# Conditionally Active Biologics: Transforming Cancer Therapy

**Corporate Presentation** 

August 2022



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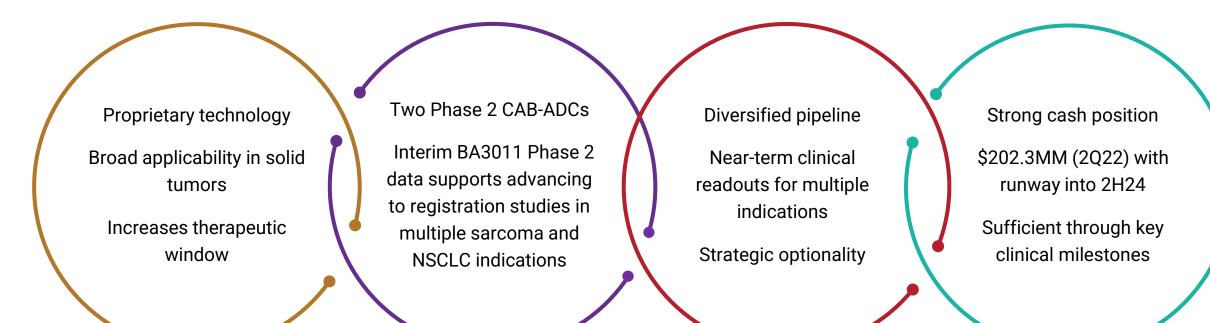
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#### **BioAtla**<sup>©</sup> is a clinical stage company focused on transforming cancer therapy with Conditionally Active Biologics (CABs)





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SeattleGenetics ZYMOGENETICS

## Selective and targeted CAB technology widens therapeutic window,

thus has the potential to enhance clinical outcomes in multiple tumor types



BioAtla discovered that acidic pH at the cancer cell surface unveils binding sites that are shielded at normal pH of healthy cells



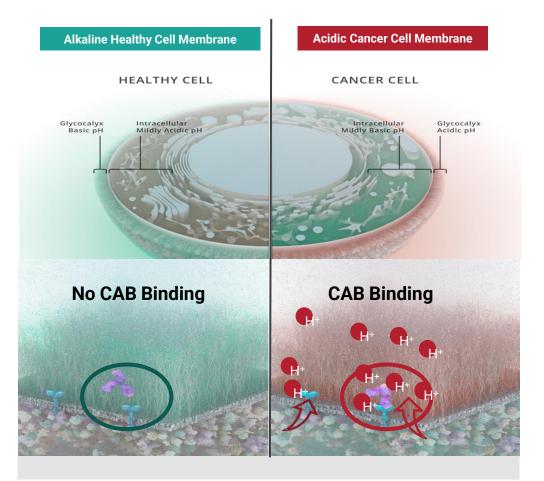
BioAtla invented CAB technology, creating antibodies that bind **only** to these unveiled sites on cancer cells



CAB binding region is not masked or caged and thus different from prodrugs that require irreversible enzymatic cleavage to become activated



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

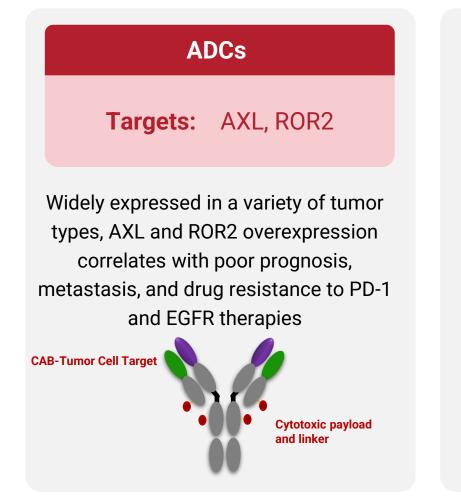


Chang, H.W., Frey, G., Liu, H., Xing, C., Steinman, L, Boyle, B.J., & Short, J.M. (2021) PNAS 118(9): 1-10, Suppl. 1-19.



# Broad applicability of BioAtla's CAB platform across several antibody types

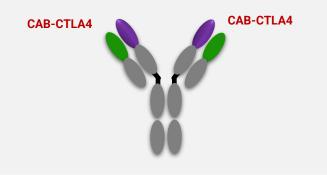
has the potential to treat multiple solid tumors



Naked Antibodies

Target: CTLA-4

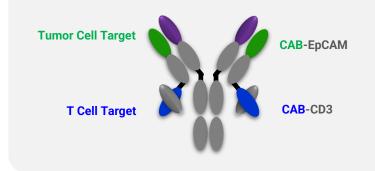
CTLA-4 blockade activates effector T cells, thereby enhancing antitumor immunity



#### **Bispecifics**

Target: EpCAM & CD3

Bispecific antibodies bridge cancer cells and cytotoxic T lymphocytes, activating T cells and promoting cancer cell lysis





# 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	Anticipated Milestones
CAB-ADCs	<b>BA3011</b> Mecbotamab Vedotin	AXL	STS & Bone Sarcoma NSCLC Ovarian Cancer*				<ul> <li>Interim sarcoma results – achieved go criteria to advance UPS and osteosarcoma into Phase 2 part 2</li> <li>Initial interim NSCLC results – achieved go criteria to advance to Phase 2 part 2</li> <li>Ovarian IIT dosing</li> </ul>
	<b>BA3021</b> Ozuriftamab Vedotin	ROR2	NSCLC Melanoma SCCHN Ovarian Cancer*				<ul> <li>Phase 2 interim NSCLC data and melanoma update 2H22</li> <li>SCCHN trial dosing 3Q</li> <li>✓ Ovarian IIT dosing</li> </ul>
CAB-I/O	BA3071	CTLA-4	Multiple tumor types**				✓ Phase 1 / 2 dosing
CAB-Bi- specifics	BA3182	EpCAM & CD3	Adenocarcinoma** Multiple tumor types**				<ul> <li>IND submission and Phase 1 initiation 2H2022</li> </ul>
	Additional programs	Various	Multiple tumor types**				• 2023 and beyond



IIT, investigator-initiated trial; IND, investigational new drug; NSCLC, Non-small Cell Lung Cancer; RCC, Renal Cell Carcinoma; SCCHN, Squamous Cell Carcinoma of the Head and Neck; STS, Soft Tissue Sarcoma.

\* Phase 2 investigator-initiated trial for Ovarian Cancer \*\* Indications based upon tumor target expression BioAtla | Overview 7



#### **CAB-AXL-ADC** Platform

BA3011 Mecbotamab Vedotin: Sarcoma and NSCLC

## Potential market opportunity in UPS and Osteosarcoma

UPS

1

- 2<sup>nd</sup> most common Soft Tissue Sarcoma (STS) subtype (~15% of all STS)<sup>1</sup>
- High-grade aggressive subtype with high recurrence rates<sup>1</sup>
- 3 3k 4k AXL+ addressable patients per year in the U.S.<sup>1,4</sup>

- **Current Treatments**
- Chemotherapy, chemoradiation or regional limb therapy for unresectable cases
- No approved targeted therapies for UPS
- Approved treatments for sarcoma ORR ~15%<sup>5</sup>

Osteosarcoma

- Most common malignant primary bone tumor (30% of all such malignancies)<sup>2</sup>
- 2 ~20% of patients have metastases at diagnosis; of the remainder, 50% progress to clinical metastasis<sup>3</sup>
- 3 2k 3k AXL+ addressable patients per year in the U.S.<sup>2-4</sup>

#### **Current Treatments**

- 1st-line surgical resection +/- chemo / radiation
- No approved therapies for 2L+
- Independent Phase 2 study showed PFS rate for placebo at 8 weeks = ~0%<sup>6</sup>

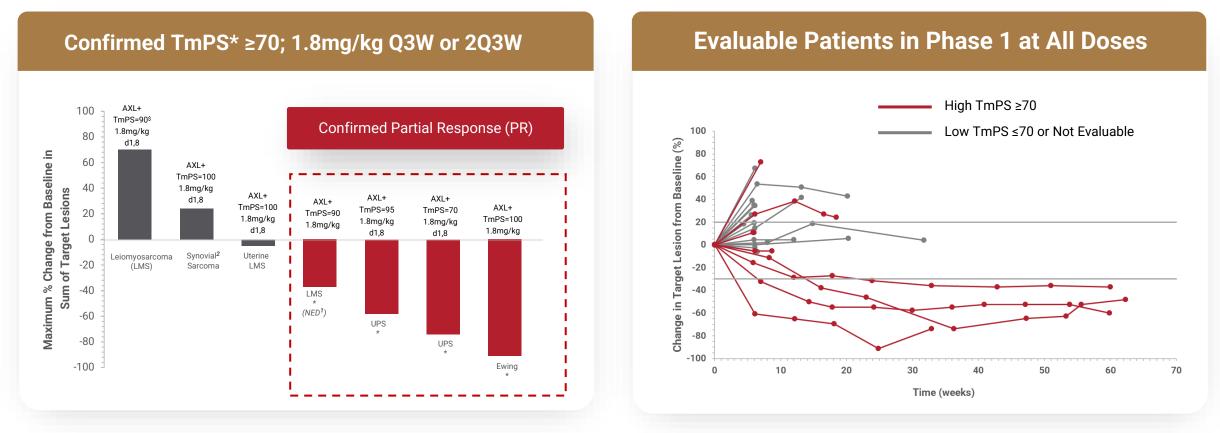
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<sup>1</sup><u>Undifferentiated Pleomorphic Sarcoma - StatPearls - NCBI Bookshelf (nih.gov)</u>; Annals of Oncology 30: 1143–1153, 2019. <sup>2</sup><u>https://www.cancernetwork.com/view/bone-sarcomas.</u> <sup>3</sup><u>https://www.cancer.org/cancer/osteosarcoma/detection-diagnosis-staging/staging.html</u>; https://www.texasoncology.com/types-of-cancer/bone-cancer/osteosarcomaoverview/recurrent-osteosarcoma. <sup>4</sup>Company estimates <sup>5</sup>Product USPIs. <sup>6</sup>*Lancel Oncol* 2019 Jan;20(1):120-133.

2L, second line; 2L+, second line or greater; ORR, objective response rate (best objective response as confirmed complete response or partial response); PBO, placebo; STS, soft tissue sarcoma; UPS, undifferentiated pleomorphic sarcoma.

# Encouraging Phase 1 results with Mecbotamab Vedotin (BA3011)

#### in refractory sarcoma



- PR was achieved in 4/7 high TmPS patients receiving the clinically-meaningful 1.8 mg/kg dose
- Antitumor activity correlates with higher levels of AXL tumor membrane expression in sarcoma patients



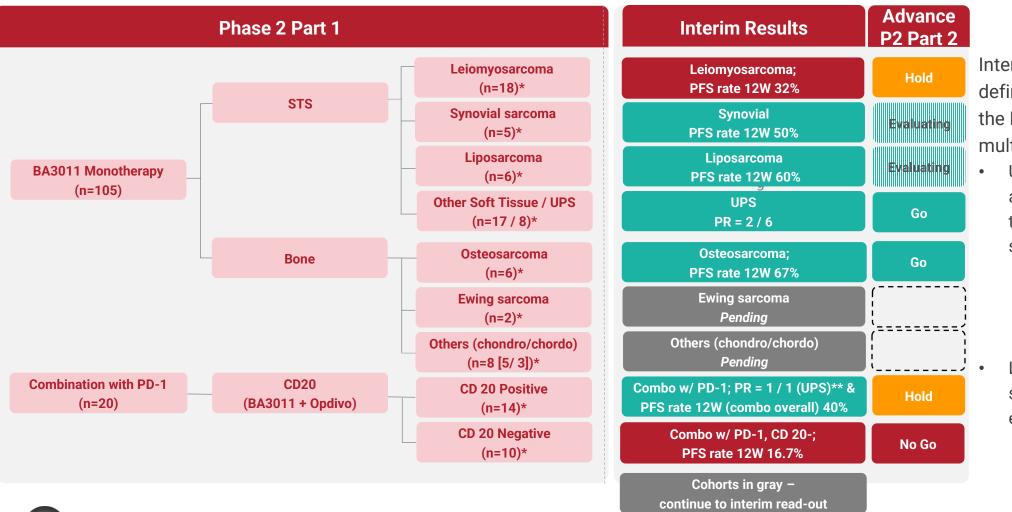
Notes:

All patients: Multiple cycles of antineoplastic agents received prior to starting treatment with BA3011 \*AXL Tumor membrane Percent Score or TmPS = % Score ≥1+; <sup>\$</sup>Tissue biopsy from resection, over 1 year old prior to trial entry

<sup>1</sup> NED = No evidence of disease; <sup>2</sup> Synovial sarcoma patient delayed treatment due to unrelated SAE led to progression

# Phase 2 Part 1 Topline Interim Analysis Results Confirm Phase 1 Signal

#### following BA3011 in refractory sarcoma subtypes



Interim results satisfied predefined 'Go' criteria into part 2 of the Phase 2 BA3011 study in multiple sarcoma subtypes:

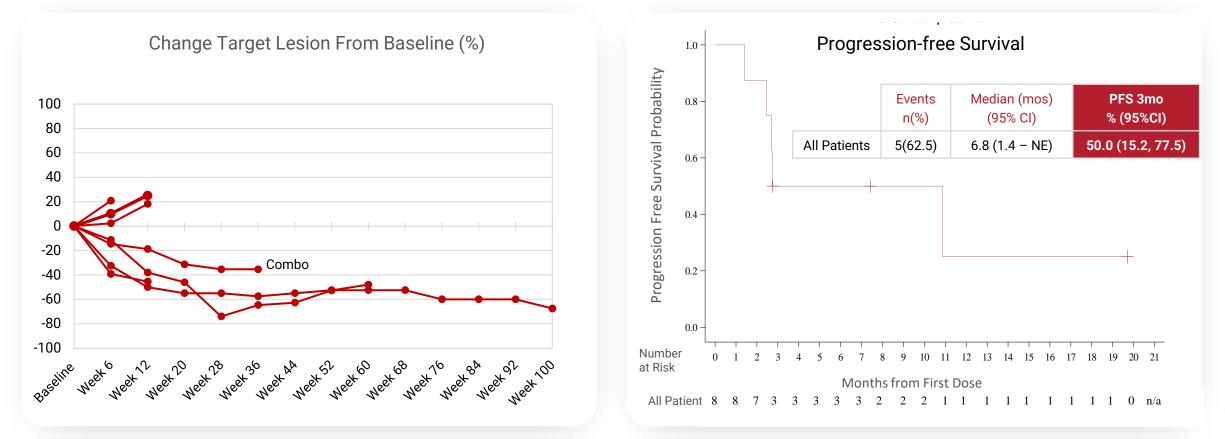
- UPS and osteosarcoma advancing as separate cohorts to potentially registration studies (Phase 2 part 2).
  - Additional detail for part 2 will become available following FDA written response
- Liposarcoma and synovial sarcoma next steps under evaluation



Pre-defined criteria for each subgroup up to 10 patients: 'No Go' if 0 CR/PR and PFS rate at 3 months <40%; 'Go' if ≥1 CR/PR or PFS rate at 3 months ≥40%. \* As of data cut-off Jul 25, 2022; Cohorts in gray continuing enrollment until sufficient sample size is achieved. \*\*Included in UPS cohort. BA3011 dose 1.8 mg/kg Q2W. PFS, progression-free survival; PR, partial response; UPS, undifferentiated pleomorphic sarcoma.

# **Undifferentiated Pleomorphic Sarcoma (UPS):**

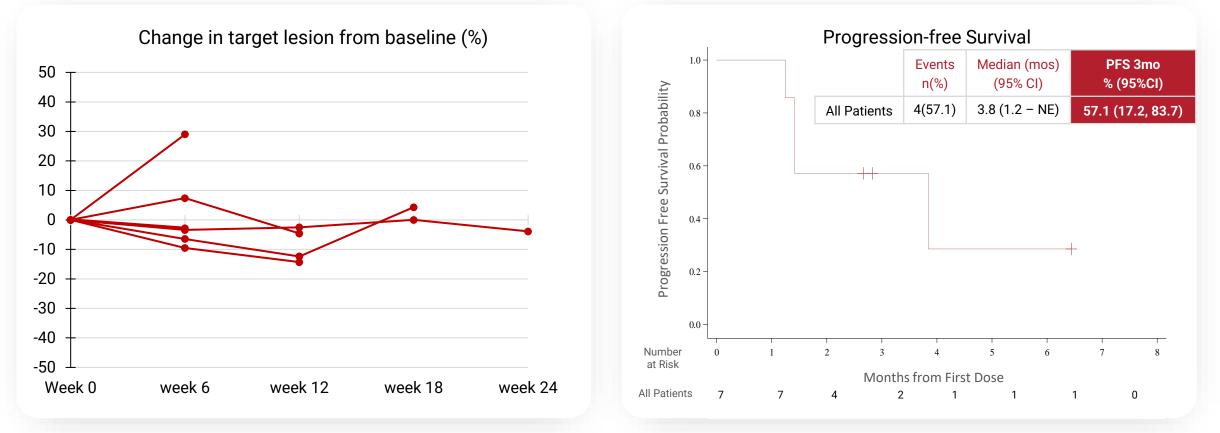
Phase 1 & 2 Change in Target Lesion and Progression Free Survival (1.8mg/kg; n=8)



- 4 / 8 patients achieved PRs, with an ORR of 50% and PFS rate at 3 months of 50%
- Responses to BA3011 treatment are durable, with partial responders remaining on treatment for extended periods of time
- Interim results satisfied the pre-defined Go criteria of UPS cohort into part 2 of the Phase 2 study

#### Osteosarcoma:

Phase 1 & 2 Change in Target Lesion and Progression Free Survival (1.8mg/kg; n=7)

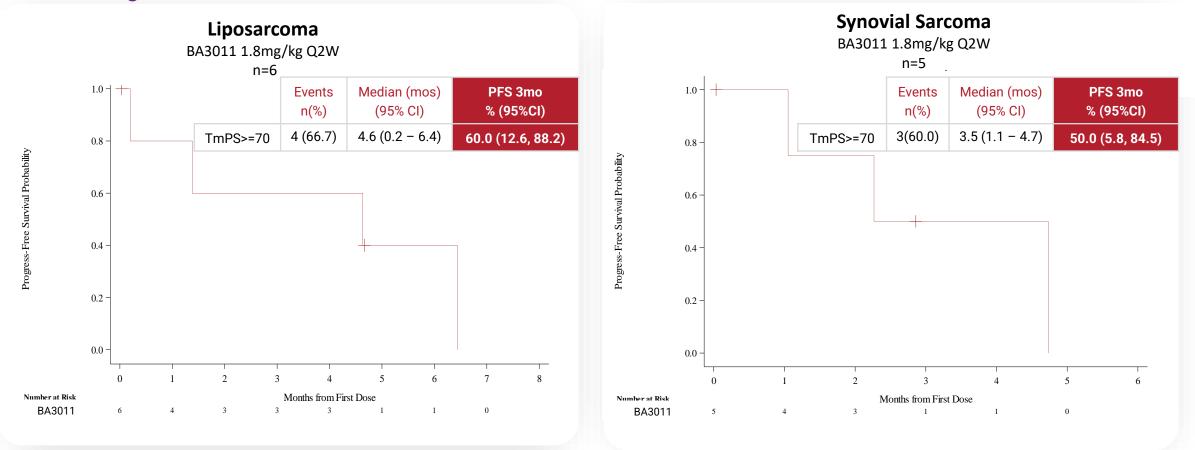


- Of 7 patients enrolled, PFS rate at 3 months was 57%
- When combining all Phase 1 & 2 bone sarcoma patients, a total of 7 patients were enrolled and observed a PFS rate at 3 months of 56%
- Interim results satisfied the pre-defined Go criteria of osteosarcoma cohort into part 2 of the Phase 2 study



## Liposarcoma and Synovial sarcoma:

**Phase 2 Progression Free Survival** 



- Phase 2 PFS rate at 3 months of 60% for liposarcoma and 50% for synovial sarcoma BA3011 monotherapy in patients with 3 or more prior systemic therapies
- Interim results satisfied the pre-defined Go criteria of liposarcoma and synovial sarcoma cohorts into part 2 of the Phase 2 study.
   Next steps under evaluation.

Interim data- Data cut-off of Jul 25, 2022

# Continued promising safety and tolerability profile in Sarcoma

#### Phase 2 at the RP2D 1.8 mg/kg Q2W

Characteristic	BA3011 (N=71)
Any Adverse Events (AEs)	64 ( 90%)
Related AEs with CTCAE <sup>1</sup> Grade 3 or 4 <sup>2</sup>	17 ( 24%)
Any related serious AEs <sup>2</sup>	6 ( 8%)
Related AEs leading to death <sup>2</sup>	0
Related AEs leading to treatment discontinuation <sup>2</sup>	2 (3%)§

Constipation	Grade 1-2 (19%)		
Constipution	Grade 3-4 (0%)		
Peripheral Neuropathy	All Grade 1-2 (21%)		
Diarrhea	Grade 1-2 (19%)		
Darried	Grade 3-4 (0%)		

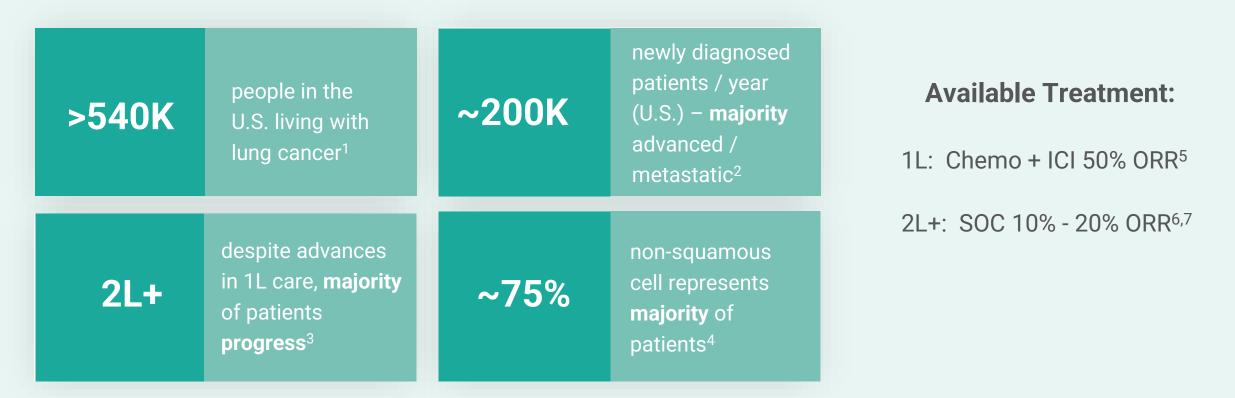
Low-grade constipation observed is consistent with baseline levels seen in advanced cancer patients

- No treatment-related deaths
- Few treatment-related SAEs, consistent with MMAE-based toxicity, including reversible myelosuppression, transient liver enzyme elevation, metabolic disturbances
- Very few related AEs leading to treatment discontinuation
- No clinically meaningful on-target toxicity observed over background
- Differentiated profile due to avoiding on-target off-tumor toxicity



Interim data- Data cut-off of May 16, 2022 Note: 1CTCAE: 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. © §Grade 2 peripheral neuropathy tal

## Potential market opportunity in metastatic NSCLC

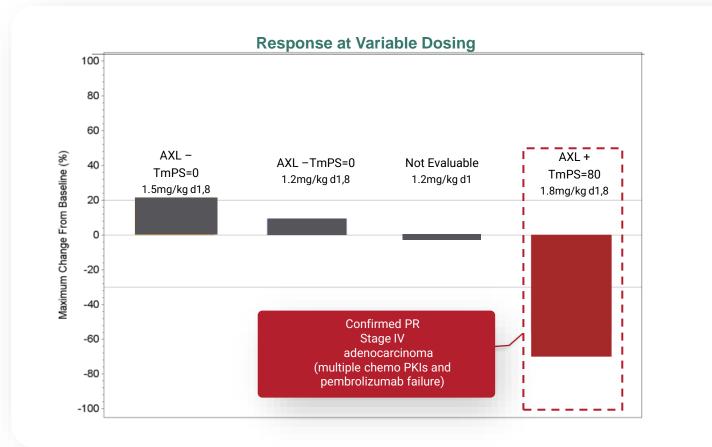


- Target population: ~50K AXL+ addressable 2L+ patients/year in the U.S.<sup>8</sup>, based on AXL positivity rate of ~35%
- Internal success threshold: 2L+ ORR of ~15% 20% (approvability bar); 20%+ (commercially relevant) following BA3011 monotherapy



<sup>1</sup>https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet <sup>2</sup>https://www.cancer.net/cancer-types/lung-cancer-nonsmall-cell/statistics, <sup>3</sup>Wang F, Wang S and Zhou Q (2020) The Resistance Mechanisms of Lung Cancer Immunotherapy. *Front. Oncol.* 10:568059. doi: 10.3389/fonc.2020.568059, <sup>4</sup>https://thoracickey.com/carcinomas-of-the-lung-classification-and-genetics/#F1-72 <sup>5</sup>Transl Lung Cancer Res 2021;10(7):3093-3105. <sup>6</sup>Ann Oncol. 2017;28(11):2698–706. <sup>7</sup>DOI: 10.1200/JCO.22.00912 *Journal of Clinical Oncology* Published online June 03, 2022. <sup>8</sup>Clarivate, Disease Landscape and Forecast: NSCLC (2022).

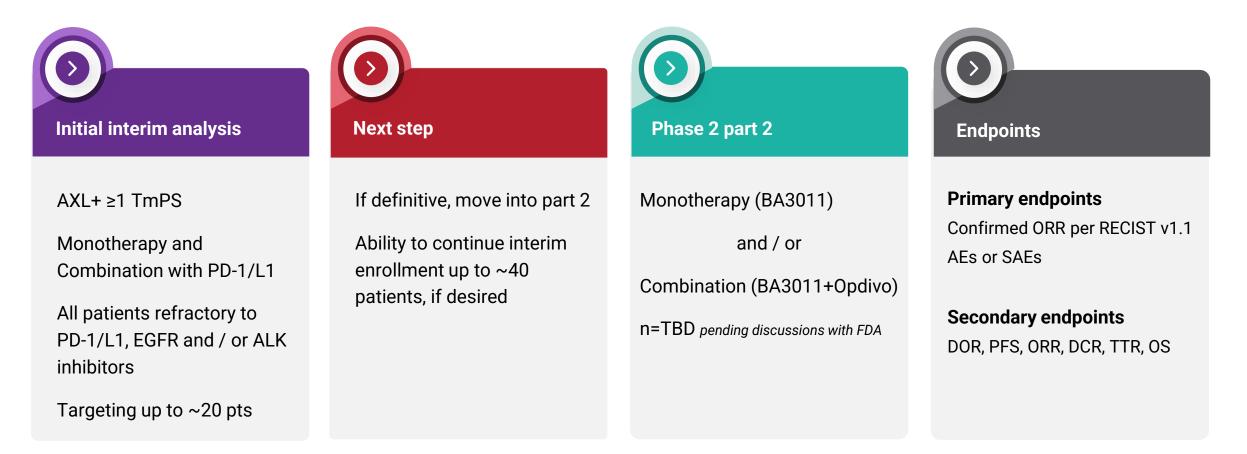
#### Encouraging Phase 1 results with Mecbotamab Vedotin (BA3011) in refractory NSCLC patients



 A partial response was achieved in the AXL-high NSCLC patient refractory to multiple chemo PKIs and pembrolizumab failure



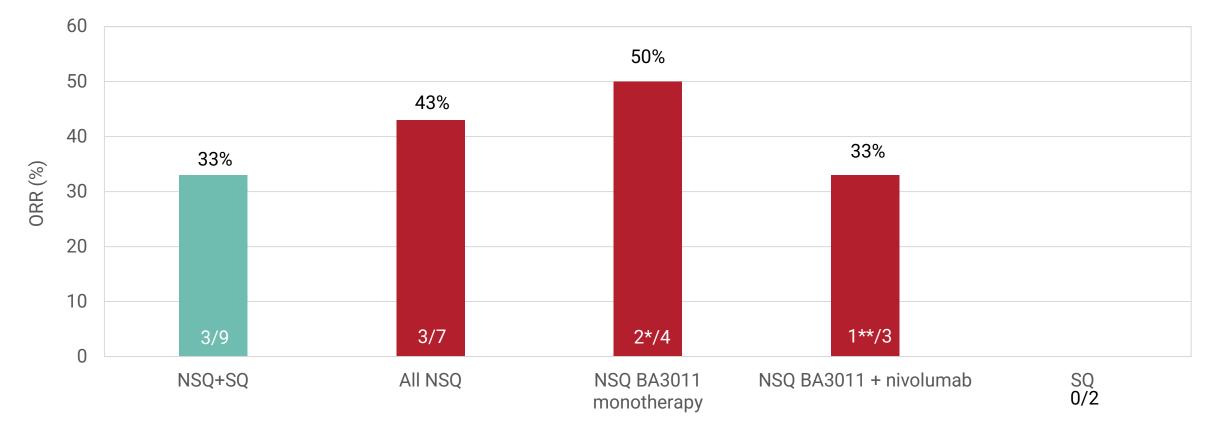
## Phase 2 study design with BA3011 (Mecbotamab Vedotin) in refractory NSCLC patients





# Phase 2 part 1 BA3011 NSCLC initial interim analysis confirms Phase 1 signal

#### supports advancing preparations for part 2 in refractory NSCLC



NSQ - non-squamous; SQ - squamous

Responses include 2 confirmed partial responses (\*) and one confirmed complete response (\*\*)



15 patients enrolled as of July 2022: 4 patients currently on treatment did not yet have the opportunity to be followed for 3 months; 2 patients are not efficacy-evaluable; 9 efficacy evaluable patients - All patients failed prior PD-1 treatment(s) – median prior lines of therapy = 2.5

# Promising safety and tolerability profile emerging in NSCLC

#### Phase 2 at the RP2D 1.8 mg/kg Q2W

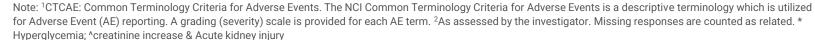
Character	ristic	BA3011 (N=7)	BA3011 + Opdivo (N=4)
Any Adve	erse Events (AEs)	6 (86%)	4 (100%)
Related A	AEs with CTCAE <sup>1</sup> Grade 3 or $4^2$	1 (14%)	2 (50%)
Any relat	ed serious AEs <sup>2</sup>	1 (14%)*	2 (50%)^
Related A	AEs leading to death <sup>2</sup>	0	0
Related A discontir	AEs leading to treatment nuation <sup>2</sup>	0	0
	Constipation	Grade 1-2 (9%)	
	constipution	Grade 3-4 (0%	)
	Peripheral Neuropathy	All Grade 1-2 (	0%)
	Diarrhea	Grade 1-2 (18%	b)
		Grade 3-4 (0%)	

No treatment-related deaths

- Few treatment-related SAEs
- No AEs leading to treatment discontinuation
- No clinically meaningful on-target toxicity observed over background
- Differentiated profile due to avoiding on-target off-tumor toxicity

Low-grade constipation observed is consistent with baseline levels seen in advanced cancer patients

Interim data- Data cut-off of June 2, 2022



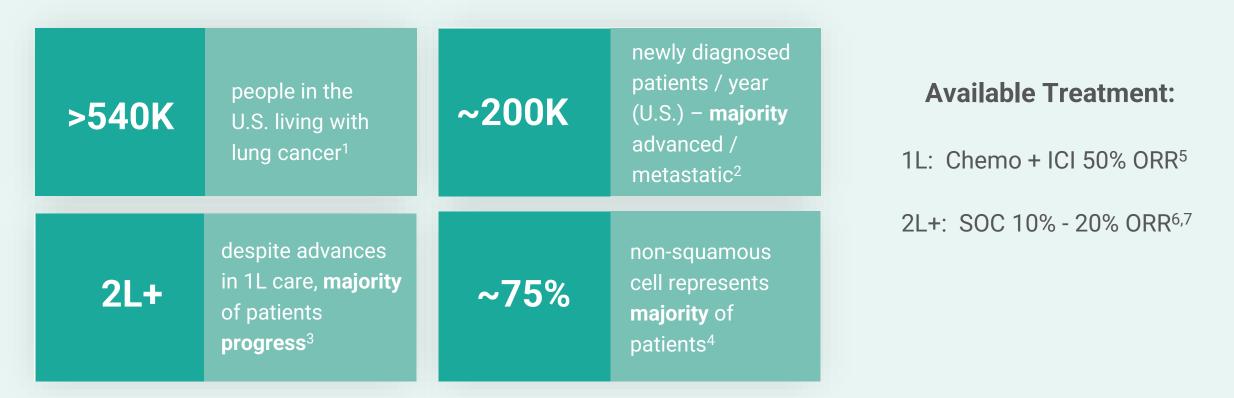




#### **CAB-ROR2-ADC** Platform

BA3021 Ozuriftamab Vedotin – NSCLC, Melanoma, SSCHN

## Potential market opportunity in metastatic NSCLC

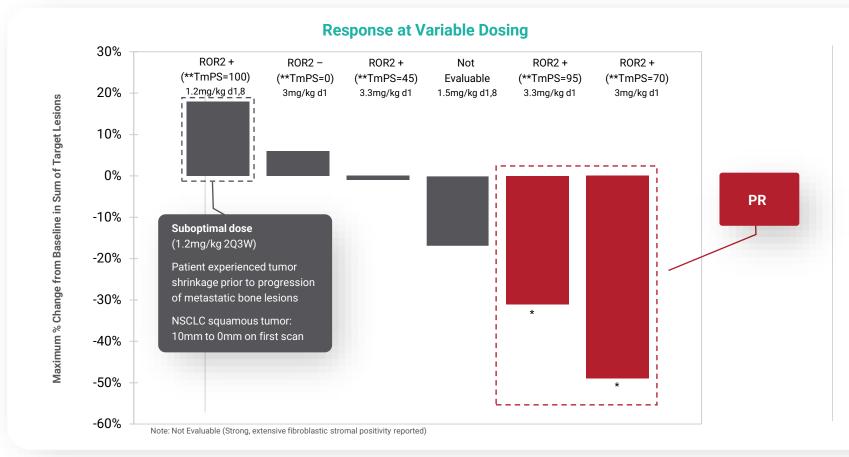


- Target population: ~40K ROR2+ addressable 2L+ patients/year in the U.S.<sup>8</sup>, based on ROR2 positivity rate of ~30%
- Internal success threshold: 2L+ ORR of ~15% 20% (approvability bar); 20%+ (commercially relevant) following BA3011 monotherapy



<sup>1</sup>https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet <sup>2</sup>https://www.cancer.net/cancer-types/lung-cancer-nonsmall-cell/statistics, <sup>3</sup>Wang F, Wang S and Zhou Q (2020) The Resistance Mechanisms of Lung Cancer Immunotherapy. *Front. Oncol.* 10:568059. doi: 10.3389/fonc.2020.568059, <sup>4</sup>https://thoracickey.com/carcinomas-of-the-lung-classification-and-genetics/#F1-72 <sup>5</sup>Transl Lung Cancer Res 2021;10(7):3093-3105. <sup>6</sup>Ann Oncol. 2017;28(11):2698–706. <sup>7</sup>DOI: 10.1200/JCO.22.00912 *Journal of Clinical Oncology* Published online June 03, 2022. <sup>8</sup>Clarivate, Disease Landscape and Forecast: NSCLC (2022).

# Encouraging Phase 1 results with BA3021 (Ozuriftamab Vedotin) in refractory patients with NSCLC



 Two out of three ROR2+ patients had a confirmed partial response following ozuriftamab vedotin treatment



\*\*Suboptimal dose 1.2 mg/kg 2Q3W. Tumor shrinkage occurred prior to progression of metastatic bone lesions. NSCLC squamous tumor 10mm to 0mm on first scan. TmPS = 16%, patient was refractory to four prior lines of therapy including cetuximab and pembrolizumab.

## Potential market opportunity in metastatic melanoma



- Target population: ~5K ROR2+ addressable 2L+ patients/year in the U.S.<sup>1</sup>, based on a ROR2 positivity rate of ~10%
- Internal success threshold: 2L+ ORR of ~20% (approvability bar); 25%+ (commercially relevant) following BA3011 monotherapy



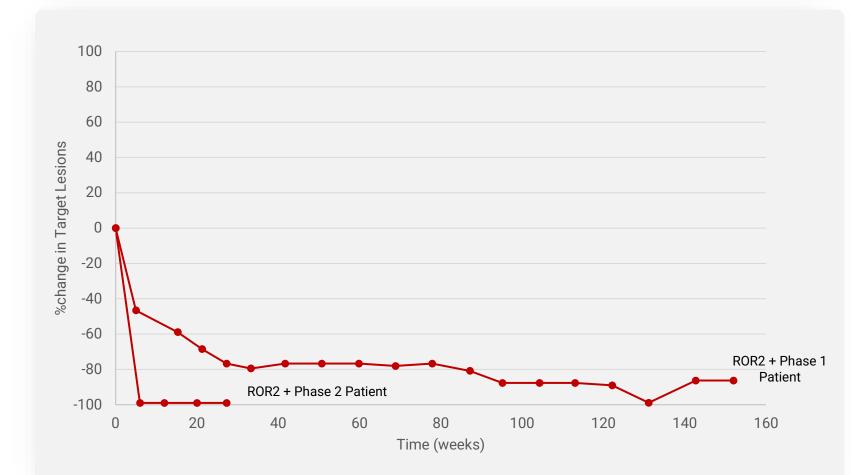
<sup>1</sup>Clarivate, Disease Landscape and Forecast: Malignant Melanoma (2022). www.cancer.net; <u>www.cancer.org</u>; <sup>2</sup>Oncology (Williston Park). 33(4):141-8. <sup>3</sup>Keytruda USPI accessed June 2022; Opdivo USPI accessed June 2022. <sup>4</sup>VanderWalde A, Moon J, Bellasea S, et al. Ipilimumab plus nivolumab versus ipilimumab alone in patients with metastatic or unresectable melanoma that did not respond to anti-PD-1 therapy. Presented at: 2022 AACR Annual Meeting; April 8-13, 2022; New Orleans, LA. Abstract CT013.

1L, first line; 2L+, second line or greater; ICIs – Immune checkpoint inhibitors.

## Phase 1 & 2 Results in Stage IV Multi-Refractory Melanoma

#### **Complete Response Observed in 2 out of 2 ROR2+ Patients**

Data on file.



## Phase 1

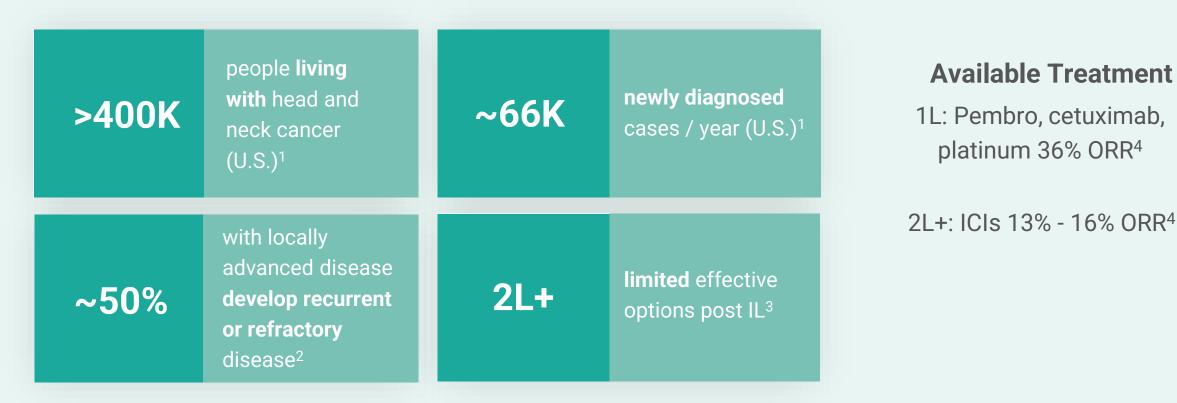
#### **Patient Details:**

- Prior treatment failure: nivolumab followed by nivolumab + ipilimumab combination
- Clearance of pulmonary metastases followed by normalization of adenopathy
- Continued CR off-treatment for over 2 yrs

#### Phase 2 Patient Details:

- Prior treatment failure: nivolumab followed by Dacarbazine
- ✓ Complete Response on 1st scan (3 doses)

## **Potential market opportunity in SCCHN**



- Target population: ~12K ROR2+ addressable 2L+ patients/year in the U.S.<sup>1</sup>, based on a ROR2 positivity rate of ~60%
- Internal success threshold: 2L+ ORR of ~15% (approvability bar); 15%+ (commercially relevant) following BA3011 monotherapy

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<sup>1</sup>Clarivate, Disease Landscape and Forecast: SCCHN (2022). www.cancer.net; <sup>2</sup>Argiris A, et al.(2017) Evidence-Based Treatment Options in Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck. *Front. Oncol.* 7:72; <sup>3</sup>Future Oncology, Jan. 2019. Vol. 15, No. 8; <sup>4</sup>Ketruda USPI accessed June 2022; Opdivo USPI access June 2022.

SCCHN, squamous cell carcinoma of the head and neck; 1L, first line; 2L, second line; 2L+, second line or greater; ICIs – Immune checkpoint inhibitors.

# Phase 1 results with BA3021 support advancing into Phase 2 in multiple indications

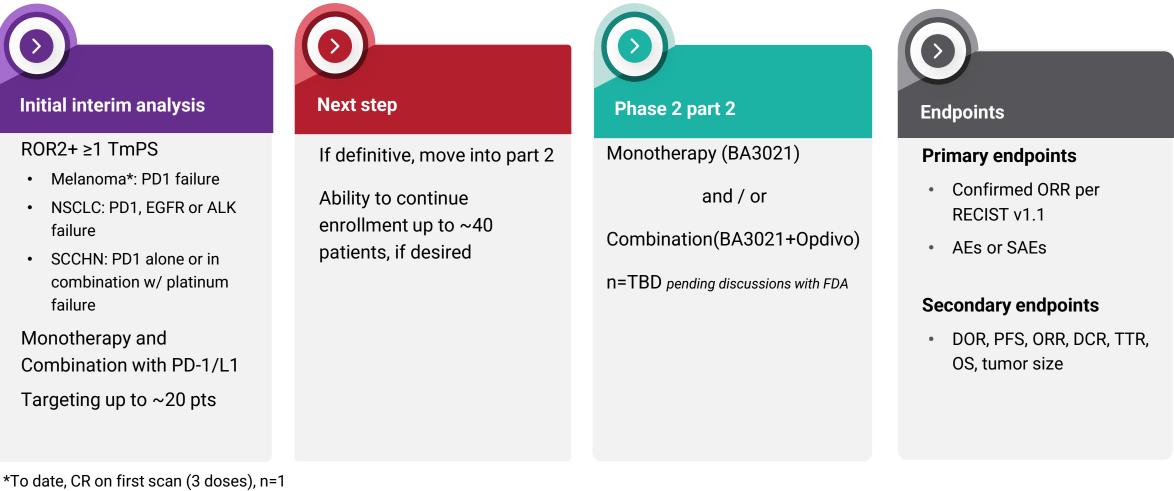
ROR2+ Tumor Types	Results		
NSCLC	<ul> <li>PR in 2 / 3 patients who previously experienced failure on PD-1 and who received Ph2 dose or higher</li> </ul>		
Melanoma	<ul> <li>CR in 1 / 1 patient who previously experienced failure on PD-1</li> <li>Clearance of pulmonary metastases followed by normalization of adenopathy</li> <li>Continued CR off treatment for over 2 years</li> </ul>		
SCCHN	<ul> <li>PR in 1 / 1 ROR2+ refractory to four prior lines of therapy including cetuximab and PD-1 (pembrolizumab)</li> </ul>		
Promising safety and tolerability profile across multiple tumor types			

No ROR2 ADC or small molecules in the clinic to date, suggesting CAB-ROR2-ADC is a first-in-class therapy across multiple tumor types



# Phase 2 study design with BA3021 (Ozuriftamab Vedotin) in refractory patients

for each indication: NSCLC, Melanoma, and SCCHN



# bicatla



## Naked Antibody Platform:

CTLA-4 (BA3071) – Basket Trial

## **BA3071 (CAB-CTLA-4)**

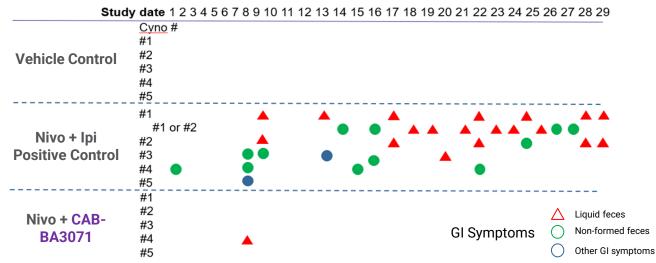
#### **Best-in-class and potential for disruption of the I/O Market**

Research demonstrates challenges and opportunity in combining two Immune Checkpoint Inhibitors\*

- Improves efficacy, but increases adverse events
- Greater % of patients discontinue therapy
   relative to monotherapy

Clinical Endpoint	Nivolumab (PD-1)	Nivolumab (PD-1) + Ipilimumab (CTLA4)	
Progression Free Survival	6.9 months	11.5 months	
Grade 3 or 4 Adverse Events	16.3%	55.0%	
Discontinued Treatment	7.7%	36.4%	

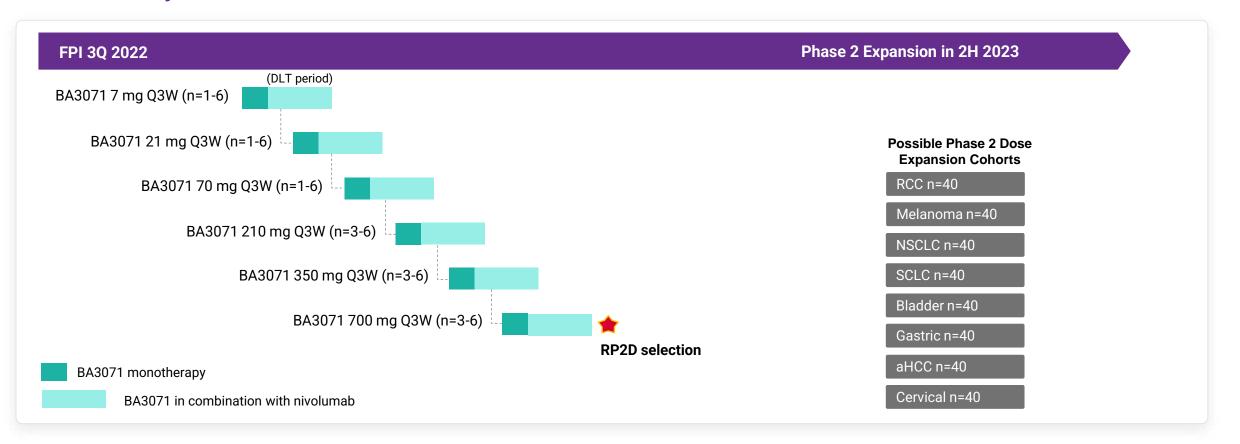
In NHP study, BA3071 achieved similar exposure levels to Ipi analog with significantly less toxicity in combination with nivo\*\*





\*Larkin et al., New Eng. J. Med.,373: 23-34, 2015
\*\*Chang et al., PNAS 118 (9): 1-10, 2021
Nivo: 20mg/kg QW (12X human dose); Ipi or CAB-CTLA: 15mg/kg QW (45 - 60X human dose)
Once weekly for four weeks exposure to Nivo + Ipi or CAB CTLA4
AUC<sub>168</sub> = Area under the serum drug concentration-time curve from time zero to 168 hours; C<sub>max</sub> = Highest drug concentration observed in serum

#### Phase 1/2 trial design for CAB-CTLA-4 Naked Antibody (BA3071) A basket study



#### **Objectives**

- Determine Phase 2 dose and MTD
- Characterize safety and clinical activity of BA3071 monotherapy and in combination with a PD-1 inhibitor (Nivolumab)
- Characterize PK, ADA and biomarkers

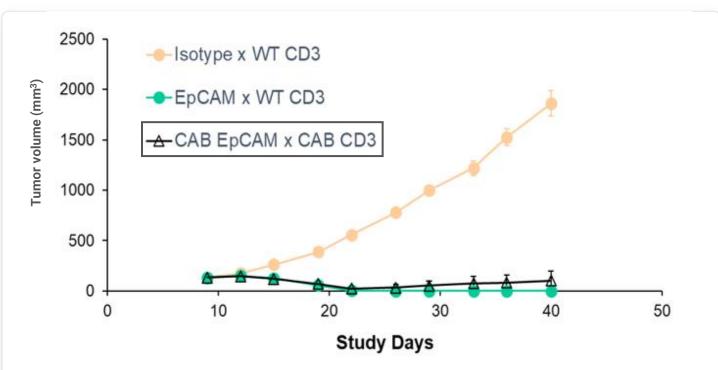




### **Bispecific Platform**

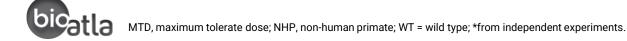
EpCAM x CD3 (BA3182) – Basket Trial

#### Promising preclinical results with CAB-EpCAM x CAB-CD3 bispecific antibody in NHP and a colorectal cell line



**MiXeno Model with HCT116 = Colorectal Cancer Cell Line** 1mg/kg twice/week in mice (equivalent to 0.25mg/kg in non-human primates)

- CAB-EpCAM x CAB-CD3 bispecific demonstrates efficient tumor shrinkage in a colorectal cancer cell line
- In non-GLP and GLP tox studies in NHP, dual selection results in high selectivity
  - >160x higher therapeutic index
  - MTD not reached (5mg/kg highest dose studied=NOAEL)
    - No Cytokine release observed
  - Long half-life in Cyno (~4 days)
- These promising results will enable IND submission and Phase 1 initiation for multiple solid tumors 2H2022



## A number of key upcoming milestones in 2022

CAB-ADCs

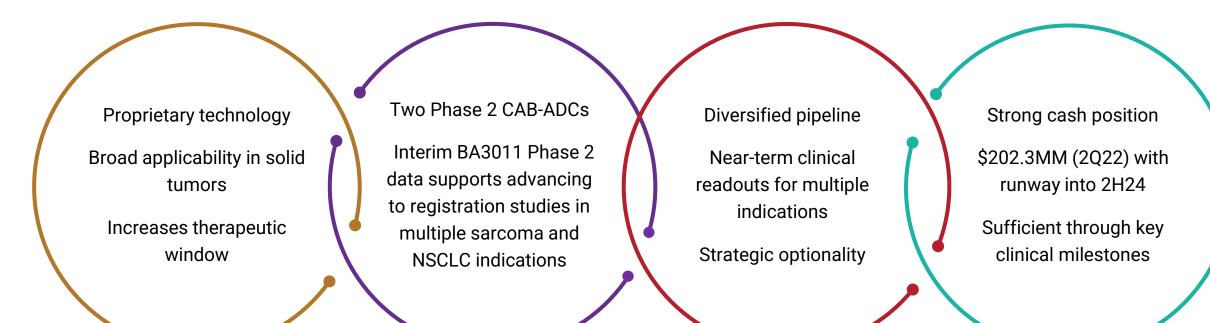
CAB-I/O

CAB-Bispecifics

	Indications	2022			
Program		1H	2H		
	STS and bone sarcoma	Phase 2 interim updat	te	Phase 2 part 2 initiation	
<b>BA3011</b> Mecbotamab Vedotin	NSCLC		Phase 2 initial interim data	Phase 2 interim data	
	Ovarian*	Phase 2 IIT dos	sing		
	NSCLC			Phase 2 initial interim data	
BA3021	Melanoma			Phase 2 interim update	
Ozuriftamab Vedotin	SCCHN		🔀 Phase 2 dosing		
	Ovarian*	Phase 2 II1	dosing		
BA3071	Multiple tumor types**		Phase 1 / 2 dosing		
BA3182	Adenocarcinoma** Multiple tumor types**		11	ND submission / Phase 1 initiation	

\*Phase 2 Investigator-initiated trial combination with PD-1 (n=60) in platinum failure patients. Initial sites activated. \*\*Anticipated indications based upon tumor target expression.

#### **BioAtla**<sup>©</sup> is a clinical stage company focused on transforming cancer therapy with Conditionally Active Biologics (CABs)







#### APPENDIX

#### **Board of Directors and Advisors**



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