



# BerGenBio

*Building upon a strong scientific foundation to  
create significant value for patients and  
shareholders*

**Q2 2023 Report**





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# A global leader in targeting AXL biology

- We are selectively targeting AXL biology, known to play a key role in the progression of cancer, respiratory diseases and fibrosis – and we have two proprietary clinical stage programs: bemcentinib (lead program) and tilvestamab
- Multiple Ph2 trials of bemcentinib validate clinical benefits of selective AXL inhibition in **NSCLC** and AML, MDS, and Mesothelioma
- We are focused on developing bemcentinib in 1L NSCLC where we have a strong competitive position, significant market opportunity and supportive pre-clinical and clinical data – opportunities beyond 1L NSCLC is pursued through partnering
- Recent Rights Issue of NOK 250M combined with a streamlined organization support runway through 2024 – and potentially into H2 2025 if all granted warrants from Rights Issue are exercised
- Our planned activities holds the potential to unlock significant value and provide guidance for pivotal trials in NSCLC.
- Additional value potential from out-licensing of tilvestamab and ADC program (out-licensed to ADC-Therapeutics)





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**Bemcentinib offers an  
attractive opportunity to  
address a significant  
unmet medical need in  
NSCLC**



# Bemcentinib, a highly differentiated AXL tyrosine kinase inhibitor

Highly selective, potent oral inhibitor of AXL – a key driver of chemo- and immuno-therapy resistance

Unlike most "AXL inhibitors" such as cabozantinib, highly selective for AXL

Selectivity provides better AXL inhibition potency, few off-target adverse events

Concentrates in the lung (40x) and crosses the BBB – key importance in NSCLC where brain mets are common

Combines successfully with chemo, targeted and CPI\* drugs

NSCLC Fast Track designations in combination with ICI & in STK11m pts

Extensive patent portfolio with expected protection until 2042+



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\*Checkpoint inhibition

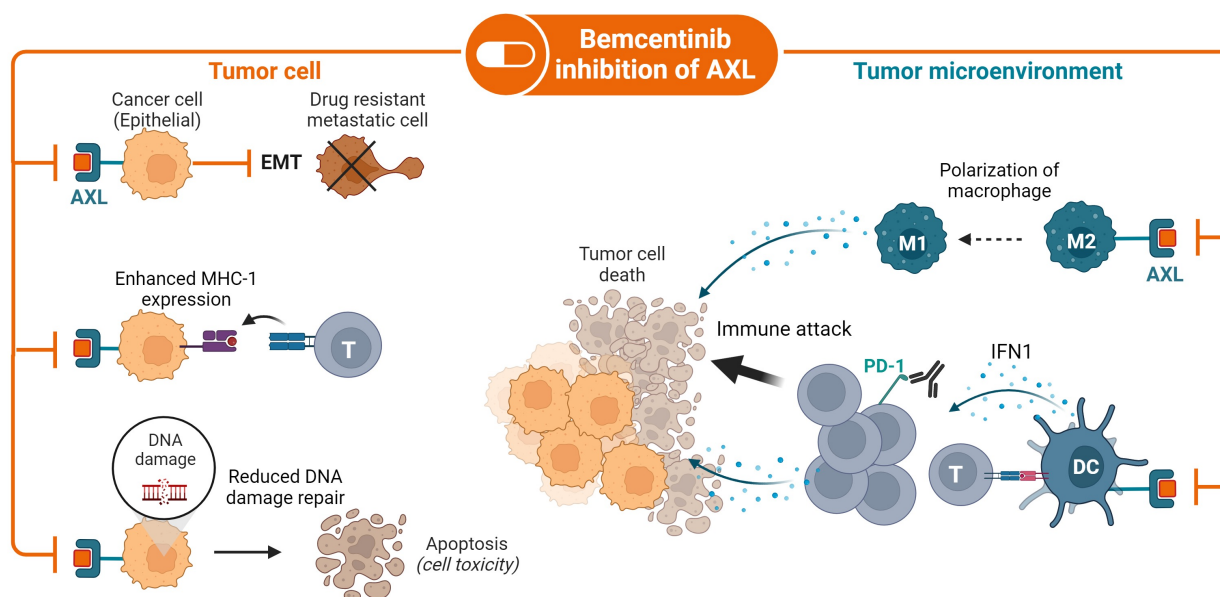


# AXL inhibition by bemcentinib leads to improved response to CPI and/or chemo

Reduces EMT driven immune evasion, drug resistance

Enhances MHC-1 antigen presentation

Reduces DNA damage repair and enhanced cell death



Reactivates innate immunity, proliferation of TCF1+ CD8+ T Cells to re-engage with CPI and polarization towards M1 macrophages



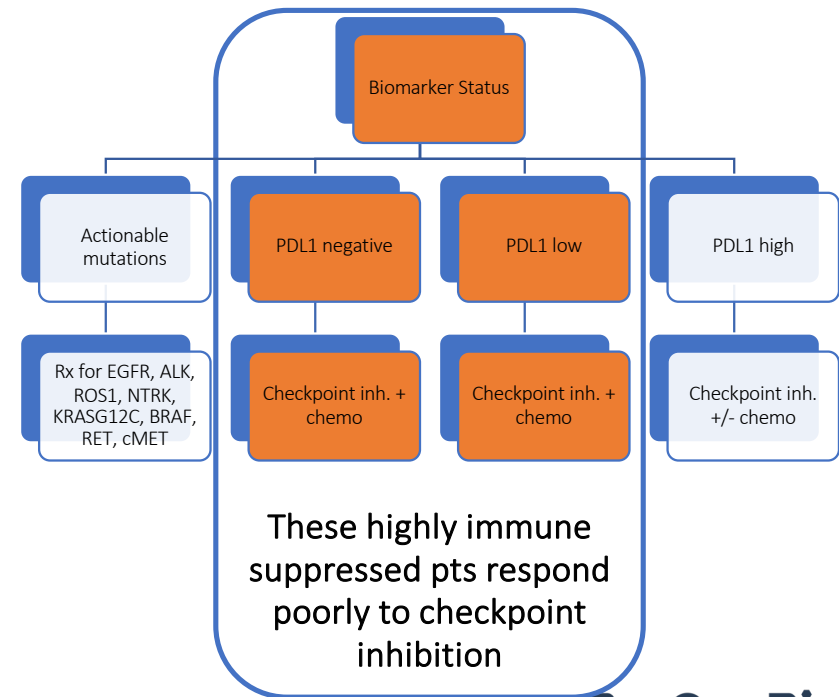
# Treatment of NSCLC requires new approaches for patients unresponsive to current therapies

Lung Cancer: A Leading Cause of Death



- Most prevalent cancer worldwide with highest mortality rate
- Non-Small Lung Cancer represents 85% of lung cancers
- Patients often diagnosed with incurable metastatic disease with hallmarks of hampered immune systems (no-low PDL1)

Targeted Therapies Only Available for ~ 50% of mNSCLC 1L Patients



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# Recently announced clinical data validates the potential for bemcentinib in NSCLC



- Encouraging data from multiple Phase 2 trials in NSCLC, AML/MDS and mesothelioma provide clinical validation of selective AXL inhibition with bemcentinib
- NSCLC clinical trials of >100 patients indicate that patients with AXL expression on their tumor or immune cells live longer with bemcentinib + pembrolizumab treatment (statistically significant)
- Detailed pre-defined biomarker analyses in the BGBC008 Ph2 study of 2L NSCLC point to significant potential in 1L NSCLC STK11m patients and other significant NSCLC patient populations with hampered immune systems



# BGBC008 (2L+NSCLC) supports our focus

## BGBC008 Study Design Ph2 Bemcentinib + Pembrolizumab in 2L NSCLC

### Inclusion criteria

Non-squamous (adenocarcinoma) histology  
PD-L1 All comers

### Regimen

Pembrolizumab 200mg fixed  
Bemcentinib 400mg loading, 200mg OD

### Primary endpoint

Objective Response Rate

### Secondary endpoints

Duration of Response  
Disease Control Rate  
Progression Free Survival  
Median Overall Survival  
Survival at 12 months  
Response by Biomarker expression  
Safety, PK

### Cohort A (n=44)

Prior 1L platinum chemotherapy treatment

- 2<sup>nd</sup> line metastatic Non-Squamous NSCLC

### Cohort B (n=27)

Prior 1L anti-PD-1/L1 treatment

- Disease control on 1L for  $\geq 12$  wks. before progression
- 2<sup>nd</sup> or 3<sup>rd</sup> line metastatic Non-Squamous NSCLC

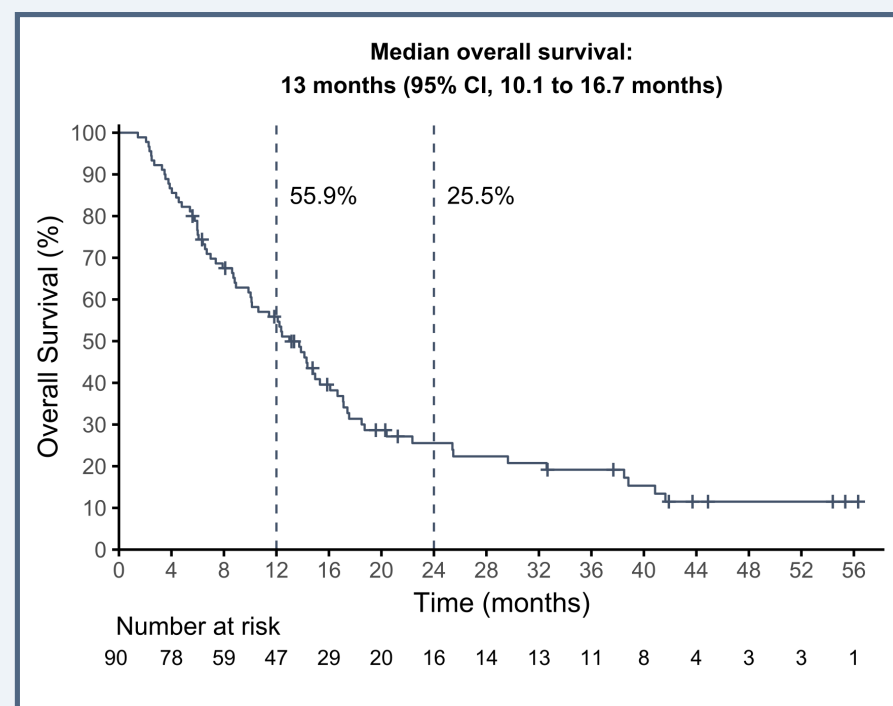
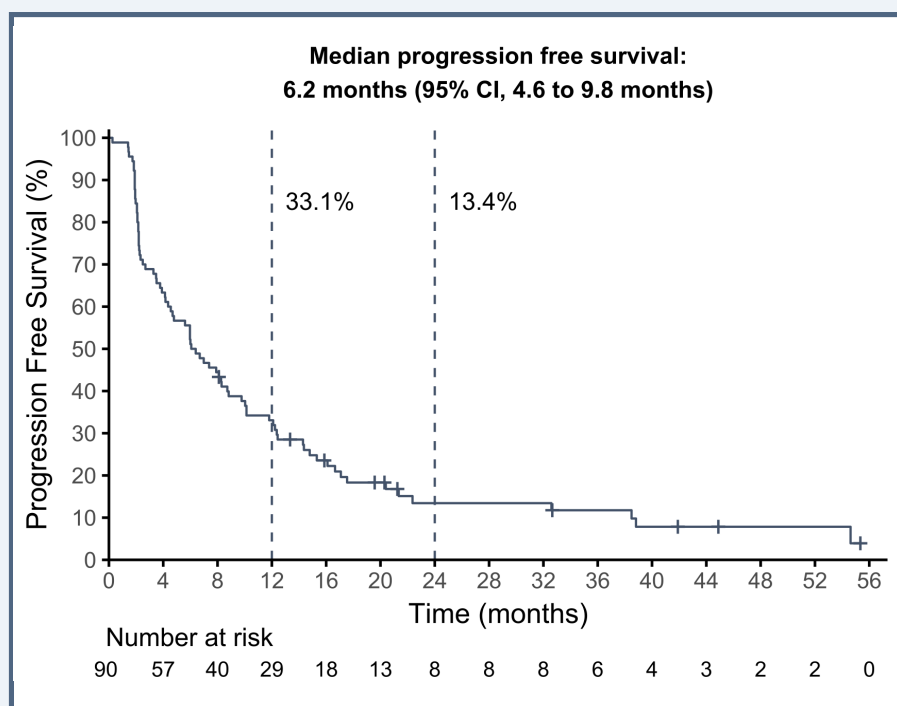
### Cohort C (n=19)

Prior 1L anti-PD-1/L1 + platinum-chemo treatment

- Disease control on 1L for  $\geq 12$  wks. before progression
- 2<sup>nd</sup> or 3<sup>rd</sup> line metastatic Non-Squamous NSCLC



# Encouraging efficacy observed in all evaluable patients – 25% alive at 2 yrs



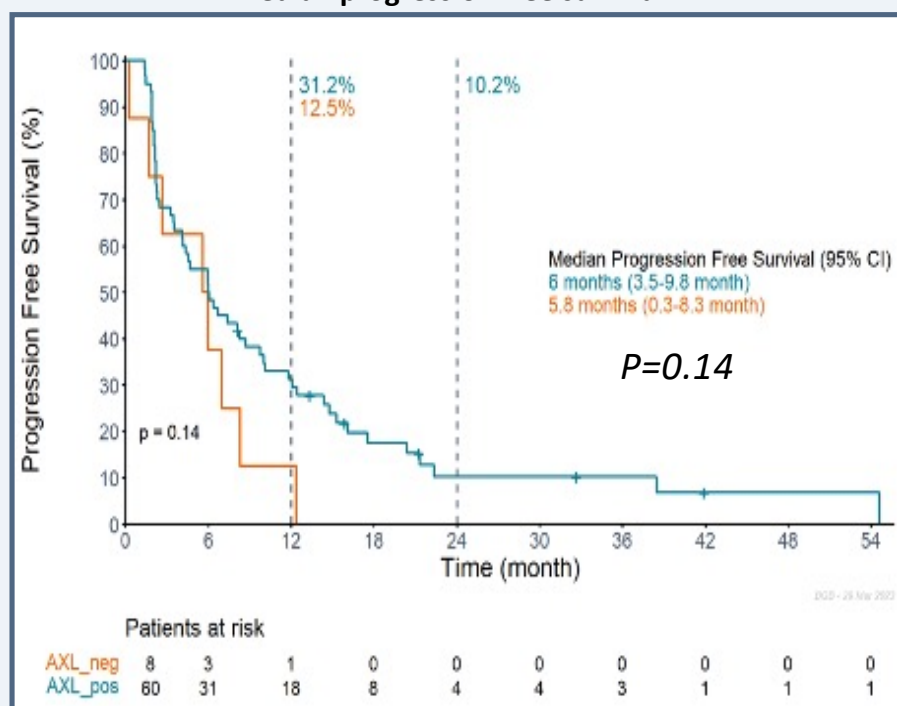
BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

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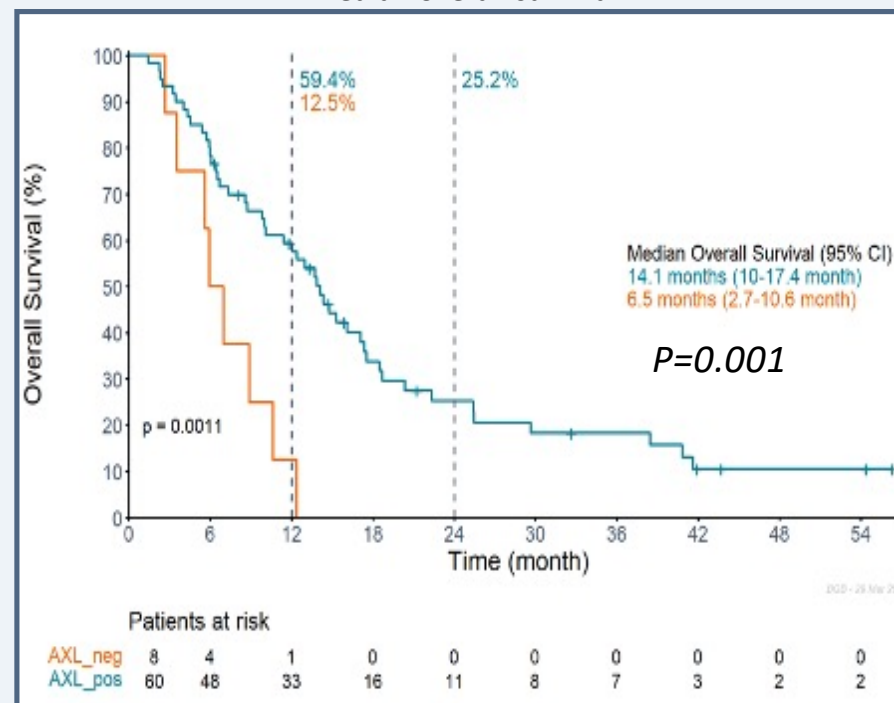


# The majority (88%) are AXL+ patients\* who lived longer, with statistical significance

Median progression free survival



Median overall survival



\*AXL positive in tumor cells (H>=5) /or immune cells (H>1) vs. pts with no or lower AXL levels

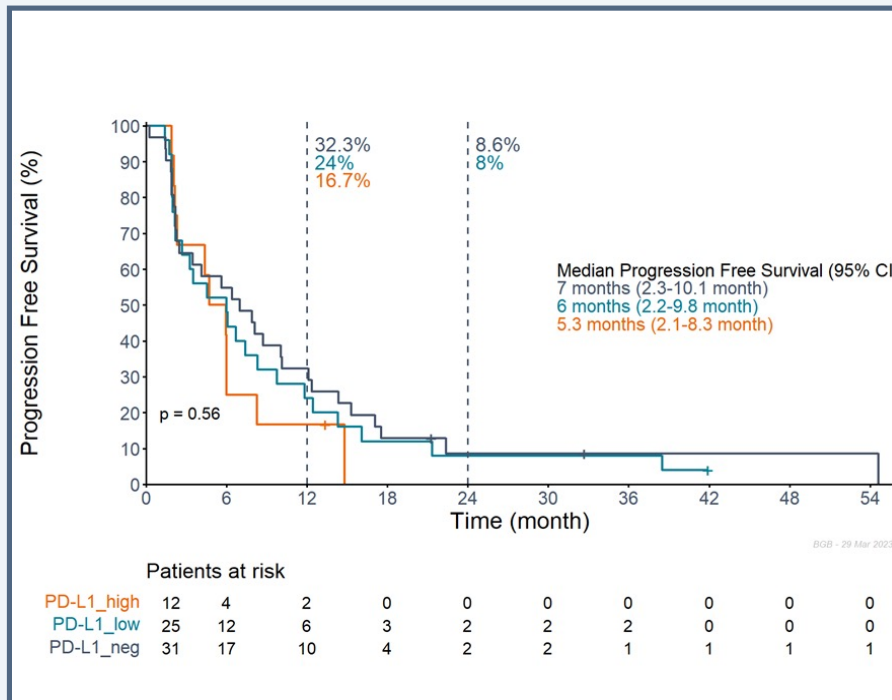
BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

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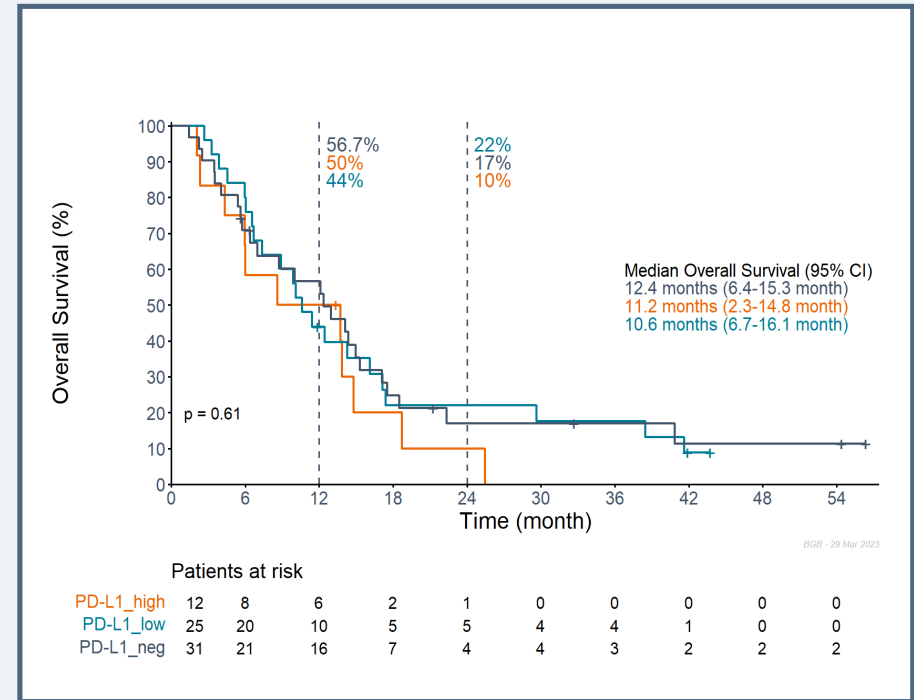


# Benefit even in neg./low PDL1 pts who typically respond less well to checkpoint inhibition

Median progression free survival



Median overall survival



BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

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- PD-L1 negative <1%; PDL1 low = 1-50% PD-L1 high >50%

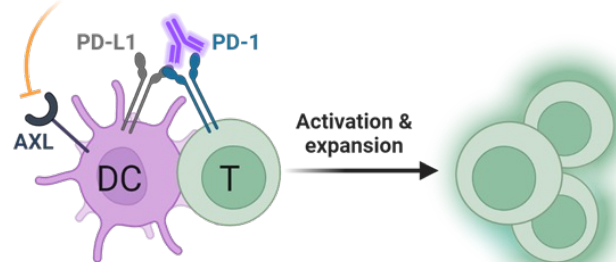


# How does bemcentinib potentiate checkpoint inhibition in PD-L1 neg/low NSCLC?

## AXL is heightened even in pts with neg./low tumor PDL1

- While rarely measured in patients, PD-L1 is present on multiple systemic immune cell types in TME & lymph nodes – dampening T cell response
- Patients can respond to immune checkpoint inhibition in the absence of PD-L1 expression in the tumor due to PD-L1 expression on immune cells

**Bemcentinib + anti-PD-1**



## Bemcentinib's MoA's complement PD-L1 inhibition in immune cells

- Enhances activation/proliferation of CD8 T-cells "released" by ICI treatment by reducing suppressive immune cells (dendritic cells, macrophages)
- Enhancement of anti-tumor cytokines therefore restoring therapeutic response to ICI treatment

Bemcentinib enhances ICI response in relevant PD-L1 neg/low in vivo models

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# Bem + pembro appears to bring mutated pts back to response of wild type pts.

Exploratory mutational analysis BGBC008

		PFS		mOS	
	% Mutated pts	Mutated pts	Wild type pts	Mutated pts	Wild type pts
STK11	10%	8.7	6.0	9.9	13.0
KEAP1	18%	4.8	6.0	11.5	12.4
KRAS	36%	9.8*	3.8*	14.1	10.0
SMARCA4	16%	7.4	6.0	14.1	12.1

- Co-occurring mutations in STK11, KEAP1, SMARCA4 in NSCLC are predictive of exceptionally poor prognosis\*\*
- Bemcentinib targets key mechanisms associated with these mutations within the tumor and TME
- Extensive biomarker analysis will be conducted in the 1L NSCLC STK11m study to validate these early findings and potentially widen the market potential for bemcentinib in NSCLC

\*Statistically significant at  $p=0.009$

\*\*Cancer Res (2022) 82 (12\_Supplement): 859.



# Bem + pembro compares very favorably to existing therapies in 2L NSCLC

	BGBC008		Historical 2L Trial Comparators		
	All Comers	AXL>5	Pallis, 2010	REVEL	KEYNOTE 189*
	<i>Bemcentinib + Pembrolizumab</i>	<i>Bemcentinib + Pembrolizumab</i>	<i>Docetaxel + Carboplatin</i>	<i>Ramucirumab + Docetaxel</i>	<i>Pembrolizumab</i>
ORR	11.1%	21.9%	10.4%	23%	18%
mPFS, mos	6.2	8.7	3.3	4.5	2.8
mOS, mos	13.0	14.1	10.3	10.5	6.9

\* Cross-over population following 1L CIT



# Bem + pembro safety comparable to pembro alone in 2L NSCLC

	Bemcentinib 200mg fixed + pembrolizumab BGBC008	Pembrolizumab Monotherapy KEYNOTE-010
Population	2L NSCLC	2L NSCLC
Top TRAEs , all grades		
AST increase	22%	26%
ALT increase	21%	22%
Diarrhea	21%	9%
Blood creatinine increased	15%	NR
Asthenia	14%	7%
Fatigue	12%	16%
Nausea	8%	12%
Amylase increased	8%	NR
Anemia	8%	4%
Pruritis	8%	NR
Decreased appetite	8%	13%

Safety profile of combination comparable to pembro alone

- No new safety signals
- Majority of AEs grades 1-2
- Bemcentinib studied w/ 400mg loading followed by 200mg/qd
- Future studies planned w/out loading & ~100-150mg/qd

NR= Not Reported (only AE's  $\geq 10\%$  reported, Source: Keytruda USPI April 2023; KEYNOTE-010 cross-over monotherapy in 2L NSCLC)

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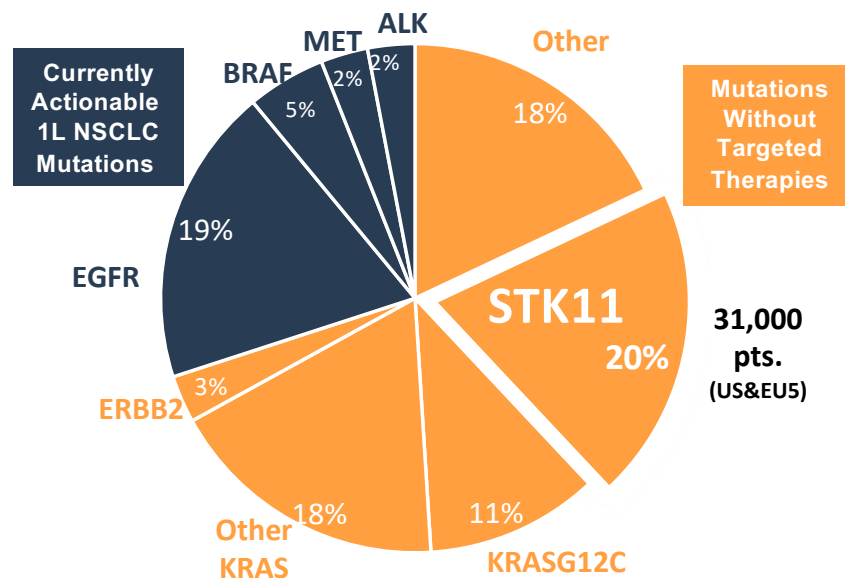
# Our strategy in NSCLC

- Through a thorough scientific and commercial analysis we have identified 1L NSCLC STK11m as the most attractive to advance alone to value infection:
  - ✓ Supportive preclinical and clinical evidence
  - ✓ No targeted therapy available; AXL widely present in STK11m pts
  - ✓ Bemcentinib is the most advanced compound in development specifically for 1L STK11m
  - ✓ Strong intellectual property position
- Based on our data and the unmet medical need, 2L NSCLC remains an attractive additional indication for bemcentinib; our goal is to find a late-stage development/commercialization partner to advance this opportunity



# Why STK11<sup>mut</sup> NSCLC?: a large underserved patient population

STK11<sup>mut</sup> – A significant 1L “non-actionable” mutation\*



Attributes of STK11<sup>mut</sup> NSCLC make it a highly attractive target for bemcentinib

- Lower response rate, PFS and overall survival with SOC
- No targeted therapy currently available
- 1L STK11m pts have almost universal AXL expression
- Although unactionable today – STK11m are identified on all major NSCLC liquid tumor biopsy panels

\* Sources: Oncogenic driver mutations in non-small cell lung cancer: Past, present and future. *World J Clin Oncol*. 2021 Apr 24; 12(4): 217–237  
Prognostic Impact of KRAS Mutation Subtypes in Metastatic Lung Adenocarcinoma. *J Thor Onc*. 2015; 10(3):431-437

\*\* Source: Global Data estimate in US, UK, Fr, Gr, Sp, It



# A wealth of data indicate poor outcome in STK11<sup>mut</sup> pts with current therapies

	Real World Data		
	STK11m	STK11wt	P value*
ORR	25.1%	40.5%	<0.001
PFS, mos	3.9	6.3	<0.001
OS, mos	10.4	15.2	0.004

- 707 patients at Dana Farber & Memorial Sloan Kettering treated with 1L immune checkpoint inhibition + chemotherapy in 1L NSCLC
- Outcomes document poor outcome in STK11<sup>mut</sup> patients vs. STK11wt patients



# A significant market potential in >30,000 1L STK11 NSCLC pts in US/EU5

## 2023 US Market Potential



= \$2.9B USD/yr

## 2023 Market Potential in EU5



= \$1.4B USD/yr.

**Total market  
potential  
in major 5 territories  
\$4.3B USD/year**

Key assumptions: Patient population based on GlobalData 2023; STK11m have a low ~4% rate of 1L actionable mutations; pricing estimates based on recent launch pricing in relevant territory; months of treatment based on real world data for wild type STK11 patients with 1L immunotherapy + doublet chemotherapy

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# A strong competitive position within 1L STK11m NSCLC

## Few Clinical Trials Specifically in STK11m NSCLC

Candidate/Company/Target	Current Phase	Patient Population
<b>BerGenBio/bemcentinib/AXL</b>	<b>Ph1b/2a</b>	<b>STK11m 1L NSCLC</b>
Mirati/adagrasib KRASG12C	Ph2	KRASG12Cm + STK11m 1L NSCLC
Amgen/sotorasib KRASG12C	Ph2	KRASG12Cm + STK11m 1L NSCLC
Novartis/JDQ443	Ph2	KRASG12Cm + STK11m 1L NSCLC
JacoBio/ KRASG12C	Ph1/2	KRASG12Cm + STK11m 2L NSCLC
Regeneron/anti-IL6R + anti-PD1	Ph1/2	EGFRm or STK11m NSCLC any line
Tango/coREST inhibitor + anti-PD1	Ph1/2	STK11m 2L NSCLC

Sources: clinicaltrials.gov, EU clinical trials register, company websites

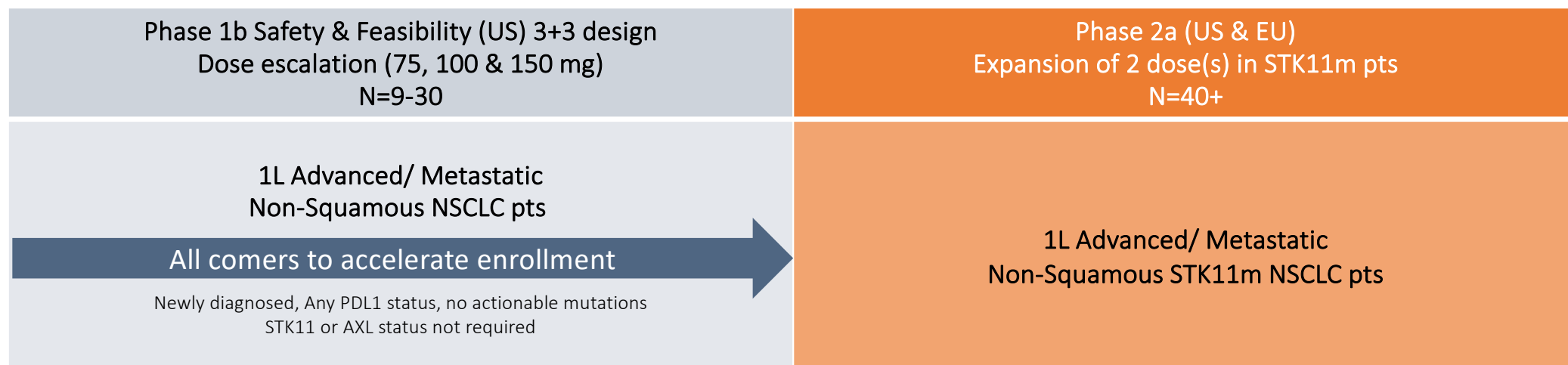
Note: does not include Investigator Sponsored Trials

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# On-going global 1L STK11m NSCLC Ph1b/2a

*Open label study of bemcentinib + SoC (pembrolizumab + doublet chemo)*



- Multiple sites identified and activated
- Ph 2a expansion in STK11m pts may start while last dose cohort is on-going in Ph1b
  - Primary endpoint – efficacy ; safety secondary
- Expected biomarker: STK11m (on major liquid biopsy panels); AXL will be measured but unlikely to be prospective biomarker given almost universal expression in STK11m pts



# Selective AXL inhibition as an important new treatment modality in 1L STK11<sup>mut</sup> NSCLC

## High unmet medical need

- ✓ Common non-actionable mutation (> 30,000 patients in US and EU5) resulting in a poor prognosis
- ✓ No available targeted therapies
- ✓ A significant market potential estimated > USD 4 billion

## High incidence of AXL expression which can be targeted by bemcentinib

- ✓ A highly immunosuppressed and "toxic" tumor microenvironment in which AXL is expressed in approx. 88% of patients
- ✓ Inhibition of AXL may delay resistance to chemotherapy and rescue anti-tumor immune response
- ✓ Strong proprietary position in STK11<sup>mut</sup> NSCLC including multiple layers of patent protection and a clear competitive lead



## Other potential value drivers

- **Bemcentinib** – Severe Respiratory Infections
  - Substantial evidence from two Ph2 trials indicating efficacy in hospitalized COVID-19
  - Preclinical data under development in other SRIs
- **Tilvestamab** – Ph2 ready AXL selective mAb – active out-licensing discussions on-going
- **ADCT-601** – BGB mAb outlicensed to ADCT as targeting agent for ADC therapy in cancer; candidate currently in Ph1b





# Financials

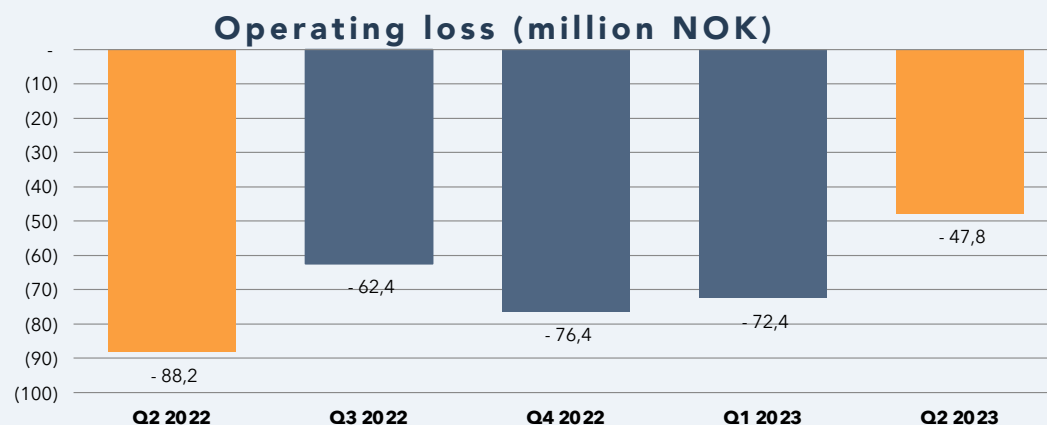
Update of current financials



# Key financials Q2 2023

(NOK million)	Q2 2023	Q2 2022	YTD 2023	YTD 2022	FY 2022
Operating revenues	0,0	0,0	0,0	0,0	0,4
Operating expenses	47,8	88,2	120,2	166,8	306,0
Operating profit (-loss)	-47,8	-88,2	-120,2	-166,8	-305,6
Profit (-loss) after tax	-48,8	-84,1	-120,8	-165,1	-302,1
Basic and diluted earnings (loss) per share (NOK)	-0,15	-0,95	-0,57	-1,86	-3,41
Net cash flow in the period	154,2	-70,3	79,0	-141,5	-282,1
Cash position end of period	226,0	292,1	226,0	292,1	150,8

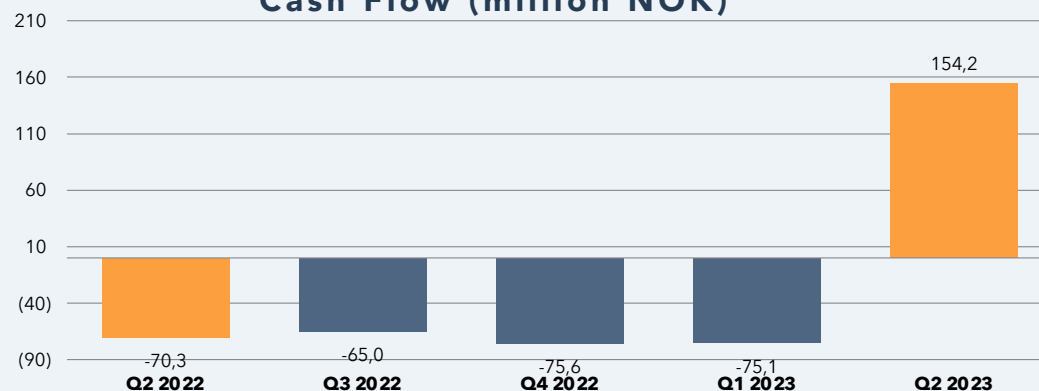
- Operating loss affected by cost savings including organizational change and closure of historical trials.
- Operating loss Q2 2023:  
47.8 mNOK / 4.5 mUSD
- Historical operating loss Q2 22 – Q2 23:  
69.5 mNOK / 6.9 mUSD





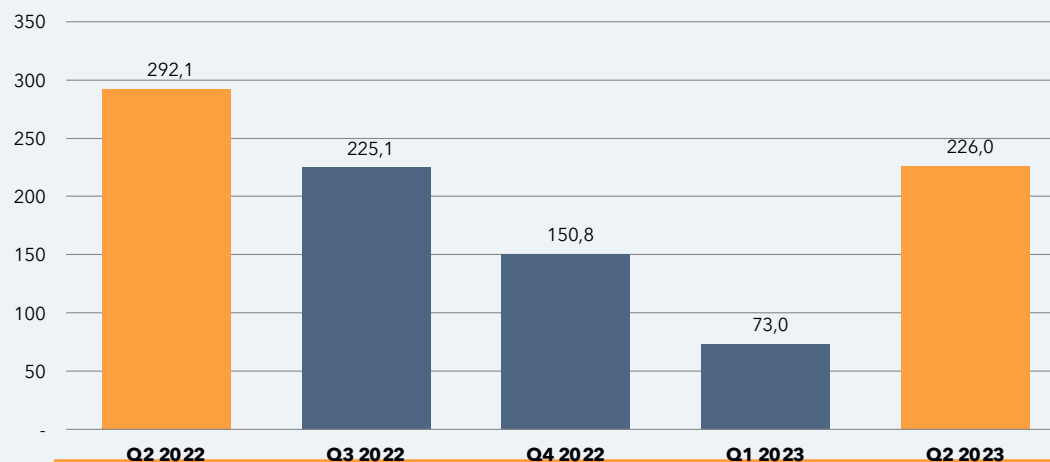
# Key financials Q2 2023

Cash Flow (million NOK)



- Cash position end of Q2 2023:
  - 226 mNOK/21 mUSD
- Average historical operating cash burn Q2 22 – Q2 23:
  - 67.7 mNOK / 6.7 mUSD

Cash position (million NOK)



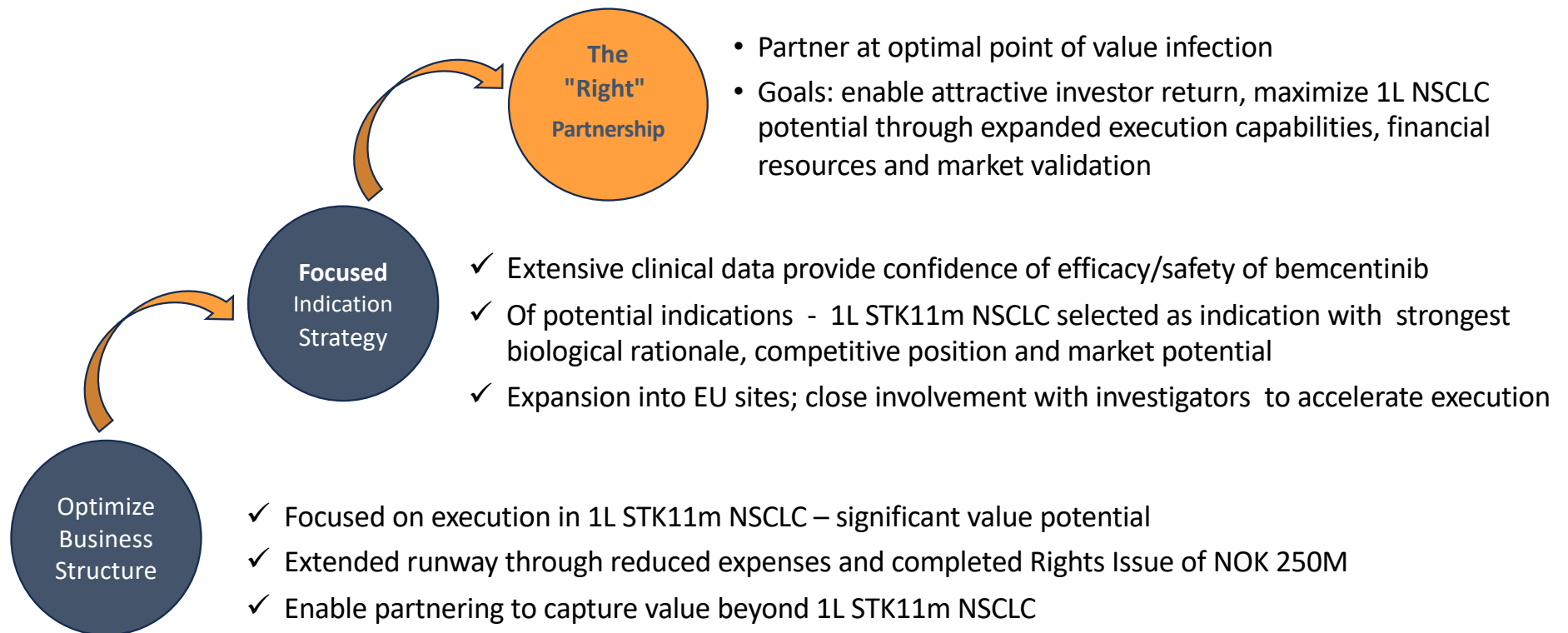


# News flow expected in 2023/2024

Core Clinical Strategy		H1 2023	H2 2023 / H1 2024
1L STK11m NSCLC	✓	FPFV and additional sites activated for Ph1b/2a	• Ph1b data and selection of doses for Ph2a
	✓	STK11 loss data presented at AACR	• Initiation of Ph2a
Severe Respiratory Infections (SRIs)	✓	Promising biomarker data from 2L study supports potential expansion of 1L NSCLC patient populations	• FDA advice to elucidate pivotal trial requirements in NSCLC
			• Additional MoA data from BGBC008
Other News Flow		H1 2023	H2 2023 / H1 2024
Other Clinical Data	✓	Positive AML/MDS data (BGBC003) reported	• Presentation of data at major oncology conferences
	✓	Data in mesothelioma presented at ASCO – primary end-point met	• Potential clinical trial manuscript publications in major journals
Tilvestamab	✓	Manuscript published by MD Anderson collaborator re: bem. + doce. in 2L NSCLC	
	✓	Update on out-licensing progress (discussions on-going)	• Complete out-licensing progress



# Implementing our vision for value creation





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