

Research and Development Day  
July 25, 2024



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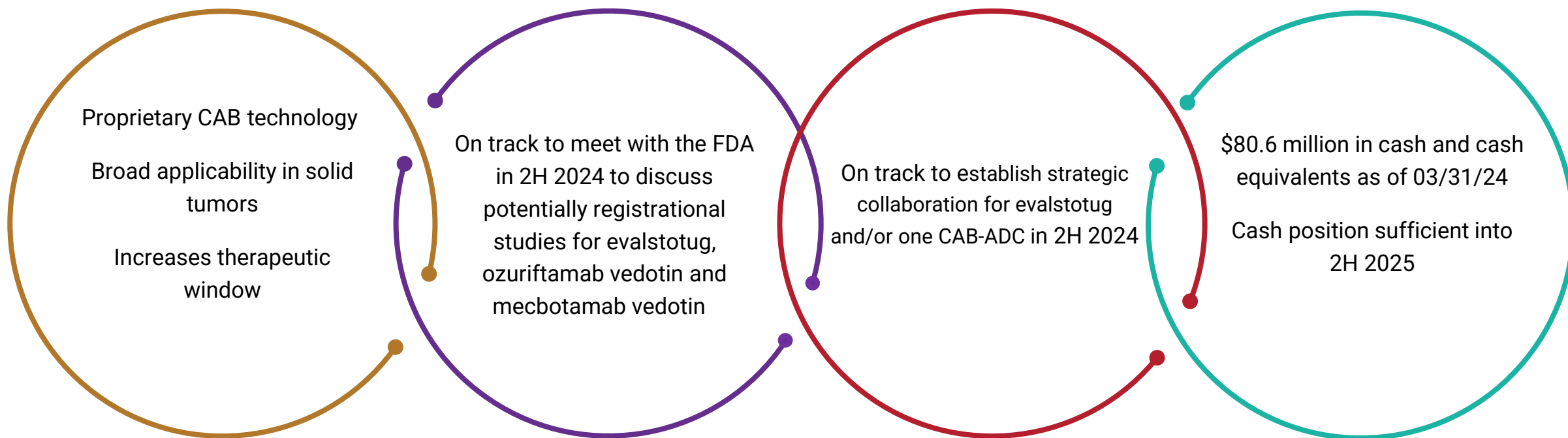
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# BioAtla<sup>®</sup> Is A Clinical Stage Company Focused On Transforming Cancer Therapy with **Conditionally Active Biologics (CABs)**



# Agenda



**Opening Remarks**



**Mecbotamab Vedotin (CAB-AXL-ADC)**



**Evalstotug (CAB-CTLA-4)**

# CAB Technology Widens Therapeutic Index

Selective and targeted to enhance clinical outcomes in multiple tumor types



Acidic pH at the cancer cell surface unveils binding sites that are shielded at normal pH



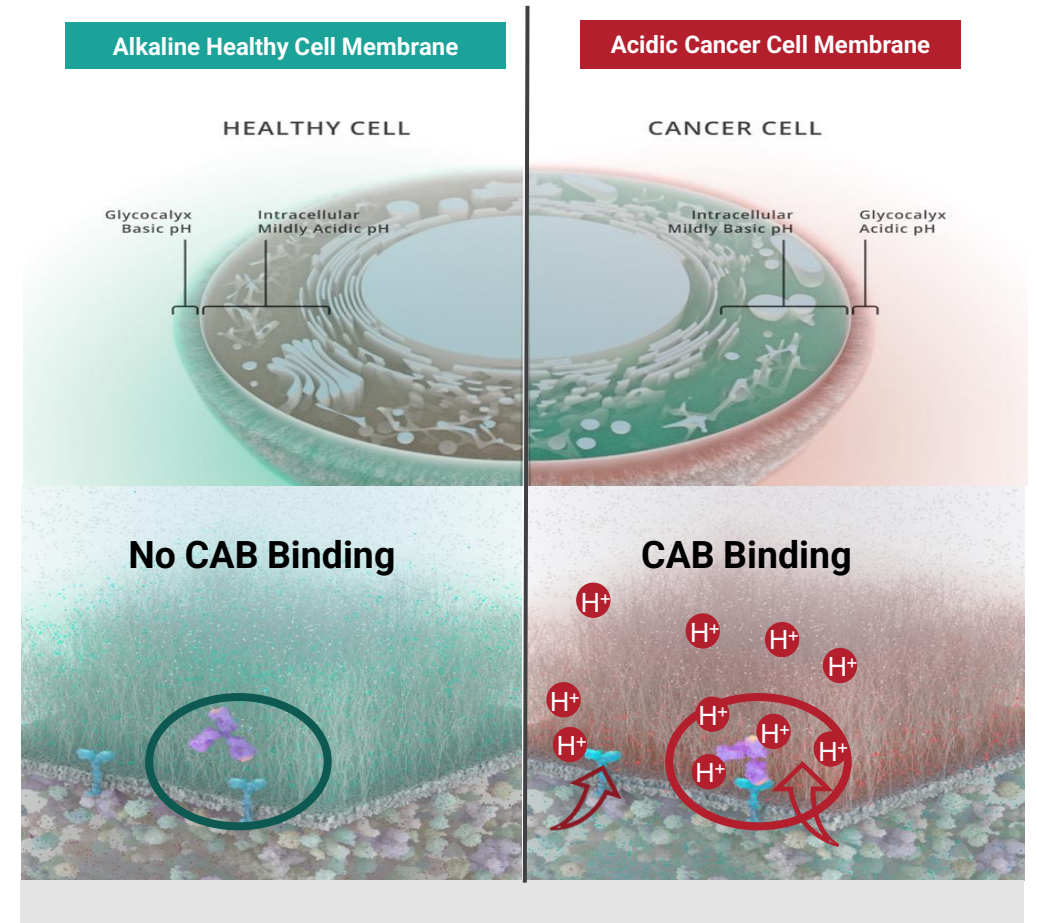
BioAtla invented CAB technology, creating antibodies that bind **only** to these unveiled sites on cancer cells



Not masked or caged and thus different from prodrugs that require irreversible enzymatic cleavage



CABs have the potential for increased efficacy with improved safety relative to traditional antibodies



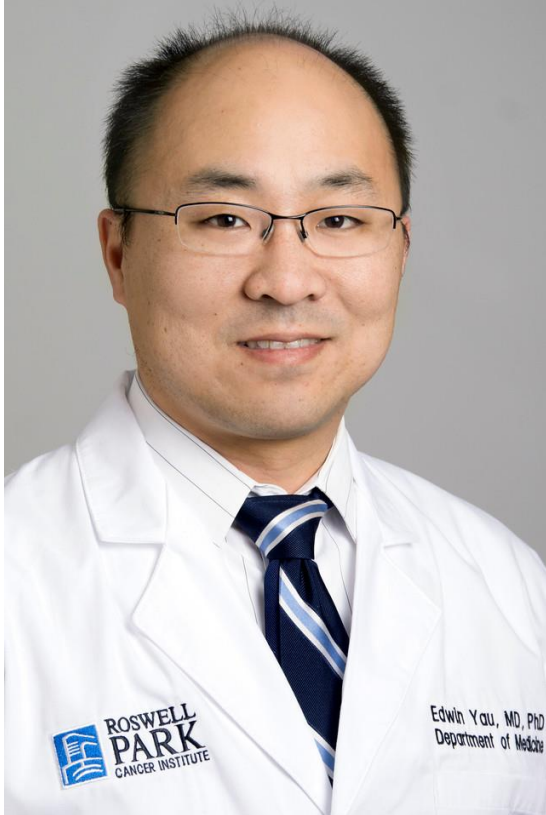
Chang, H.W., Frey, G., Liu, H., Xing, C., Steinman, L, Boyle, B.J., & Short, J.M. (2021) PNAS 118(9): 1-10, Suppl. 1-19.

Mecbotamab Vedotin (CAB-AXL-ADC)



# Edwin Yau, MD, PhD

Roswell Park Comprehensive Cancer Center



Dr. Yau is a physician-scientist at the Roswell Park Comprehensive Cancer Center where he is an assistant professor in oncology and serves as the clinical chief for Thoracic Medicine.

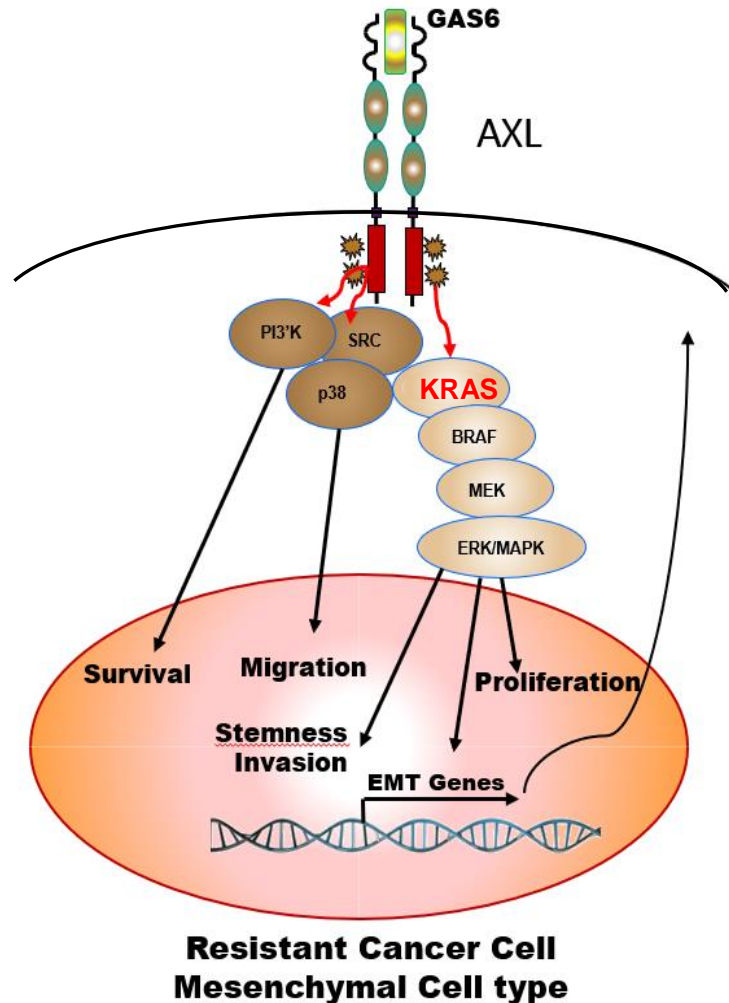
He is involved in translational research focused on KRAS mutant lung cancers in the Department of Genetics and Genomics and a member of the Roswell Park Developmental Therapeutics research program.

He served as the principal investigator of multiple clinical trials for KRAS inhibitors such Adagrasib and RMC-6291.

He received his Hematology and Oncology fellowship training at the University of California San Diego (UCSD) as part of the Physician Scientist Research.

Dr. Yau received his combined MD and PhD degrees at the University at Buffalo School of Medicine and Biological sciences.

# AXL Target – Strongly Associated with Tumor Treatment Resistance



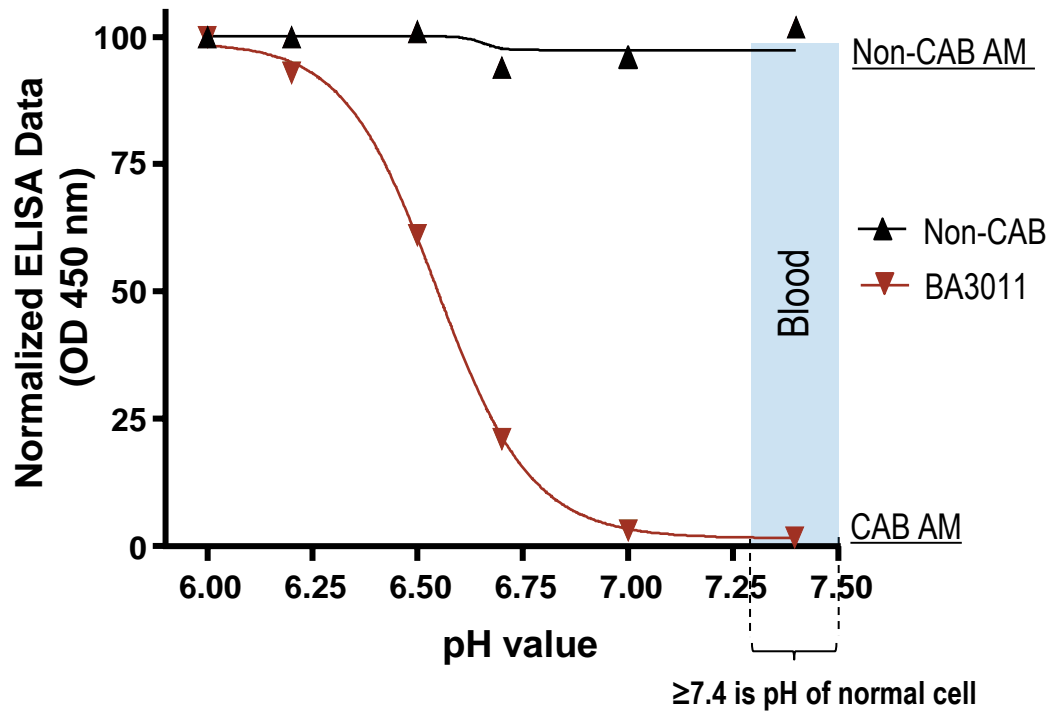
- Mutations in tumor drivers leading to alterations in downstream pathways especially in the MAPK pathway dominate the landscape of Non-Small Cell Lung cancer (NSCLC) with the most common mutations found in KRAS and EGFR. Activation of MAPK signaling results in cancer cell stemness, proliferation, migration and survival
- AXL expression is highly expressed in a subset of NSCLC and associated with poorer survival and appears to be a critical mechanism in treatment resistance



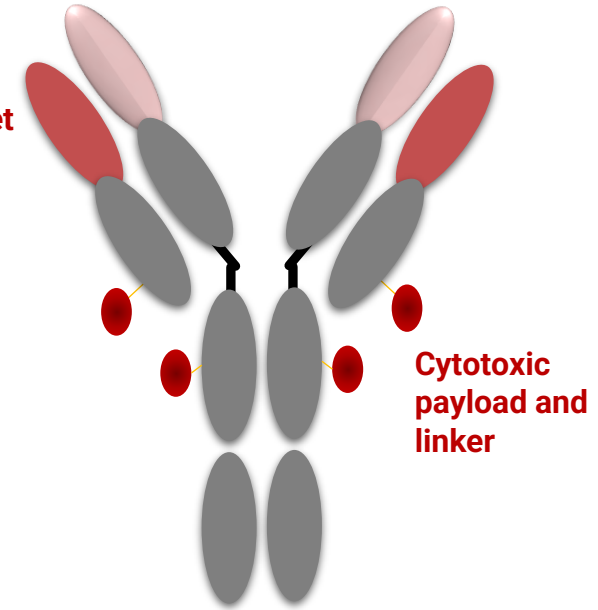
# Mecbotamab Vedotin: CAB-AXL-ADC

## Improved therapeutic index via pH selectivity

BA3011 pH binding inflection point adjusted for tumor microenvironment selectivity



CAB-tumor cell target



Cytotoxic payload and linker

- Humanized anti-AXL IgG1
- ~100 pM affinity (pH 6.5)
- VC-MMAE (DAR 4) linker and payload
- Epitope in Ig loop region

# Phase 2 Mecbotamab Vedotin in Non-Small Cell Lung Cancer

Multicenter, Phase 2, open-label trial evaluating the efficacy and safety of mecbotamab vedotin alone and in combination with nivolumab

## Patient disposition:

- Confirmed locally advanced or metastatic NSCLC
- Age  $\geq$  18 years
- ECOG performance status of 0 or 1
- Treatment failure of a PD-1/L1 inhibitor or approved therapy for EGFR or ALK genomic tumor aberrations

**mecbotamab vedotin**  
1.8 mg/kg Q2W or 2Q3W

**mecbotamab vedotin  
+ nivolumab**  
1.8 mg/kg Q2W

## Primary endpoint:

- ORR via RECIST v1.1
- Incidence and severity of AEs\*

## Secondary endpoints:

- DOR
- PFS
- BOR, DCR, TTR, OS

\*Coded by MedDRA and graded according to NCI CTCAE v5

- 3Q4W enrollment was stopped due to lack of compliance

Abbreviations: ORR: overall response rate; AEs: adverse events; DOR: duration of response; PFS: progression-free survival; BOR: best overall response; DCR: disease control rate; TTR: time to response; OS: overall survival

# Phase 2 Mecbotamab Vedotin in PD-1 Refractory NSCLC: Demographics

(includes squamous, nonsquamous, mEGFR, wtEGFR)

Evaluate anti-tumor activity based on AXL expression, dose, and genotype

1.8 mg/kg 2Q3W monotherapy	2Q3W (N=33)
Age, y, mean (range)	67 (46-82)
ECOG Status, n (%)	
0	7 (21%)
1	26 (79%)
# of prior systemic therapies, n (%)	
1	3 (9%)
2	8 (24%)
3	9 (27%)
≥4	13 (39%)

# AXL Expression is Associated with Clinical Benefit

PD-1 refractory NSCLC (including squamous, nonsquamous, mEGFR, wtEGFR); median 3 prior lines of tx

mecbotamab vedotin 1.8 mg/kg 2Q3W monotherapy

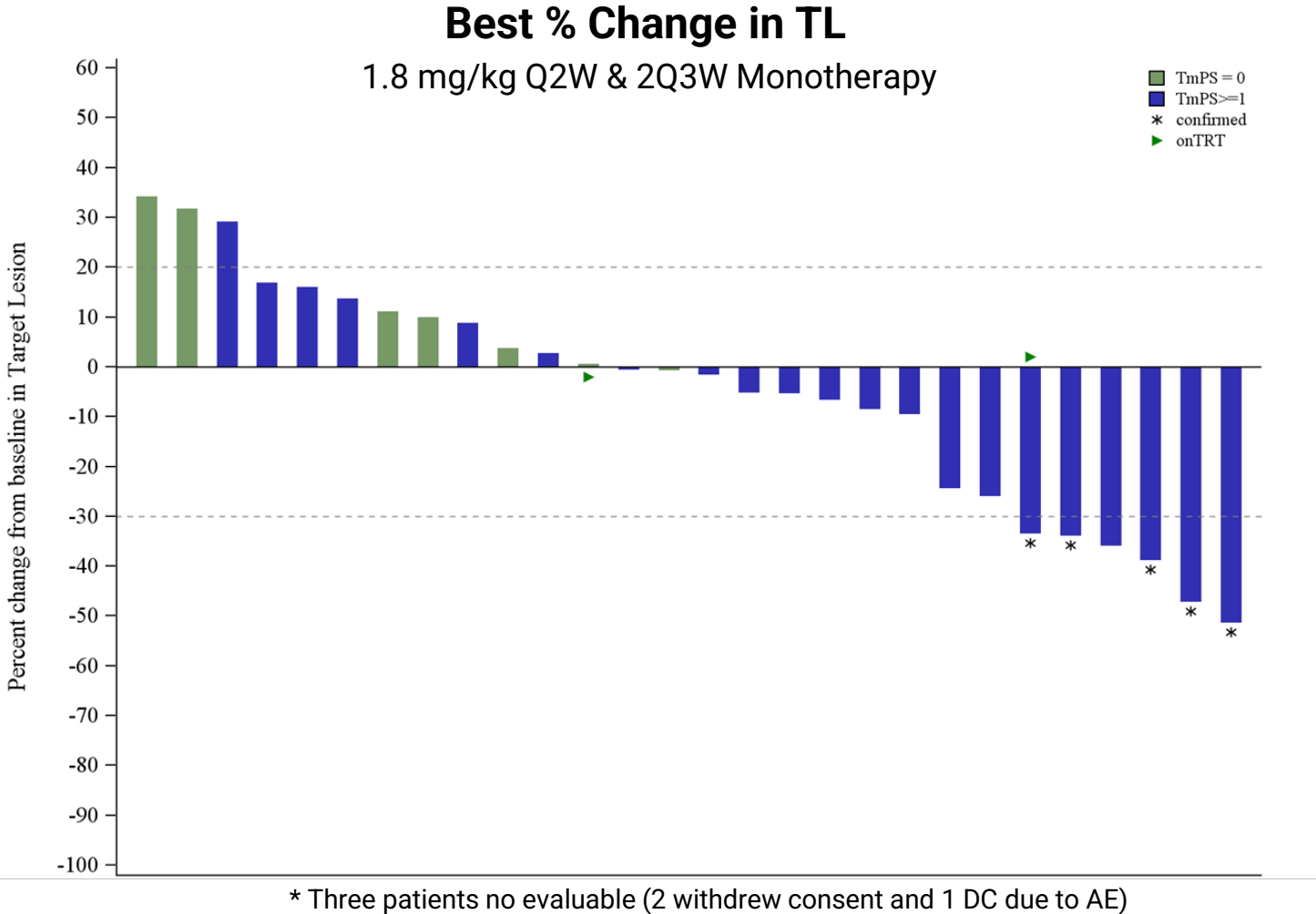
Median 3 prior lines of tx	AXL+ (N=15)	AXL- (N=13)	Total (N=28)
<b>Responder</b>	3	0	3
<b>SD</b>	6	7	13
<b>PD</b>	6	6	12

\* Evaluable patients defined as patients with at least one tumor scan after receiving AXL-ADC

5 patients not evaluable

# Phase 2 Mecbotamab Vedotin: NSCLC, NSQ, wtEGFR

AXL expression  $\geq 1\%$  biomarker correlated with clinical benefit

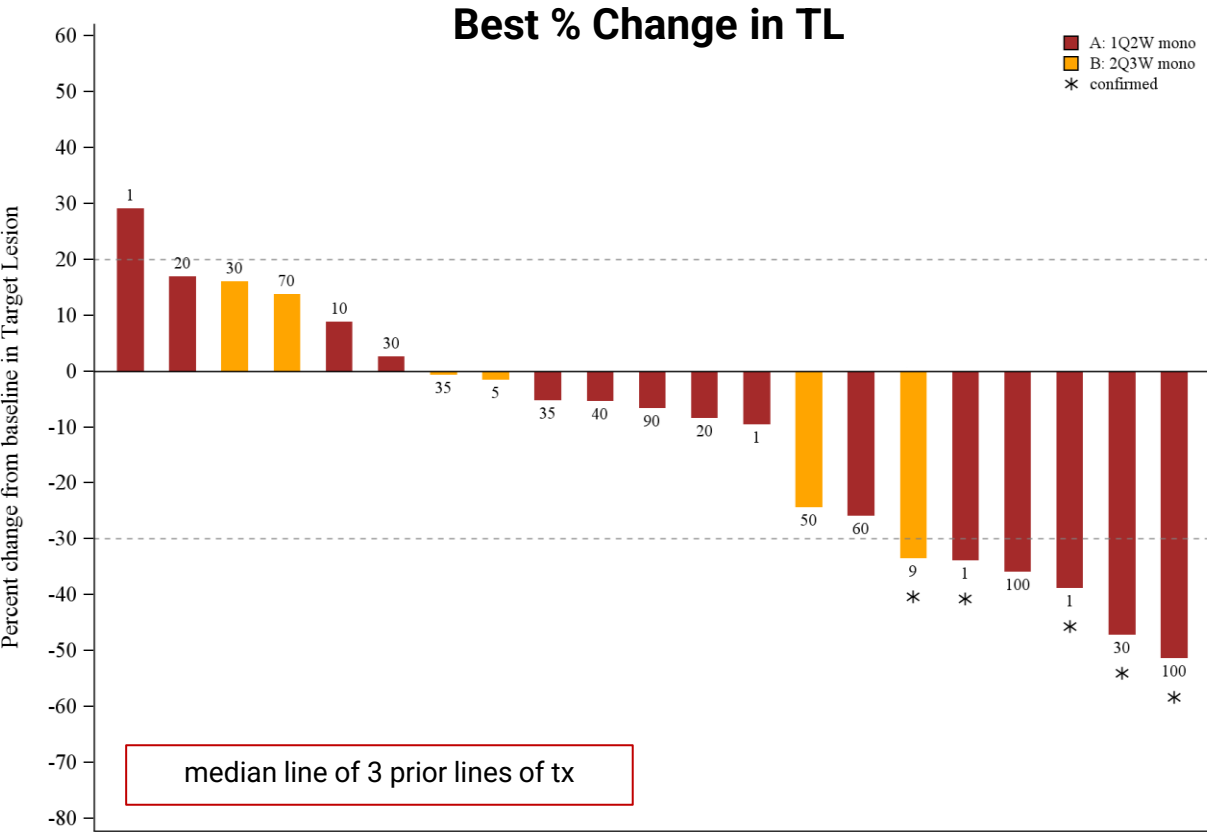


Data Cut Date: 14Jun2024 Live database



# Clinical Benefit Observed in Both Q2W and 2Q3W Dosing Regimens

Non-squamous, wtEGFR, AXL+; median of 3 prior lines of tx



TmPS is presented on each bar.

	<b>Total (N=21)</b>
<b>ORR All*</b>	<b>6 (29%)</b>
<b>ORR confirmed*</b>	<b>5 (24%)</b>
<b>DCR</b>	<b>81%</b>
<b>DOR</b>	<b>5.9 months</b>

\* Three patients not evaluable (2 withdrew consent and 1 DC due to AE)

**No new safety signals identified with high dose intensity regimen**



# Evaluate Genotype (KRAS) Status Across All Treated Patients

## Emerging opportunity in patients with mutated KRAS (mKRAS) variants

mutant KRAS; all NSCLC (SQ+NSQ); median of 3 prior lines of tx for both mKRAS and wtKRAS

	Q2W (N=25)	2Q3W (N=33)	Q2W + Nivo (N=19)	Total (N=77)
Age, y, mean (range)	67 (53-80)	67 (46-82)	68 (50 - 81)	67 (46-82)
KRAS Status				
wtKRAS	8 (32)	17 (52)	10 (52)	35 (45)
mKRAS	9 (36)	4 (12)	8 (42)	21 (27)
Pending*	8 (32)	12 (36)	1 (5)	21 (27)

\*additional work ongoing to characterize all patients KRAS status

**mKRAS constitutes 30% of all NSCLC patients**

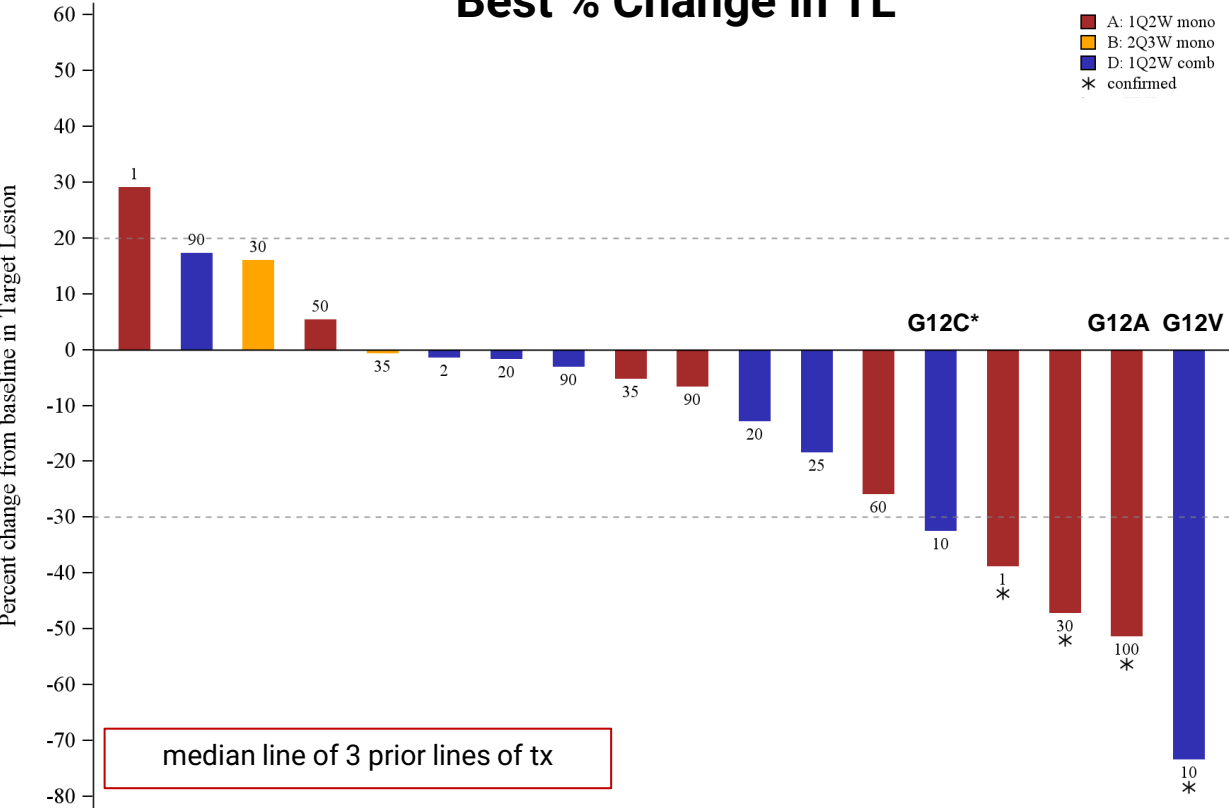
**mKRAS is associated with increased AXL expression**

Morimoto et al. *Cancer Lett.* 2024;587:216692

# Confirmed Responses Across KRAS Mutation Variants (G12A, G12C, G12V) - ongoing

## 1.8 mg/kg Q2W, 2Q3W, and Q2W+nivo

**Best % Change in TL**



TMPS scores represented above the bar  
 \* Patient was previously treated with Sotorasib

<b>Median of 3 prior lines of tx</b>	<b>mKRAS N=18</b>
<b>ORR all</b>	<b>5 (28%)</b>
<b>ORR confirmed</b>	<b>4 (22%)</b>
<b>DCR</b>	<b>78%</b>
<b>DOR</b>	<b>4.8 months</b>
<b>PFS</b>	<b>4.5 months</b>
<b>OS</b>	<b>12.6 months</b>

Three patients not evaluable (2 withdrew consent and 1 DC due to AE)

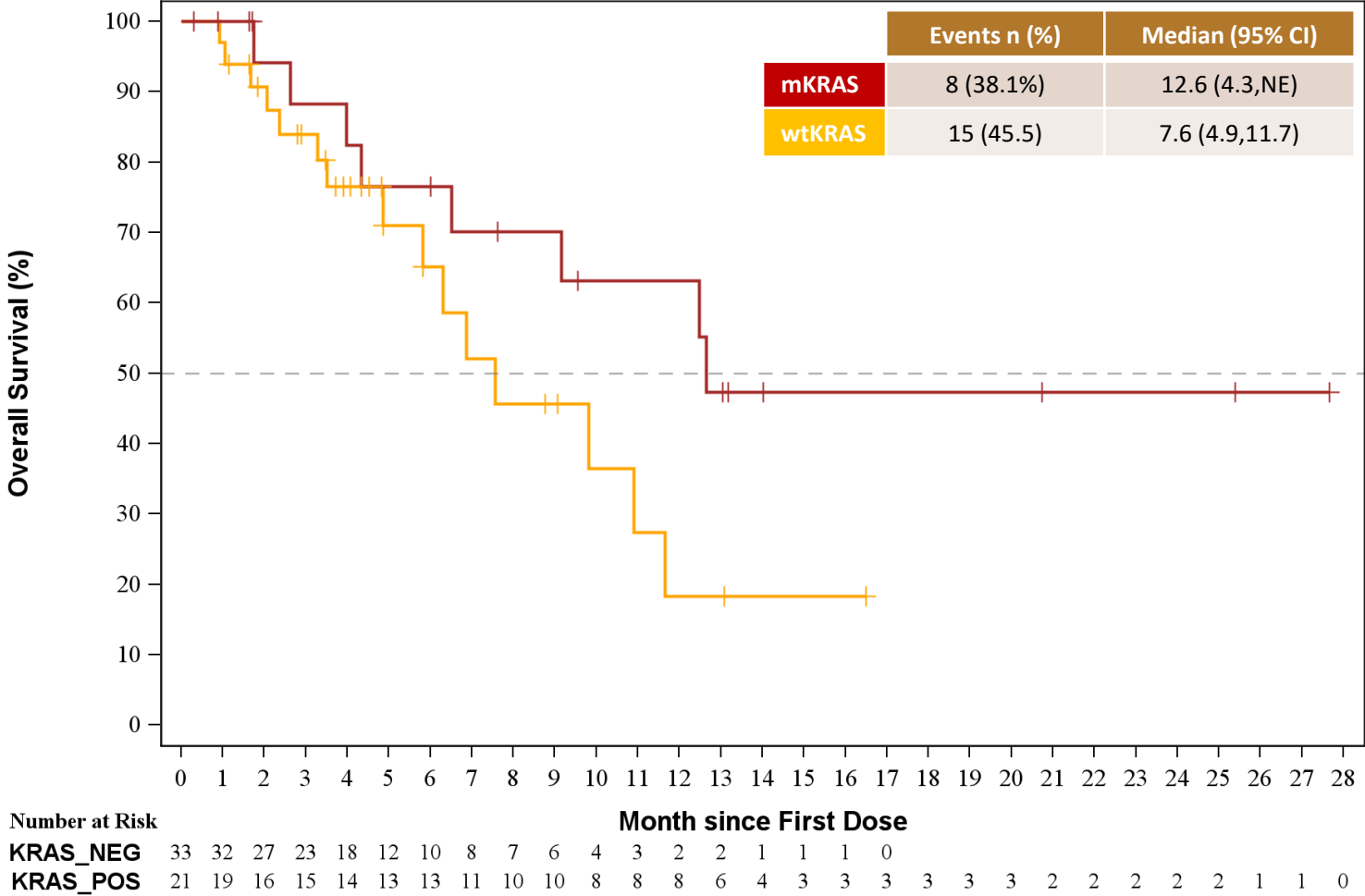
additional work ongoing to characterize all patients KRAS status

Data Cut Date: Live Database as of July 11, 2024



# Overall Survival - ongoing

mKRAS vs wtKRAS; median of 3 prior lines of tx



additional work ongoing to characterize all patients KRAS status

Data Cut Date: Live Database as of July 11, 2024



# Mecbotamab Vedotin: Overall Safety Summary of NSCLC patients

Generally well-tolerated

	Q2W (N=25)	2Q3W (N=33)	Q2W + Nivo (N=19)	Total (N=77)
Any Adverse Events (AEs)	25 (100.0)	31 (93.9)	19 (100.0)	<b>75 (97%)</b>
Related AEs with CTCAE <sup>1</sup> Grade 3 or 4 <sup>2</sup>	9 (36.0)	8 (24.2)	4 (21.1)	<b>21 (27%)</b>
Any Related Serious AEs <sup>2</sup>	3 (12.0)	2 (6.1)	1 (5.3)	<b>6 (8%)</b>
Possibly Related AEs leading to death <sup>2</sup>	0	0	0	<b>0</b>
Related AEs leading to treatment discontinuation <sup>2</sup>	1 (4.0)	2 (6.1)	1 (5.3)	<b>4 (5%)</b>

<sup>1</sup>CTCAE: Common Terminology Criteria for Adverse Events. The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which is utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.

<sup>2</sup>As assessed by the investigator. Missing responses are counted as related.



# Mecbotamab Vedotin: Phase 2 Safety Data of NSCLC patients

## Most frequent treatment-emergent Adverse Events by Treatment Group; >15%

	BA3011 Q2W (N=25)		BA3011 2Q3W (N=33)		BA3011 + Nivo (N=19)		TOTAL (N=77)	
Preferred Term	All Grades	Grade 3-4	All Grades	Grade 3-4	All Grades	Grade 3-4	All Grades	Grade 3-4
Number of Subjects with at Least One TEAE	23 (92.0)	9 (36.0)	24 (72.7)	8 (24.2)	18 (94.7)	4 (21.1)	<b>65 (84%)</b>	<b>21 (27%)</b>
Fatigue	9 (36.0)	0	5 (15.2)	0	8 (42.1)	0	<b>22 (29%)</b>	<b>0 (0%)</b>
Diarrhoea	7 (28.0)	1 (4.0)	7 (21.2)	1 (3.0)	6 (31.6)	0	<b>20 (26%)</b>	<b>2 (3%)</b>
Nausea	5 (20.0)	0	4 (12.1)	0	7 (36.8)	0	<b>16 (21%)</b>	<b>0 (0%)</b>
Peripheral Neuropathy	7 (28.0)	1 (4.0)	5 (15.2)	0	4 (21.1)	0	<b>16 (21%)</b>	<b>1 (1%)</b>
Decreased Appetite	5 (20.0)	1 (4.0)	5 (15.2)	0	4 (21.1)	0	<b>14 (18%)</b>	<b>1 (1%)</b>
Neutropenia	7 (28.0)	2 (8.0)	5 (15.2)	5 (15.2)	1 (5.3)	0	<b>13 (17%)</b>	<b>7 (9%)</b>
Aspartate Aminotransferase Increased	4 (16.0)	2 (8.0)	4 (12.1)	0	4 (21.1)	1 (5.3)	<b>12 (16%)</b>	<b>3 (4%)</b>
Alanine Aminotransferase Increased	4 (16.0)	2 (8.0)	4 (12.1)	0	2 (10.5)	1 (5.3)	<b>10 (13%)</b>	<b>3 (4%)</b>

# Mecbotamab Vedotin NSCLC Summary

## Median of 3 prior lines of tx

- AXL expression correlates with improved clinical benefit
- Clinical benefit associated with both Q2W and 2Q3W
- mKRAS is associated with increased AXL expression
- Encouraging anti-tumor activity in highly pre-treated patient population with manageable safety
  - Responders in multiple mKRAS variants
  - Achieved and maintained CR for over two years

Evalstotug (CAB-CTLA-4)

# Omid Hamid, MD

## The Angeles Clinic and Research Institute

Omid Hamid, MD, is Chief, Translational Research and Immunotherapy, and Director, Melanoma Therapeutics at The Angeles Clinic and Research Institute.

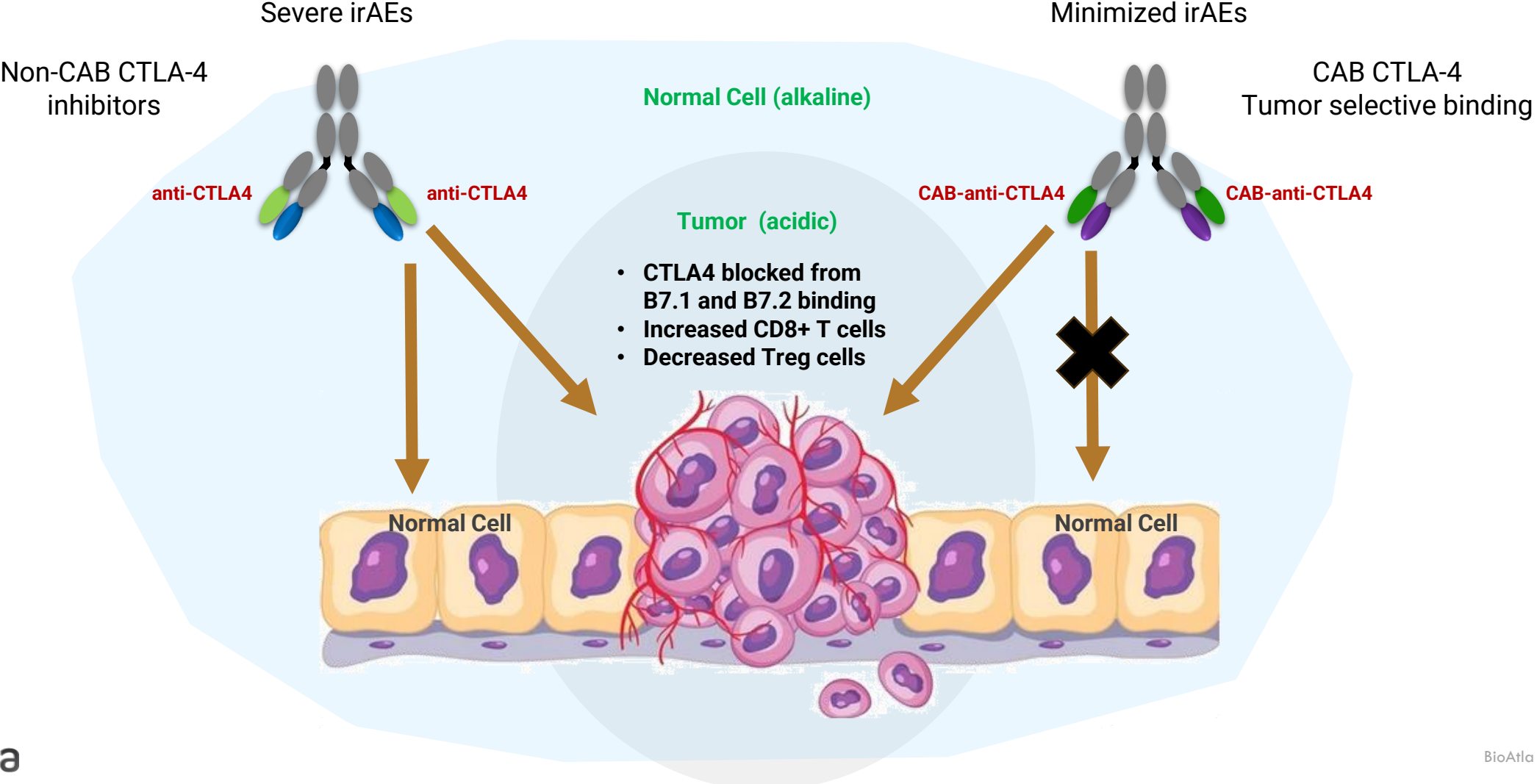
Dr. Hamid has been instrumental in bringing new therapies to clinic for patient benefit such as:

- PD-1 inhibitors (pembrolizumab, nivolumab, atezolizumab)
- checkpoint inhibitors (ipilimumab)
- therapies against tumor angiogenesis
- targeted agents that block internal processes in tumor cell's function (BRAF/MEK).

Dr. Hamid is recognized internationally as a key opinion leader in Immuno-Oncologic Drug Development and Melanoma Therapeutics.



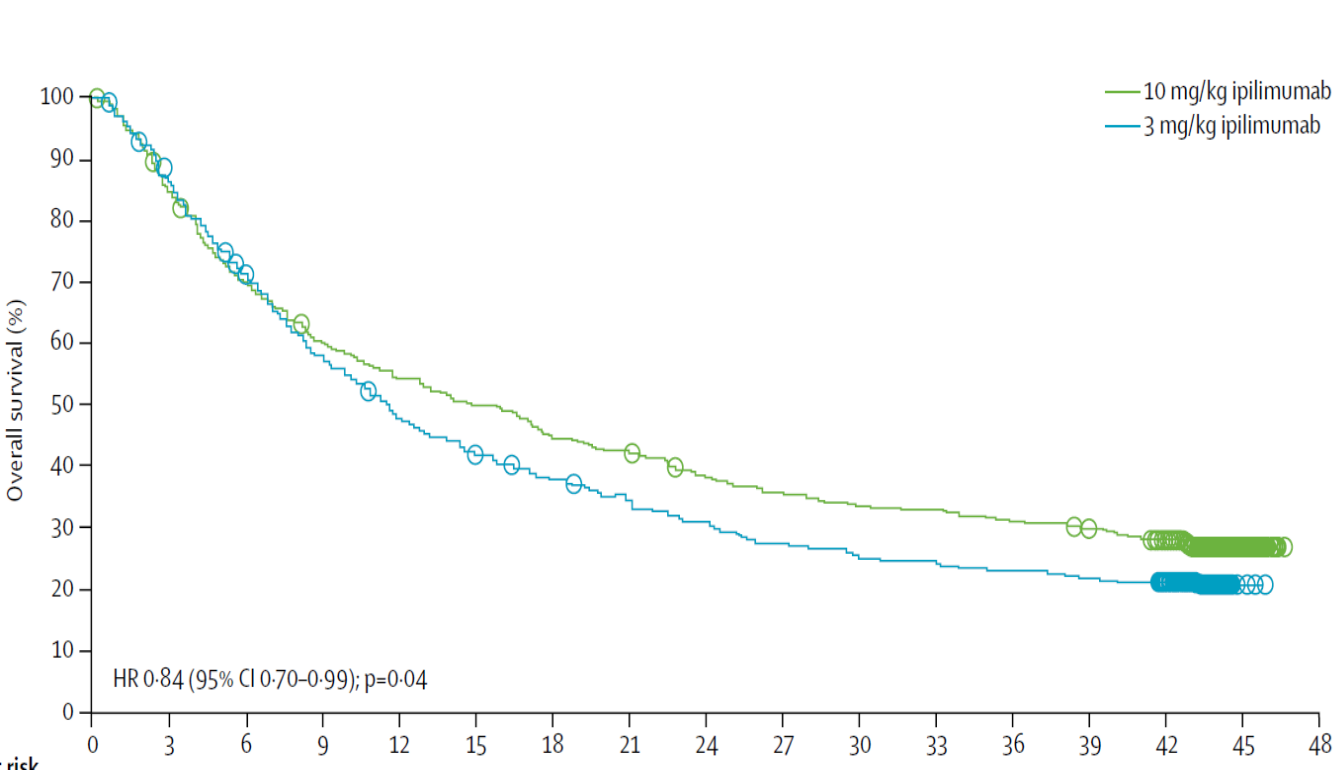
# CAB-CTLA-4 Selectively Active in Tumor Microenvironment, thereby Reducing Immune Related Adverse Events





# Higher Monotherapy Dose CTLA Blockage Improved Survival, but Limited by Toxicity

Unmet needs for safer CTLA-4 blockage drugs that can be used at higher dose



Ipilimumab Monotherapy		
Safety	3mg/kg	10 mg/kg
Grade 3-4 AEs	12%	<b>24%</b>
Treatment related SAE	18%	<b>37%</b>
AE leading to treatment discontinuation	19%	<b>31%</b>

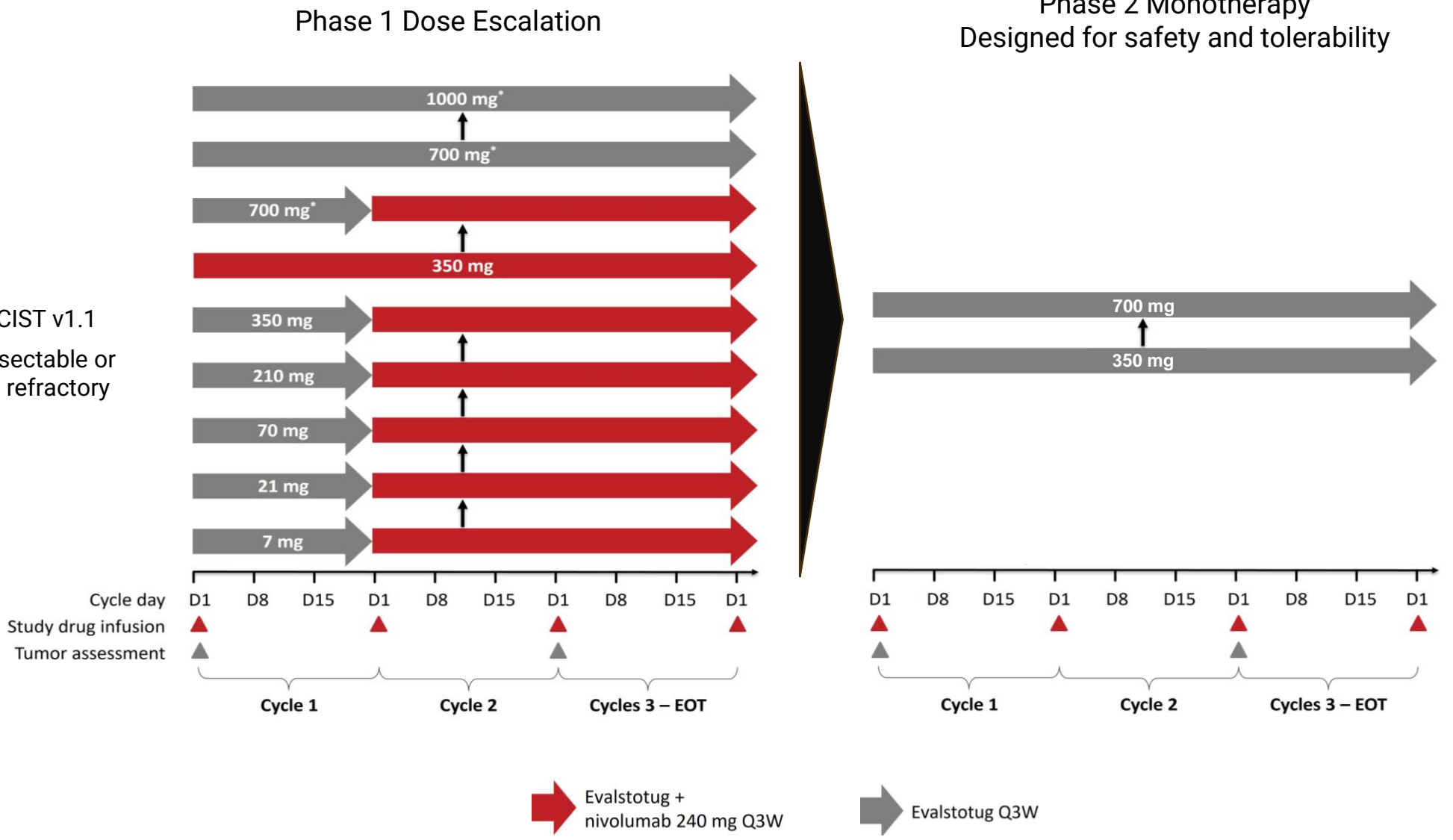
Evalstotug provides similar PK exposure and  $T_{1/2}$  at 5 and 10 mg/kg dosing levels to Ipilimumab



# Multicenter, Open-Label, Ph1 Dose Escalation and Ph2 Monotherapy

## Key Eligibility Criteria:

- Age ≥ 18 years
- ECOG 0 or 1
- Anti-CTLA-4 naive
- Measurable disease per RECIST v1.1
- Ph1: Locally advanced unresectable or metastatic, relapsed and/or refractory solid tumors
- Ph2: Treatment refractory melanoma/carcinoma



# Phase 1: Demographic – Tumor Types

All patients experienced failure of prior PD-1 treatment

	Total (N=21)		Total (N=21)	Prior # of treatments
<b>Age, y, mean (SD)</b>	62 (12)	<b>Tumor type, n (%)</b>		
<b>Sex, n (%)</b>		Melanoma	6 (29)	1–4
Female	8 (38)	Gastric	4 (19)	2–6
Male	13 (62)	Renal cell	4 (19)	1–6
<b>White race, n (%)</b>	19 (90)	Cervical	3 (14)	1–3
<b>ECOG, n (%)</b>		NSCLC	2 (10)	3–7
0	13 (62)	Urothelial	1 (5)	4
1	8 (38)	SCLC	1 (5)	3
<b>Prior Anti-PD-1 Therapy, n (%)</b>	21 (100)			

# Phase 1: Grade 3+ Adverse Events of Special Interest

Most related AEs were low grade; no related grade 4 or 5 events

## All Grade 3 related events (N=4 pts):

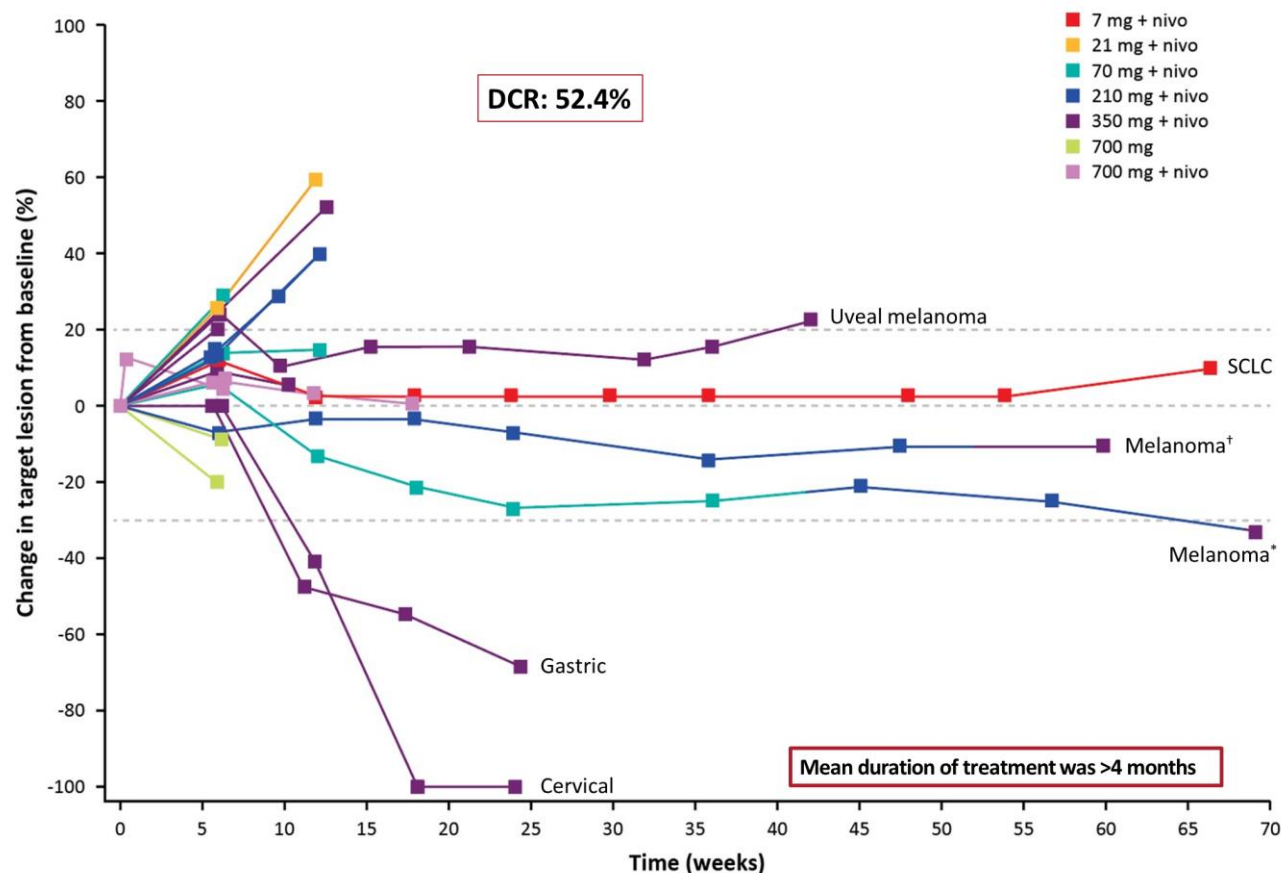
- CRS-like events:
  - New onset atrial fibrillation (only AE to meet DLT criteria)
  - Readily reversible hypertension
- Immune Mediated:
  - Endocrine: Hyperglycemia/DKA
  - GI Lipase increase and Gastritis/Diarrhea

Only 2/21 pts discontinued due to an adverse event (atrial fibrillation and gastritis)

NUMBER OF PATIENTS WITH ANY, n (%)	All AE		Related	
	All grades	Grade 3-4	All grades	Grade 3-4
<b>All (n=21)</b>	20 (95)	10 (48)	17 (81)	4 (19)
Fatigue	9 (43)	2 (10)	3 (14)	0
Chills	8 (38)	0	8 (38)	0
Vomiting	7 (33)	0	3 (14)	0
Diarrhea	5 (24)	1 (5)	2 (10)	1 (5)
Pyrexia	5 (24)	0	5 (24)	0
Arthralgia	5 (24)	0	3 (14)	0
Nausea	5 (24)	0	3 (14)	0
Abdominal pain	4 (19)	1 (5)	1 (5)	0
Pruritus	4 (19)	0	4 (19)	0
Headache	4 (19)	0	1 (5)	0
Back pain	4 (19)	0	0	0

# Confirmed Responses (n=3) and Stable Disease (n=8) Among 19 Evaluable Patients

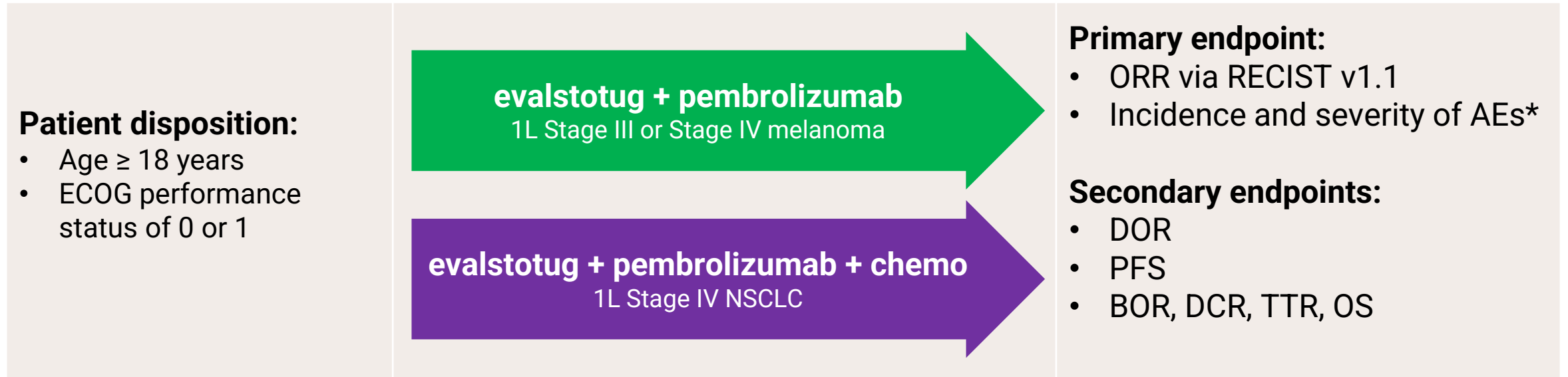
- Of the 8 patients who received evalstatog 350 mg there was 1 CR and 2 PRs, now all confirmed
- Multiple patients (2 with cutaneous melanoma; 1 with SCLC) on therapy without progression for >1 year.
- One uveal melanoma patient without progression for 9.8 months.



Data Cut Date: 29Mar24

# Phase 2 Multicenter, Open-Label, Evalstotug in combination with PD-1

Evaluate the efficacy and safety of evalstotug in combination



\*Coded by MedDRA and graded according to NCI CTCAE v5

Abbreviations: ORR: overall response rate; AEs: adverse events; DOR: duration of response; PFS: progression-free survival; BOR: best overall response; DCR: disease control rate; TTR: time to response; OS: overall survival

# Ankit Mangla, MD

## University Hospitals



Ankit Mangla, MD is the Co-Director of the Sarcoma and Cutaneous Oncology Disease team at University Hospitals Seidman Cancer Center, Cleveland, Ohio and an Assistant Professor in the Division of Hematology and Oncology at Case Western Reserve University.

He is the institutional PI on several Phase I/II and III clinical trials at UH SCC. His research focus is on developing novel checkpoint inhibitors and targeted therapies for the treatment of patients with advanced cancers.

Dr. Mangla has been an invited lecturer, expert panelist and poster presenter at numerous annual meetings and conferences.

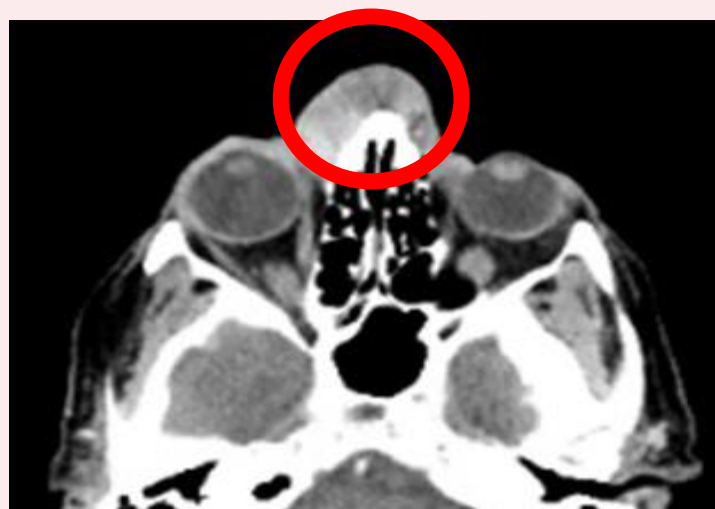
# New Confirmed Response - Melanoma

75-year-old female, stage IV cutaneous melanoma, BRAF positive, post-anti-PD-1



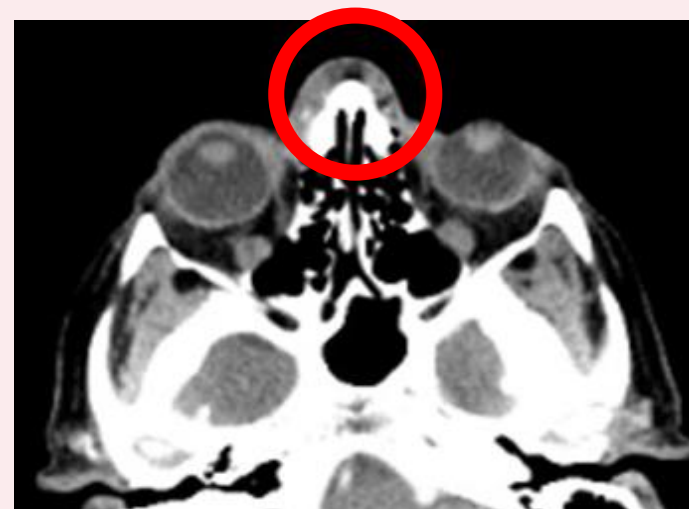
## Baseline

First dosed at 70 mg evalstotug



## Tumor assessment – SD

Therapy well-tolerated. Became symptomatic with nasal obstruction, and biopsy showed persistence of disease. Dose escalated to 210 mg with resultant SD and symptom improvement



## Tumor assessment – PR

Therapy well-tolerated for >1 year. Further dose escalated to 350 mg with resultant PR

**Clinical improvement and achievement of PR was temporally associated with increased evalstotug dosing, emphasizing the importance of higher CTLA-4 dosing to drive improved outcomes**



## Phase 2: Monotherapy Demographic – Tumor Types

14 different tumor indications enrolled to characterize safety

	350mg Q3W (N=17)	700mg Q3W (N=2)	Tumor type, n (%)	Total (N=19)	Prior # of Tx
<b>Age, y, mean (SD)</b>	59 (10)	54 (31)	adenocarcinoma adrenal gland	1 (5%)	2
<b>Sex, n (%)</b>			cervical cancer	1 (5%)	3
Female	9 (53)	0	cholangiocarcinoma	1 (5%)	4
Male	8 (47)	2 (100)	colorectal carcinoma	1 (5%)	4
<b>White race, n (%)</b>	16 (94)	0	papillary urothelial carcinoma	1 (5%)	5
<b>ECOG, n (%)</b>			melanoma	5 (26%)	2 - 6
0	10 (59)	1 (50)	metastatic acral lentiginous melanoma	1 (5%)	2
1	7 (41)	1 (50)	metastatic squamous cell carcinoma	1 (5%)	2
<b>Prior Anti-PD-1 Therapy, n (%)</b>	11 (65)	1 (50)	NSCLC	2 (11%)	1 - 2
			papillary thyroid	1 (5%)	2
			pleomorphic adenoma of sphenoid sinus	1 (5%)	0
			rectal adenocarcinoma	1 (5%)	3
			SCLC	1 (5%)	2
			sertoli cell tumor	1 (5%)	2

## Phase 2: Monotherapy Related TEAE

No grade 3-4 Colitis; No grade 4-5 related AE

Preferred Term	350 mg Q3W Mono (N=17)		700 mg Q3W Mono (N=2)		Total (N=19)	
	All Grades	Grades 3	All Grades	Grades 3	All Grades	Grades 3
Chills	6 (35)	0	1 (50)	0	7 (37)	0
Pyrexia	5 (29)	0	1 (50)	0	6 (32)	0
Infusion related reaction	4 (24)	0	1 (50)	0	5 (26)	0
Cytokine release syndrome	3 (18)	1 (6)	1 (50)	0	4 (21)	1 (5)
Nausea	3 (18)	0	0	0	3 (16)	0
Headache	2 (12)	0	0	0	2 (11)	0
Pruritus	2 (12)	0	0	0	2 (11)	0
Vomiting	1 (6)	0	0	0	1 (5)	0
Fatigue	1 (6)	0	0	0	1 (5)	0
Confusional state	1 (6)	0	0	0	1 (5)	0
Hypotension	0	0	1 (50)	0	1 (5)	0

As of July 16, 2024 following additional G3 imAE occurred  
700 mg – 1 imAE: Lipase increase

## Phase 2: Monotherapy Overview – Study ongoing

No grade 4 related TEAEs and MTD not reached

BA3071 Q3W	350 mg Q3W (N=17)	700 mg Q3W (N=2)
<b>CTCAE grade 3 or 4</b>	<b>4 (24)</b>	<b>0</b>
Related (only grade 3 observed)	1 (6)	0
<b>Serious AEs</b>	<b>4 (24)</b>	<b>0</b>
Related	1 (6)	0
<b>AEs leading to treatment d/c</b>	<b>0</b>	<b>0</b>
Related	0	0
<b>AEs leading to death</b>	<b>0</b>	<b>0</b>
Related AEs leading to death	0	0

- Most related AEs were low grade; no related grade 4 or 5 events
- 10 Stable Disease seen across 14 different cancer types.

## Conclusion

- High doses of evalstotug are associated with manageable safety that allow patients to continue treatment for extended intervals.
- Relatively low incidence and severity of immune-mediated AEs were observed in Phase 1 and 2 to date
- Multiple patients experienced prolonged progression-free survival (>40 weeks); confirmed responses were observed in patients receiving high doses of evalstotug.
- Phase 2 study exploring 700mg evalstotug + pembrolizumab in 1<sup>st</sup> line NSCLC and melanoma is currently enrolling.

## Q & A Session