A Phase 1/2 Study of BA3071 monotherapy and in combination with PD-1 in patients with Advanced Solid Tumors

Research and Development Day

December 13, 2023

bioatla

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Agenda

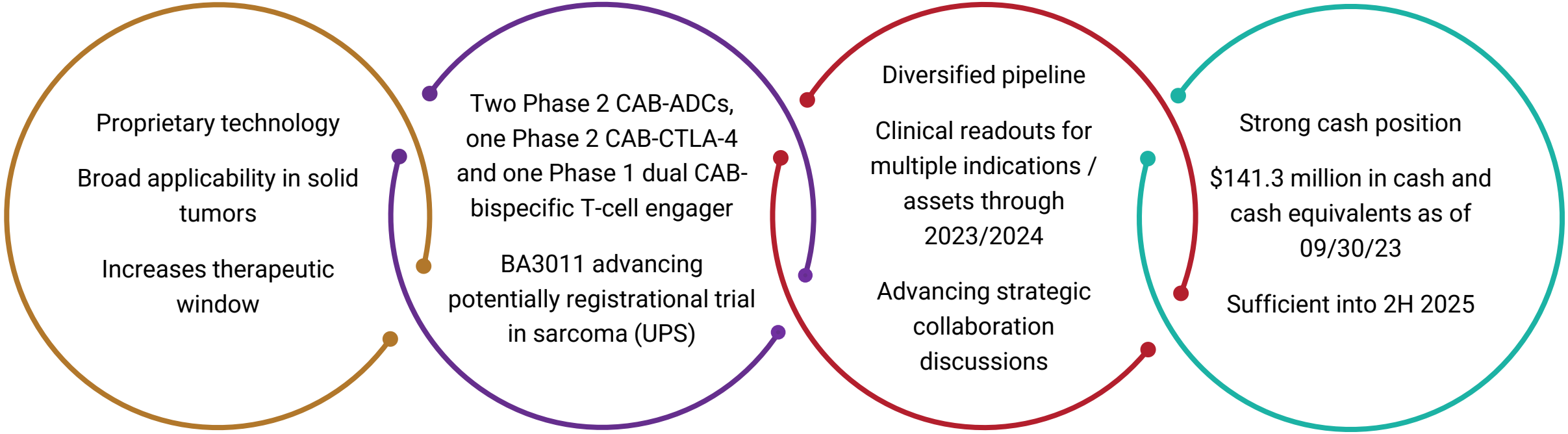
1. **Opening Remarks**
   CAB Technology & Preclinical Data Highlights

2. **BA3071**
   Clinical Data

3. **Q & A Session**

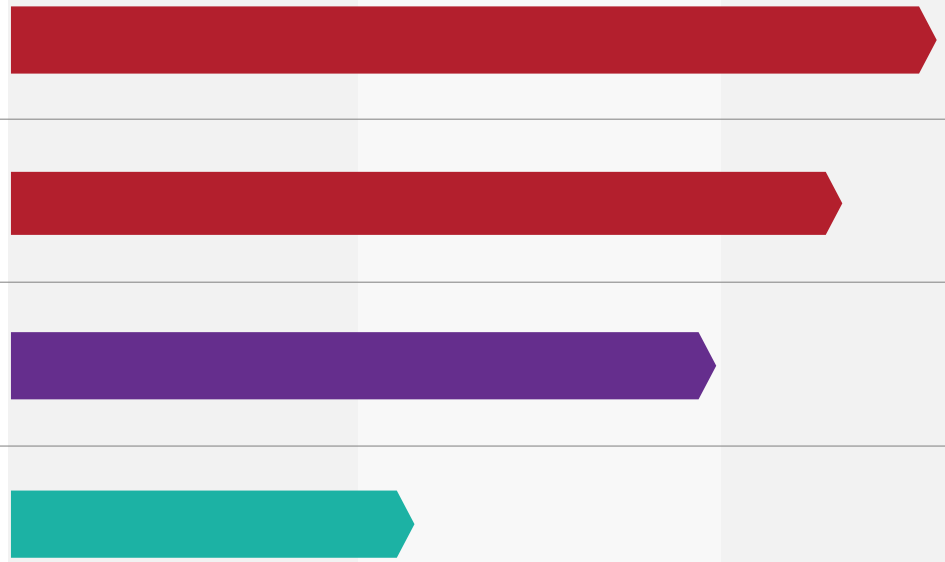
BioAtla© is a Clinical Stage Company Focused on Transforming Cancer Therapy

with **C**onditionally **A**ctive **B**iologics (CABs)



Focused Pipeline with Broad Applicability of Differentiated CAB Assets Designed to Deliver Near-term value

	CAB Program	Target	Indications	IND Enabling Pre-Clinical	Phase 1 Clinical	Phase 2 Clinical
CAB-ADCs	**BA3011** *Mecbotamab Vedotin*	AXL	UPS NSCLC			
	BA3021 *Ozuriftamab Vedotin*	ROR2	Melanoma SCCHN			
CAB-I/O	**BA3071**	CTLA-4	Multiple tumor types			
CAB-Bispecific TCE	**BA3182**	EpCAM x CD3	Multiple tumor types			
CAB	Additional programs	Various	Multiple tumor types			

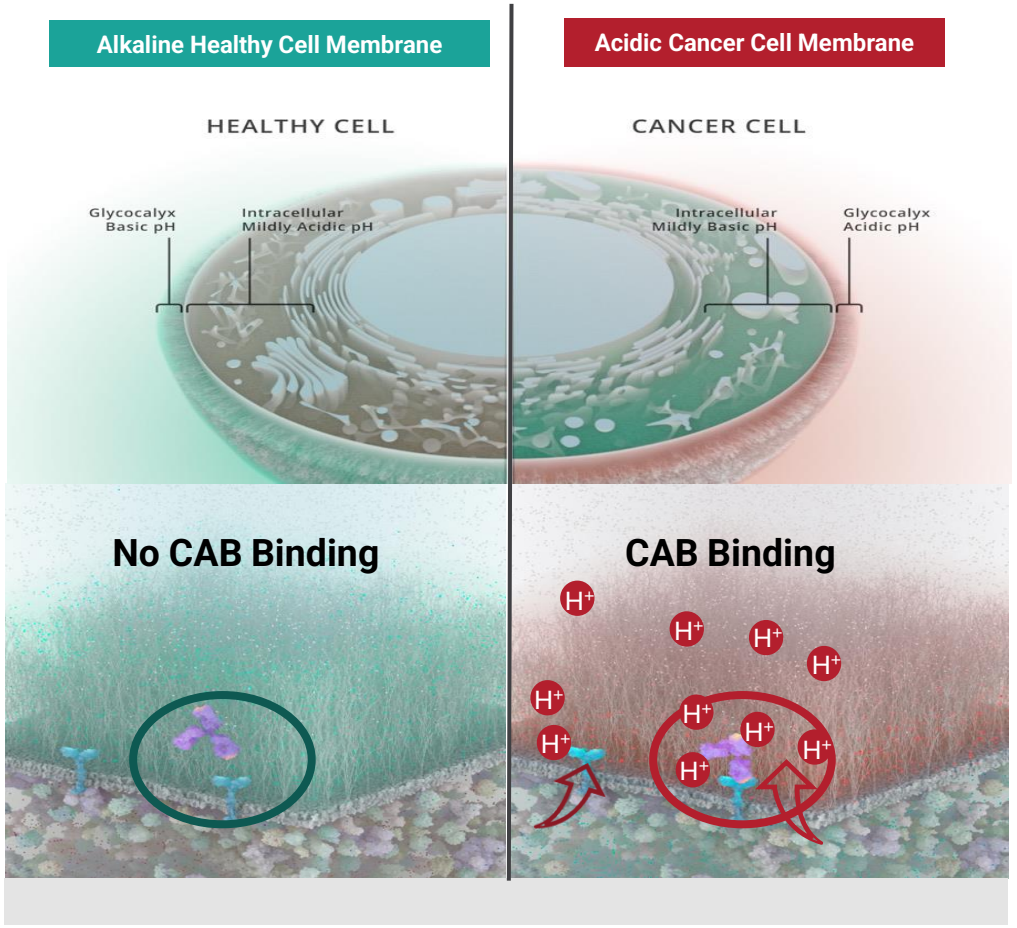


IND, investigational new drug; UPS, Undifferentiated Pleomorphic Sarcoma; NSCLC, Non-small Cell Lung Cancer; SCCHN, Squamous Cell Carcinoma of the Head and Neck

CAB Technology Widens Therapeutic Index

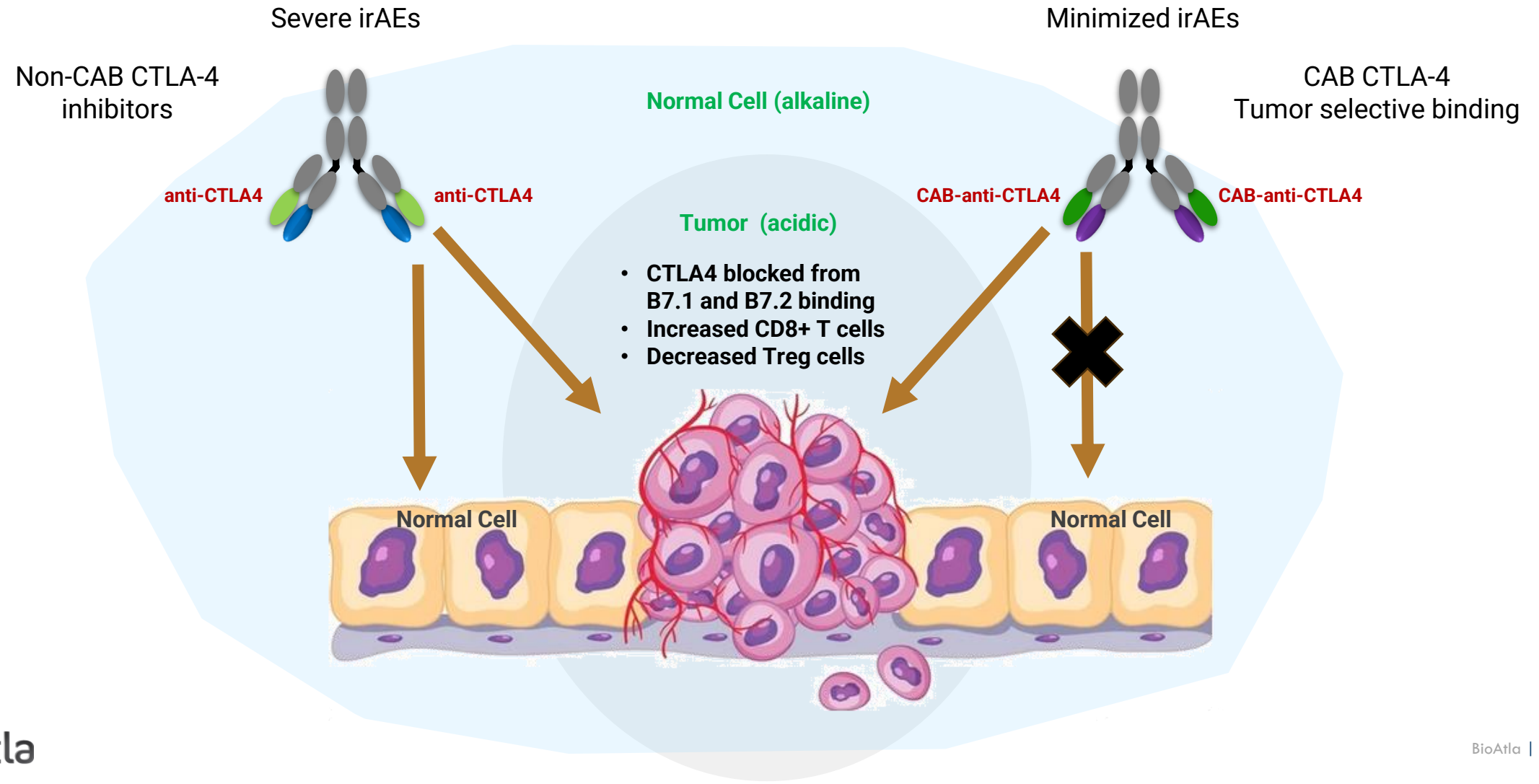
Selective and targeted to enhance clinical outcomes in multiple tumor types

- 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.

CAB-CTLA4 Selectively Active in Tumor Microenvironment, thereby Reducing Immune Related Adverse Events



BA3071 Selectivity and Efficacy in Human Target Knock-In Models

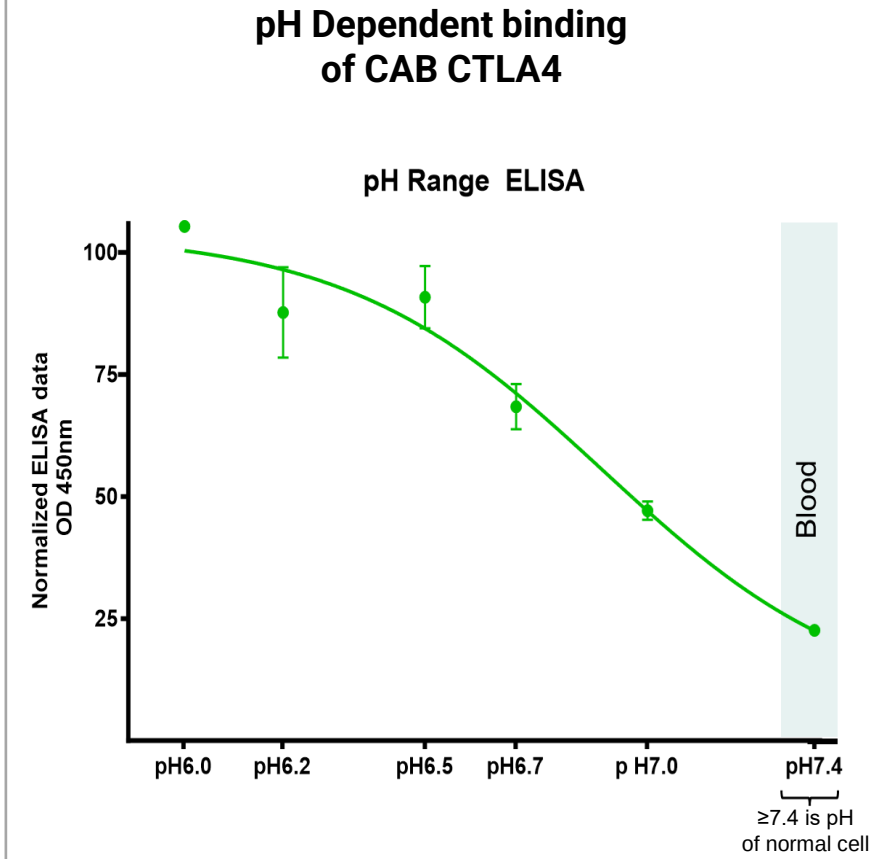
Conditional binding yields complete tumor regression

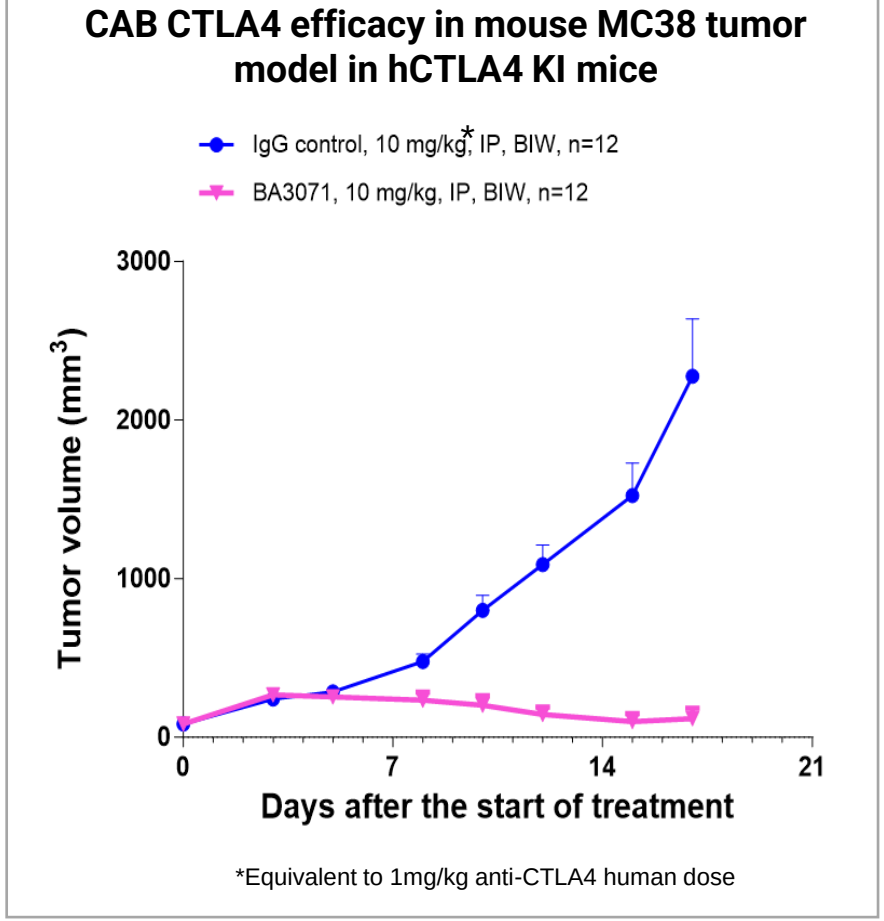
Left panel:

CAB CDR engineering redirects binding to acidic tumor pH

Right panel:

BA3071 demonstrates complete tumor regression in mouse tumor model





Chang et al., PNAS 118 (9): 1-10, 2021

BA3071 Selectivity and Efficacy in Human Target Knock-In Models

Maintains T-cell activity in tumor and reduces T-cell activity in normal tissue

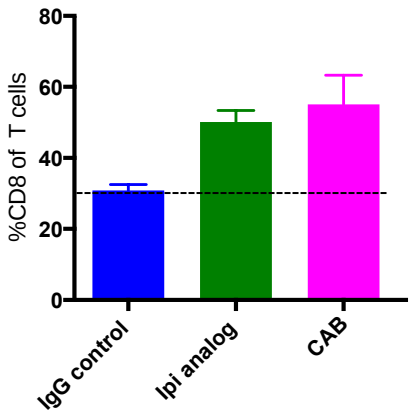
BA3071-

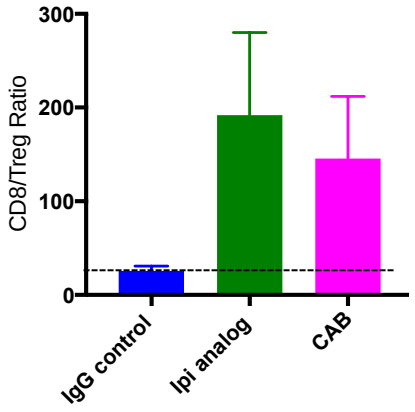
Increases T cell activity in the tumor, *i.e.*

- Increased CD8+ T cells
- Decreased Treg Cells

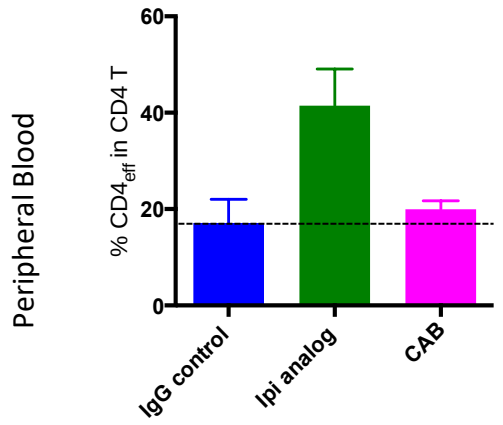
Avoids stimulation of CD4+ helper T cells in the periphery

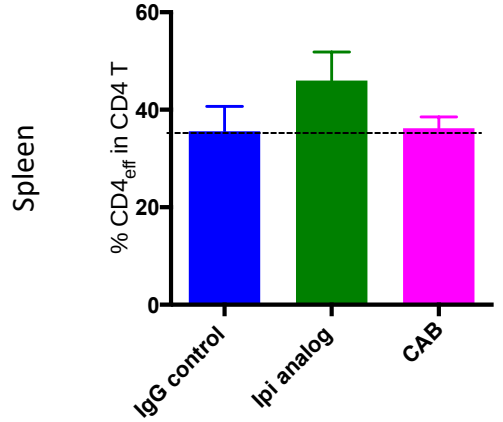
Tumor infiltrating lymphocytes





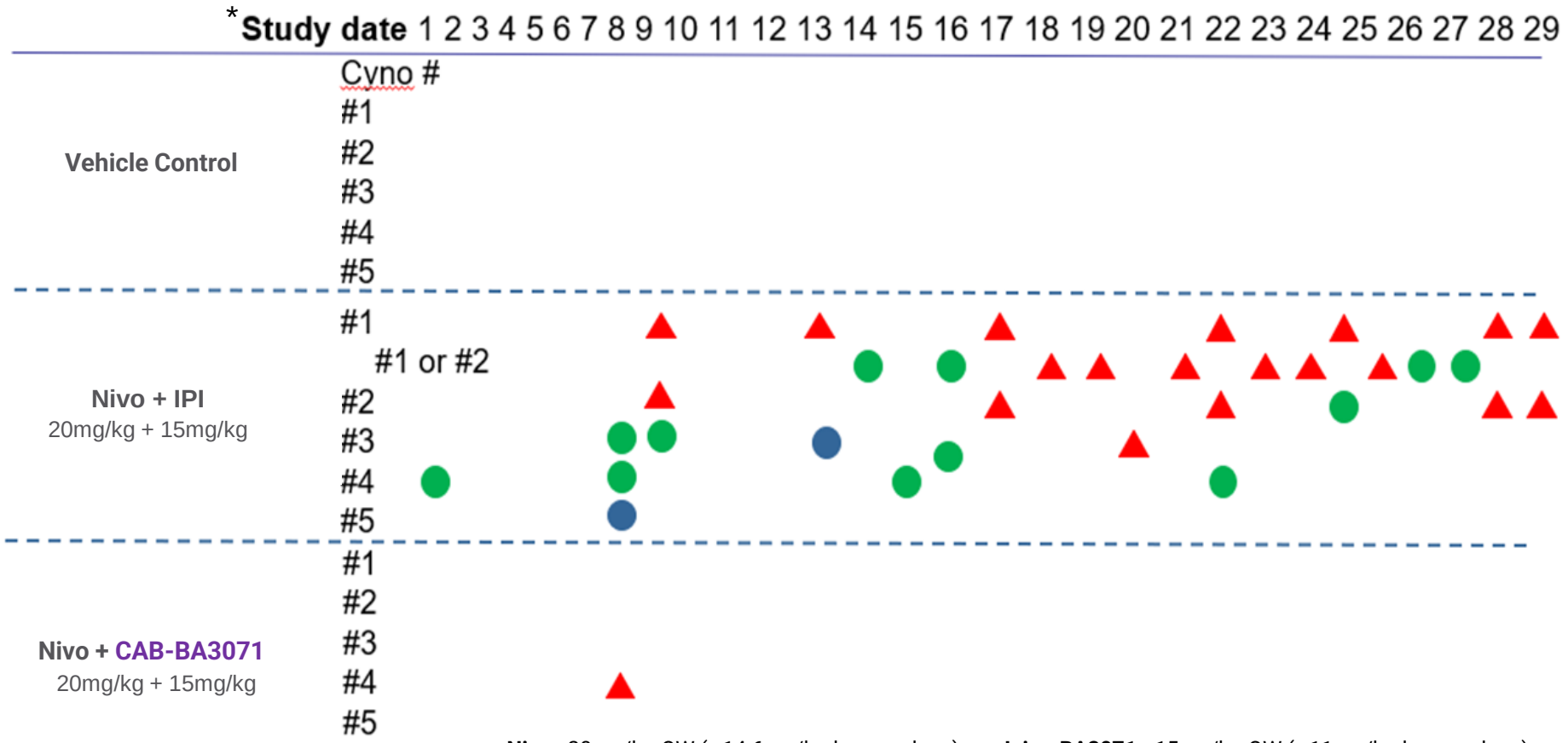
Normal tissue lymphocytes





Chang et al., PNAS 118 (9): 1-10, 2021

CAB BA3071 Effectively Reduces Clinically Relevant GI Toxicity in NHP



Nivo: 20mg/kg QW (~14.6mg/kg human dose) + **Ipi or BA3071:** 15mg/kg QW (~11mg/kg human dose)
Once weekly for four weeks exposure to Nivo + Ipi or BA3071
NHP – Nonhuman primates
*Chang et al., PNAS 118 (9): 1-10, 2021

BA3071 significantly reduces GI toxicity relative to ipilimumab analog in combination with nivo

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.

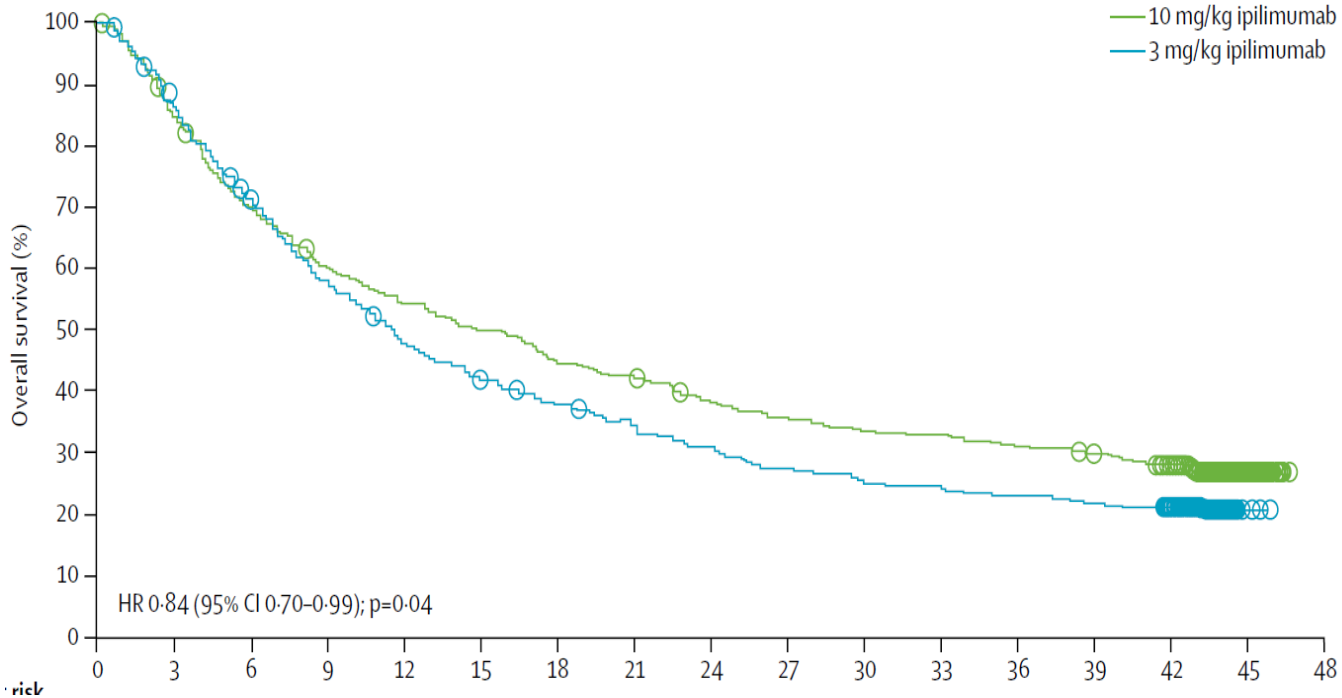
Dr. Hamid has been instrumental in bringing new therapies to clinic for patient benefit such as:

- 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.

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%	**24%**
Treatment related SAE	18%	**37%**
AE leading to treatment discontinuation	19%	**31%**

Ascierto et al., Lancet 18: 618-622, 2017

Phase 1 Dose Escalation ongoing

Key Objectives:

Define safety profile and determine Phase 2 dose and MTD

Evaluate antitumor activity and immunogenicity

Determine PK parameters

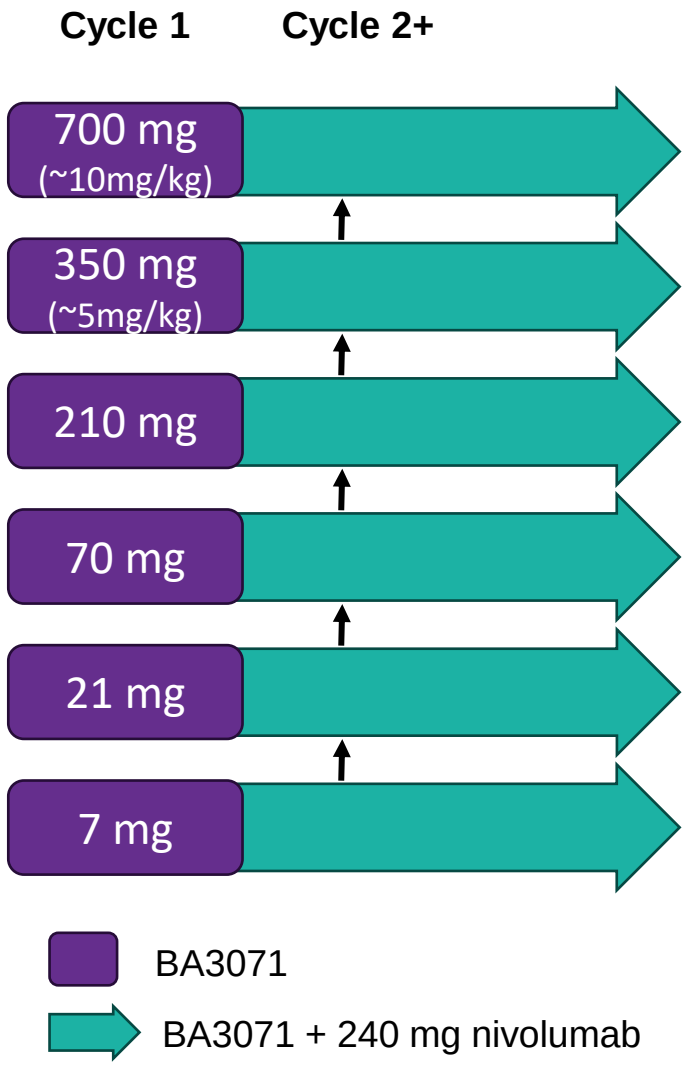
Key Eligibility Criteria:

CTLA-4 naïve

Treatment refractory:

- melanoma
- non-small cell lung cancer (NSCLC)
- renal cell carcinoma
- urothelial cancer
- gastric cancer
- hepatocellular carcinoma (HCC)
- cervical cancer
- small cell lung cancer (SCLC)

Combination Therapy (Q3W)



Further dose escalation planned to 1000 mg

Demographic - Baseline Patient Characteristics

Median of at least 3 prior lines of treatment

	Total (N=18)
Age, y, mean (range)	**65.5 (43 - 79)**
ECOG Status, n (%)	
0	**10 (55.6)**
1	**8 (44.4)**
# of prior systemic therapies, n (%)	
1	**5 (27.8)**
2	**2 (11.1)**
3	**4 (22.2)**
≥4	**7 (38.9)**

Data Cut Date: 15Nov23

Demographic – Tumor Types

All patients experienced failure of prior PD1 treatment

Tumor Type	Total (N=18)	Prior Number of Tx	Prior Treatment
Cervical	**1 (5.6)**	3	pt, anti-VEGF, anti-PD1
Gastric	**4 (22.2)**	4 – 6	anti-PD1 and pt chemotherapies
Melanoma	**5 (27.8)**	1 – 2	anti-PD1
Uveal	3 (16.7)		
Cutaneous	2 (11.1)		
Renal cell	**4 (22.2)**	1 – 6	prior anti-PD1 and TKI
Urothelial	**1 (5.6)**	4	pt chemotherapies, anti-PD1 and ADC
NSCLC	**2 (11.1)**	3 – 7	pt chemotherapies, taxanes, anti-PD1, TKI, anti-VEGF
SCLC	**1 (5.6)**	3	pt chemotherapies, anti-PD1

Pt – Platinum;
Data Cut Date: 15Nov23

Grade 3+ Adverse Events of Special Interest

BA3071 Q3W + nivolumab 240 mg Q3W	7 mg (N=1)	21 mg (N=1)	70 mg (N=3)	210 mg (N=3)	350 mg (N=7)*	700 mg (N=3)	Total (N=18)
Number of subjects with at least one Grade 3+ AESI	0	0	2	0	1	2	**5 (27.8)**
GI Toxicity	0	0	1	0	1	0	**2 (11.1)**
Abdominal pain	0	0	1	0	0	0	**1 (5.6)**
Diarrhea	0	0	0	0	**1**	0	**1 (5.6)**
Liver Toxicity	0	0	2	0	0	0	**2 (11.1)**
AST increased	0	0	1	0	0	0	**1 (5.6)**
ALP increased	0	0	2	0	0	0	**2 (11.1)**
Pulmonary Toxicity	0	0	0	0	0	1	**1 (5.6)**
Pneumonia	0	0	0	0	0	1	**1 (5.6)**
Endocrine Toxicity	0	0	0	0	0	1	**1 (5.6)**
Diabetic ketoacidosis	0	0	0	0	0	**1**	**1 (5.6)**

^Patient with diarrhea also experienced Grade 3 gastritis
* 1 Pt at 350 mg dose for Phase 2 included
Red text denotes immune related AEs
Data Cut Date: 15Nov23
AST - Aspartate aminotransferase; ALP - Alkaline phosphatase

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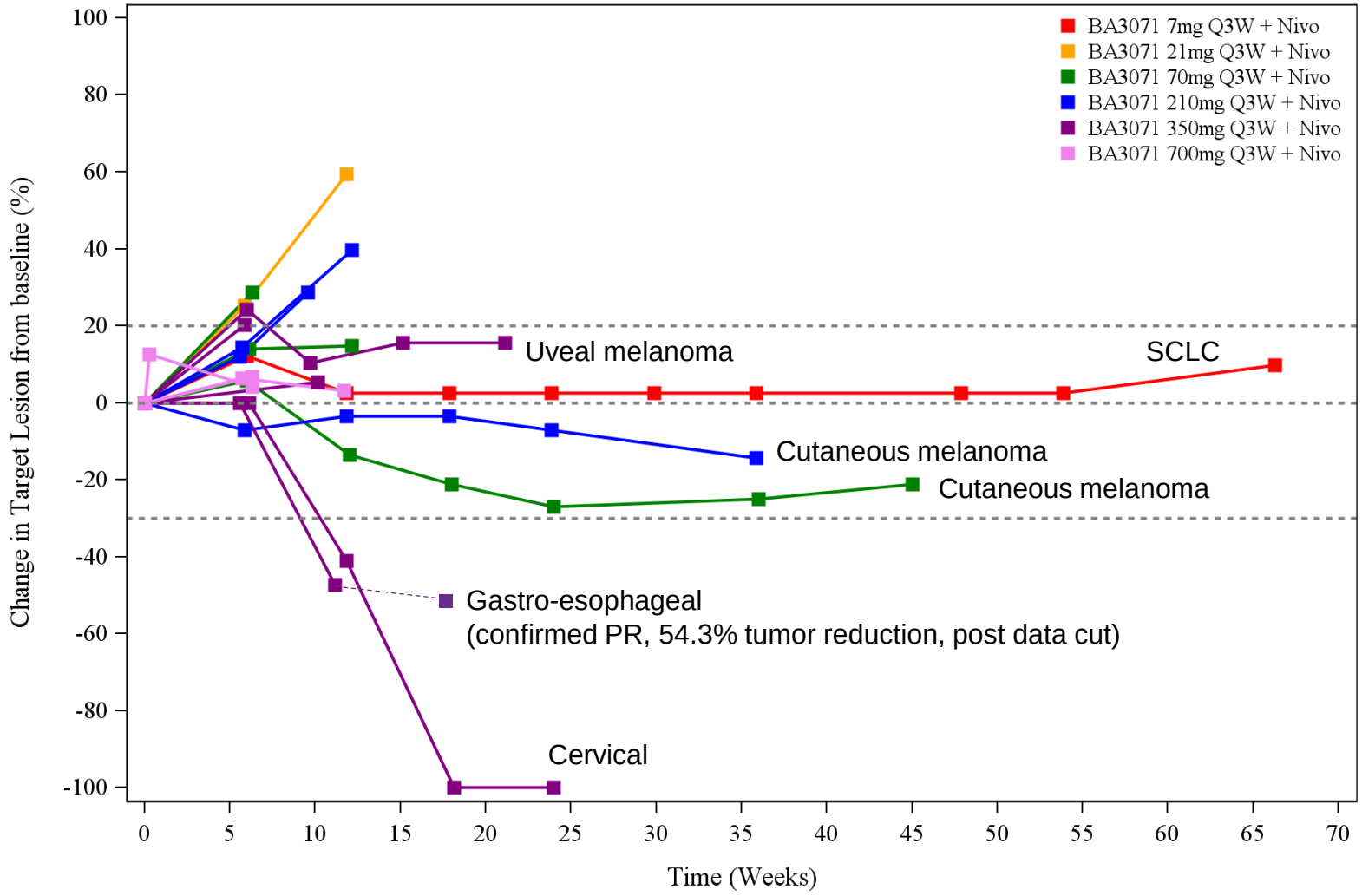
Diarrhea	0	0	0	0	1	0	**1 (5.6)**
Liver Toxicity						0	**2 (11.1)**
AST increased						0	**1 (5.6)**
ALP increased	0	0	2	0	0	0	**2 (11.1)**
Pulmonary Toxicity	0	0	0	0	0	1	**1 (5.6)**
Pneumonia	0	0	0	0	0	1	**1 (5.6)**
Endocrine Toxicity	0	0	0	0	0	1	**1 (5.6)**
Diabetic ketoacidosis	0	0	0	0	0	1	**1 (5.6)**

Only 2 patients with immune related AEs observed among 18 treated patients

^Patient with diarrhea also experienced Grade 3 gastritis
* 1 Pt at 350 mg dose for Phase 2 included
Red text denotes immune related AEs
Data Cut Date: 15Nov23
AST - Aspartate aminotransferase; ALP - Alkaline phosphatase

Confirmed Responses (n=2) and Stable Disease (n=9) Among 16 Evaluable Patients

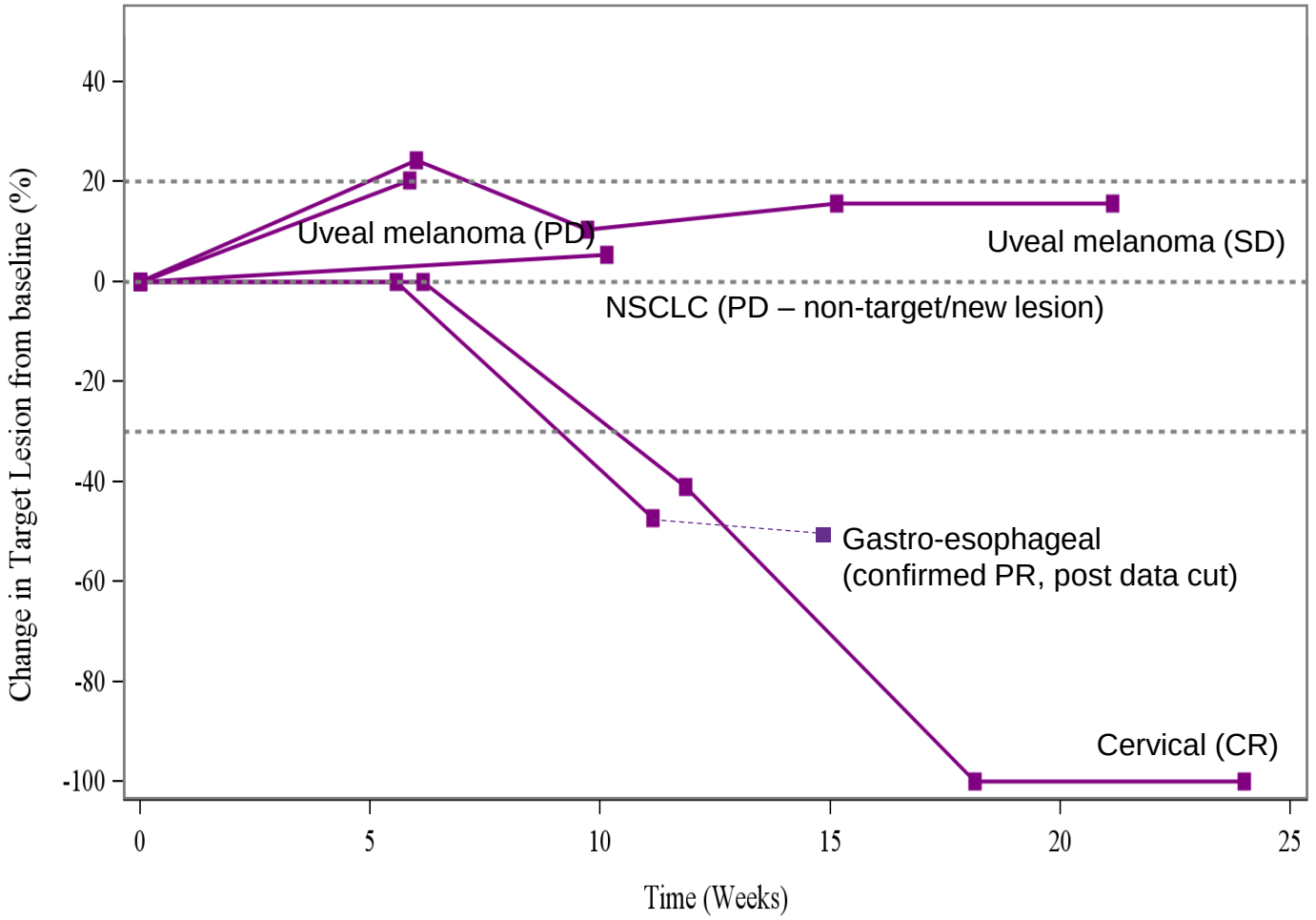


Data Cut Date: 15Nov23

Meaningful Clinical Benefit at 350 mg in Combination with PD1

Confirmed Partial and Complete Responses

Overall Response to date	N=5
Complete Response	1
Partial Response	1
Stable Disease	1
Progressive Disease	2

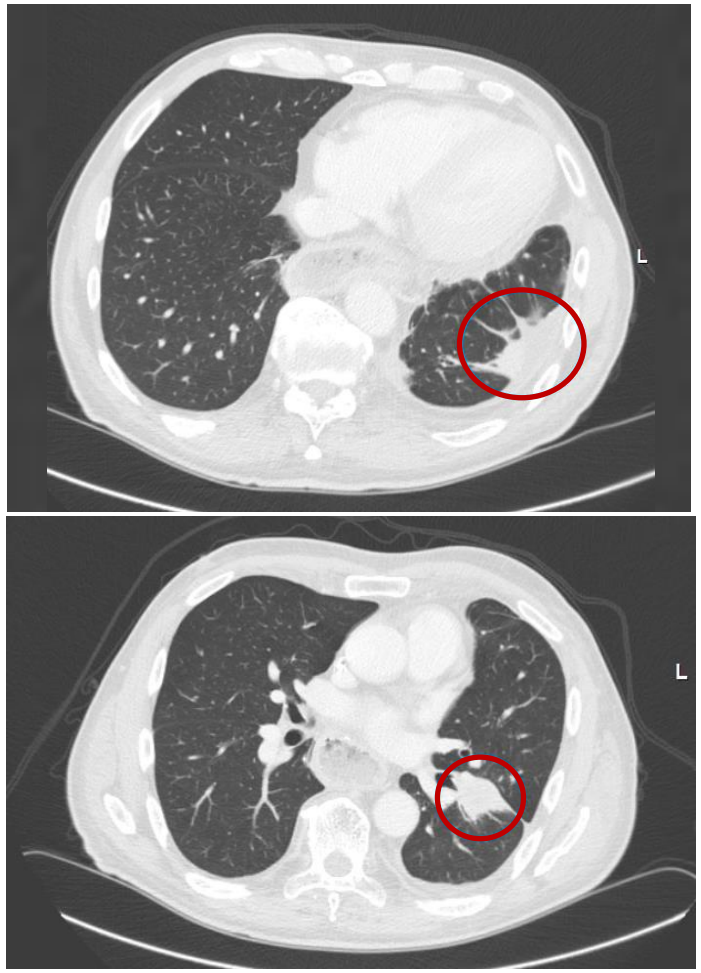


Data Cut Date: 15Nov23

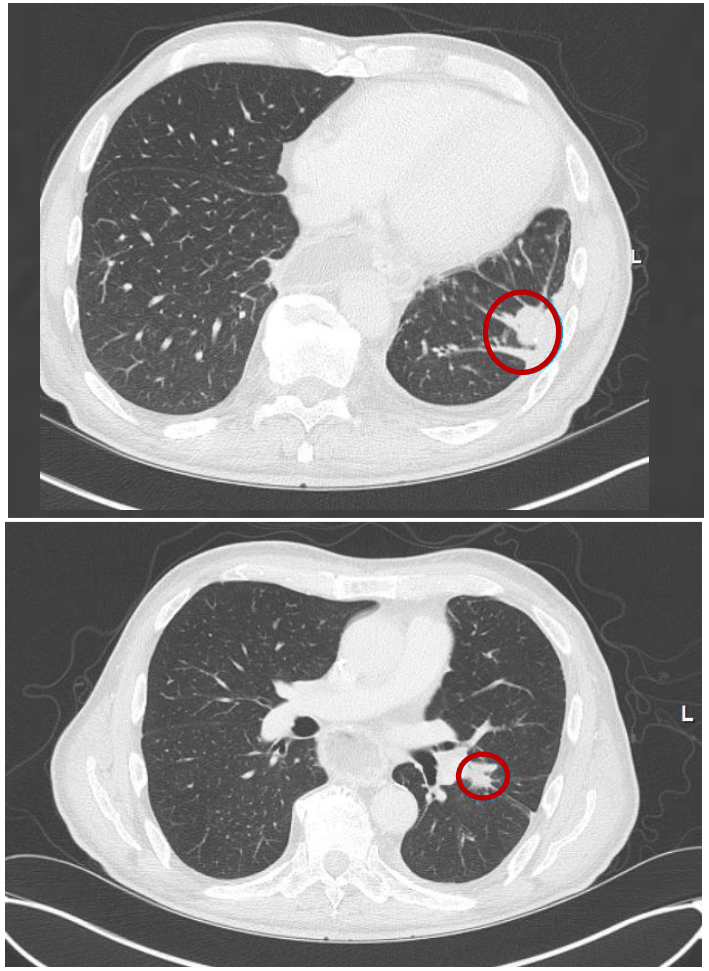
Confirmed PR - Gastro-esophageal Cancer

63-year-old male, stage IV gastro-esophageal cancer HER2 negative, post-FOLFOX, taxane, TKI, anti-PD1 and anti-VEGFI

Baseline - July 31,2023



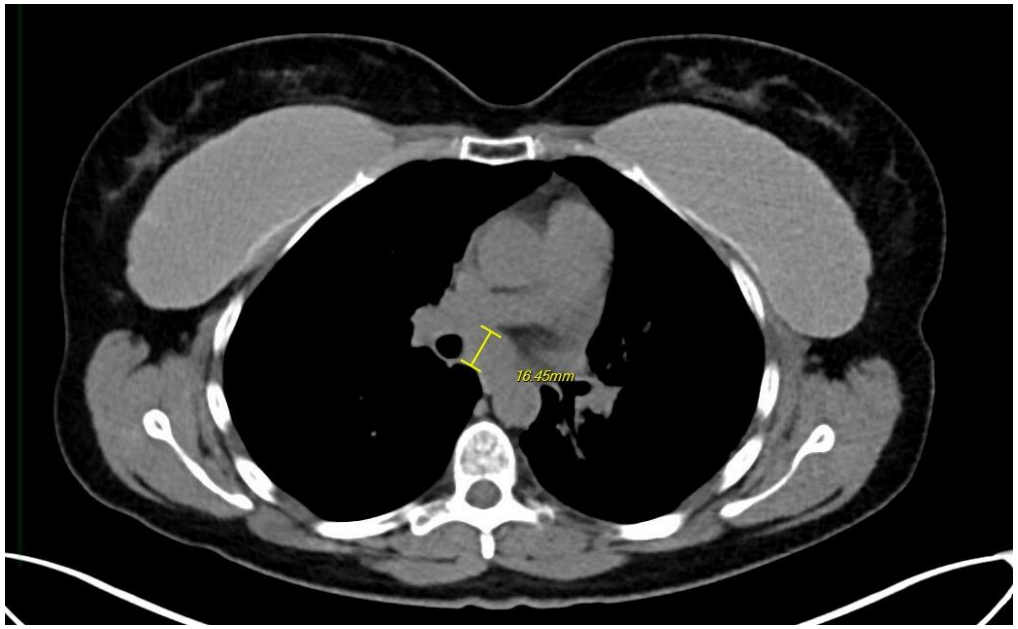
On Treatment - October 23, 2023



Confirmed CR - Cervical Cancer

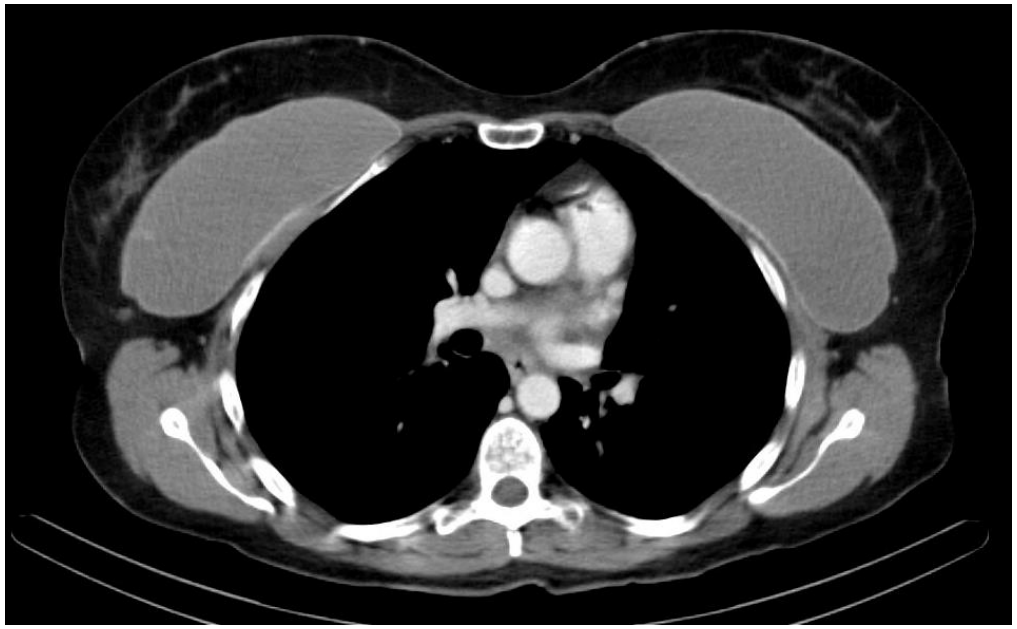
43-year-old female, stage IV cervical cancer HPV+16 positive, post-platinum, taxane, anti-PD1 and anti-VEGF

Baseline – March 23, 2023



"Multiple enlarged mediastinal, paraesophageal, and right hilar lymph nodes…"

On Treatment – August 9, 2023



"No enlarged mediastinal, hilar or axillary lymph nodes are present. There is persistent resolution of previously noted enlarged mediastinal and paraesophageal lymph nodes."

BA3071-001 Dose Titration Ongoing

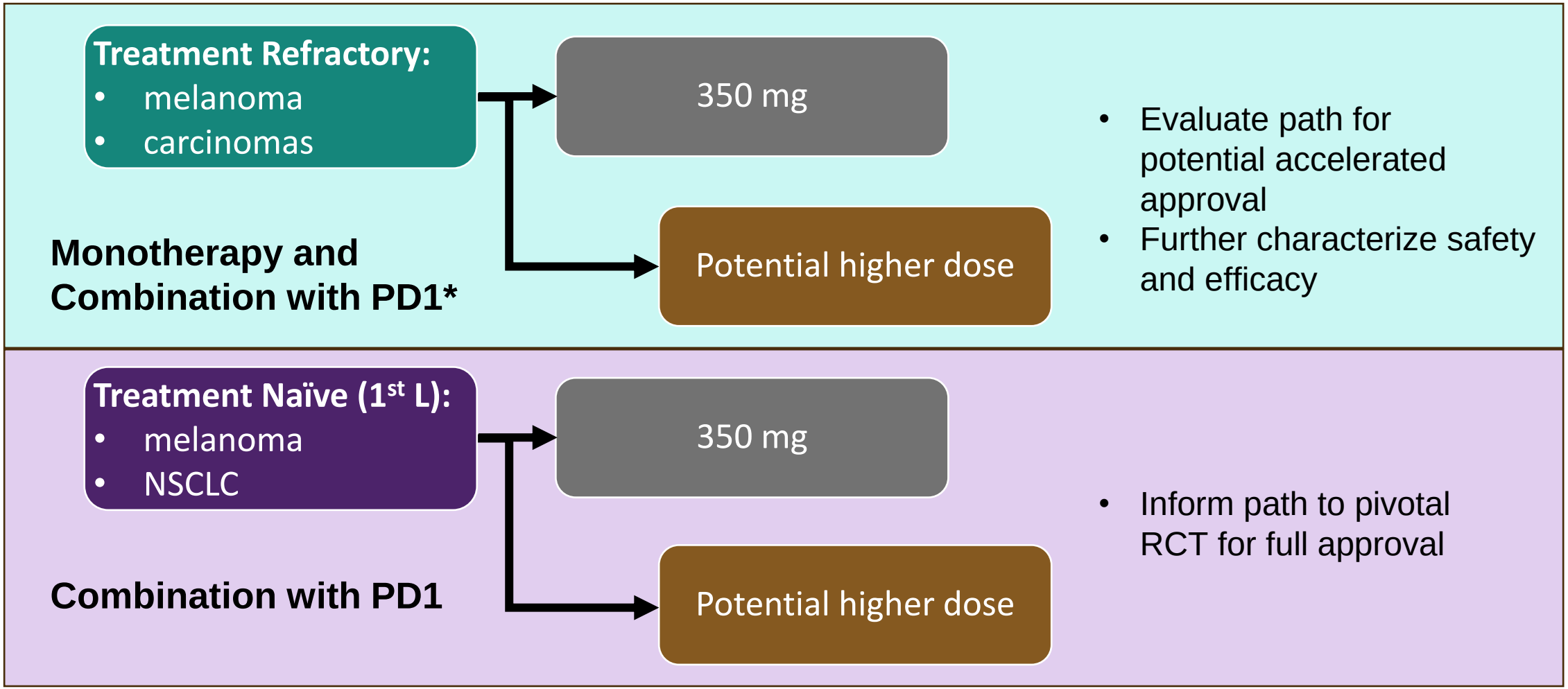
3 patients dosed at 700 mg Q3W in combination with nivolumab

Cancer Type	Age	Prior Tx	Adverse Events	DLT	Cycles Completed	Overall Response	Disposition
Renal cell	78	5	G1 fever and chills; G2 transient hypoxia	No	6	SD	Ongoing
Gastro-esophageal	66	4	G1 fever and chills	No	2	SD	DC - Subject Decision
NSCLC	76	7	G1 fever and chills; G2 transient hypoxia	Yes (atrial fibrillation)	2	SD	DC - AE

- Renal cell patient commenced prophylactic tocilizumab cycle 4 onward, now post 6 cycles and tolerating continued therapy
- Further evaluation of 700 mg and potentially 1000 mg both with prophylactic tocilizumab

Phase 2 Mono and Combo Study Currently Underway

Study designed for multiple approval paths



*Clarification post event at JPM fireside chat Dec 18; combination with PD1 planned post monotherapy study

Conclusion

- Promising efficacy signals observed – durable responses and disease control
- Emerging, differentiated safety profile enables exploration of higher dose levels
- Phase 2 study designed for both potential accelerated approval and confirmatory, full approval

Q & A Session