# **C**onditionally **A**ctive **B**iologics: Transforming Cancer Therapy

Corporate Presentation

March 2024

bioatla

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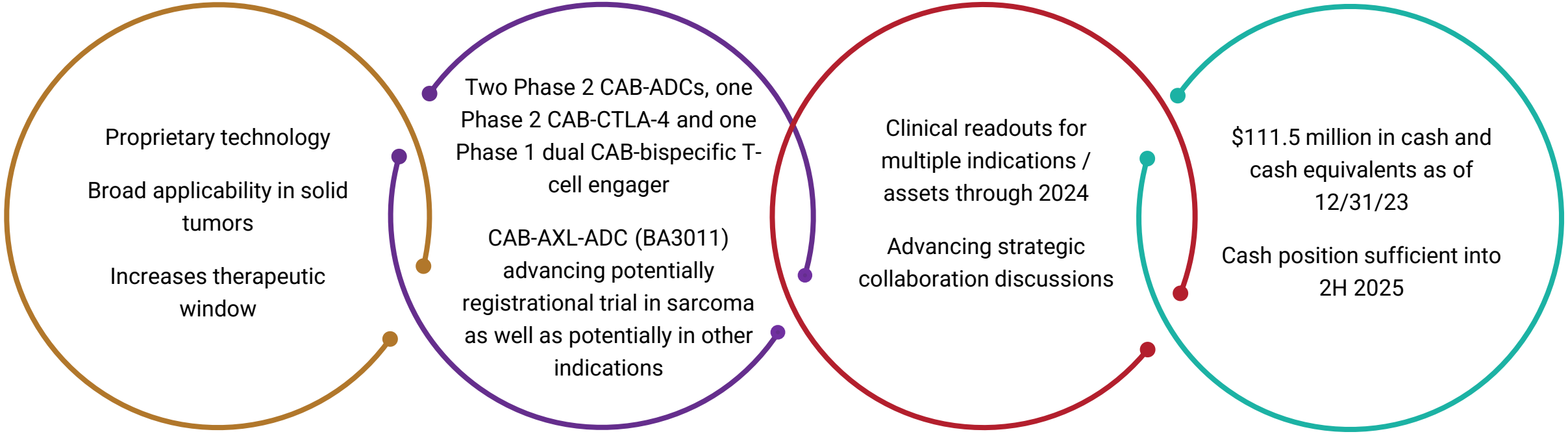
# Bioatla© Is A Clinical Stage Company Focused On Transforming Cancer Therapy

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



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Scientific Advisor

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MD Anderson Cancer Center
Scientific Advisor

Michael Manyak, MD
GlaxoSmithKline
Scientific Advisor

# Selective And Targeted CAB Technology Widens Therapeutic Window

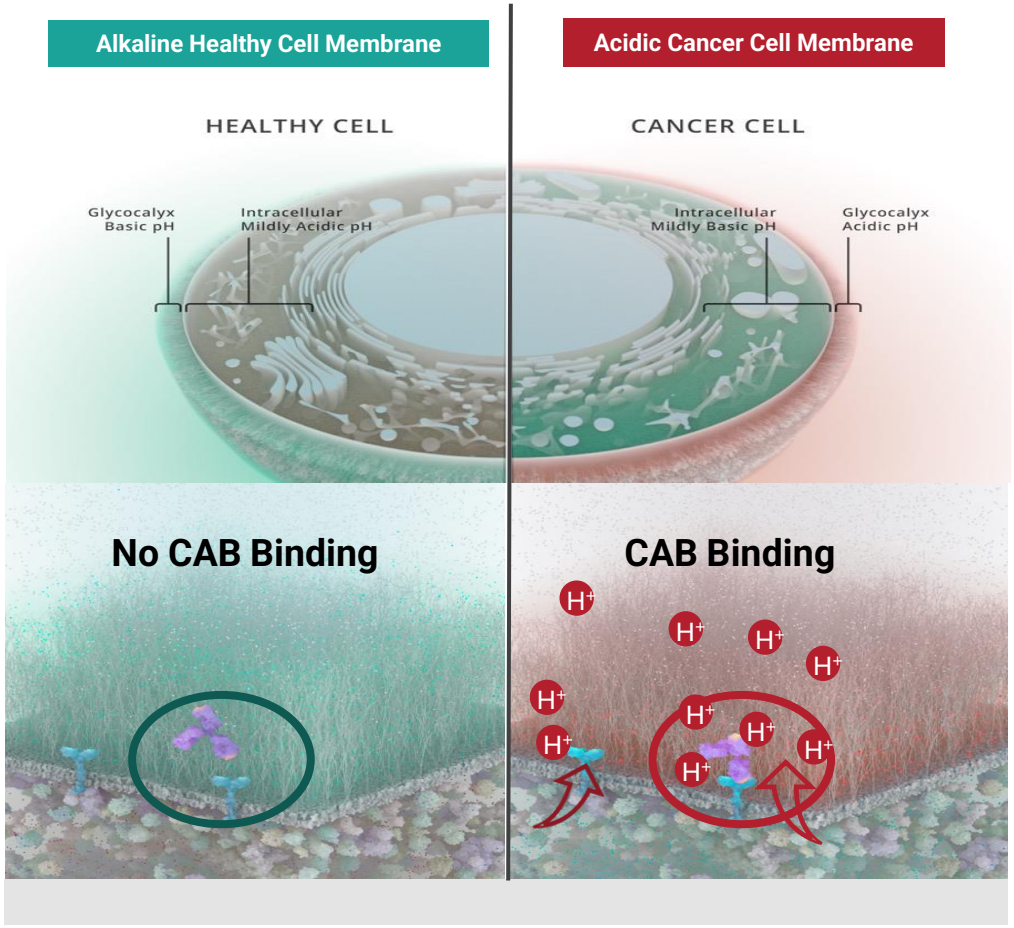
## Thus has the potential to enhance clinical outcomes in multiple tumor types

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



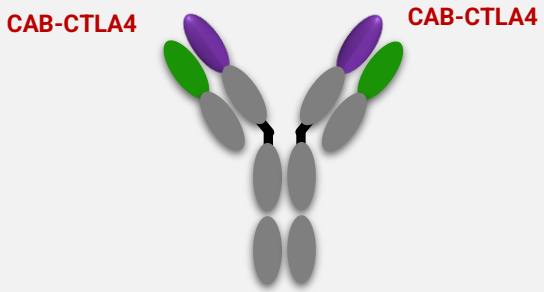

Chang, H.W., Frey, G., Liu, H., Xing, C., Steinman, L, Boyle, B.J., & Short, J.M. (2021) PNAS 118(9): 1-10, Suppl. 1-19.

# Broad Applicability Of BioAtla's CAB Platform Across Several Antibody Types

## I/O Antibodies

**Target:** CTLA-4

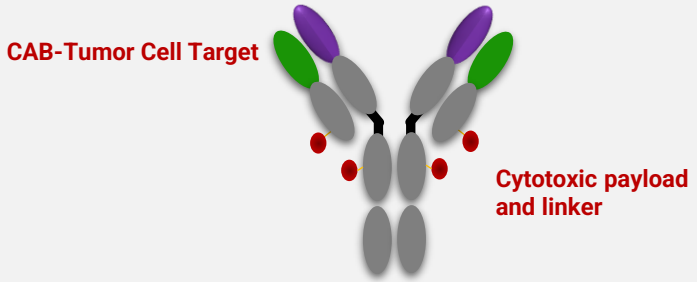
CTLA-4 blockade activates effector T cells, thereby enhancing anti-tumor immunity




## ADCs

**Targets:** ROR2, AXL

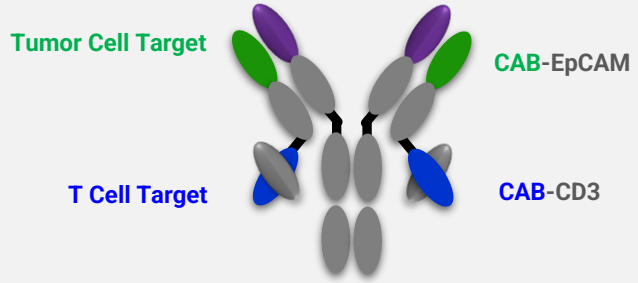
Widely expressed in a variety of tumor types, ROR2 and AXL overexpression correlates with poor prognosis, metastasis, and drug resistance to PD-1 and EGFR therapies




## Bispecific TCE

**Target:** EpCAM & CD3

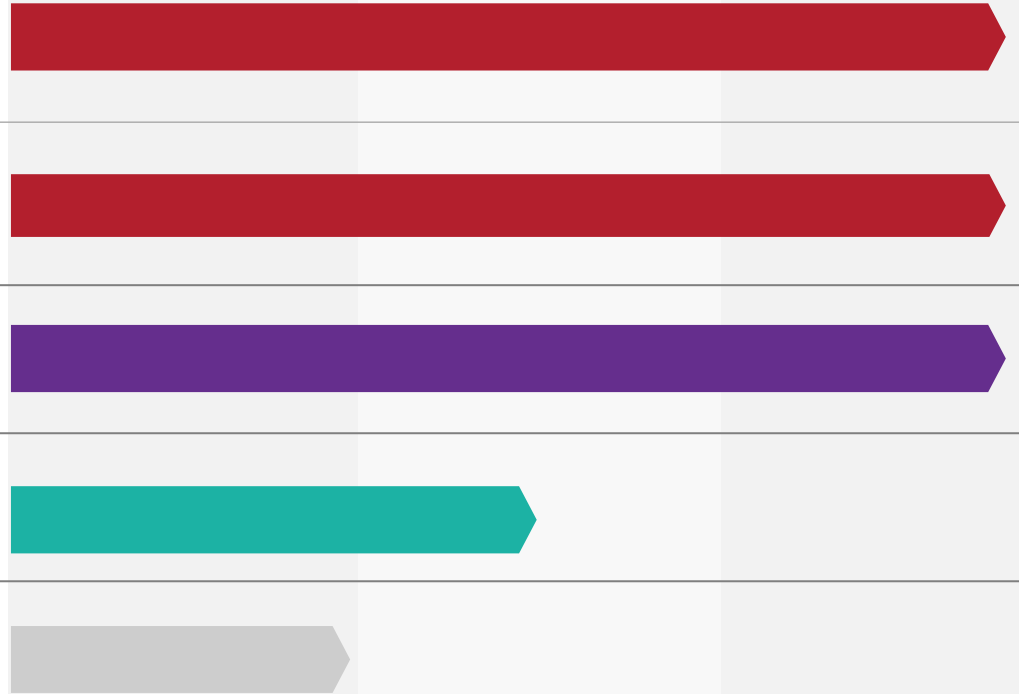
Bispecific antibodies bridge cancer cells and cytotoxic T lymphocytes, activating T cells and promoting cancer cell lysis




ADC – antibody drug conjugate; IO – immuno-oncology; TCE – T-cell engager

# 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** *Evalstotug* | CTLA-4 | Melanoma NSCLC Carcinomas | | | |
| CAB-Bispecific TCE | **BA3182** | EpCAM x CD3 | Adenocarcinomas | | | |
| Next Gen CAB-ADC | BA3361 | Nectin-4 | Multiple tumor types | | | |

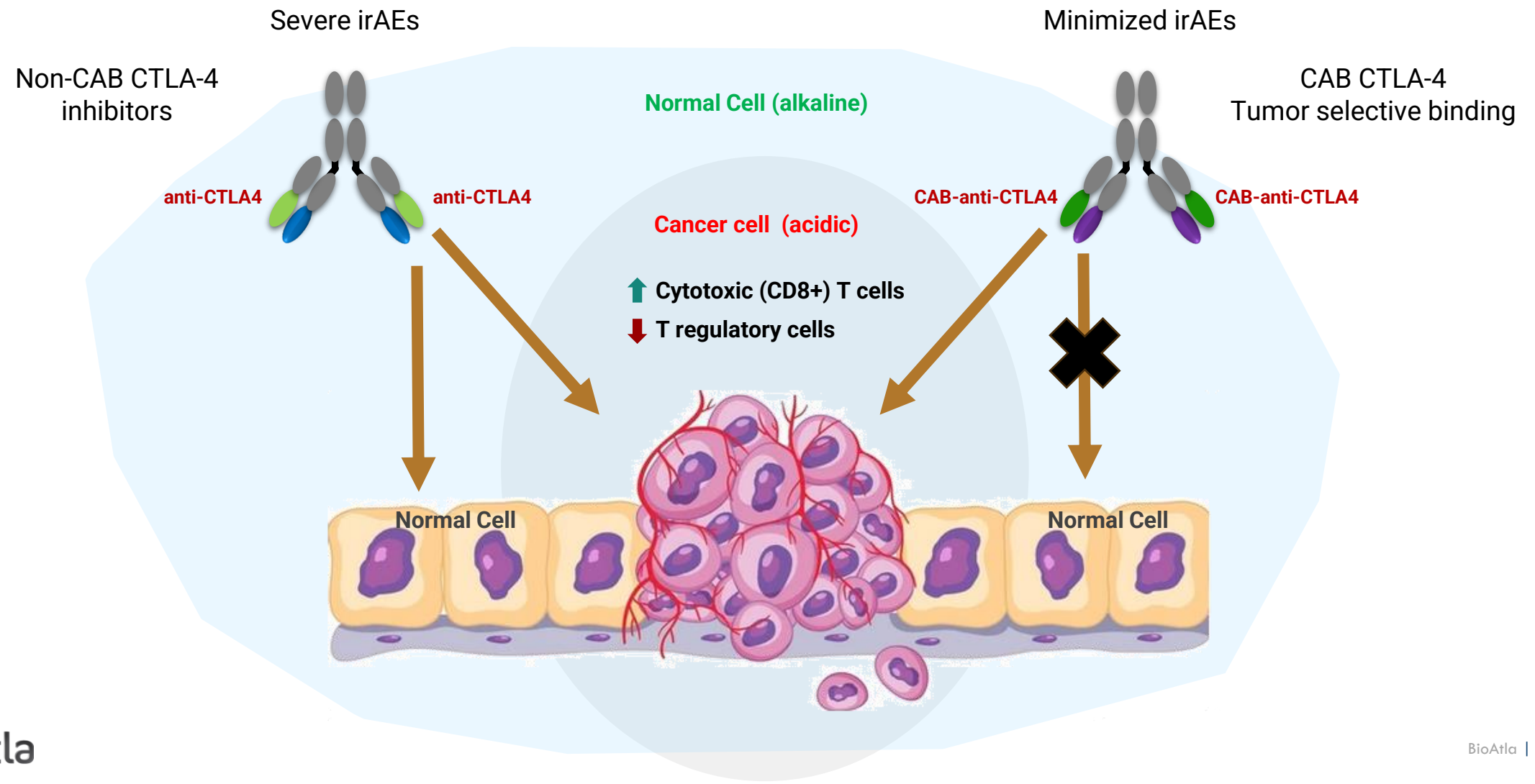


IND, investigational new drug; UPS, Undifferentiated Pleomorphic Sarcoma; NSCLC, Non-small Cell Lung Cancer; SCCHN, Squamous Cell Carcinoma of the Head and Neck

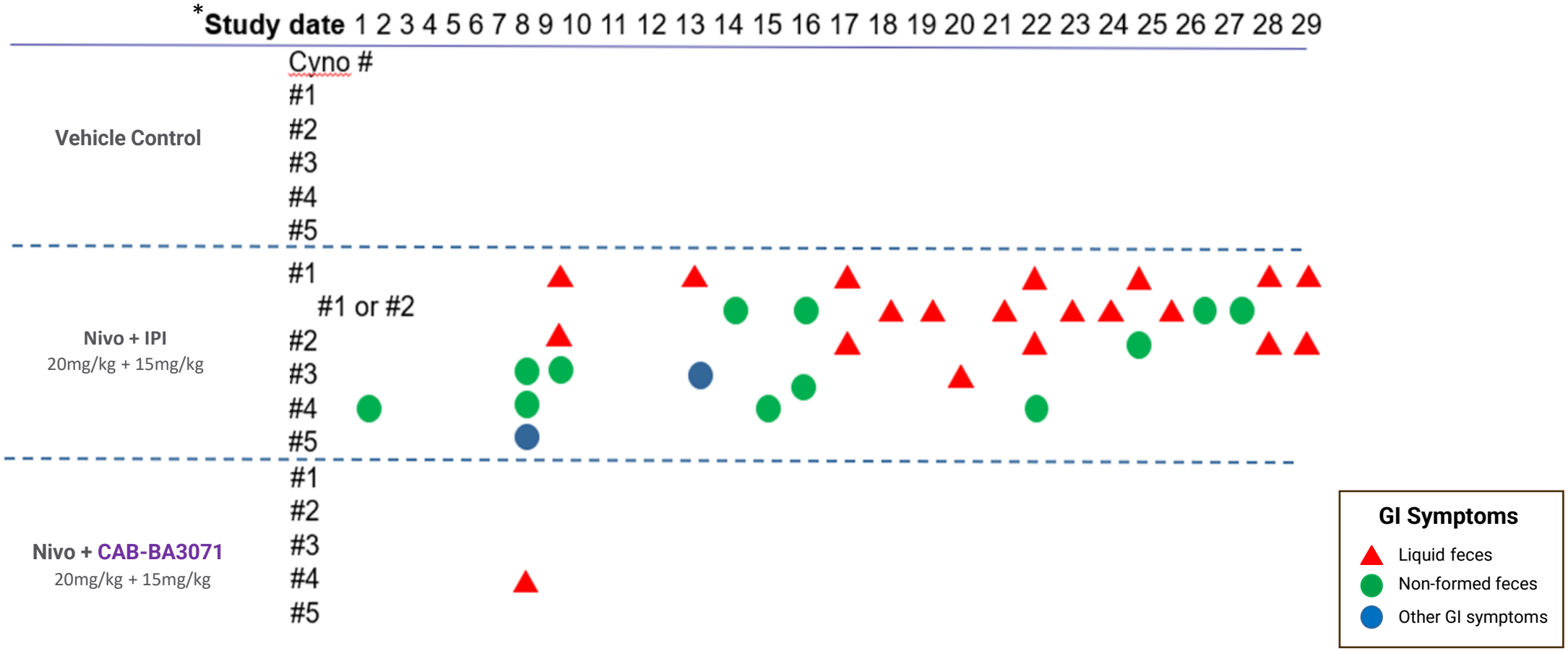
# I/O Antibody Platform:

CAB-CTLA-4 (BA3071) – Basket Trial

# CAB-CTLA4 Selectively Active in Tumor Microenvironment, Thereby Reducing Immune Related Adverse Events (irAEs)



# CAB-CTLA-4 (BA3071) Effectively Reduces Clinically Relevant GI Toxicity in Nonhuman Primates




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

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

# Phase 1 CAB-CTLA-4 (BA3071) Dose Escalation (Q3W)

## Key Objectives:

Define safety profile and determine Phase 2 dose and MTD

Evaluate antitumor activity and immunogenicity

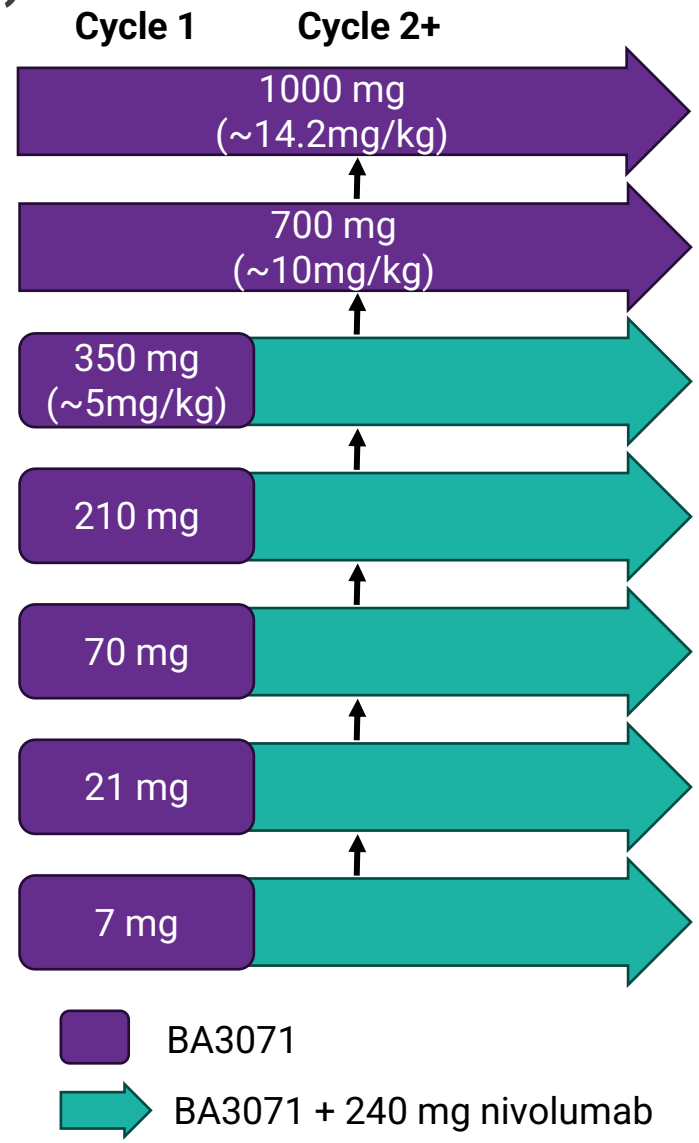
Determine PK parameters

## 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)



# Phase 1 CAB-CTLA-4 (BA3071): Demographics - 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

# Phase 1 CAB-CTLA-4 (BA3071): Demographics – 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

# CAB-CTLA-4 (BA3071) 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

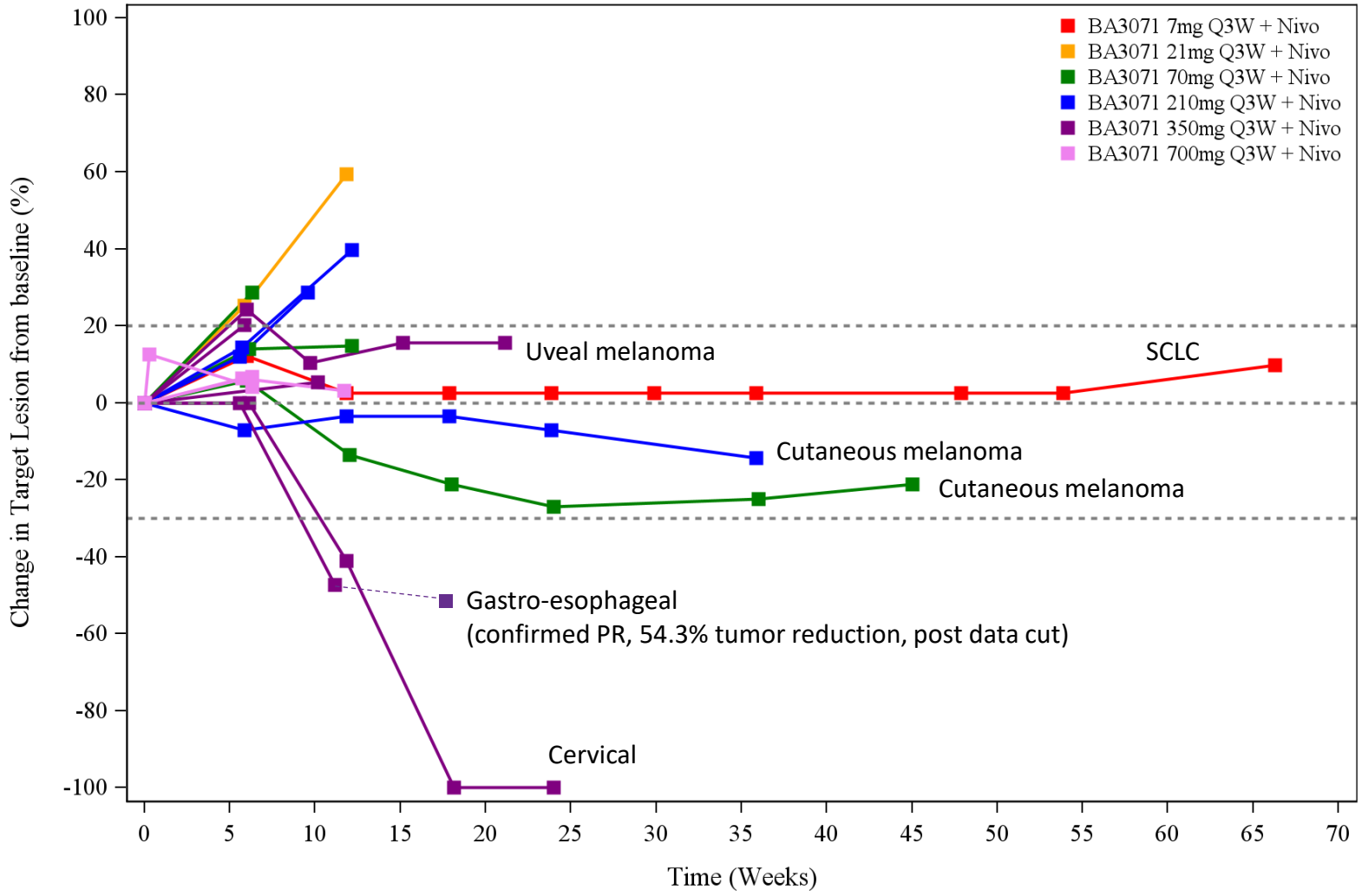
# CAB-CTLA-4 (BA3071) Grade 3+ Adverse Events of Special Interest

| 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 | **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

# Phase 1 CAB-CTLA-4 (BA3071): Confirmed Responses (n=2) and Stable Disease (n=9) Among 16 Evaluable Patients

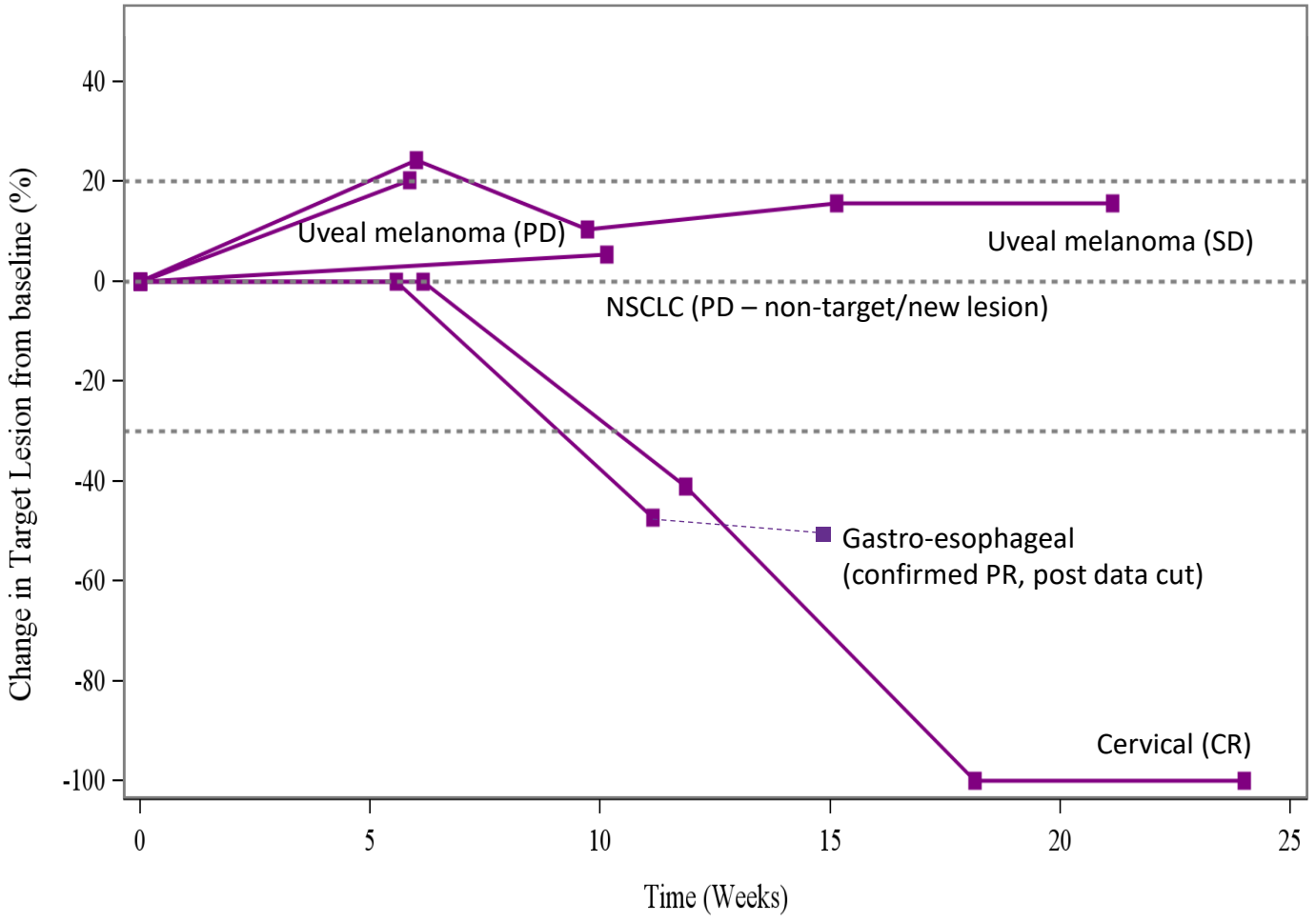



Data Cut Date: 15Nov23

# Phase 1 CAB-CTLA-4 (BA3071): 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 |

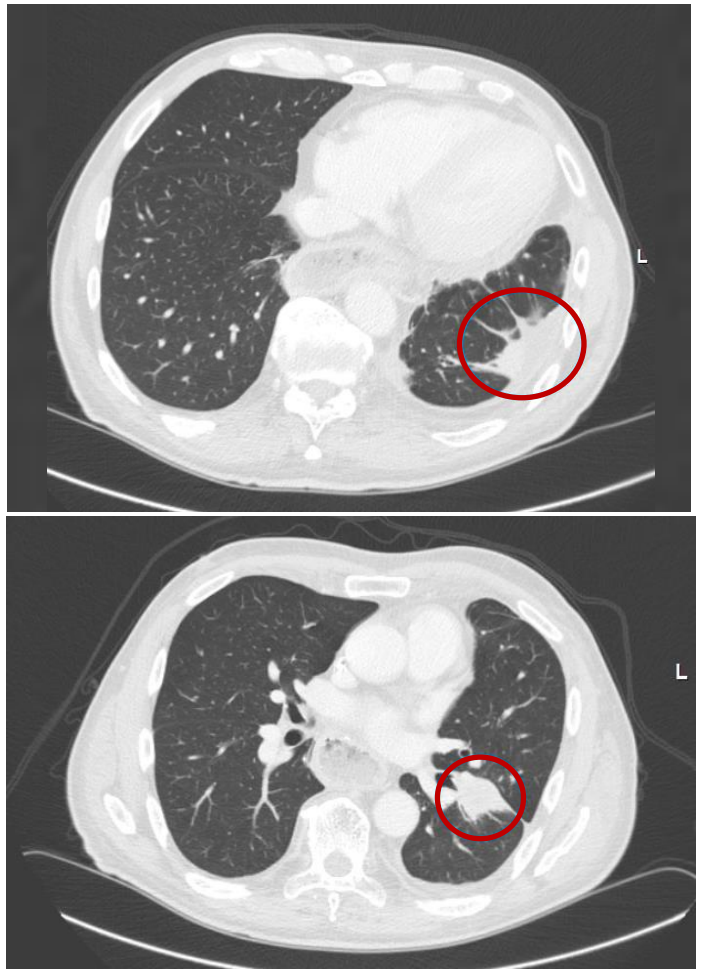



Data Cut Date: 15Nov23

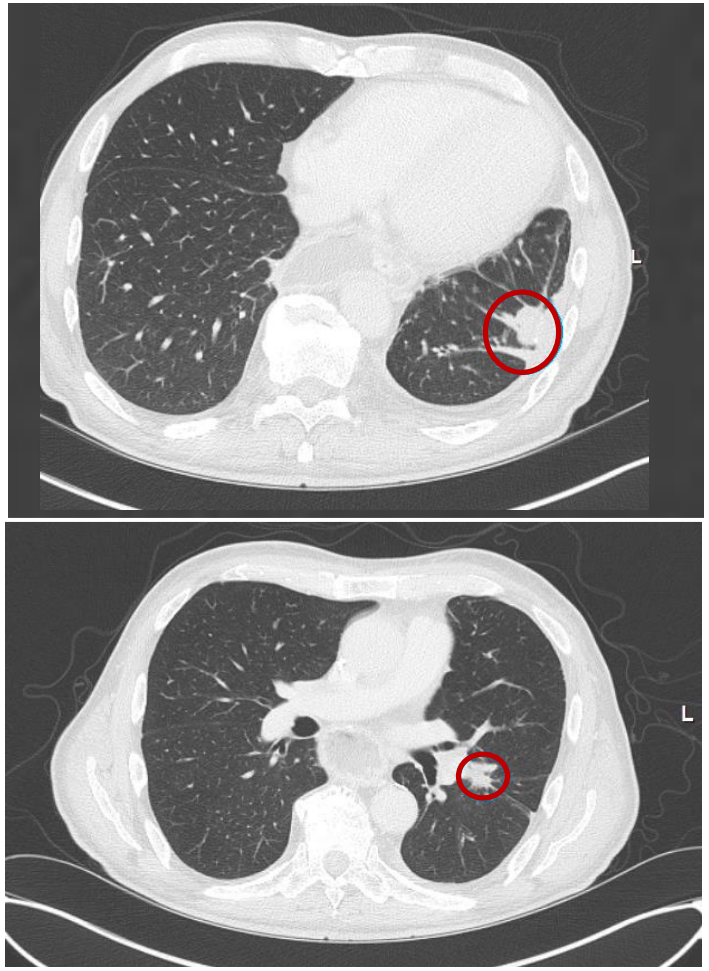
# CAB-CTLA-4 (BA3071) Confirmed Partial Response - Gastro-esophageal Cancer

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

Baseline - July 31,2023



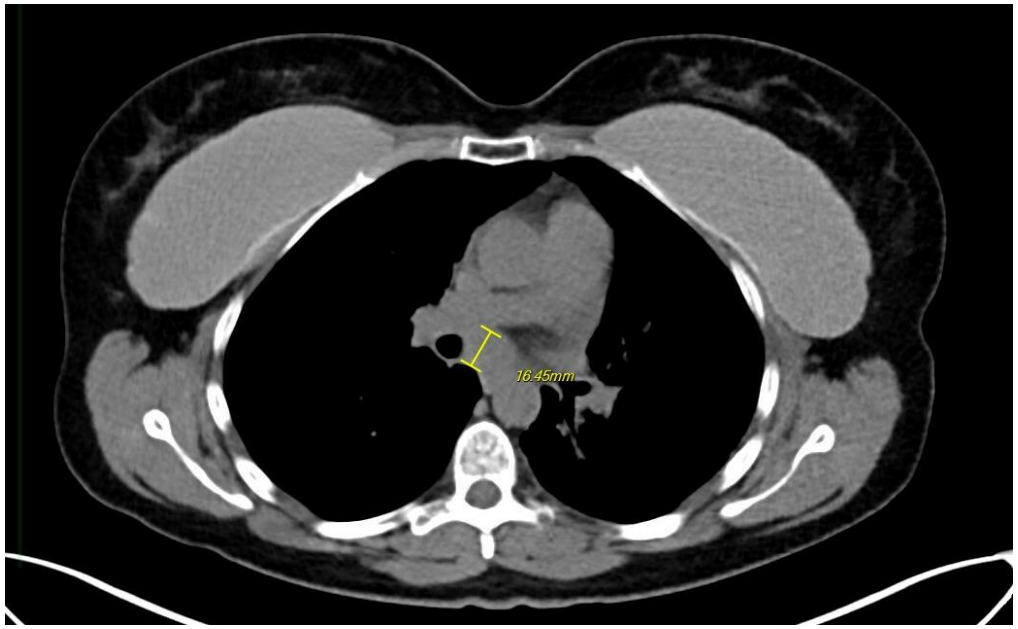
On Treatment - October 23, 2023



# CAB-CTLA-4 (BA3071) Confirmed Complete Response - Cervical Cancer

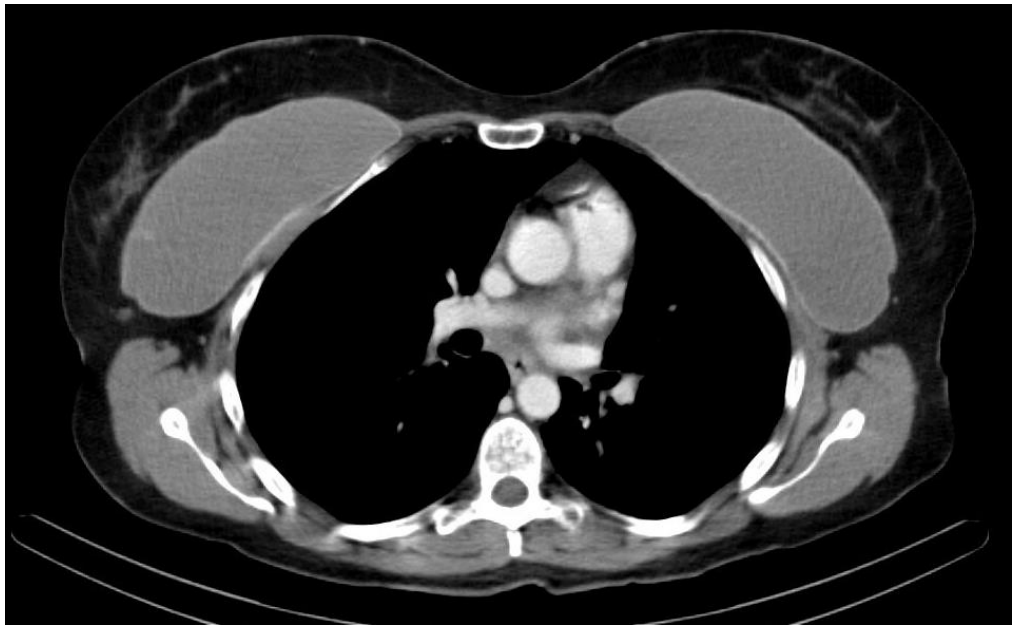
## 43-year-old female, stage IV cervical cancer HPV+16 positive, post-platinum, taxane, anti-PD1 and anti-VEGF

**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."

# CAB-CTLA-4 (BA3071)* – Clinical Development Plan

- Phase 1 Dose Escalation ongoing
  - Cleared 700 mg (10 mg/kg for 70 kg person) Q3W
  - Now evaluating 1000 mg (14.2 mg/kg for 70 kg person) Q3W
  - Anticipate data read out in 2Q 2024
- Phase 2 ongoing
  - Monotherapy in treatment refractory solid tumors (350 mg cohort completed, n=17; 700 mg now enrolling, n≅3)
  - Combination with pembrolizumab in front-line melanoma (350 mg; 700 mg now enrolling)
  - Combination with pembrolizumab and chemotherapy in front-line NSCLC (700 mg now enrolling)
  - On track for data read out in 2024

*700 mg and higher includes prophylactic tocilizumab for two cycles

# CAB-ROR2-ADC

BA3021 Ozuriftamab Vedotin – Squamous Cell Carcinoma Head and Neck (SCCHN), Melanoma

# Potential Market Opportunity in Squamous Cell Carcinoma Head and Neck

| | |
|---|---|
| **>400K** | people **living with** head and neck cancer (U.S.)[1] |
| **~66K** | **newly diagnosed** cases / year (U.S.)[1] |
| **~50%** | with locally advanced disease **develop recurrent or refractory** disease[2] |
| **2L+** | **limited** effective options post 1L[3] |

## Available Treatment

1L: Pembro + platinum
36% ORR[4]

2L+: Cetuximab
13% ORR[5]

[1]Clarivate, Disease Landscape and Forecast: SCCHN (2022). www.cancer.net; [2]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; [3]Future Oncology, Jan. 2019. Vol. 15, No. 8; [4]Ketruda USPI accessed 2024; [5]Erbitux USPI accessed 2024.

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

# Potential Market Opportunity in Metastatic Melanoma

| | |
|---|---|
| **~1.3MM** | people in the U.S. **living with** melanoma[1] |
| **~100K** | **newly diagnosed** invasive cases / year (U.S.)[1] |
| **~50%** | **do not respond** to PD-1 therapy in 1L setting[2] |
| **30-40%** | initial responders **progress**[2] |

## Available Treatment

1L: ICIs 33% - 50% ORR[3]; (BRAF / MEK inhibitors for BRAF+)

2L+: ICIs 9% - 28% ORR (mono – combo, respectively)[4]

[1]Clarivate, Disease Landscape and Forecast: Malignant Melanoma (2022). www.cancer.net; www.cancer.org; [2]Oncology (Williston Park). 33(4):141-8. [3]Keytruda USPI accessed June 2022; Opdivo USPI accessed June 2022. [4]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 with CAB-ROR2 (BA3021) Demonstrates Clinical Benefit in Multiple Indications

| Tumor Types | Results* |
|---|---|
| SCCHN | ▪ Two partial responses (PRs) observed at 1.8 mg/kg 2Q3W, including in a ROR2 TmPS negative** patient |
| Melanoma | ▪ Four PRs observed at 1.8 mg/kg Q2W, including in ROR2 TmPS negative** patients<br>▪ One complete response at 3.0 mg/kg Q3W; continued off treatment for over 4 years<br>▪ 2Q3W not evaluated |
| 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**

*Early data previously disclosed – SCCHN (2 patients evaluable); Melanoma (8 patients evaluable). Data readouts from ongoing Phase 2 studies for both indications anticipated in May 2024.
**Based on immunohistochemical assay

# Phase 1 and 2 CAB-ROR2-ADC (BA3021) Status of Clinical Studies

| Indication | Monotherapy Dosing Regimen (1.8 mg/kg) | Patient (N) | Status |
|---|---|---|---|
| SCCHN | Q2W | 12 | Fully enrolled; on track for data readout 2Q 2024 |
| | 2Q3W | 21* | Fully enrolled; on track for data readout 2Q 2024 |
| Melanoma | Q2W | 29** | Fully enrolled; on track for data readout 2Q 2024 |

*Includes 1 patient from Phase 1 who received 1.8 mg/kg 2Q3W **Includes 1 patient from Phase 1 who received 3.0 mg/kg Q3W (this dose has an equivalent $C_{avg}$ to 1.8 mg/kg Q2W)
SCCHN: Squamous Cell Carcinoma Head and Neck

# CAB-AXL-ADC

BA3011 Mecbotamab Vedotin: Sarcoma and NSCLC

# Potential Market Opportunity In Undifferentiated Pleomorphic Sarcoma (UPS)

| | |
|---|---|
| **~15%** | 2nd most common Soft Tissue Sarcoma (STS) subtype[1,2] |
| **0** | Targeted therapies specifically approved to treat UPS |
| **~55%** | patients developing recurrent or metastatic disease[3,4] |
| **1 year** | Median time to metastatic/local recurrence[4,5,6] |

## Available Treatment:

1L: Approved treatments for sarcoma ORR ~15%[7]

[1]Brennan MF, Antonescu CR, Moraco N, Singer S. Lessons learned from the study of 10,000 patients with soft tissue sarcoma. Ann Surg. 2014;260(3):416–21; [2] Penel N, Coindre J-M, Giraud A, Terrier P, Ranchere-Vince D, Collin F, et al. Presentation and outcome of frequent and rare sarcoma histologic subtypes: a study of 10,262 patients with localized visceral/soft tissue sarcoma managed in reference centers. Cancer. 2018;124(6):1179–87; [3]Vodanovich DA, Spelman T, May D, Slavin J, Choong PFM. Predicting the prognosis of undifferentiated pleomorphic soft tissue sarcoma: a 20-year experience of 266 cases. ANZ J Surg. 2019;89(9):1045-1050; [4]Roland CL, May CD, Watson KL, et al. Analysis of Clinical and Molecular Factors Impacting Oncologic Outcomes in Undifferentiated Pleomorphic Sarcoma. Ann Surg Oncol. 2016;23(7):2220-2228; [5]Delisca GO, Mesko NW, Alamanda VK, et al. MFH and high-grade undifferentiated pleomorphic sarcoma-what's in a name?. J Surg Oncol. 2015;111(2):173-177; [6]Winchester D, Lehman J, Tello T, et al. Undifferentiated pleomorphic sarcoma: Factors predictive of adverse outcomes. J Am Acad Dermatol. 2018;79(5):853-859; [7]Product USPIs

ORR, objective response rate (best objective response as confirmed complete response or partial response)

# CAB-AXL-ADC (BA3011) Undifferentiated Pleomorphic Sarcoma (UPS)

## Clinical development update

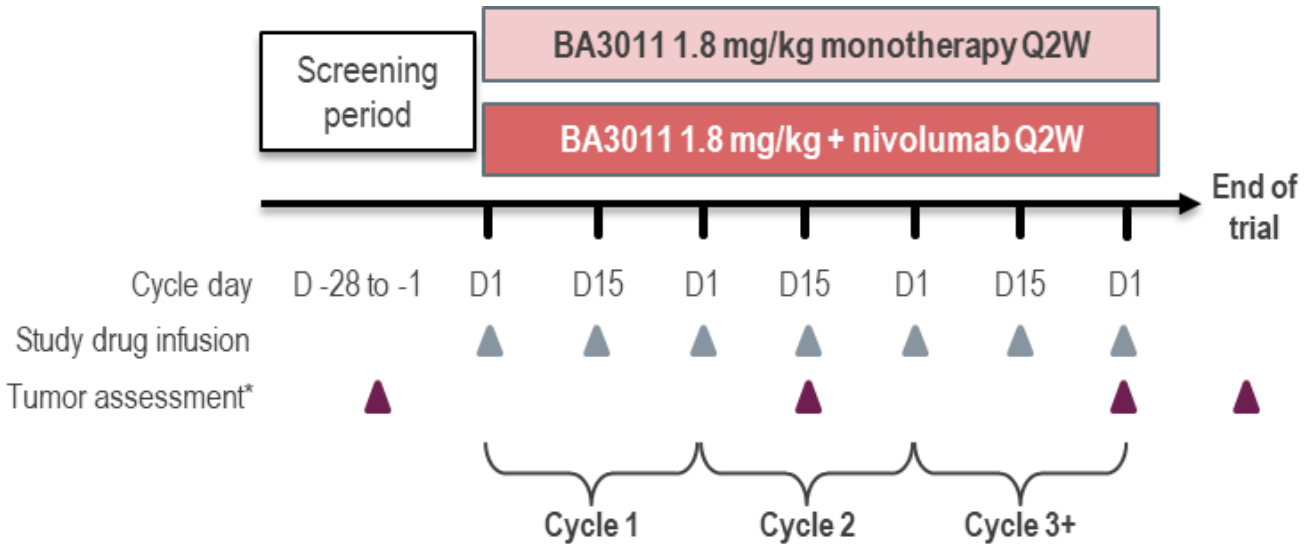
- UPS Phase 2 potentially registrational study
  - Employs 1.8 mg/kg with more intensive Day 1 and 8 dosing of a 3-week cycle
  - Initial 20 patients at 2Q3W (AXL target agnostic)
- Enrollment on track for 20 patients in April 2024
- Anticipate all 20 patients to have multiple scans followed by FDA meeting for guidance on the remaining portion of the registration trial in 2H 2024

# CAB-AXL-ADC (BA3011) in Bone and Soft Tissue Sarcoma

## Phase 2 part 1 open-label study design - ~80% had ≥2 prior lines of therapy

**Sarcoma Subtypes**

- Leiomyosarcoma
- Synovial
- Liposarcoma
- STS Other
- Osteosarcoma
- Ewing sarcoma
- Bone Other: (Chondro/Chordo)




**Endpoints**

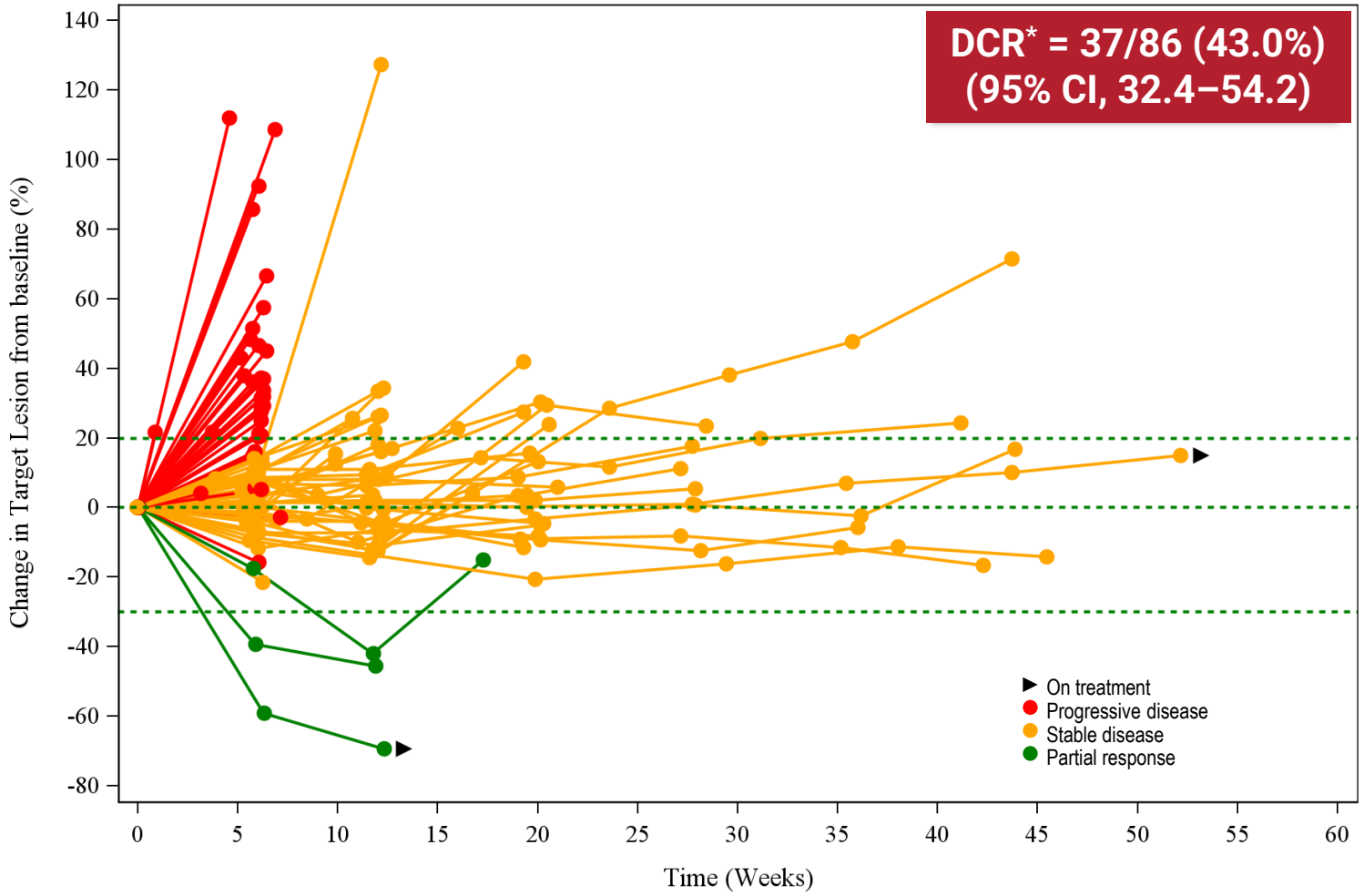
- DCR (objective response or stable disease for ≥12 weeks)
- Number of responders (complete or partial)
- PFS rate at week 12
- TEAEs

*Tumor assessment by CT or MRI every 6 weeks from C1D1 until 12 weeks, then every 8 weeks up to 1 year, then every 12 weeks thereafter.
Abbreviations: STS, soft tissue sarcoma; D, day; DCR, disease control rate; PFS, progression-free survival; Q2W, every 2 weeks; TEAE, treatment-emergent adverse event.

Pollack SM, Conley AP, Tap W, et al. Results from a Phase 2 part 1 trial of mecbotamab vedotin (BA3011), a CAB-AXL-ADC, in patients with advanced refractory sarcoma. Abstract presented at: ESMO Sarcoma and Rare Cancers Congress; March 14-16, 2024; Lugano, Switzerland.

# Phase 2 part 1 Sarcoma Study of CAB-AXL-ADC (BA3011) 1.8 mg/kg Q2W

## Monotherapy antitumor activity observed encouraging clinical benefit across sarcoma subtypes



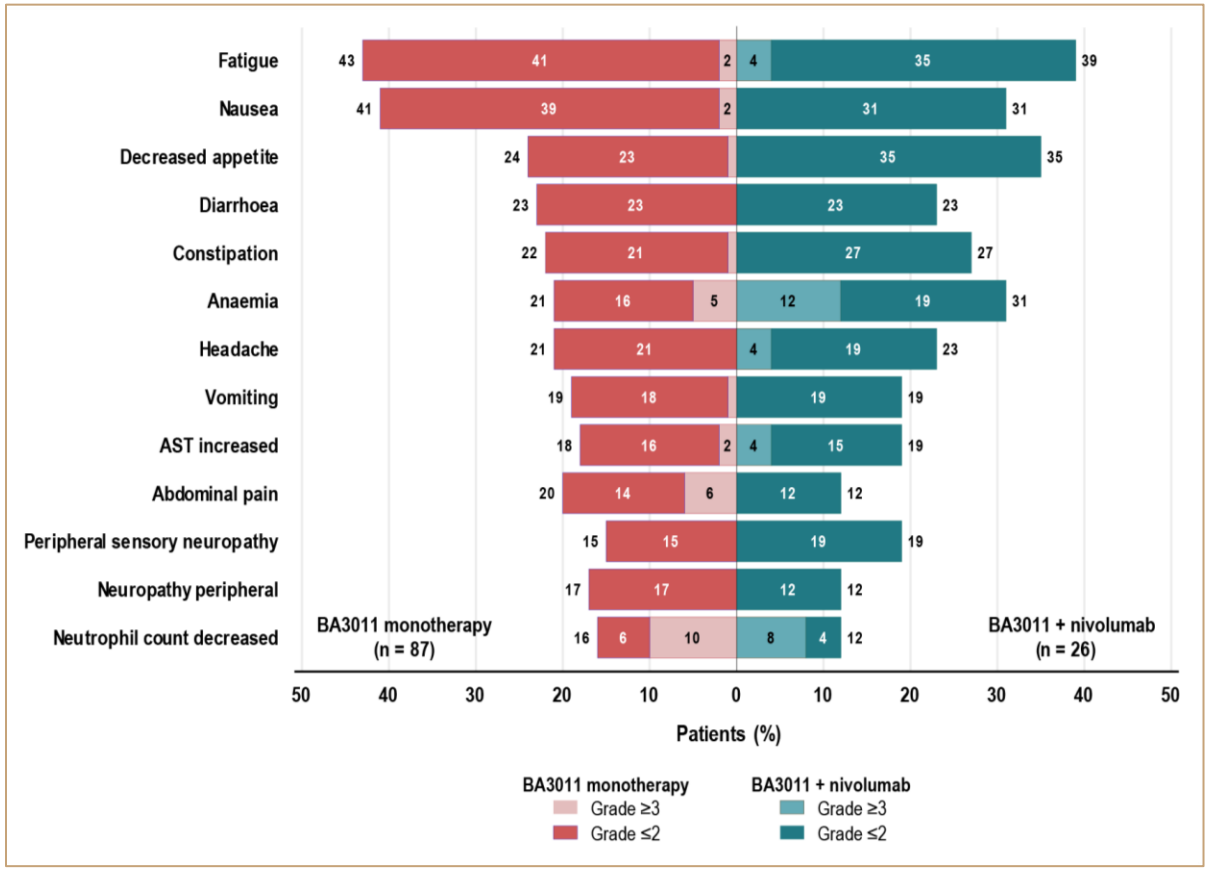

Data cutoff date: November 27, 2023.
*Disease control rate (DCR) defined as objective response or stable disease for ≥12 weeks (RECIST 1.1); 1 patient lost to follow-up was not efficacy-evaluable.

Pollack SM, Conley AP, Tap W, et al. Results from a Phase 2 part 1 trial of mecbotamab vedotin (BA3011), a CAB-AXL-ADC, in patients with advanced refractory sarcoma. Abstract presented at: ESMO Sarcoma and Rare Cancers Congress; March 14-16, 2024; Lugano, Switzerland.

# Phase 2 part 1 Sarcoma Study of CAB-AXL-ADC (BA3011) 1.8 mg/kg Q2W

## Broadly well tolerated; most events low-grade and reversible

### Most frequent TEAEs (≥15% of patients)




### Summary of TEAEs

| Characteristic, n (%) | BA3011 monotherapy (n=87) | BA3011 + nivolumab (n=26) |
|---|---|---|
| Any TEAE | 85 (97.7) | 24 (92.3) |
| Related TEAEs with CTCAE grade 3 or 4* | 26 (29.9) | 11 (42.3) |
| Related serious TEAEs* | 4 (4.6) | 6 (23.1) |
| Related TEAEs leading to death* | 0 | 0 |
| Related TEAEs leading to treatment discontinuation* | 7 (8.0) | 1 (3.8) |

*As assessed by the investigator. Missing responses were counted as related.

### Related TEAEs of Special Interest

| Characteristic, n (%) | BA3011 monotherapy (n=87) | | BA3011 + nivolumab (n=26) | |
|---|---|---|---|---|
| | All grades | Grades 3–4 | All grades | Grades 3–4 |
| Peripheral neuropathy | 27 (31.0) | 0 | 7 (26.9) | 0 |
| Neutropenia | 18 (20.7) | 14 (16.1) | 5 (19.2) | 4 (15.4) |
| Abnormal liver function tests | 14 (16.1) | 3 (3.4) | 3 (11.5) | 1 (3.8) |
| Hyperglycemia | 3 (3.4) | 1 (1.1) | 1 (3.8) | 0 |

Data cutoff date: November 27, 2023.
Abbreviations: AST, aspartate aminotransferase; CTCAE, Common Terminology Criteria for Adverse Events; TEAE, treatment-emergent adverse event.

Pollack SM, Conley AP, Tap W, et al. Results from a Phase 2 part 1 trial of mecbotamab vedotin (BA3011), a CAB-AXL-ADC, in patients with advanced refractory sarcoma. Abstract presented at: ESMO Sarcoma and Rare Cancers Congress; March 14-16, 2024; Lugano, Switzerland.

# CAB-AXL-ADC (BA3011) Sarcoma Summary

## Encouraging disease control rate with excellent tolerability profile

- Monotherapy dosing of 1.8 mg/kg Q2W obtained 43% disease control rate among patients with treatment-refractory bone and soft-tissue sarcomas (N=86)*
- Manageable toxicity with few high-grade related adverse events reported
  - No high-grade peripheral neuropathy observed to date
  - Very few related adverse events led to treatment discontinuation

Phase 2 trial: NCT03425279
*Excludes the UPS potentially registrational trial at 1.8 mg/kg 2Q3W.

# Potential Market Opportunity In Metastatic NSCLC

| | |
|---|---|
| **>540K** | people in the U.S. living with lung cancer[1] |
| **~200K** | newly diagnosed patients / year (U.S.) – **majority** advanced / metastatic[2] |
| **~75 - 80%** | non-squamous represents **majority** of NSCLC patients[3] |
| **2L+** | despite advances in 1L care, **majority** of patients **progress**[4] |

## Available Treatment:

1L: Chemo + ICI 50% ORR[5]

2L+: SOC 14% - 23% ORR[6];
median PFS 4.5 months[6]

[1]https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet [2]https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics, [3]https://thoracickey.com/carcinomas-of-the-lung-classification-and-genetics/#F1-72, [4]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, [5]*Transl Lung Cancer Res* 2021;10(7):3093-3105. [6]Cyramza package insert (accessed March 2023)

1L, first line; 2L+, second line or greater; NSCLC, non-small cell lung cancer; ORR, objective response rate (best objective response as confirmed complete response or partial response), SOC, standard of care (docetaxel alone, docetaxel + ramucirumab)

# CAB-AXL (BA3011) – Phase 2 Non-Small Cell Lung Cancer

## Multicenter, Phase 2, open-label trial evaluating the efficacy and safety of BA3011 alone and in combination with nivolumab

**Patient disposition:**

- Confirmed locally advanced or metastatic NSCLC
- Age ≥ 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
- AXL+ tumor staining (TmPS ≥ 1%)

**BA3011**
1.8 mg/kg Q2W

**BA3011 + 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

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

Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

# Phase 2 CAB-AXL (BA3011) NSQ NSCLC: Baseline Demographics / Characteristics

## Study enrolled a heavily pretreated 3L+ population

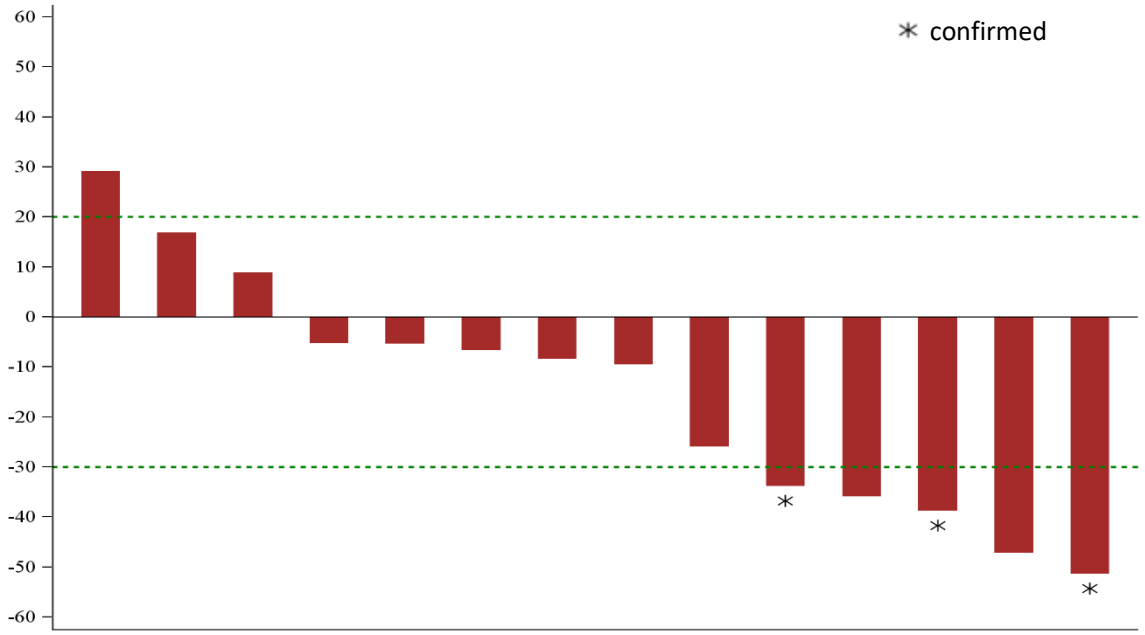
| | BA3011 monotherapy (N=23) | BA3011 + nivolumab (N=17) | Total (N=40) |
|---|---|---|---|
| **Age, y, mean (SD)** | 68.3 (8.0) | 68.9 (8.2) | 68.6 (8.0) |
| **Number of prior systemic therapies, n (%)** | | | |
| 1 | 4 (17.4) | 2 (11.8) | 6 (15.0) |
| 2 | 6 (26.1) | 3 (17.6) | 9 (22.5) |
| 3 | 9 (39.1) | 2 (11.8) | 11 (27.5) |
| ≥4 | 4 (17.4) | 10 (58.8) | 14 (35.0) |
| **Received prior anti-PD-1/L1 treatment, n (%)** | | | |
| Yes | 21 (91.3) | 15 (88.2) | 36 (90.0) |
| No | 2 (8.7) | 2 (11.8) | 4 (10.0) |
| **EGFR mutation status, n (%)** | | | |
| Wild-type | 16 (69.6) | 13 (76.5) | 27 (67.5) |
| Mutant | 4 (17.4) | 2 (11.8) | 6 (15.0) |
| Unknown or missing | 3 (13.0) | 2 (11.8) | 7 (17.5) |

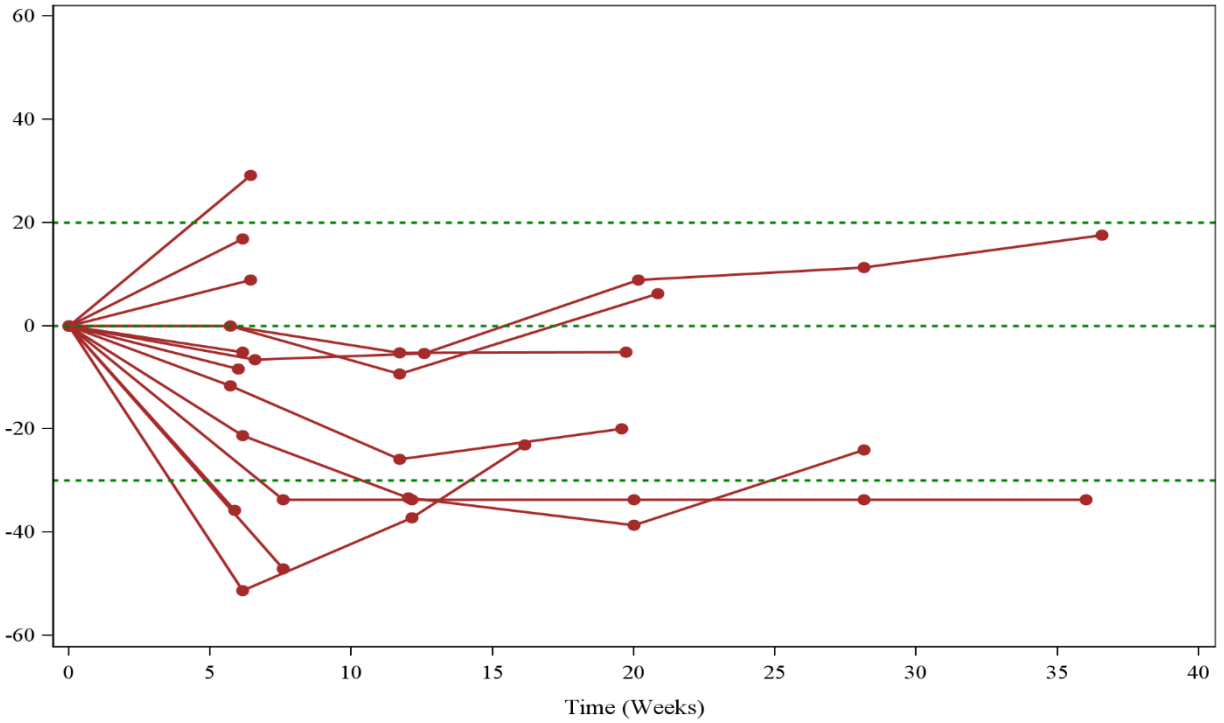
Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

Data Cut Date: 30Jun23

# Phase 2 CAB-AXL (BA3011) Nonsquamous NSCLC Interim Analysis

## BA3011 Monotherapy 1.8 mg/kg Q2W in PD-1 Failure EGFR Wildtype (n = 15)



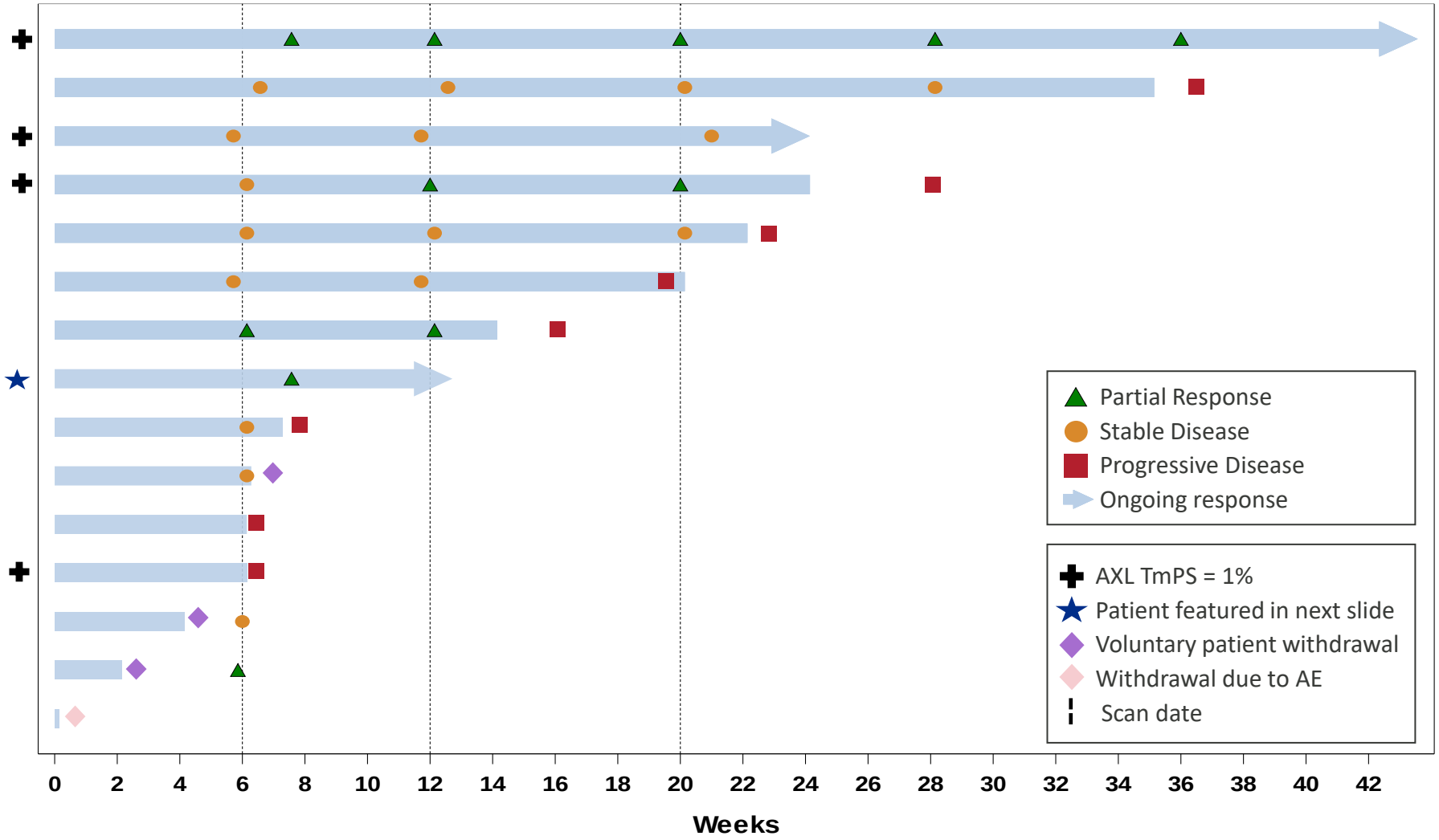

- ORR: 33% (5/15)
- Median Duration of Response was estimated to be 4.8 months with a range of 2.3-12.1+ months

Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

Data Cut Date: 30Jun23

# Phase 2 CAB-AXL (BA3011) NSCLC Interim Analysis

## BA3011 Monotherapy 1.8 mg/kg Q2W



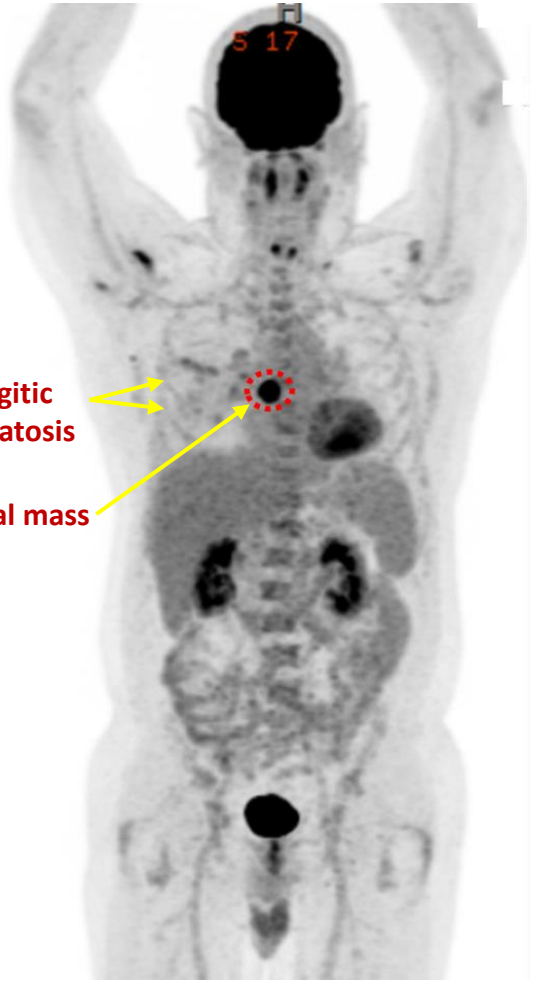

Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

Data Cut Date: 30Jun23

# Radiographic response to CAB-AXL (BA3011) monotherapy

53 yo male with adenocarcinoma of the lung,
PDL1 <1%, *TP53* mutation, 3 prior lines of tx
(carbo/pem/pembro, docetaxel, durva/treme/selumetinib)

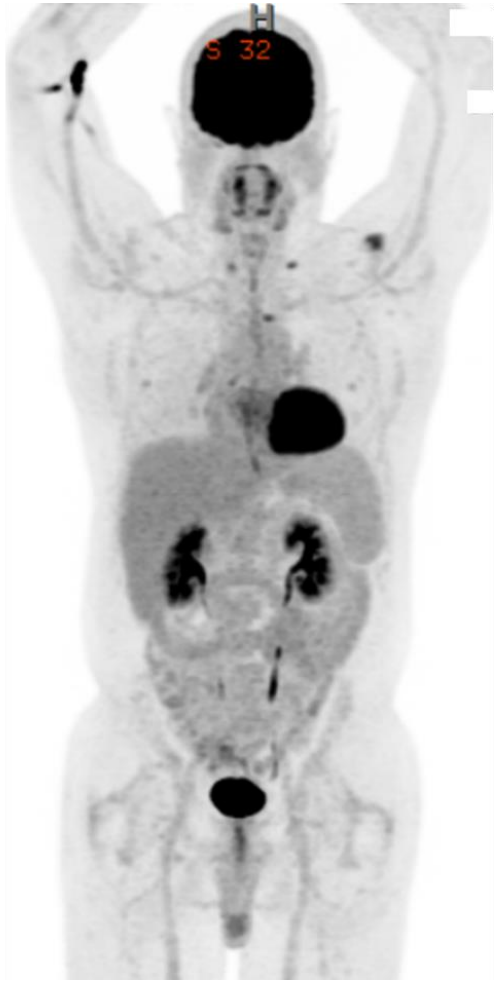
**March 6, 2023 – Baseline scan**



Lymphangitic carcinomatosis

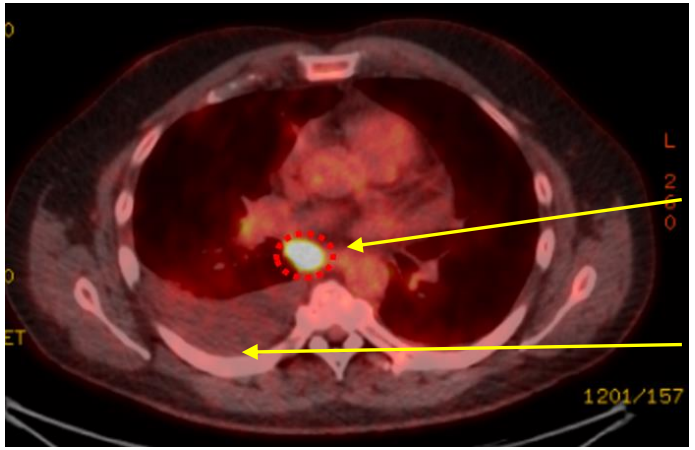
Subcarinal mass

**September 20, 2023**



Red circle on left indicates subcarinal mass, resolved on right.

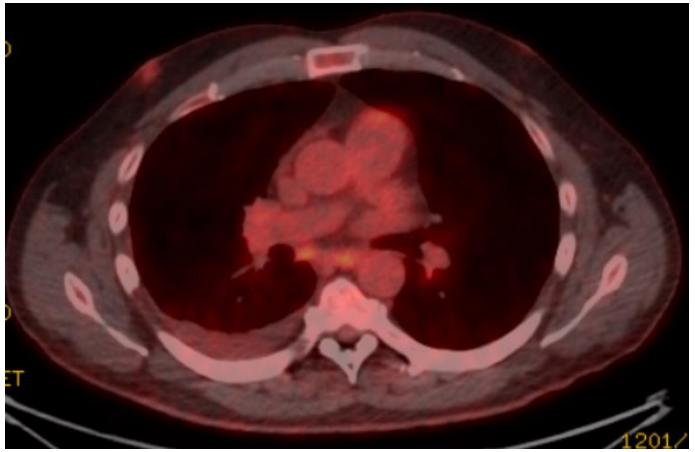
March 6, 2023
Baseline scan



Subcarinal mass

Pleural effusion

September 20, 2023



Red circle on top indicates subcarinal mass, resolved below.
Note also improvement in malignant pleural effusion.

Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

# Phase 2 CAB-AXL (BA3011): Summary of Treatment Emergent Adverse Events (Non-Squamous NSCLC)

| | BA3011 monotherapy (n=23) | BA3011 + nivolumab (n=17) | Total (N=40) |
|---|---|---|---|
| **TEAEs with CTCAE grade 3 or 4** | 15 (65.2) | 8 (47.1) | 23 (57.5) |
| **Related grade 3 or 4 AEs** | 8 (34.8) | 3 (17.6) | 11 (27.5) |
| **Any serious TEAEs** | 9 (39.1) | 5 (29.4) | 14 (35.0) |
| **Related SAEs** | 3 (13.0) | 1 (5.9) | 4 (10.0) |
| **TEAEs leading to treatment d/c** | 1 (4.3) | 1 (5.9) | 2 (5.0) |
| **Related AEs leading to treatment d/c** | 1 (4.3) | 1 (5.9) | 2 (5.0) |
| **TEAEs leading to death** | 0 | 1 (5.9) | 1 (2.5) |
| **Related AEs leading to death** | 0 | 0 | 0 |

Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

Data Cut Date: 30Jun23

# Phase 2 CAB-AXL (BA3011): Treatment Emergent Adverse Events (Non-Squamous NSCLC)

## Any grade (≥15% of patients) OR grade ≥3* (≥3% of patients) in the study population

| Preferred term | TEAEs of any grade, n (%) | TEAEs of grade 3, n (%) |
|---|---|---|
| Fatigue | 14 (35.0) | 1 (2.5) |
| Diarrhea | 10 (25.0) | 1 (2.5) |
| Constipation | 9 (22.5) | 0 |
| Decreased appetite | 9 (22.5) | 1 (2.5) |
| Anemia | 8 (20.0) | 2 (5.0) |
| Nausea | 8 (20.0) | 0 |
| Peripheral neuropathy | 7 (17.5) | 1 (2.5) |
| Increased AST | 7 (17.5) | 3 (7.5) |
| Dyspnea | 6 (15.0) | 2 (5.0) |
| Neutropenia | 6 (15.0) | 2 (5.0) |
| Increased ALT | 5 (12.5) | 3 (7.5) |

*No grade 4+ TEAEs among most frequent

Rotow J, Dy GK, Camidge DR. Poster presented at: International Association for the Study of Lung Cancer 2023 North America Conference on Lung Cancer; December 1-3, 2023; Chicago, IL.

Data Cut Date: 30Jun23

# CAB-AXL (BA3011) NSCLC Randomized Registrational Study Design

## Two Potentially Registrational Paths Enabled via the FDA Type C Meeting

2nd Line +

- **Open-label**; control: docetaxel
- Patients with NSCLC who have been previously treated with at least **one** prior line of therapy for metastatic disease
- Dual primary endpoints: Progression Free Survival and Overall Survival

3rd Line +

- **Blinded**; control: chemo monotherapy
- Patients with NSCLC who have been previously treated with at least **two** prior lines of therapy for metastatic disease
- Primary endpoint: Overall Survival

# CAB-AXL-ADC (BA3011) NSCLC Development

## Promising antitumor activity in treatment-refractory NSCLC

- Monotherapy 1.8 mg/kg Q2W shows encouraging efficacy signals in an AXL+ heavily pretreated 3L+ population
  - Five partial responses observed among 15 EGFR wild-type patients who all received prior PD-1/L1 treatment
  - Monotherapy median Duration of Response estimated to be 4.8 months with a range of 2.3-12.1+ months
- Toxicity was manageable and few high-grade related TEAEs were observed
- Monotherapy 1.8 mg/kg 2Q3W AXL agnostic cohort fully enrolled
  - Includes both squamous/non-squamous and both EGFR wt/EGFR mutated
  - On track to evaluate clinical benefit in 2Q 2024
- Poised to initiate prospective, randomized, potentially registrational trial, pending target agnostic expansion data

# CAB-EpCAM x CAB-CD3 Bispecific T-Cell Engager

BA3182 – Adenocarcinoma

# CAB-EpCAM x CAB-CD3 Bispecific T-Cell Engager (BA3182)

## Significant opportunity for safe and effective EpCAM x CD3 bispecific

- EpCAM is an attractive, but challenging therapeutic target because it's expressed in most solid tumors, as well as in normal epithelial tissues
- Historically, EpCAM-specific T-cell engagers (TCEs) were unsuccessful due to serious on-target, off-tumor drug-related toxicities
- BA3182 exhibits efficient tumor shrinkage with encouraging safety profile *in vitro* and *in vivo*[1]
- In non-GLP and GLP tox studies in NHP, dual selection results in high selectivity with 100-fold therapeutic index (TI) increase[1]
- Phase 1 dose escalation ongoing with anticipated data readout in 2H 2024

[1]Gerhard Frey, Ana Paula G. Cugnetti, Haizhen Liu, Charles Xing, Christina Wheeler, Hwai Wen Chang, William J. Boyle & Jay M. Short (2024) A novel conditional active biologic anti-EpCAM x anti-CD3 bispecific antibody with synergistic tumor selectivity for cancer immunotherapy, mAbs, 16:1, 2322562, DOI: 10.1080/19420862.2024.2322562

# Key Milestones And Catalysts Throughout 2024

| 2024 | |
|---|---|
| 1H | 2H |
| • BA3071:<br>  ○ Dose escalation:<br>  ✓ Cleared 10mg/kg<br>  ○ Evaluate safety and efficacy at 14.2mg/kg dose level<br>  ○ Initial readout Phase 2 in treatment-refractory solid tumors (~20 pts)<br>  ○ Demonstrate supportive data as mono- and combo- therapy<br>• BA3011:<br>  ○ Evaluate clinical benefit in target-agnostic NSCLC patients (~30 pts)<br>  ✓ Update UPS status<br>• BA3021: Readout final data sets in melanoma (n = ~25 pts) and SCCHN (n = ~30 pts)<br>• BA3361: IND submission | • BA3071:<br>  ○ Readout additional Phase 2 data in treatment-refractory solid tumors<br>  ○ Define pivotal path for BA3071 in treatment-refractory indications<br>• Initiate potentially registrational study with either BA3071 and/or one of our CAB-ADCs<br>• Establish strategic collaboration for BA3071 and/or one CAB-ADC<br>• BA3182: Phase 1 data readout; initiate Phase 2 as data support |

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