023,12,2439
4. Markowitz, J., Scientific Reports: Nitric oxide mediated inhibition of antigen presentation from DCs to CD4+ T cells in cancer. Nature; (2017) 7: 15424
5. Scincinski, J., et al., Redox Biology. NO to cancer: The complex and multifaceted role of nitric oxide and the epigenetic nitric oxide donor, RRx-001. Redox Biology; (2015) vol 6:1-8
6. Li et al. J Exp Clin Cancer Res: Repurposing nitric oxide donating drugs in cancer therapy through immune modulation. BMC; (2023) 42-22
7. Kim, J, NATURECOMMUNICATIONS: Thermosensitive hydrogel releasing nitric oxide donor and anti-CTLA-4 micelles for anti-tumor immuno-therapy. Nature; (2022) 13:1479,
8. Ning S., Dinitroazetidines Are a Novel Class of Anticancer Agents and Hypoxia-Activated Radiation Sensitizers Developed from Highly Energetic Materials Volume 72, Issue 10

Improved Immunogenic Profile with UNO

Intra-Tumoral Effects	UNO Preclinical* (50k ppm NO, 5 minutes)	Nitric Oxide Donors ^{1^} SNAP: Nine doses (12 days)
T cells	↑ 50%	SNAP: ↓ 21%
Cytotoxic T cells		SNAP/ISMN: ↓ 15%
Ag Specific T cells	↑ 45%	
T Central Memory	↑ 29%	SNAP: ↓ 35%
T regs		SNAP: ↑ 38%

1. Li et al. J Exp Clin Cancer Res: Repurposing nitric oxide donating drugs in cancer therapy through immune modulation. BMC; (2023) 42-22

Notes: isosorbide mononitrate (ISMN), N-acetylpenicill-amine (SNAP)

* 4T1, Day 7

^ LL2, Day 9



UNO Clinical Data Corroborates Preclinical Observations

Scientific Advisory Board



Frederick M. Dirbas, MD

Assoc. Prof. of Surgery, Div. of Surgical Oncology,
Stanford University School of Medicine

- Internationally acclaimed surgeon and pioneer in the field of breast cancer
- Published nearly 50 articles in peer-reviewed journals



Mark D. Pegram, MD

Assoc. Dean for Clinical Research Quality,
Stanford University School of Medicine

- Suzy Yuan-Huey Hung Endowed Professor of Medical Oncology at the Stanford University School of Medicine
- Medical Director of the Stanford Clinical Translational Research Unit



Sunil J. Panchal, MD

President of the
National Institute of Spine and Pain

- Minimally invasive spine and interventional pain specialist
- Editorial reviewer for *Clinical Researcher*, *Anesthesia and Analgesia*, *Pain*, *Pain Medicine*, and the *Clinical Journal of Pain*
- Former Chair of National Comprehensive Cancer Network Pain Panel

Phase 1a Designed to Establish 3 Key Objectives

Primary Objectives:

1. Determine safety profile
2. Determine maximum tolerated dose (MTD) and/or optimal biologically effective dose (OBD)
3. Recommend Phase 2 dose (RP2D)

Secondary Objective: Anti-tumor activity of single intra-tumoral escalating UNO101 dose per RECIST v1.1, iRECIST

Exploratory Objectives: Biomarkers predictive of response via itRECIST

Major Eligibility Criteria

- ≥ 18 years of age
- ECOG PS 0 – 3
- Unresectable, cutaneous or SQ primary or metastatic tumor
- Measurable disease
- Tumor 4.5 mm – 30 mm

Part A: Dose Escalation
3 + 3 Scheme
Follow-up to Day 21
(Max N = 18)

Cohort 1: 25,000 ppm gNO over 5 minutes
(expansion to 6 patients)

Cohort 2: 50,000 ppm gNO over 5 minutes

Cohort 3: 100,000 ppm gNO over 5 minutes

MTD/OBD

Patient Characteristics – SITC

Data as of November 3, 2023

Baseline Characteristics	N (%)	Mean	Min	Max
Age (yrs.) (n=5)	5* (100%)	64.4	43	81
# of Prior Treatment Regimens	5 (100%)	5.8	2	12
Time from Diagnosis to First UNO Treatment (yrs.)	5 (100%)	4.7	1.4	9.5
Male/Female	2 (33.3%) / 4 (67.7%)	--	--	--
ECOG PS 0/1/2/3 (Day 1)	0 = 3 (40%) / 1 = 3 (60%) / -- / --	--	--	--
Diagnosis				
•Squamous cell carcinoma	2	--	--	--
•Melanoma	1			
•Breast	3			

*all patients treated with 25,000 ppm NO

System Organ Class	Adverse Event (Preferred Term)	Grade 1	Grade 2	Grade 3	Grade 4
Respiratory, thoracic and Mediastinal disorders	Dyspnea ¹ (Certainly related)	✓			
	Hypoxia ² (Possibly related)				✓
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysesthesia syndrome (Certainly related)	✓			
Gastrointestinal disorders	Nausea ¹ (Possibly related)	✓			

¹ Dyspnea and Nausea were all experienced by the same patient

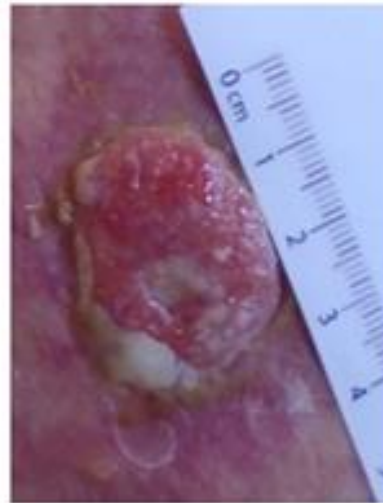
² IMO H causality assessment.

Case Report: Early Response Observed

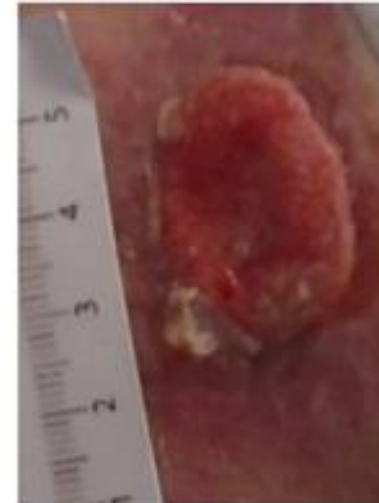
Data presented at the SITC Annual Meeting, November 2023

- 82 y/o male with history of squamous cell carcinoma: 2017 metastases to neck and back
- Received:
 - 2 prior surgeries
 - 2 prior lines of immunotherapy
 - 2 prior lines of chemotherapy/targeted therapy, and
 - 5 prior cycles of XRT.
- **Early response observed by Day 7 post UNO treatment**

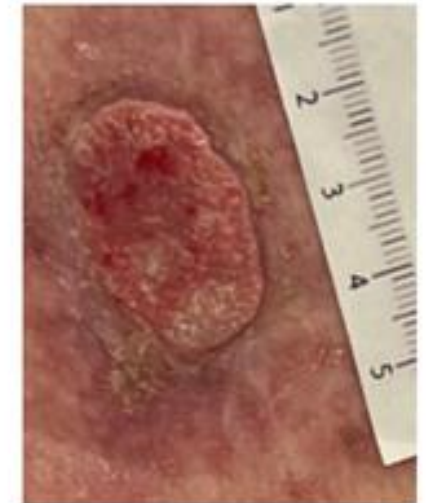
Treatment Day



Treatment Day +1



Treatment Day +7



Interim Phase 1a Biomarker Results Correlate with Preclinical Data

Systemic Effects	UNO Clinical ¹	UNO Preclinical ²	Nitric Oxide Donors ³
Cytotoxic T cells	↑ 5%	↑ 14%	N/S
Helper T cells		↑ 34%	N/S
Ag Specific T cells		↑ 400%	N/S
T Central Memory	↑ 84% ↑ 167% (day 21)	↑ 161% (100k ppm NO)	
Dendritic cells	↑ 59% ↑ 280% (day 21)	↑ 112% (day 5)	↓ Antigen presentation (<i>in vitro</i>) ⁴
T regs	↓ 36% ↓ 40% (day 21)	↓ 38% (day 3) ↓ 78% (day 5)	N/S

UNO Clinical: 25k ppm UNO101, 5 minutes, Day 7 data (unless otherwise noted)
 UNO Preclinical: 50k ppm UNO101, 5 minutes, CT26 model, Day 7 data (unless otherwise noted)
 NO Donor: GSNO, Three doses / 5 days, B16.F10-OVA, Day 6 data

1. 2023-10-30-SITC_Poster_Final.pdf (beyondcancer.com)

2. <https://beyondcancer.com/wp-content/uploads/2023/10/MOA-poster-EORTC-vFinal-5.pdf>

3. Kim, J, NATURE COMMUNICATIONS: Thermosensitive hydrogel releasing nitric oxide donor and anti-CTLA-4 micelles for anti-tumor immuno-therapy. Nature; (2022) 13:1479

4. Markowitz, J., Scientific Reports: Nitric oxide-mediated inhibition of antigen presentation from DCs to CD4+ T cells in cancer. Nature; (2017) 7: 15424

UNO is Well Tolerated and Demonstrated Proof of Concept

- Local administration of UNO is **well tolerated** in the initial cohort
- **Immune biomarkers** compare favorably to previously published murine data
- **Demonstrated proof of concept with** early response observed on Day 7 in a heavily pretreated squamous cell carcinoma
- Next Steps:
 - Advance to subsequent trial cohort
 - Combine with Immune Checkpoint Inhibitors (ICIs)
 - Introduce repeat dosing

Low Volume Study: Primary Tumor Results

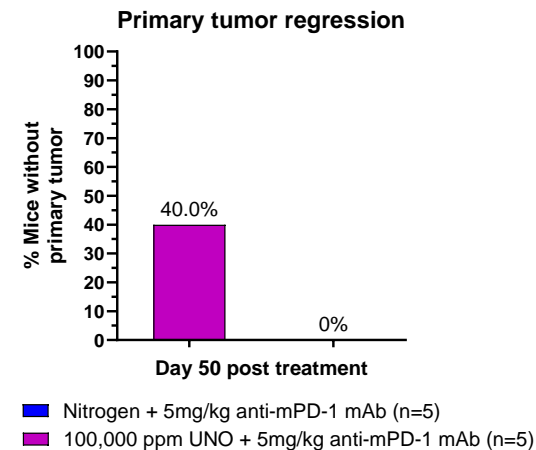
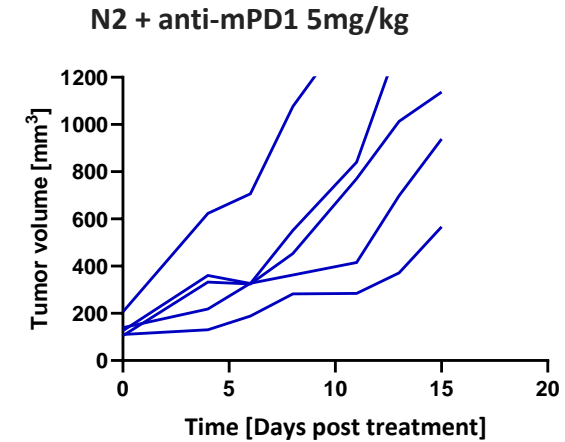
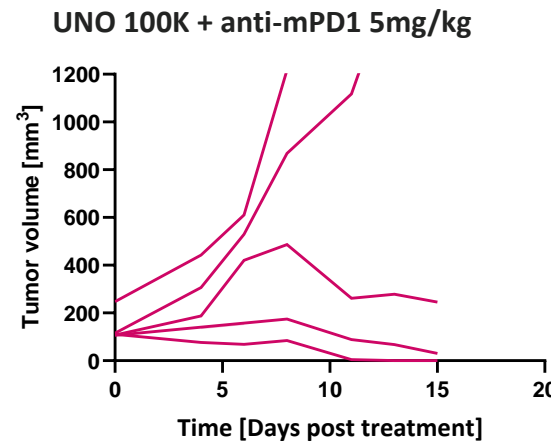
Tumor Shrinkage is seen in 3/5 tumors in UNO combo arm vs. 0/5 in N₂ combo arm at Day 15

Experimental Conditions

- 100,000 ppm NO + anti-mPD1 vs. N₂ + anti-mPD-1 (5mg/kg)
- Treatment time: 2.5 min

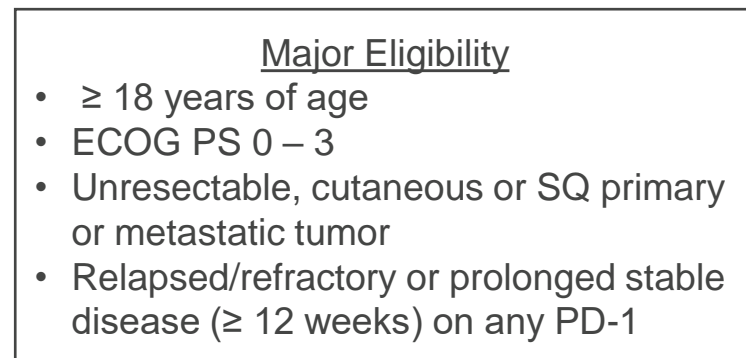
Results

- 40% of UNO-treated tumors regressed through Day 50
- No safety events



Proposed Design: Phase 1b BC-ONC-01

Hypothesis: Can UNO therapy convert “cold tumor” → “hot tumor”



Phase 1b (Low Volume) (n=20)



Primary Objective: To assess preliminary efficacy by objective response rate (ORR) and duration of response (DOR) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, and secondarily immune-related RECIST (iRECIST).

Secondary Objectives: To assess progression free survival (PFS) and overall survival (OS), clinical benefit rate (CBR: CR+PR+SD ≥ 6 months), time to response (TTR) by RECIST and iRECIST, and incidence and severity of non-serious adverse events, including immune related adverse events (irAEs).

Exploratory Objectives: To assess biomarkers that may be predictive of anti-tumor activity of an intratumoral UNO201 injection.

UNO Device Development



UNO Delivery
System



Future State
(Alpha Prototype)

Features:

Portable

Minimal User Interaction

Safety Enhancements: NO extraction/Scrub/Stop Switch

Integrated System

Precise Single-Use

Upcoming Catalysts

Timing	Milestone
2023	<ul style="list-style-type: none">✓ Present Initial Phase 1a Data✓ Additional Preclinical Data Presentations✓ Publication of Additional Manuscript in Major Scientific Journal✓ Additional Patent Issuance and Filings
2024	<ul style="list-style-type: none">■ Series B Financing■ Present Final Phase 1a Data■ Initiate Phase 1b Study■ Present Interim Phase 1b Data■ Pre-IND Filing
2025	<ul style="list-style-type: none">■ Present Final Phase 1b Data■ IPO■ U.S. IND Approval■ Initiate Phase 2 Study

Forward Looking Statements

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Contact



Investor Relations

IR@beyondcancer.com

Matt Johnson
mjohnson@beyondcancer.com
516-497-0531