Phase 2 Trial of Mecbotamab Vedotin (BA3011), CAB-AXL-ADC, Alone or in Combination with Nivolumab in Patients with Non-Squamous NSCLC

BA3011 AXL NSCLC

December 4, 2023

bioatla

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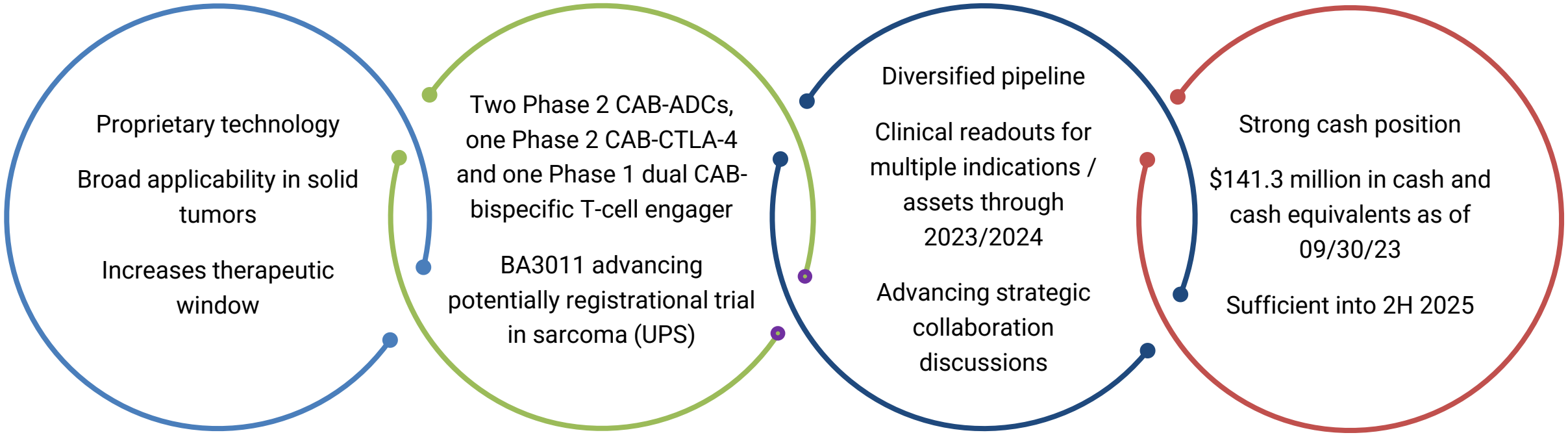
KOL AXL NSCLC Agenda

1. **Opening Remarks**
   CAB Technology
2. **BA3011**
   AXL as a prognostic factor
   Clinical data
3. **Next Steps**
   Registrational trial designs
4. **Q & A Session**

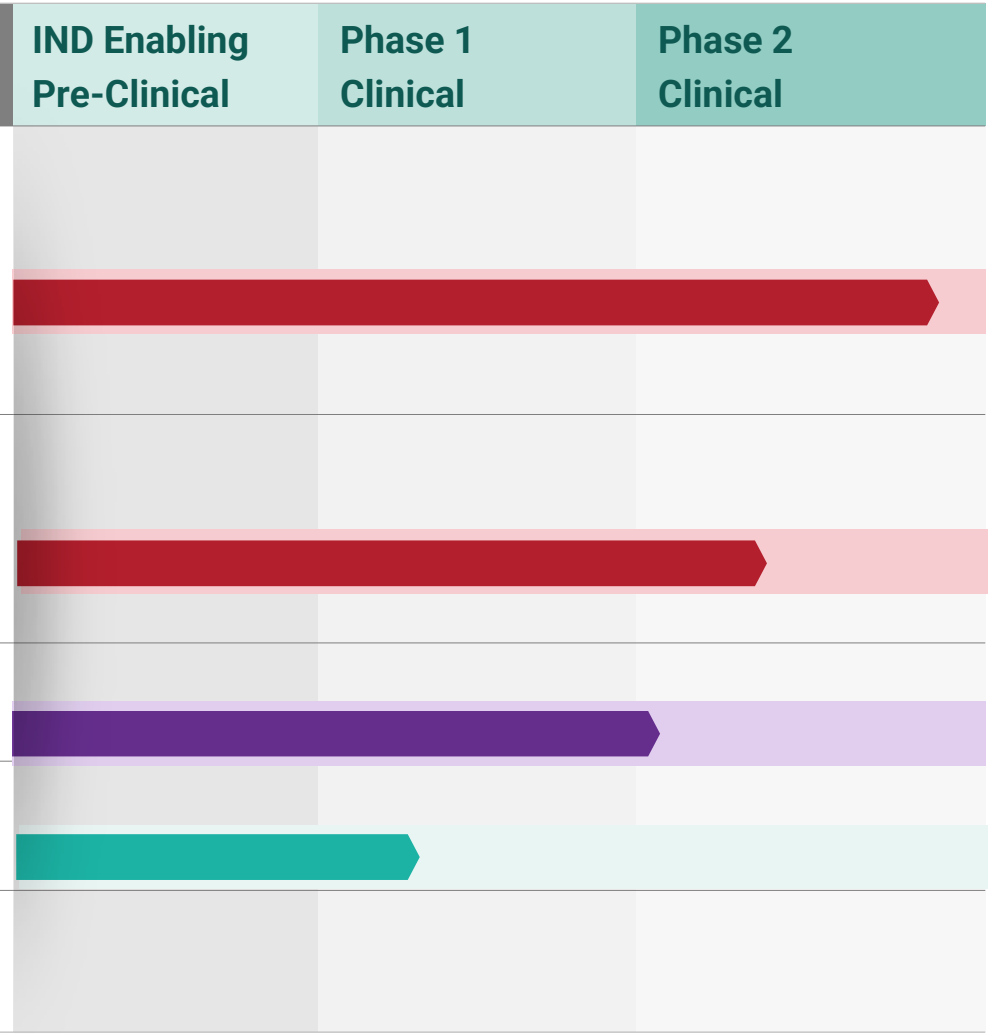
BioAtla© is a clinical stage company focused on transforming cancer therapy

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
CAB-ADCs	**BA3011** *Mecbotamab Vedotin*	AXL	Undifferentiated Pleiomorphic Sarcoma (UPS) NSCLC
CAB-ADCs	**BA3021** *Ozuriftamab Vedotin*	ROR2	Melanoma NSCLC SCCHN
CAB-I/O	**BA3071**	CTLA-4	Multiple tumor types**
CAB-Bispecific TCE	**BA3182**	EpCAM x CD3	Adenocarcinoma** Multiple tumor types**
CAB	**Additional programs**	Various	Multiple tumor types**



IND, investigational new drug; NSCLC, Non-small Cell Lung Cancer; SCCHN, Squamous Cell Carcinoma of the Head and Neck; STS, Soft Tissue Sarcoma; FPI, First Patient In.

*Phase 2 investigator-initiated trial for Ovarian Cancer
** Indications based upon tumor target expression

Selective and targeted CAB technology widens therapeutic window,

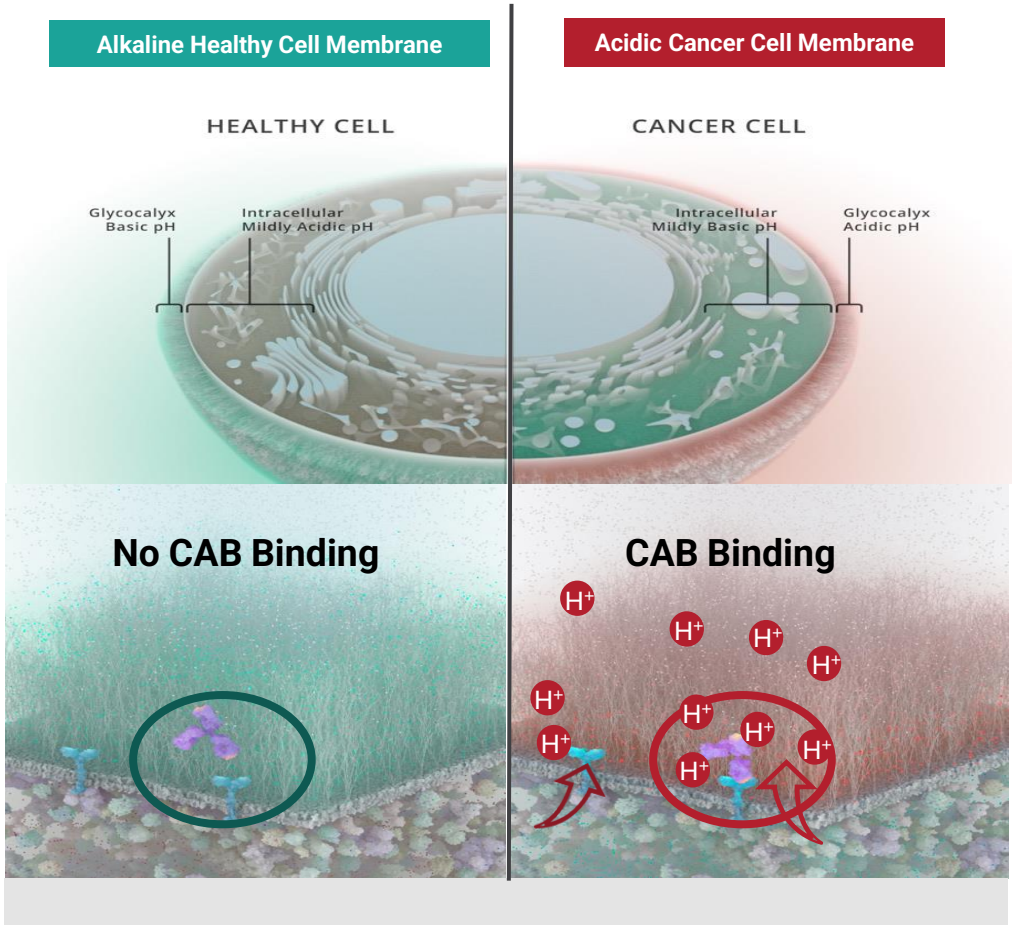
thus has the potential to enhance clinical outcomes in multiple tumor types

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

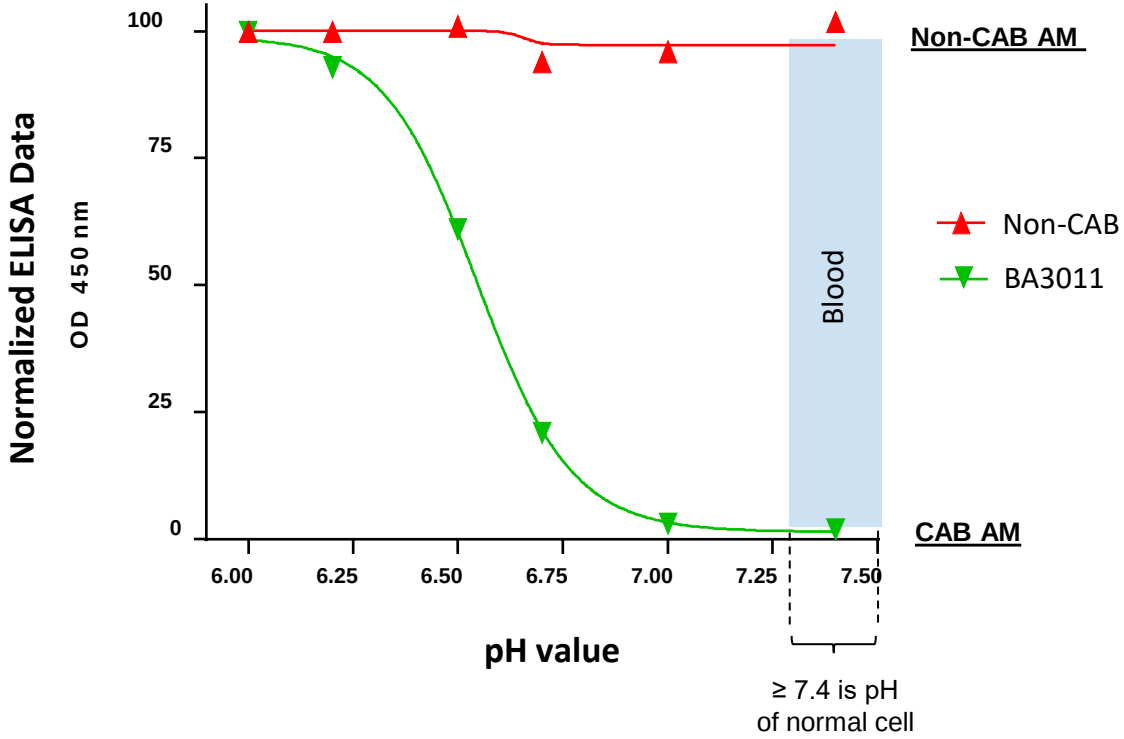
CAB antibodies have the potential for increased efficacy with improved safety relative to traditional antibodies



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.

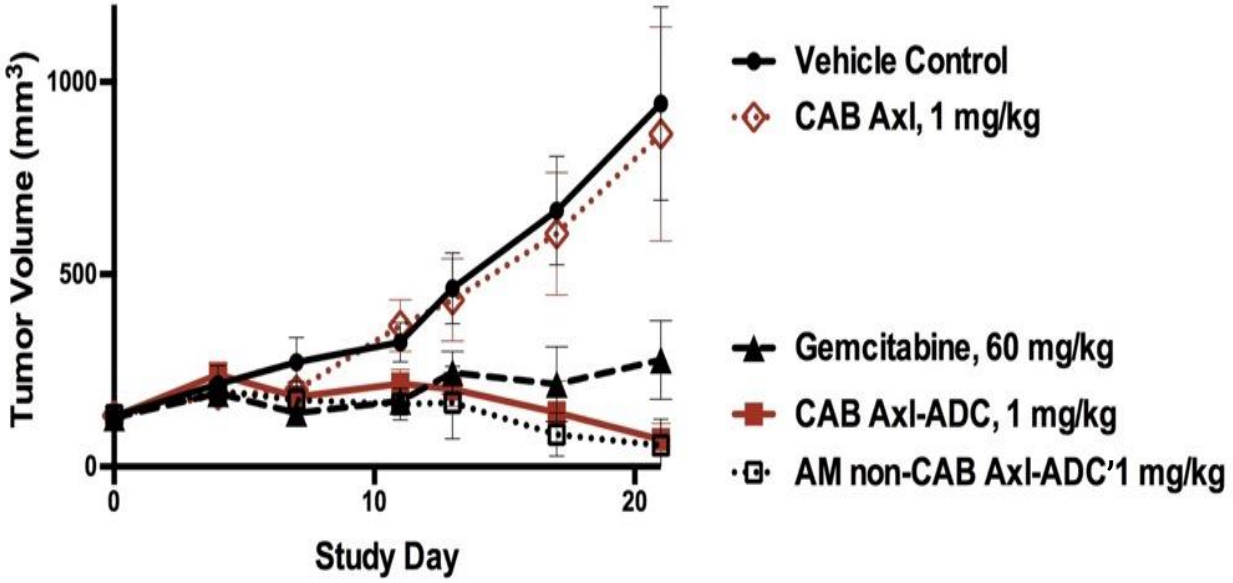
CAB AXL antibody binds selectively and reversibly based on the cellular microenvironment

CAB AXL pH binding inflection point adjusted for tumor microenvironment selectivity



CAB AXL-ADC shows significant antitumor activity in human pancreatic cancer model

(MiaPaCa xenograft)



Carl M. Gay, MD, PhD

Assistant Professor, Department of Thoracic-Head & Neck Med Onc at MD Anderson Cancer Center

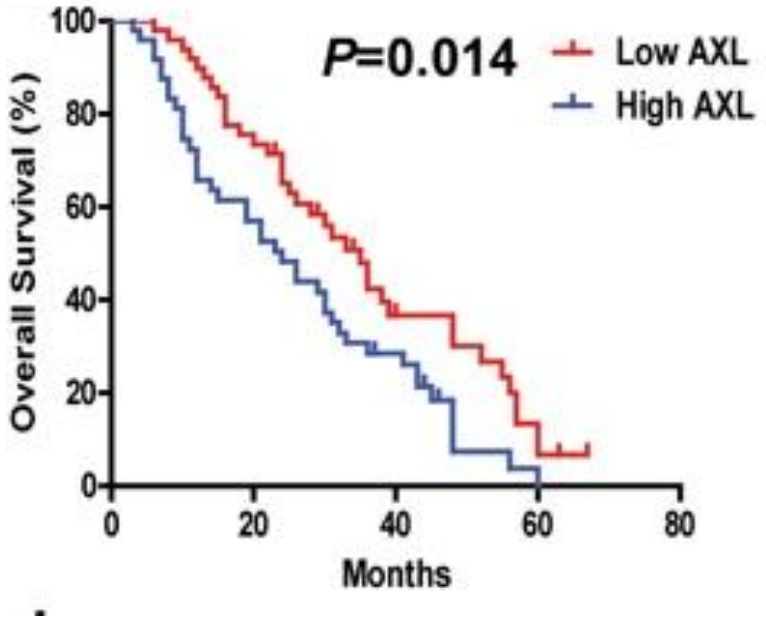
Dr. Gay graduated from Johns Hopkins University in 2005 (BA, Biology) and then enrolled at New York University School of Medicine, where he obtained his PhD (2011, Cellular & Molecular Biology) and MD (2013) degrees.

He completed his residency at the University of Texas Health Science Center at Houston before joining MD Anderson Cancer Center in 2015 as a clinical fellow. In 2019, Dr. Gay was appointed Assistant Professor in the Department of Thoracic/Head & Neck Medical Oncology.

As a clinical investigator, Dr. Gay designs and oversees clinical trials for a variety of thoracic malignancies with a particular focus in small cell lung cancer. Dr. Gay's research includes identifying novel therapeutics and predictive biomarkers for patients with lung cancer including the receptor tyrosine kinase AXL.

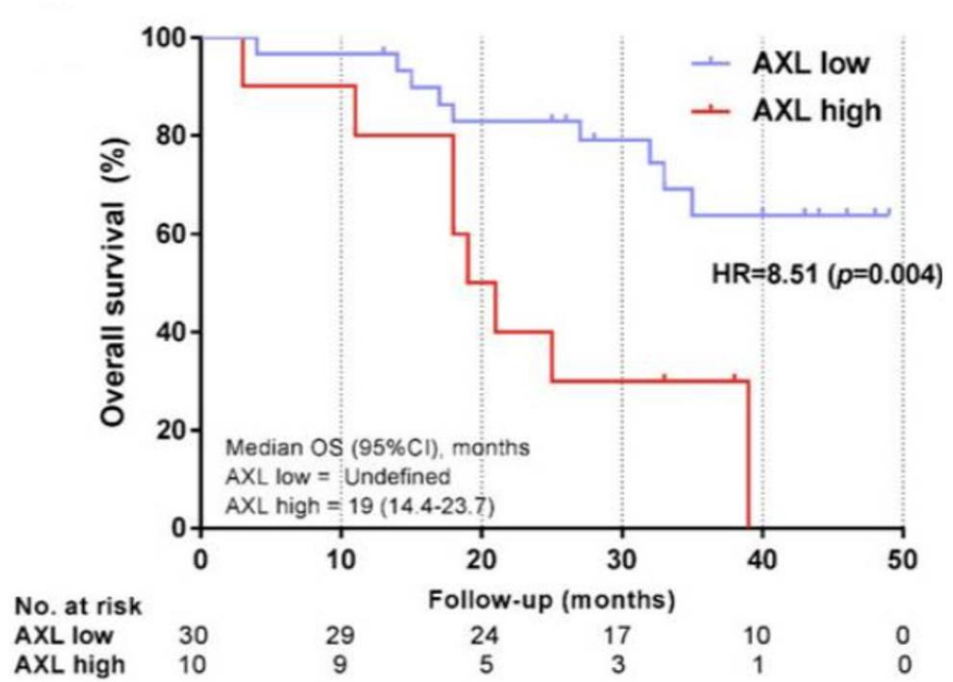
Dr. Gay has been the recipient of the American Society of Clinical Oncology Young Investigator Award, the Cancer Research Prevention Institute of Texas Early Clinical Investigator Award, and the LUNGevity Foundation's Career Development Award.

AXL expression is associated poor prognosis in metastatic NSCLC



In a cohort of 98 patients with metastatic NSCLC, OS was significantly worse for those patients with high AXL expression by IHC

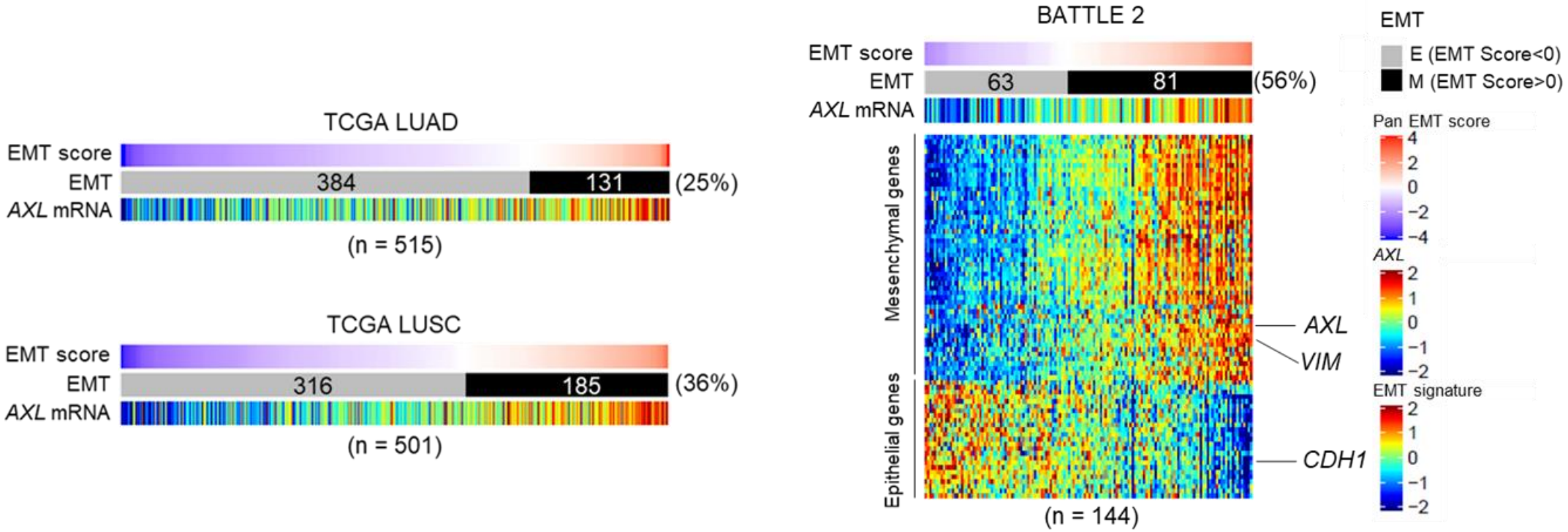
Wu et al., J Cancer Res and Clin Oncol, 2017



Lower overall survival (OS) in patients with early stage, surgically resected lung adenocarcinoma with high levels of tissue AXL

Reproduced from de Miguel-Pérez D, et al. 2019

In NSCLC, AXL and EMT are inextricably linked with therapeutic resistance



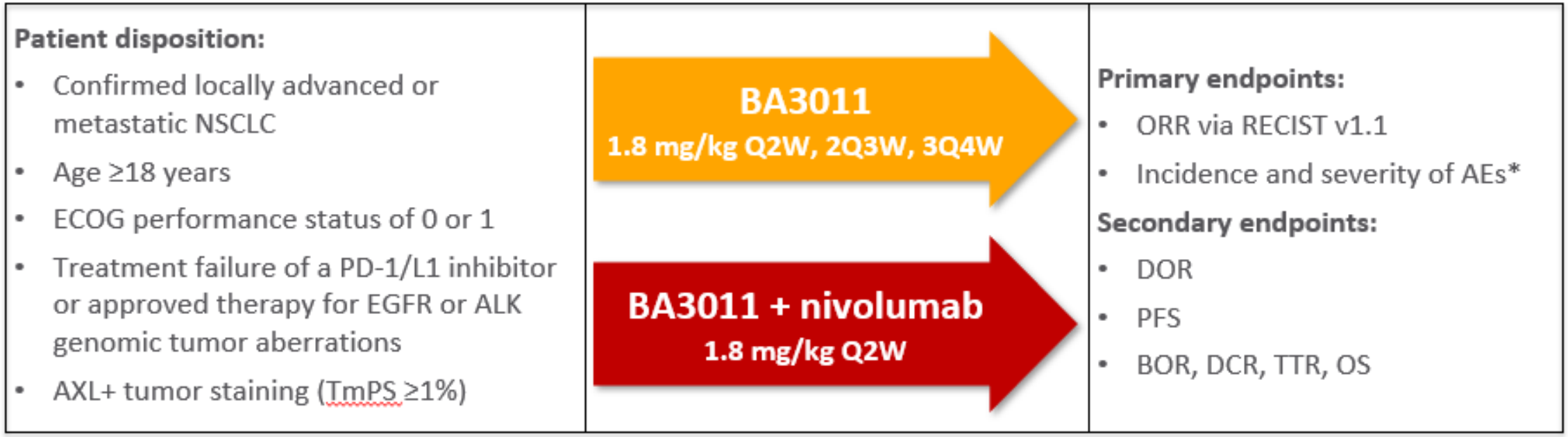
EMT and AXL expression are correlated, and both are more common in relapsed/chemorefractory NSCLC patient samples (BATTLE 2) than treatment-naïve samples (TCGA).

EMT - epithelial to mesenchymal transition

Ramkumar K, et al. *Mol Canc Res*, 2021

BA3011-002 Non-Small Cell Lung Cancer

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



*Coded by MedDRA and graded according to NCI CTCAE v5

Phase 2 BA3011-002 NSQ NSCLC: Baseline Demographics and Characteristics

BioAtla 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)

Data Cut Date: 30Jun23

Phase 2 BA3011 Non-Squamous NSCLC

Monotherapy 1.8 mg/kg Q2W shows encouraging efficacy signals

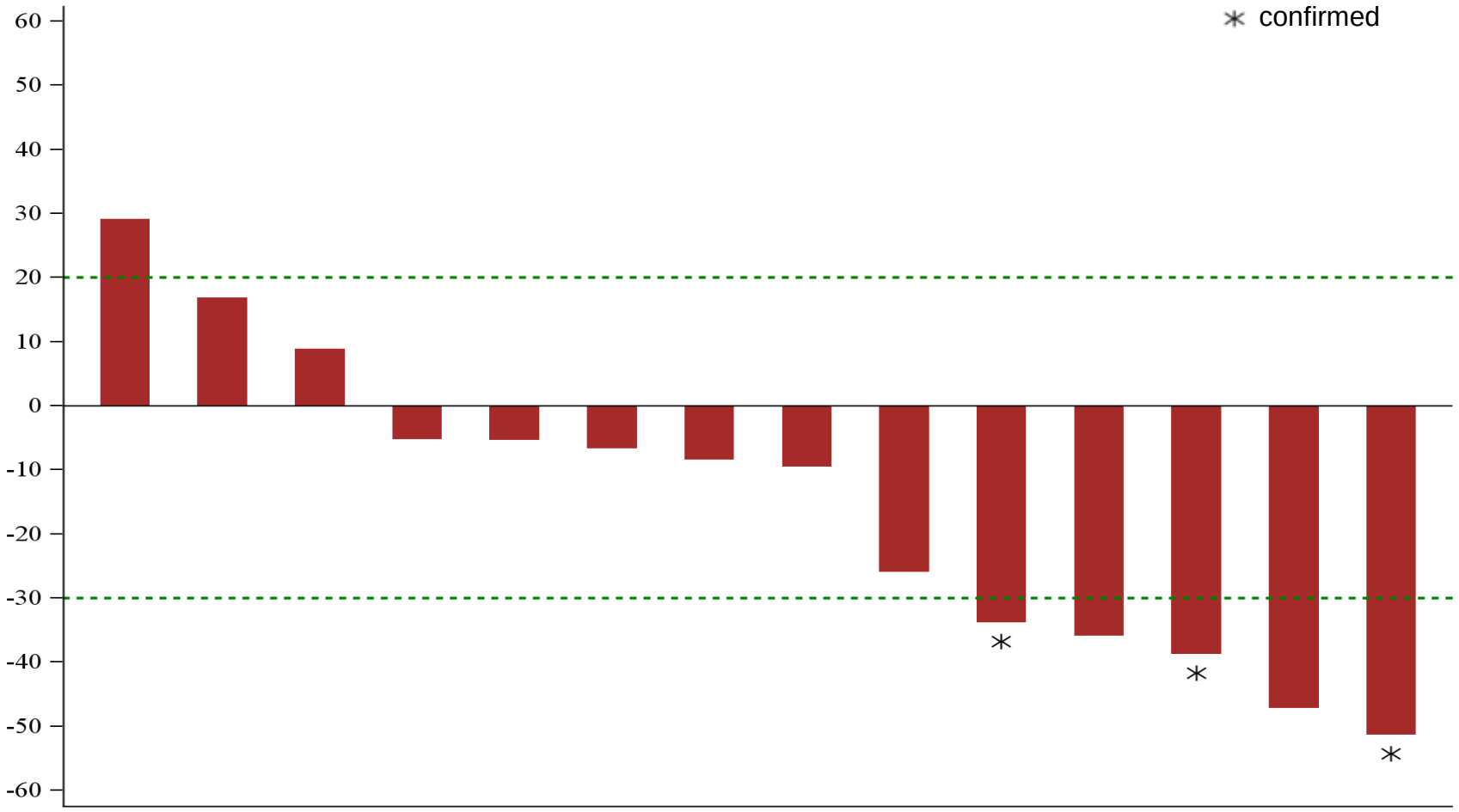
Data Cut Date: 30Jun23	Prior PD-1/L1 treatment EGFR wild-type (N=15)	Prior PD-1/L1 treatment (N=18)
Best Overall Response, n (%)		
Confirmed PR	3 (20.0)	3 (16.7)
Unconfirmed PR	2 (13.3)	2 (11.1)
SD	7 (46.7)	10 (55.6)
PD	2 (13.3)	2 (11.1)
NA (early discontinuation due to AE)	1 (6.7)	1 (5.6)
Response Rate		
n (%)	5 (33.3)	5 (27.8)
Exact 95% CI	11.8, 61.6	9.7, 53.5
Disease Control Rate		
n (%)	8 (53.3)	10 (55.6)
Exact 95% CI	26.6, 78.7	30.8, 78.5

- Monotherapy median Duration of Response was estimated to be 4.8 months with a range of 2.3-12.1+ months*
- Combination therapy (n=17)*:
  - Evaluable patients (majority with 4+ prior lines of therapy) received BA3011 + nivolumab
  - One patient experienced an ongoing complete response (CR), 2 patients experienced PR, and 8 patients experienced stable disease (SD)

*As of November 20, 2023

BA3011-002 NSCLC interim analysis

BA3011 Monotherapy 1.8 mg/kg Q2W



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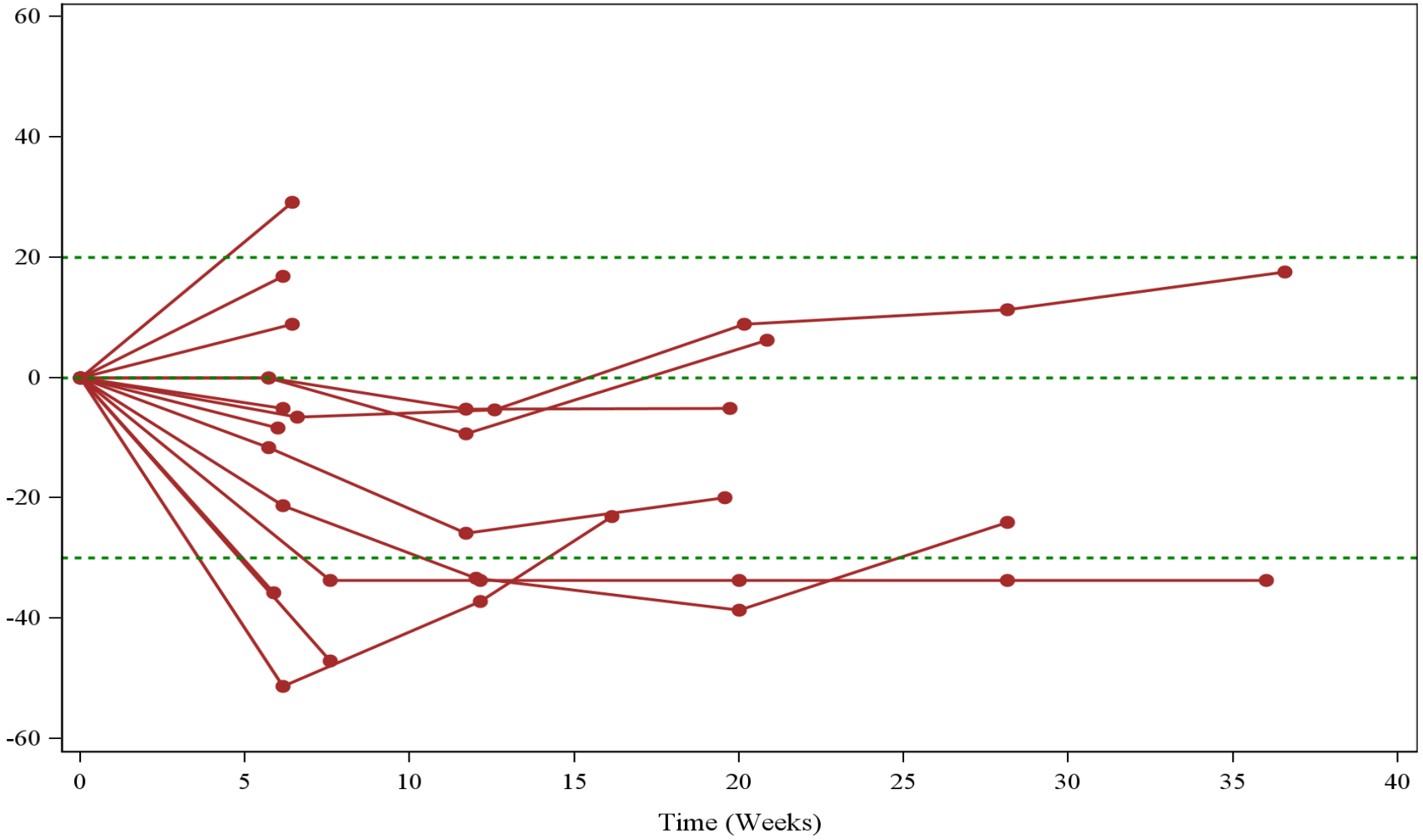
BA3011-002 NSCLC interim analysis

BA3011 Monotherapy 1.8 mg/kg Q2W



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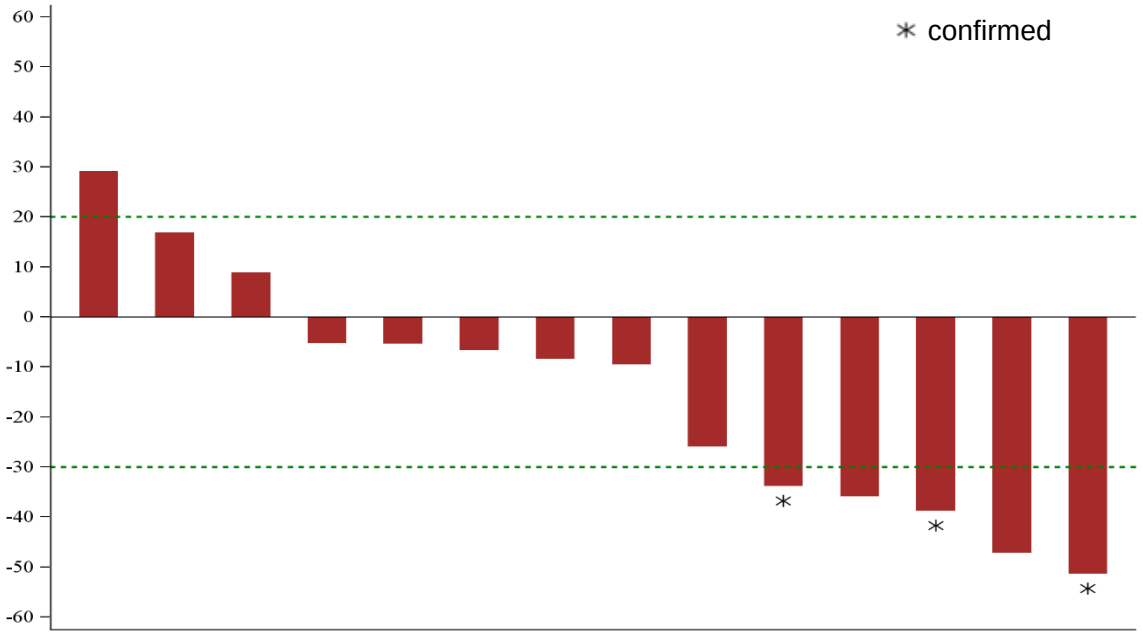
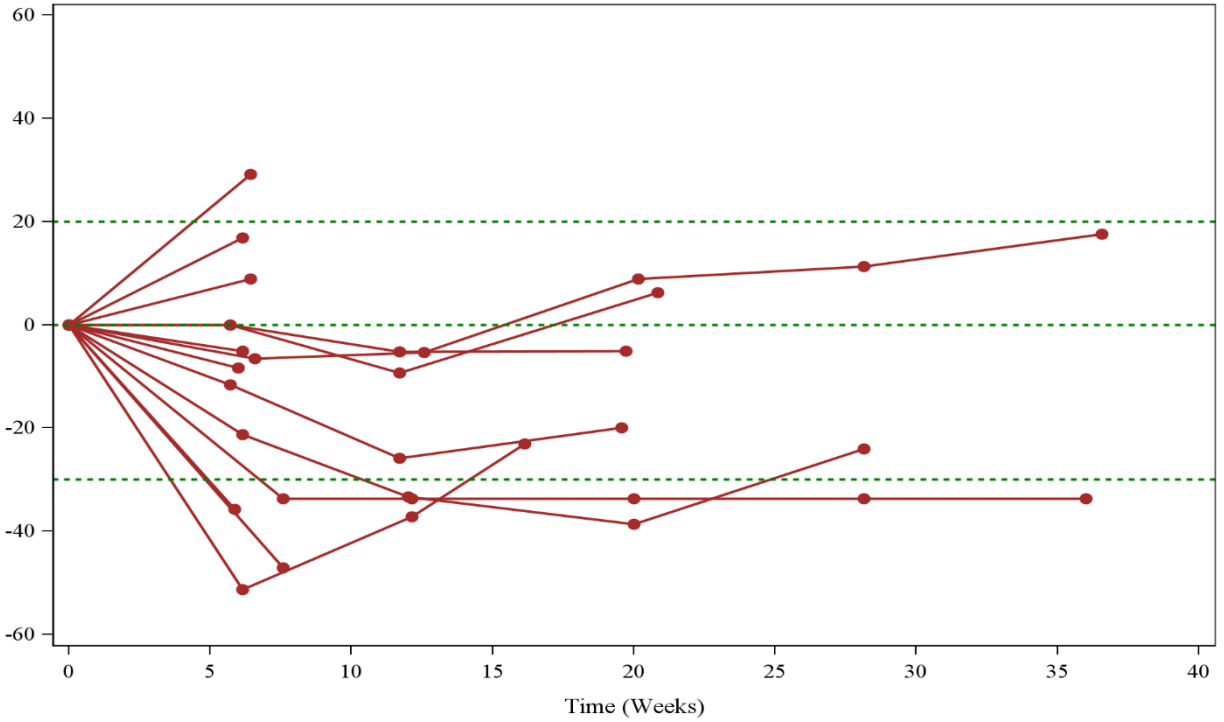
BA3011-002 NSCLC interim analysis

BA3011 Monotherapy 1.8 mg/kg Q2W





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BA3011-002 NSCLC interim analysis

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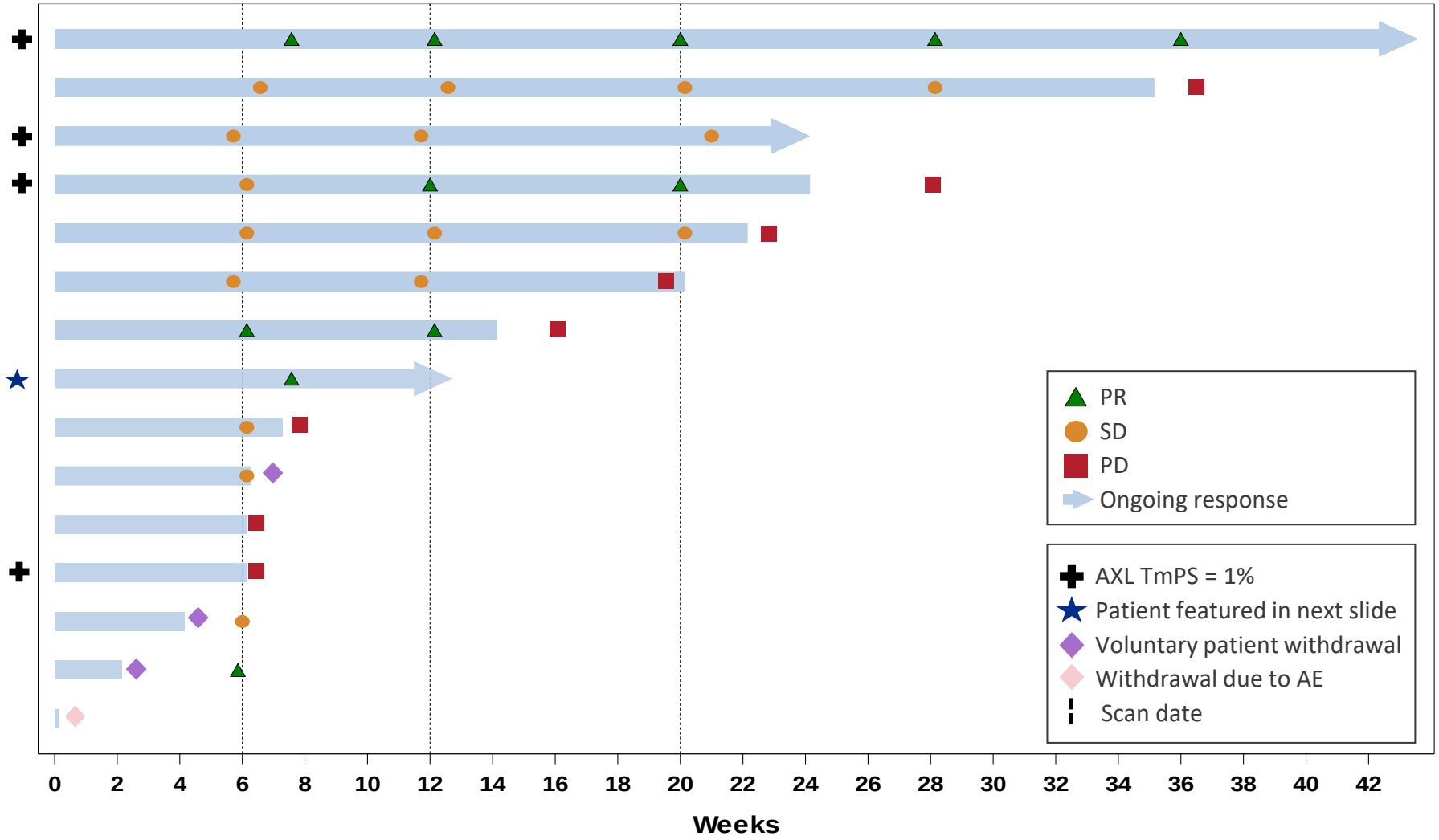
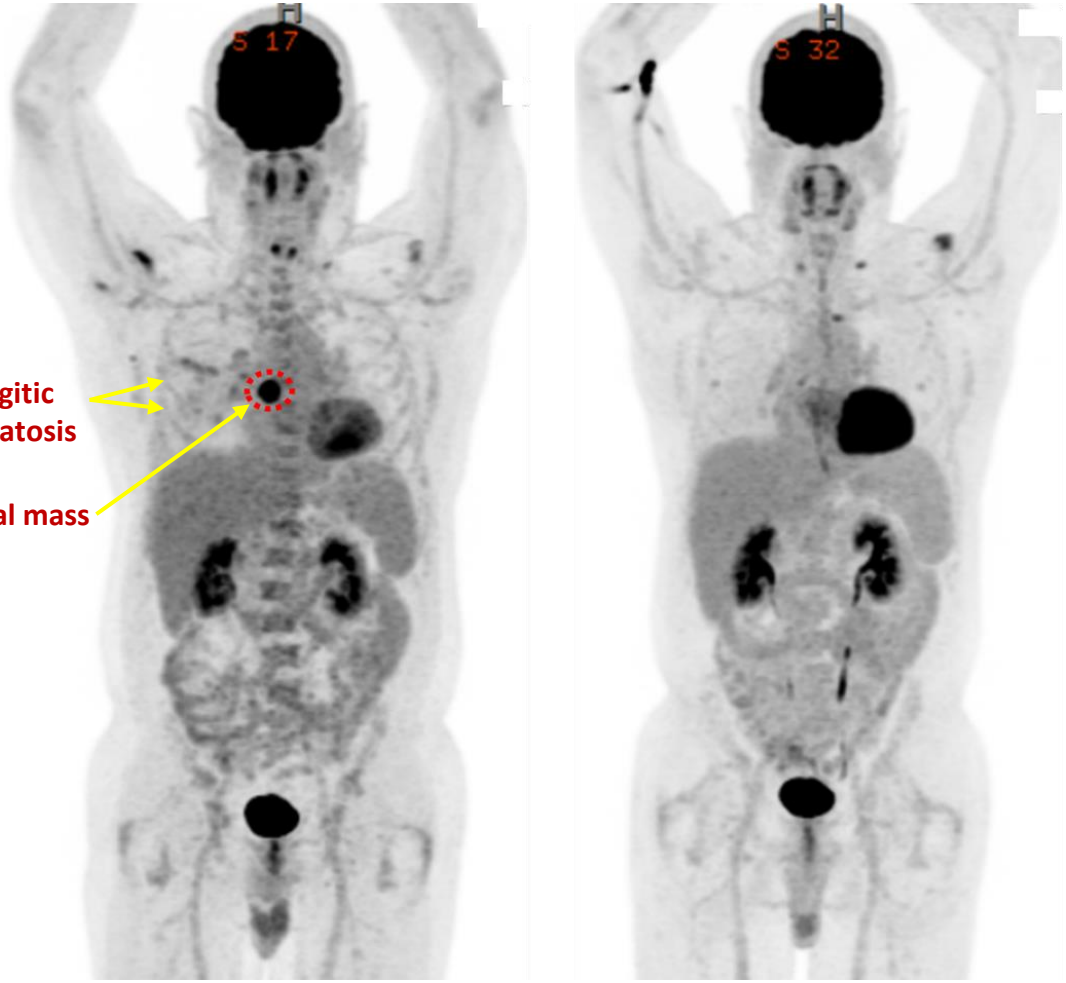


Data Cut Date: 30Jun23

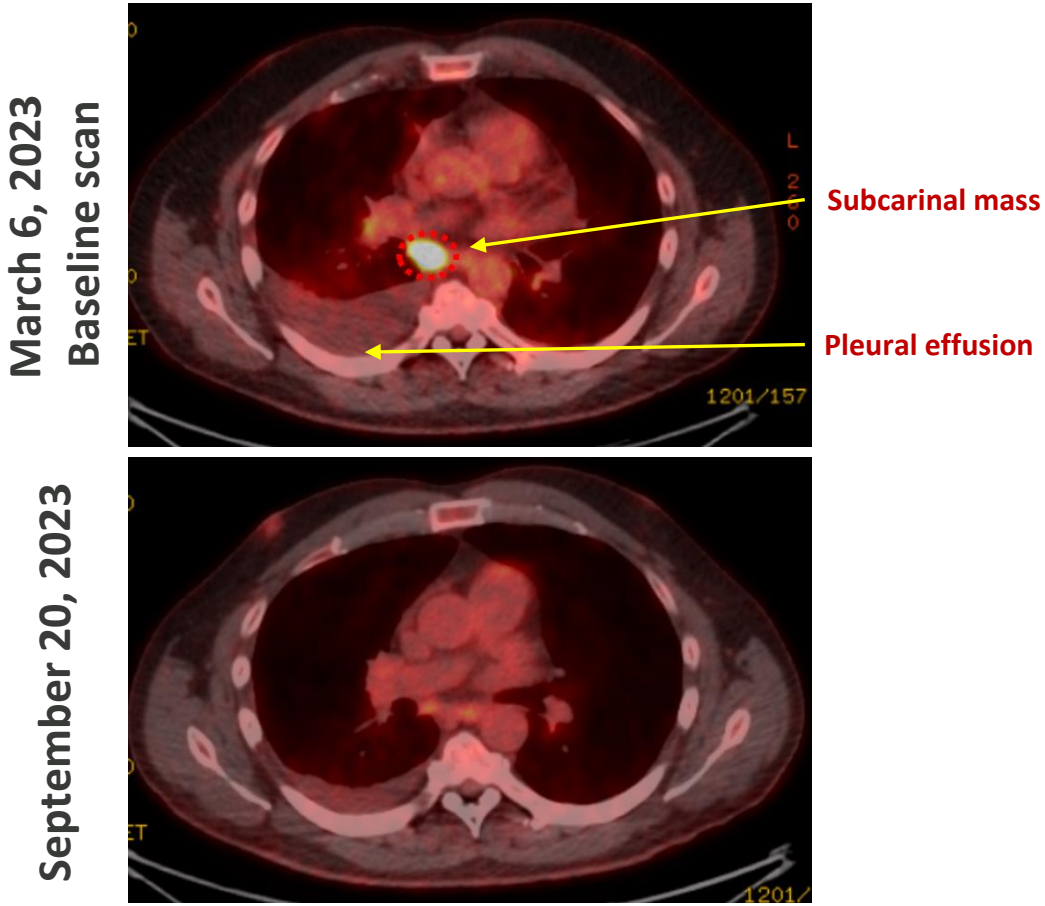
Radiographic response to BA3011 monotherapy

March 6, 2023 – Baseline scan **September 20, 2023**



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

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



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

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

Data Cut Date: 30Jun23

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.

Data Cut Date: 30Jun23

Phase 2 BA3011 NSCLC Dose Optimization

In-line with FDA Project Optimus

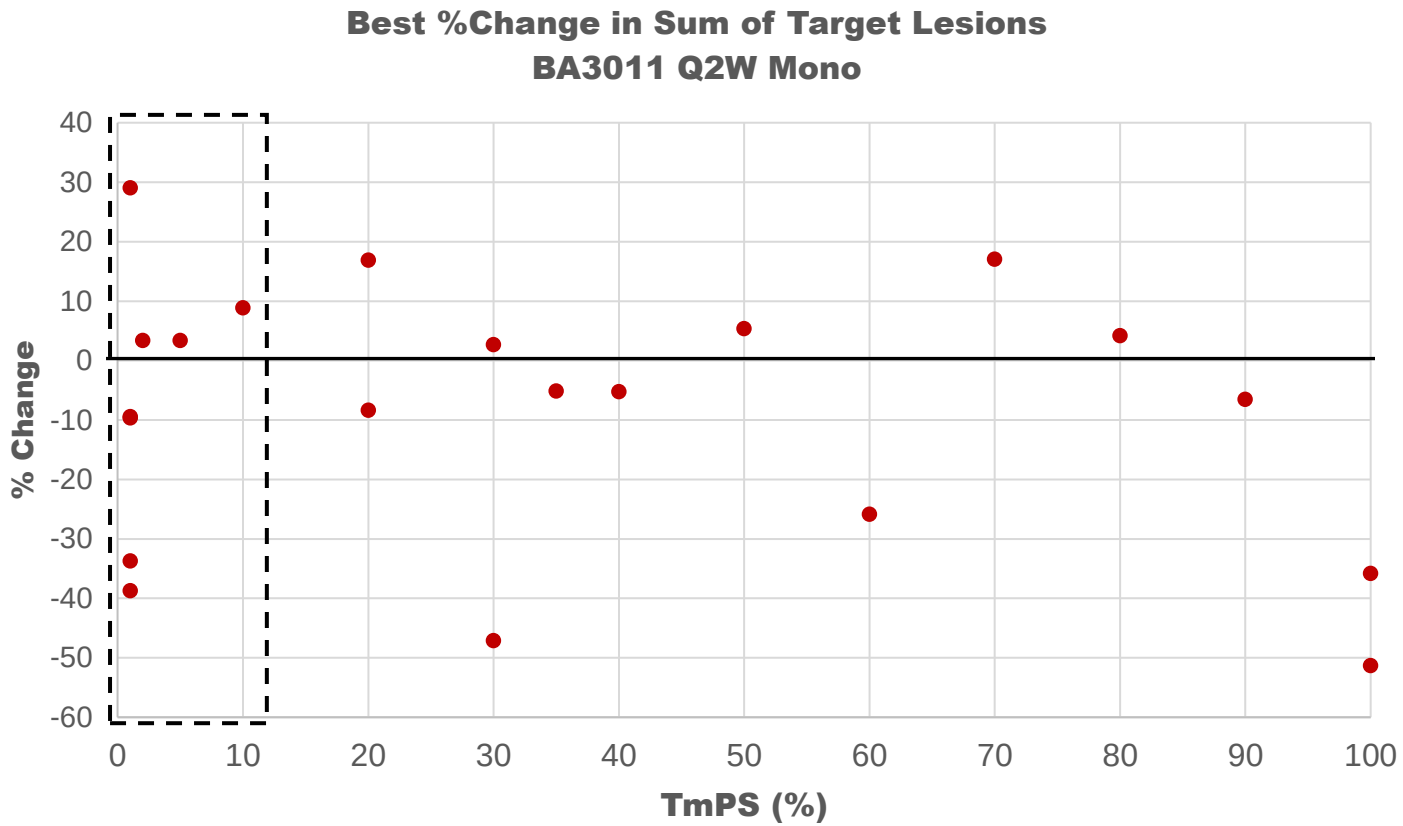
- 3Q4W dosing regimen
  - 3 patients have been evaluable (1 SD and 2 PD)
  - Suboptimal compliance observed and enrollment has been discontinued

- 2Q3W dosing regimen
  - 11 patients treated
  - 4 patients have been evaluable (3 SD and 1 PD) to date

Benefit-Risk profile observed to date with 1.8 mg/kg Q2W supports advancing this dose in registrational studies

BA3011 NSCLC AXL Expression in Relation to Anti-tumor Activity

Considerable anti-tumor activity among patients regardless of AXL expression level



Anti-tumor activity seen among patients with AXL low expression level supports target agnostic development

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

Q & A Session