



**BEYOND  
CANCER™**

Next level immuNO-oncology

**Corporate Presentation**

ASCO

May 31, 2024

# Forward Looking Statements

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Information contained herein contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities and Exchange Act of 1934, as amended. Any statements that express or involve discussions with respect to predictions, expectations, beliefs, plans, projections, objectives, goals, assumptions or future events or performance are not statements of historical facts and may be "forward looking statements". Forward looking statements are based on expectations, estimates and projections at the time the statements are made that involve a number of risks and uncertainties which could cause actual results or events to differ materially from those presently anticipated. Forward looking statements may be identified through the use of words such as "expects", "will", "anticipates", "estimates", "believes", or by statements indicating certain actions "may", "could", "should" or "might" occur.

# Agenda

- |                       |  |
|-----------------------|--|
| <b>6:00 – 6:15 pm</b> | Check-in and Refreshments  |
| <b>6:15 – 6:30 pm</b> | Introductions/Phase 1a (Dr. Monson, Beyond Cancer CMO)                   |
| <b>6:30 – 6:40 pm</b> | UNO101 Clinical Case Series (Dr. Meirovitz, Study Investigator)          |
| <b>6:40 – 6:50 pm</b> | UNO101 Clinical Data Review (Dr. Chaisson, Beyond Cancer CEO)            |
| <b>6:50 – 7:00 pm</b> | Next Clinical Steps (Dr. Chaisson, Beyond Cancer CEO)                    |
| <b>7:00 – 7:10 pm</b> | Unmet Need (Dr. Monson + Dr. Fred Dirbas, Dr. Mark Pegram, Stanford SAB) |
| <b>7:10 – 8:00 pm</b> | Q&A + Meet & Greet   |



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# Introductions/Phase 1a

Dr. Jedidiah Monson  
Chief Medical Officer, Beyond Cancer

# Biographies



**JEDD MONSON, MD, DABR**

Chief Medical Officer; Founding partner of cCare, the largest private practice oncology group in the state of California, which merged with ION Integrated Oncology Network (ION) in April 2022.



**AMICHAY MEIROVITZ, MD**

Principal Investigator; Chairman of the Oncology Department at Soroka University Medical Center, Professor of Oncology at Ben Gurion University of the Negev in Israel. Specialist in Oncology, Radiation Oncology, and Internal Medicine.



**FREDERICK M. DIRBAS, MD**

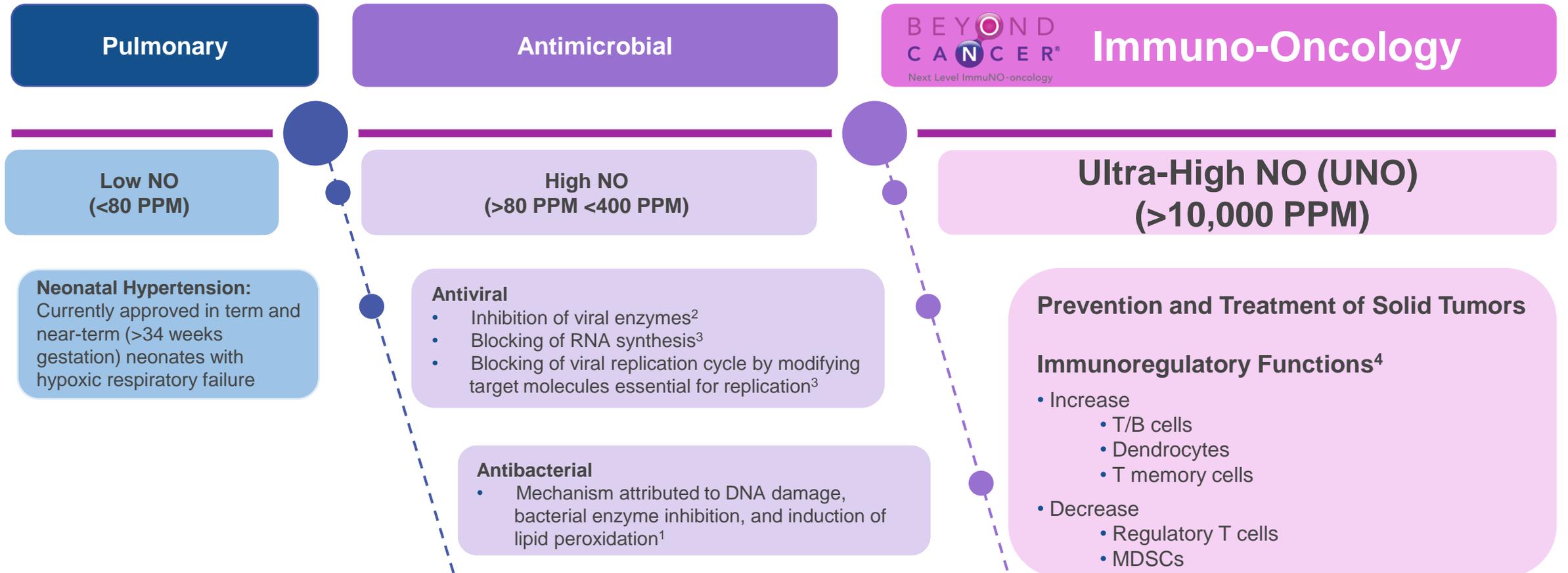
Associate Professor of Surgery, Division of Surgical Oncology, Stanford University School of Medicine. Vice Chair of the Society of Surgical Oncology (SSO) Breast Disease Site Work Group.



**MARK D. PEGRAM, MD**

Associate Dean for Clinical Research Quality and Suzy-Yuan-Huey Hung Endowed Professor of Medical Oncology, Stanford University School of Medicine; Medical Director of the Stanford Clinical Translational Research Unit.

# 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)

# 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<sup>1</sup>**
- 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 UNO101  
over 5 minutes  
(voluntary expansion to 6 patients)

**Cohort 2:** 50,000 ppm UNO101  
over 5 minutes  
(expansion to 6 patients)

**Cohort 3:** 100,000 ppm UNO101  
over 5 minutes

**MTD/OBD**

# Patient Characteristics

## Heavily Pre-Treated Population

Baseline Characteristics (N=9)	N (%)	Mean	Min	Max
Age (yrs.)		60.1	34	81
<b># of All Prior Treatments (Medications, Surgeries, Radiation, etc.)</b>		<b>10.8</b>	<b>5</b>	<b>18</b>
Time from Diagnosis to First UNO Treatment (yrs.)		5	1.4	9.5
Male/Female	3 (33.3%) / 6 (67.7%)	--	--	--
ECOG PS 0/1/2/3 (Day 1)	0 = 4 (44.4%) / 1 = 5 (55.6%) / - / -	--	--	--
Diagnosis				
• Squamous cell carcinoma	2 (22.2%)			
• Melanoma	2 (22.2%)	--	--	--
• Breast Cancer	3 (33.3%)			
• Triple Negative Breast	2 (22.2%)			

Cohort 1 = 25,000 ppm UNO (n=6); Cohort 2 = 50,000 ppm UNO (n=3)

# Treatment Related Adverse Events

## Mostly Grade 1

Cohort	Grade 1	Grade 3	Grade 4
25,000 ppm	Palmar-plantar erythrodysesthesia syndrome		
	Sub-cutaneous emphysema		
	Oxygen saturation decreased, dyspnea, nausea*		
			Hypoxia^
50,000 ppm	Hypotension, local subcutaneous emphysema		
	Oxygen saturation decreased <sup>1</sup> , fatigue, nausea, dizziness		
	Subcutaneous emphysema	Vasovagal <sup>#</sup>	

Notes:

\*Patient had 3.2L of fluid drained from lungs 1 week prior to treatment. Left Local vocal cord paralysis and pleural effusion were reported as adverse events that occurred during screening; deemed unrelated in 25,000 ppm Cohort

^Declared not DLT per protocol criteria by Safety Review Committee

<sup>#</sup>Declared as DLT per protocol criteria by the Safety Review Committee

<sup>1</sup>Not yet adjudicated



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# UNO101 Clinical Case Series

Dr. Amichay Meirovitz  
Clinical Investigator, Beyond Cancer

# 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 in anti-PD-1 + VEGF inhibitor failure**

# Case Report: Resolution of Radiation Dermatitis with Single Dose of UNO

- 34 y/o female with TNBC originally diagnosed in 2018
- Received:
  - 3 surgeries
  - 2 cycles of immunotherapy
  - 2 cycles of XRT



**Baseline**



**Day 1**



**Day 7**



**Day 21**

- Evidence of resolution of radiation dermatitis seen as early as Day 1
- Treated lesion showed dramatically lower proliferative index at Day 21 with no evidence of malignancy in the satellite lesion
- Increases in M1 macrophages and decreases in Tregs observed on Day 7



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# UNO101 Clinical Data Review

Dr. Selena Chaisson, CEO Beyond Cancer

# Systemic Murine Biomarker Response Following UNO Treatment

↑ CM T cells (increase: 160%)

↑ Dendritic cells (increase: 112%)

↑ T cells (increase: 31-37%)

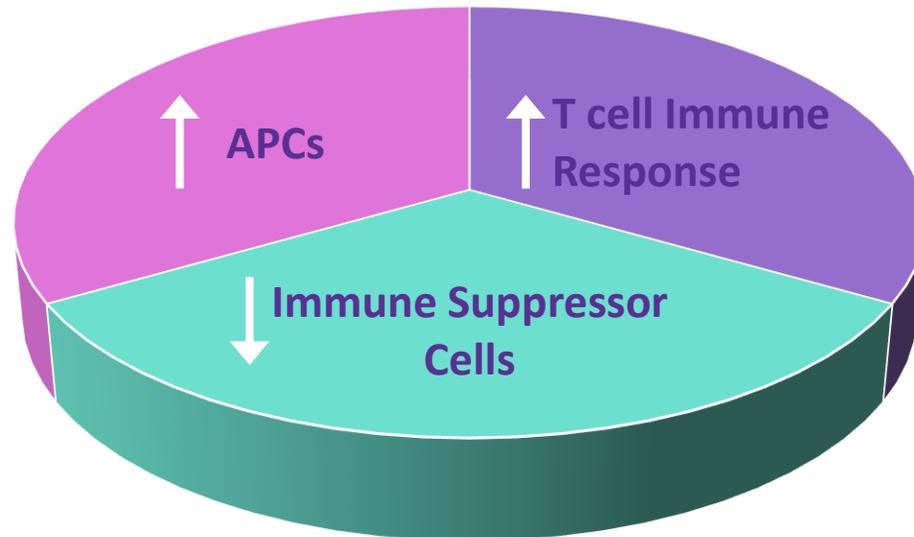
UNO

Day 0

Day 5-7

Day 21

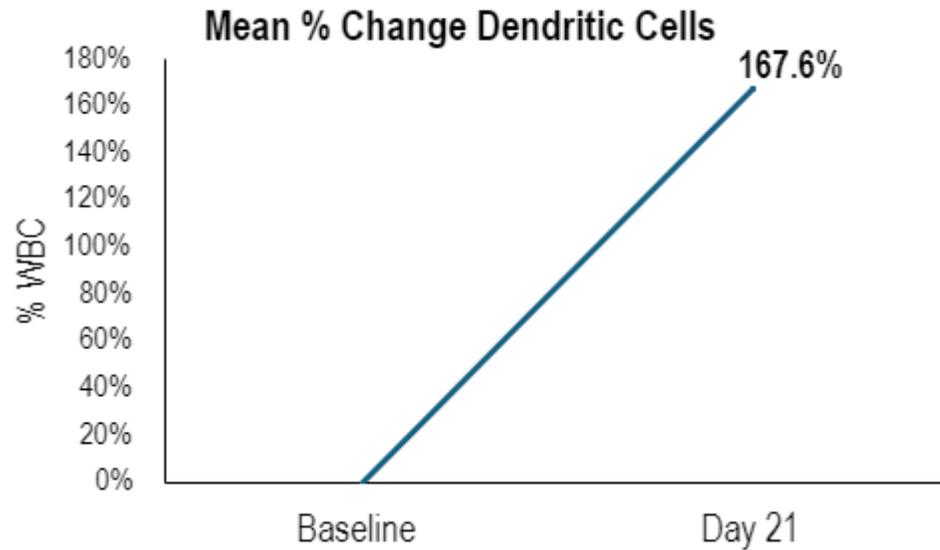
↓ pMDSCs (decrease: 15-19%)



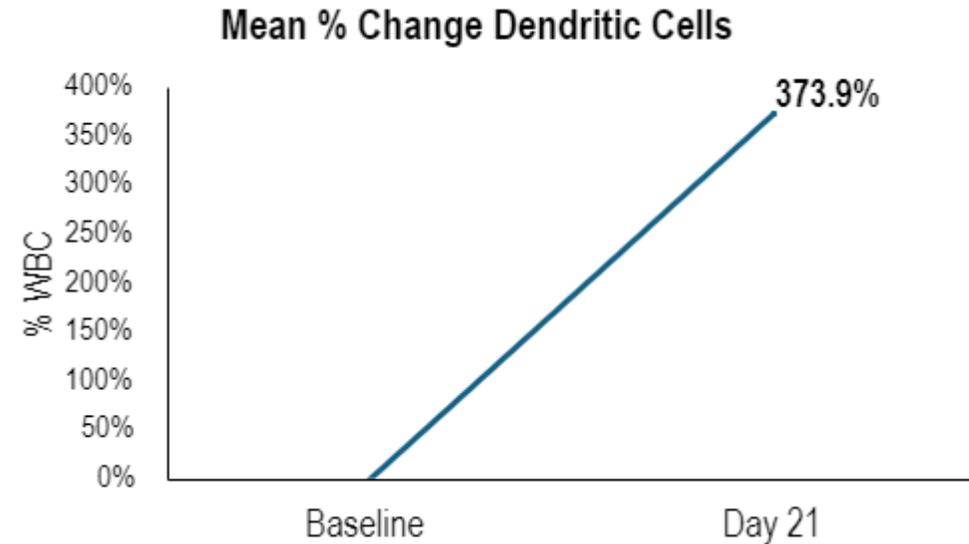
# Dendritic Cells

## Large, Durable Increases in Dendritic Cells

25,000 ppm (n=5)



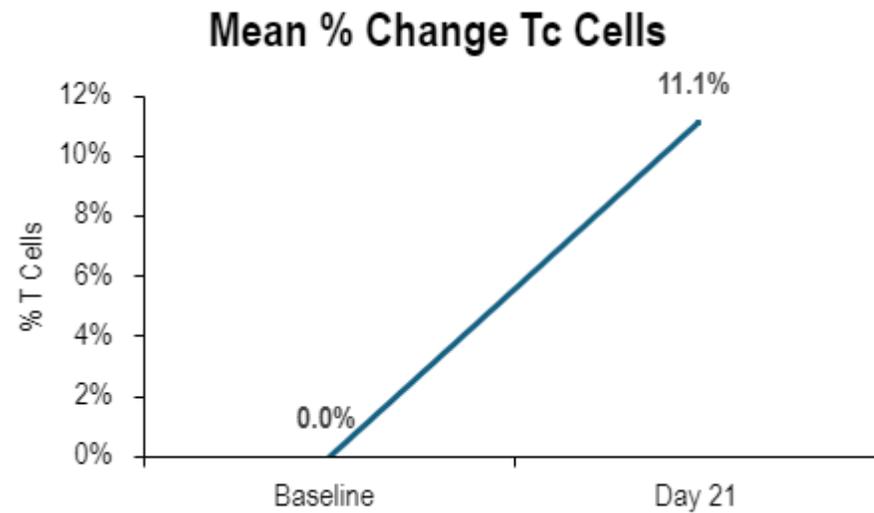
50,000 ppm (n=3)



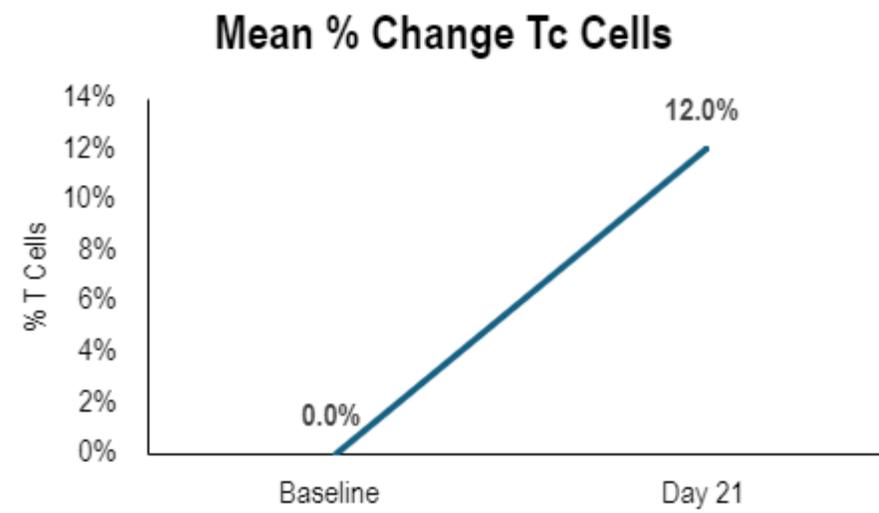
# Cytotoxic T-Cells

## Consistent Increases in Cytotoxic T-Cells

25,000 ppm (n=5)



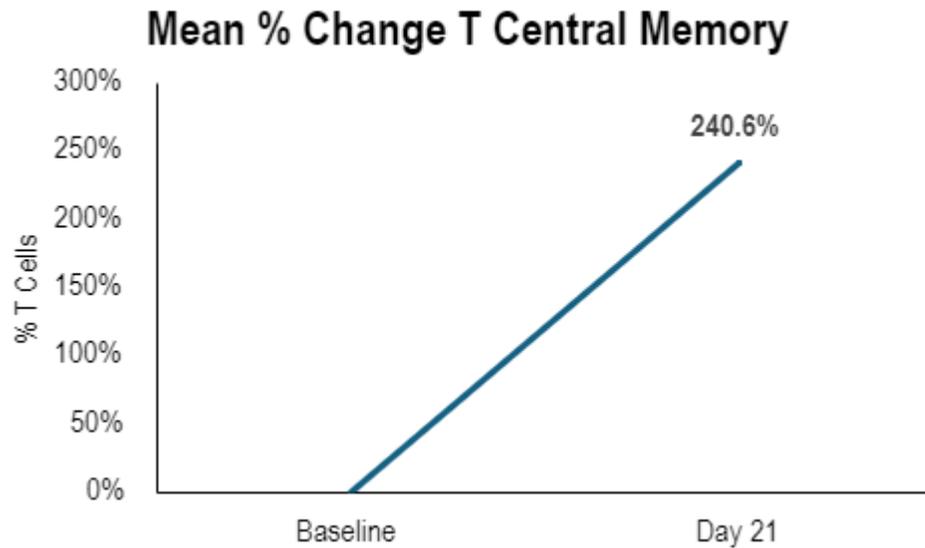
50,000 ppm (n=3)



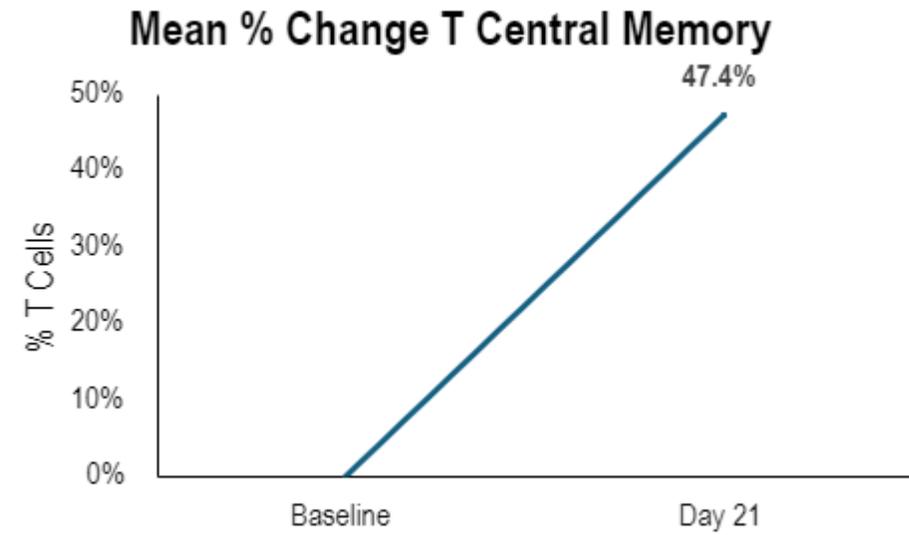
# T Central Memory

## Durable Increases in Central Memory T-Cells

25,000 ppm (n=5)

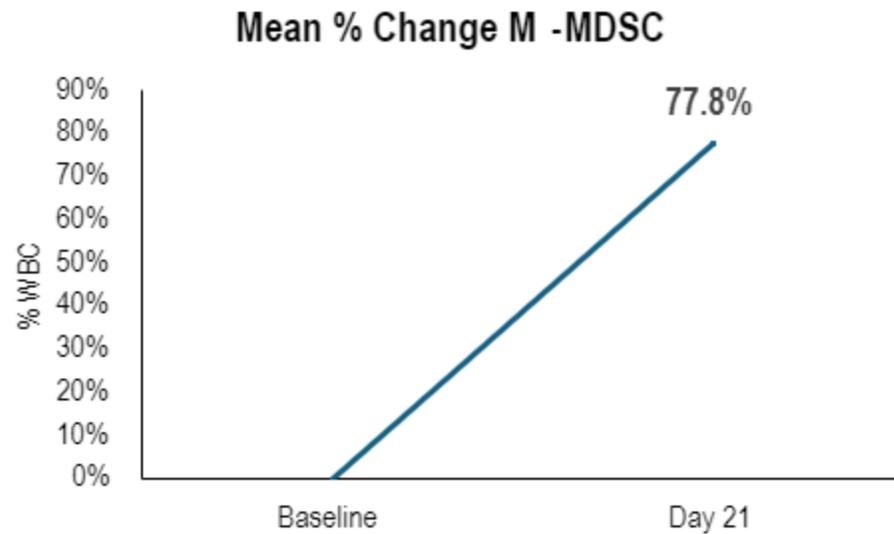


50,000 ppm (n=3)

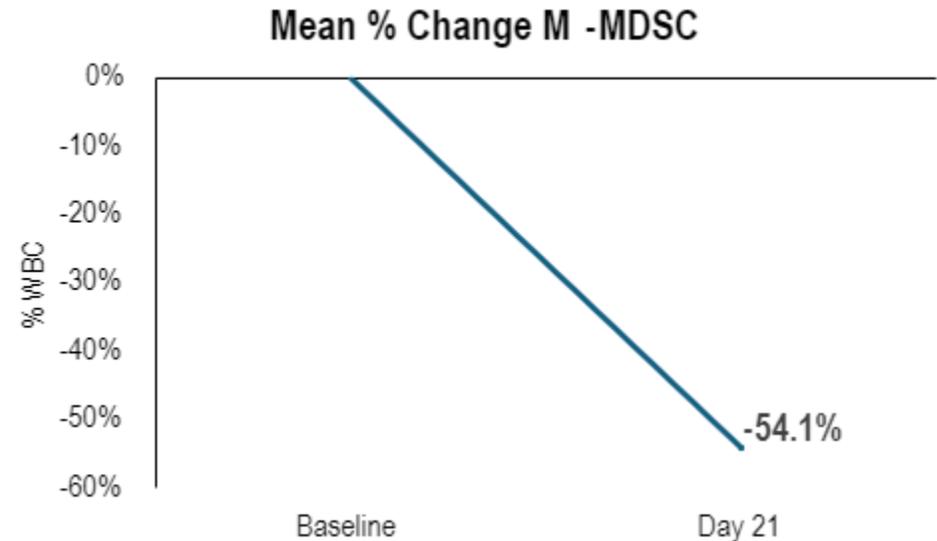


## Large Reductions in MDSCs at 50,000 ppm UNO

25,000 ppm (n=5)

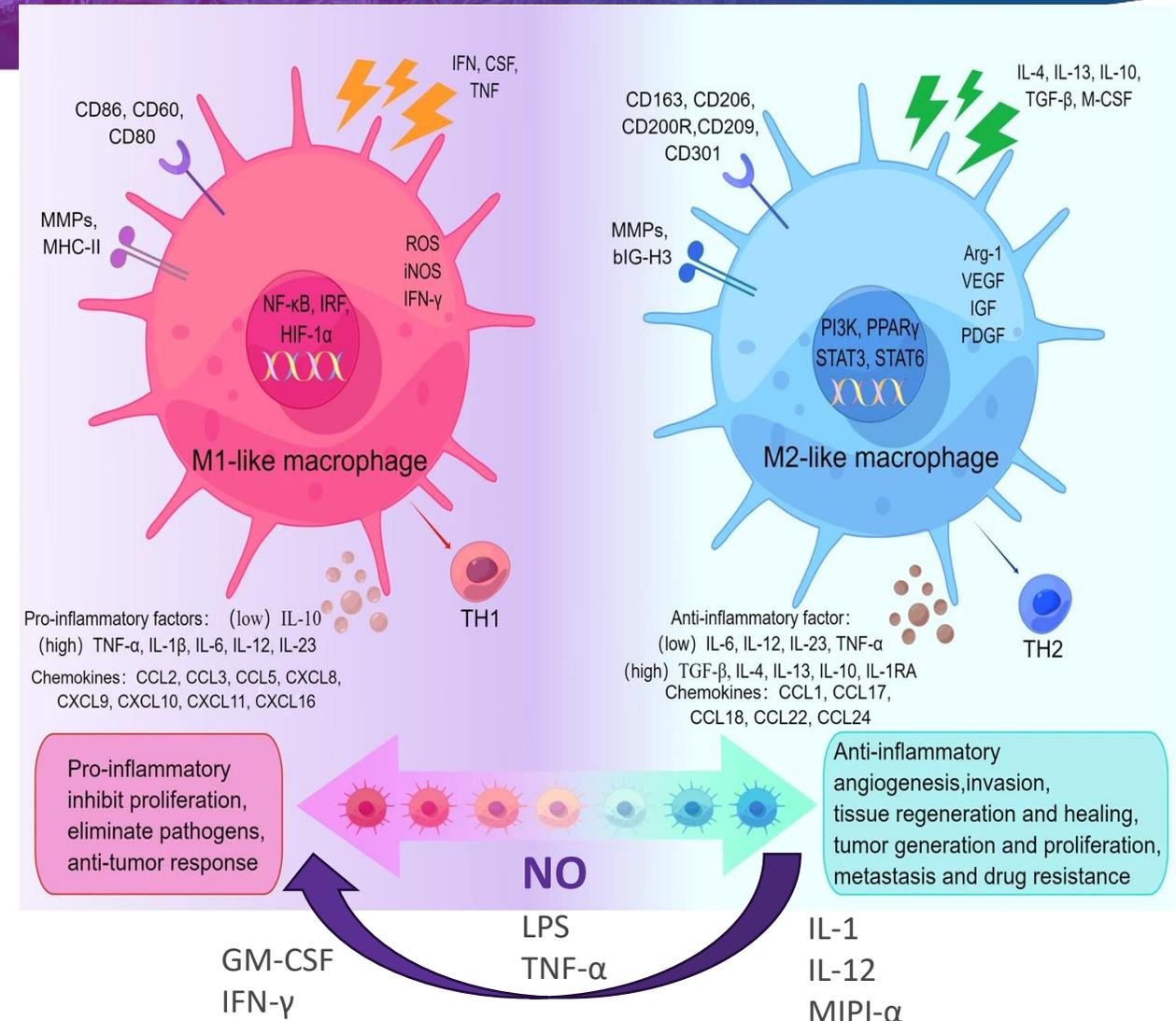


50,000 ppm (n=3)



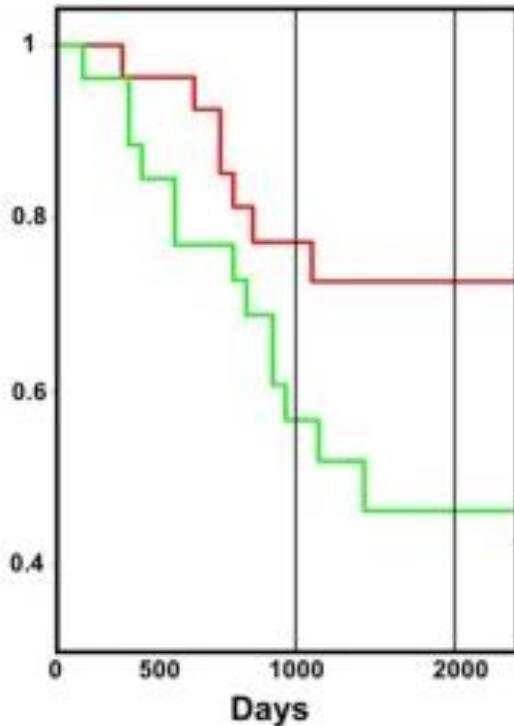
# M2→M1 Macrophage Re-Polarization

- M1 Macrophages are Anti-Tumor while M2 Macrophages are Tumorigenic
- M2 Macrophages can Re-Polarize to M1 Increasing the M1/M2 Ratio
- NO is a Potent Inflammatory Cytokine that Re-Polarizes Macrophages



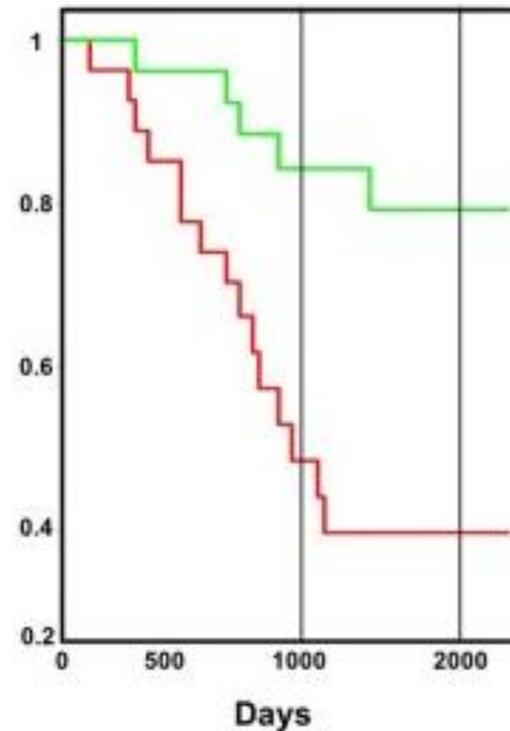
# M1/M2 Gene Expression Correlated with Survival in Certain Cancers – ex. Osteosarcoma

M1 Gene Expression



HR: 0.02 (0-0.42)  
P-Value: 0.0131

M2 Gene Expression



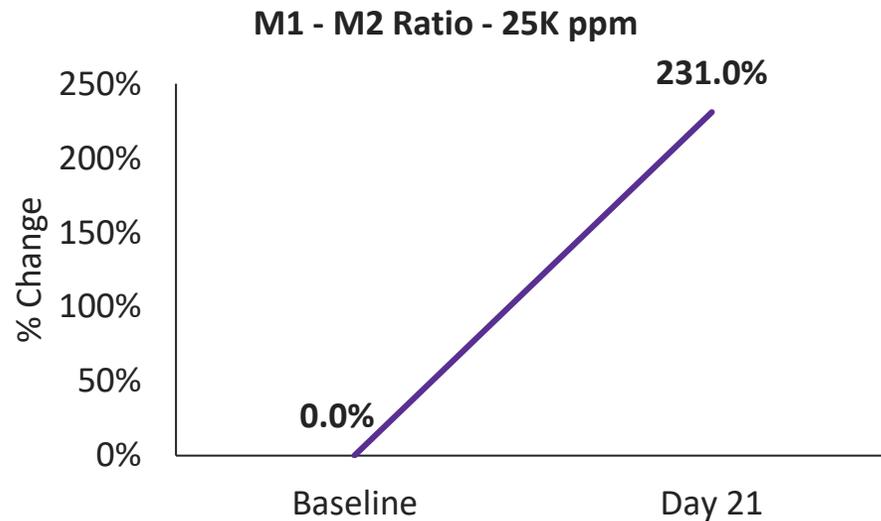
HR: 754.07 (12.2-45515.9)  
P-Value: 0.0016

 = High Expression  
 = Low Expression

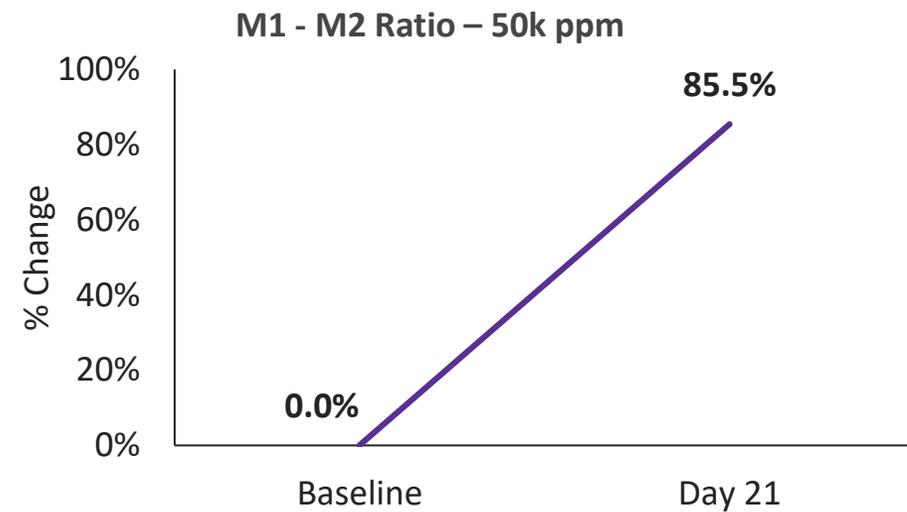
# M1-M2 Ratio

## Favorable Impact on M1/M2 Ratio in UNO Treated Patients

25,000 ppm (n=5)



50,000 ppm (n=3)



Note: n=5 in 25k ppm cohort – % change via geometric mean,  
n=3 in 50k ppm cohort average % change  
Calculated via systemic measurement of M1 and M2 reported values as a % of macrophages

# Key Takeaways From Interim Phase 1a Analysis

- Local administration of UNO is **well tolerated**
- **Immune biomarkers** show upregulation of T-cells, Dendritic cells, T-Central Memory cells, and M1/M2 ratio
- **MDSCs** are suppressed at 50,000 ppm
- Complete **resolution of radiation dermatitis** observed from a single infusion of UNO
- Demonstrated **proof of concept with early responses** observed in a heavily pretreated population
- Next Clinical Steps:
  - **Advance to Phase 1b in combination with Immune Checkpoint Inhibitors (ICIs)**



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# Next Clinical Steps

Dr. Selena Chaisson, CEO Beyond Cancer

# Can we Achieve the Same Efficacy Using <1L of UNO?

## Advantages of Low Volume vs High Volume Method

- Reduce or eliminate potential risk of methemoglobinemia  
Nitric Oxide can bind to hemoglobin to produce methemoglobin
- Reduce or eliminate potential risk of air embolism
- Reduce or eliminate need for gas-related safety equipment  
Personal Protective Equipment, fume extractors, NO/NO<sub>2</sub> gas detectors

# Low Volume Pilot Study: Primary Tumor Results

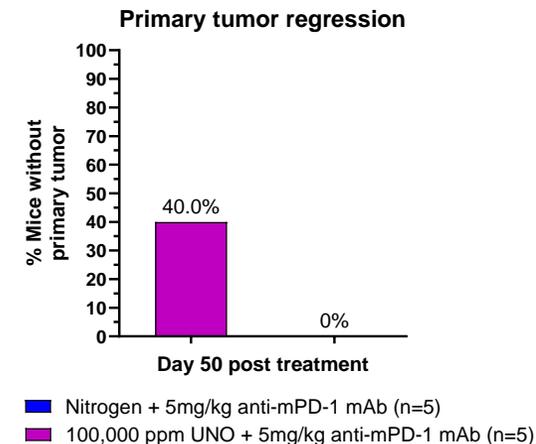
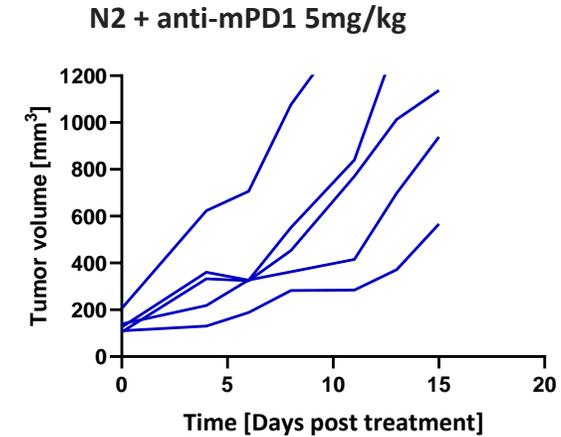
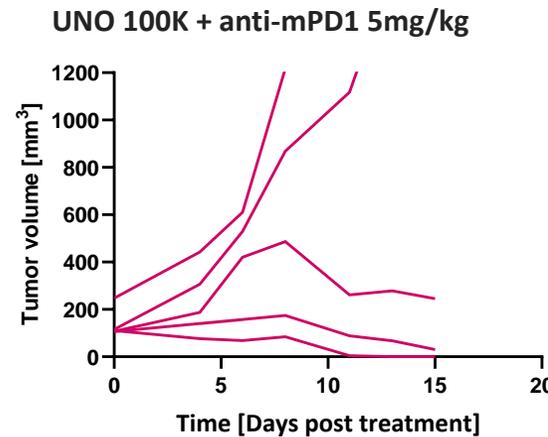
Tumor Shrinkage is seen in 3/5 tumors in UNO combo arm vs. 0/5 in N<sub>2</sub> combo arm at Day 15

## Experimental Conditions

- 100,000 ppm NO + anti-mPD1 vs. N<sub>2</sub> + anti-mPD-1 (5mg/kg)
- Treatment time: 2.5 min

## Results

- 60% of UNO treated tumors initially regressed
- 40% of UNO-treated tumors regressed through Day 50
- No safety events

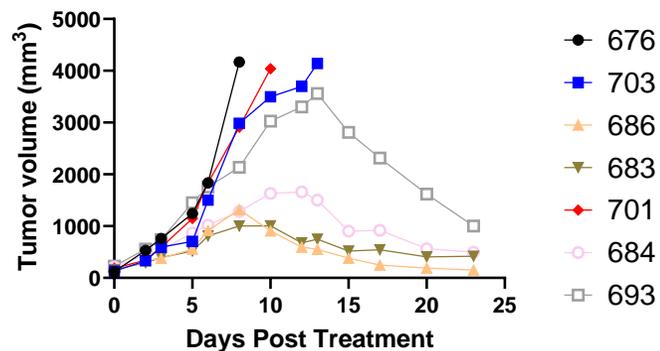


# Low Volume Validation Study in Rat Model

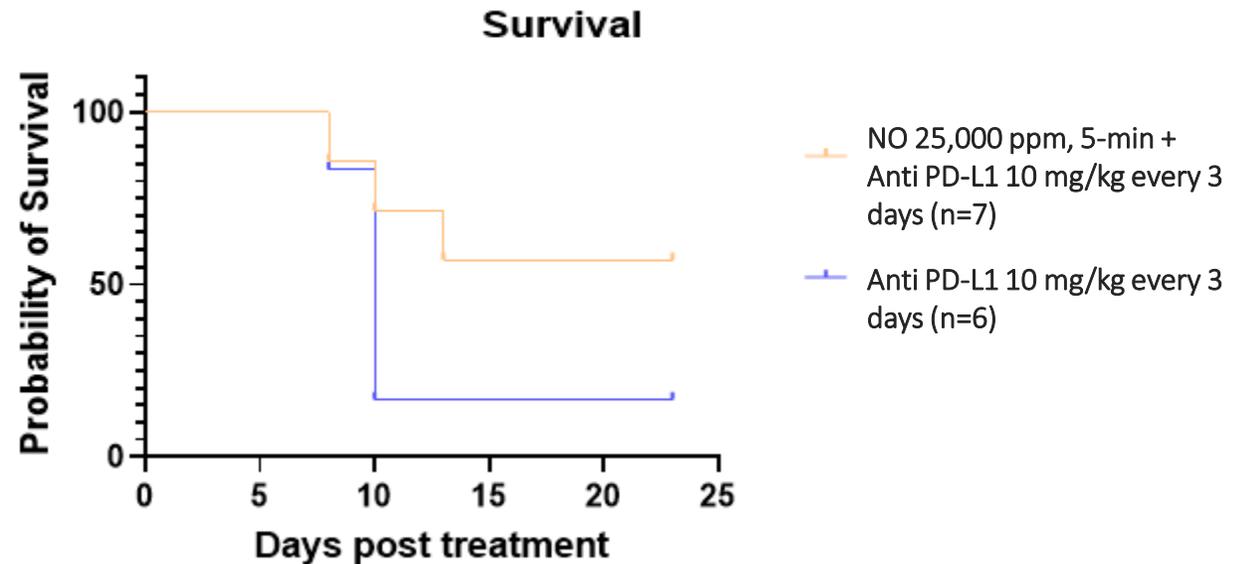
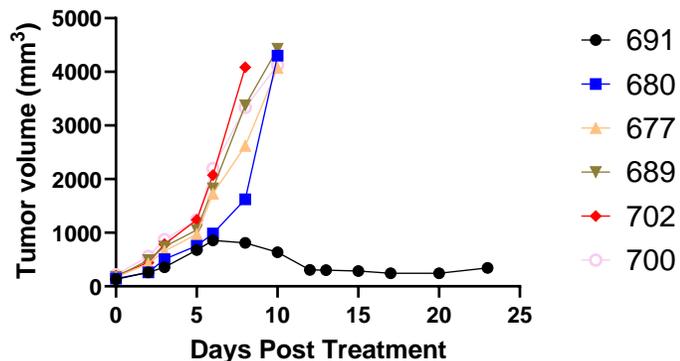
Tumor reduction in 4/7 tumors with UNO combo vs. 1/5 with Anti PD-L1

Day 23 survival advantage validates UNO's efficacy in a new animal species and tumor model

UNO + anti PD-L1 individual plots

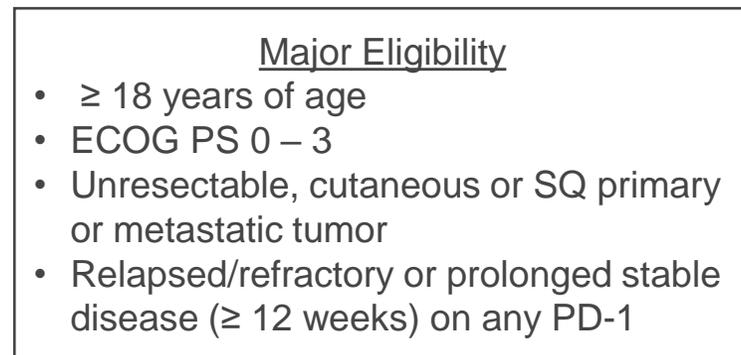


Anti PD-L1 individual plots

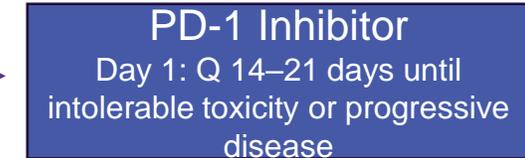
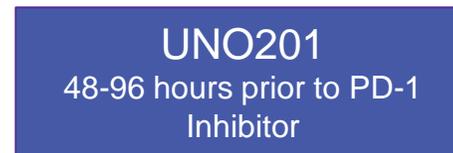


# Proposed Design: Phase 1b BC-ONC-01

**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.

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

## Upregulates Immune Activity

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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

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

## Combination Therapy

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

## Patented Delivery Approach

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



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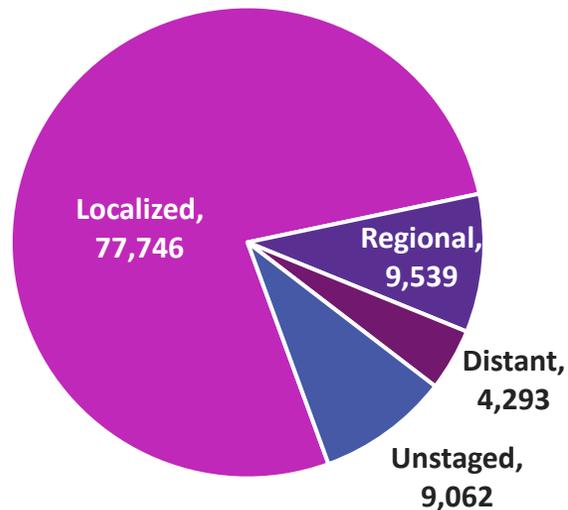
# Unmet Medical Need & Market Opportunity

Dr. Jedidiah Monson

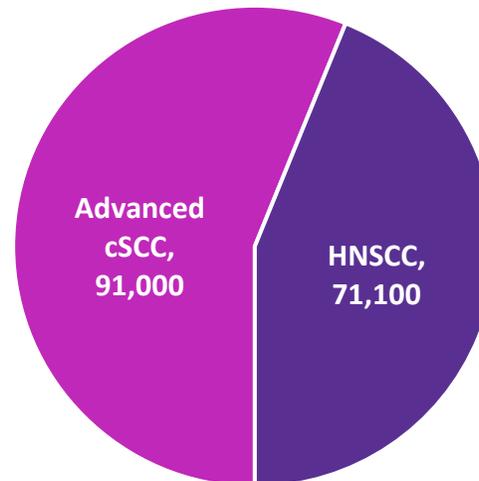
# UNO Cutaneous/Near Cutaneous Tumors

## PD-1/PD-L1 Approved Indications

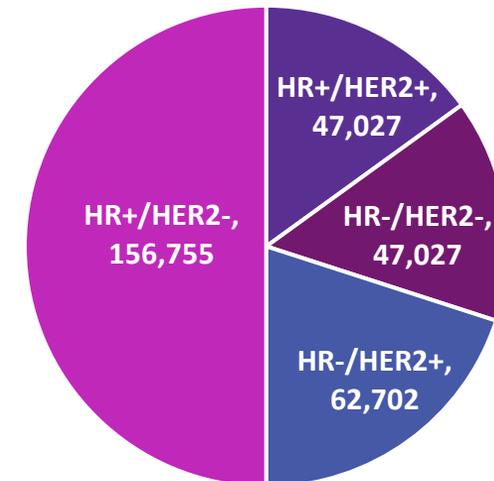
**Malignant Melanoma**  
100,640 Annual Cases



**Skin + Head & Neck Cancers**  
162,100 Annual Cases



**Breast Cancer**  
313,510 Annual Cases



**Solid Tumors** represent approximately 90% of adult human cancers<sup>1</sup>  
**Metastatic Disease** is responsible for 90% of solid tumor deaths<sup>2</sup>

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/>

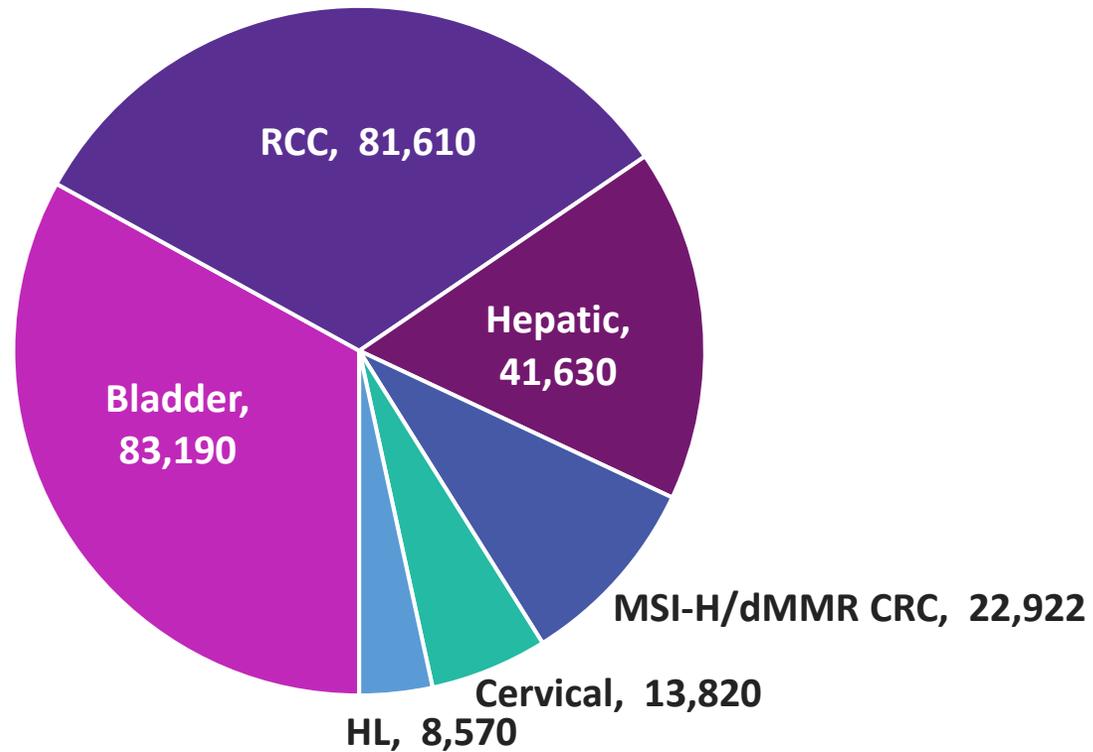
2) Fontebasso Y, Dubinett SM. Drug Development for Metastasis Prevention. Crit Rev Oncog. 2015;20(5-6):449-473. doi:10.1615/CritRevOncog.v20.i5-6.150

Chart Sources: According to the National Cancer Institute: <https://www.cancer.gov/types/common-cancers>. Accessed: May 23, 2024. Data as of January 17, 2024, *Our New Approach to a Challenging Skin Cancer Statistic*. The Skin Cancer Foundation. <https://www.skincancer.org/blog/our-new-approach-to-a-challenging-skin-cancer-statistic/>. Accessed May 23, 2024. Garcia-Foncillas J, Tejera-Vaquerizo A, Sanmartín O, Rojo F, Mestre J, Martín S, Azinovic I, Mesía R. Update on Management Recommendations for Advanced Cutaneous Squamous Cell Carcinoma. Cancers (Basel). 2022 Jan 27;14(3):629. doi: 10.3390/cancers14030629. PMID: 35158897; PMCID: PMC8833756. [SEER Cancer Stat Facts](#). Beyond Cancer, Inc. Research

# UNO Internal Tumors

## PD-1/PD-L1 Approved Indications

251,742 Annual Cases

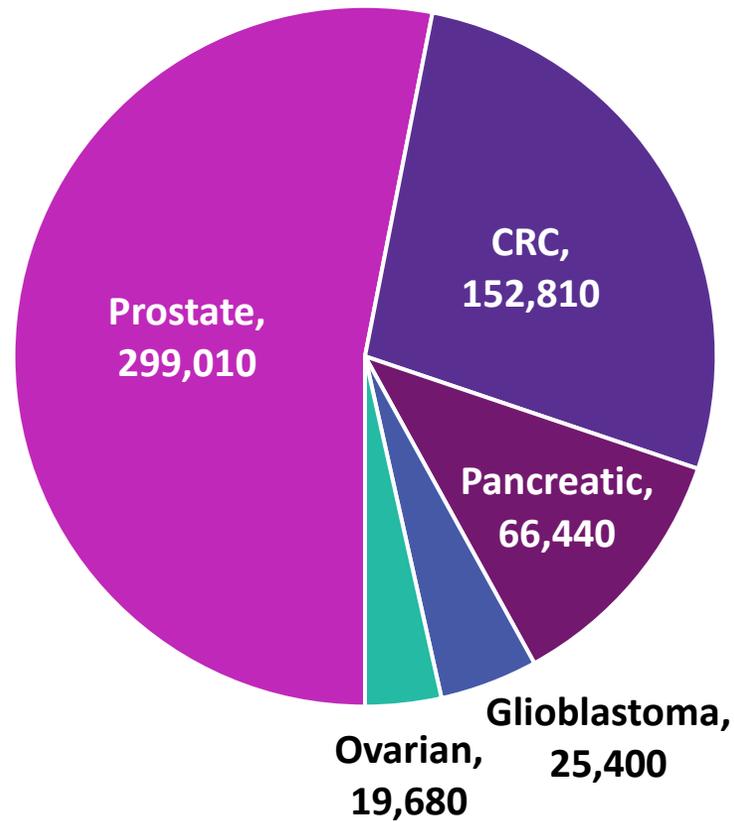


Sources: According to the National Cancer Institute: <https://www.cancer.gov/types/common-cancers>. Accessed: May 23, 2024.  
Data as of January 17, 2024, [SEER Cancer Stat Facts](https://doi.org/10.1038/s41571-020-00464-y), <https://doi.org/10.1038/s41571-020-00464-y>. Beyond Cancer, Inc. Research

# UNO Internal Tumors

## Unapproved PD-1/PD-L1 Indications

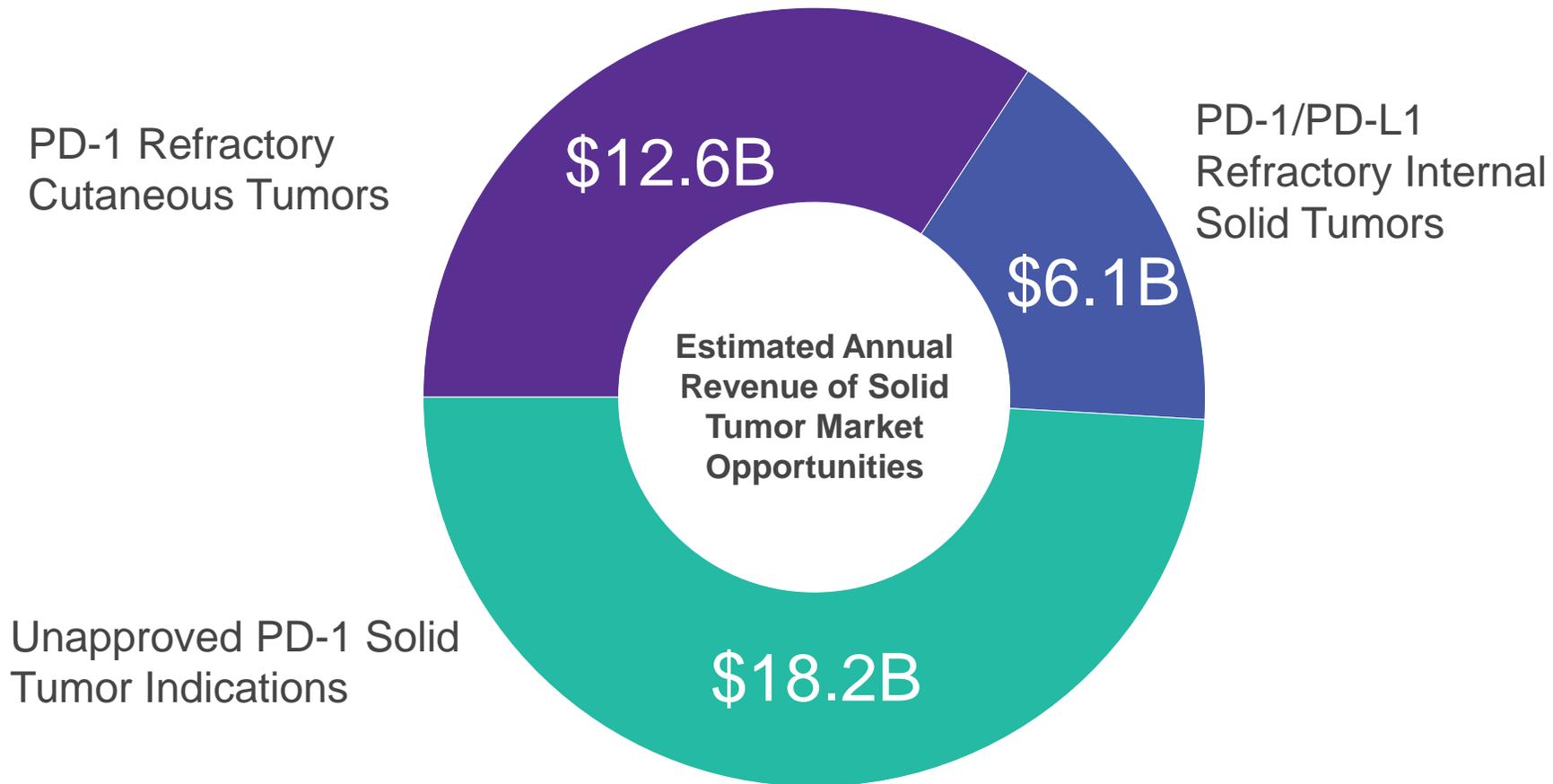
563,340 Annual Cases



Sources: According to the National Cancer Institute: <https://www.cancer.gov/types/common-cancers>. Accessed: May 23, 2024.  
Data as of January 17, 2024, [SEER Cancer Stat Facts](#). Beyond Cancer, Inc. Research

# Commercial Opportunity

*UNO + anti-PD-1 / PD-L1*



# Contact



## Investor Relations

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[IR@beyondcancer.com](mailto:IR@beyondcancer.com)

## Business Development

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