

**Carnegie Health Care Seminar**

**March 2023**



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**Transitioning a strong scientific foundation  
toward the market and significant value  
generation**

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# Forward Looking Statements

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# BerGenBio – 1<sup>st</sup>-in-class highly selective, potent AXL inhibitors for life-threatening diseases in clinical development

- BerGenBio is the leading company specifically targeting AXL biology to inhibit the host cell's ability to propagate serious disease by modulating resistance mechanisms, the innate and adaptive immune systems
- Our two clinical programs target different mechanisms of action of AXL and associated pathways

## Bemcentinib



- Oral, once a day
- Favorable benefit:risk profile
- Well tolerated alone & in combination with 600 pts treated to date
- Fast track designation in NSCLC
- Ph 2 for NSCLC and COVID-19

## Tilvestamab



- Fully humanized mAb – displaces GAS6
- Two Ph I studies completed; Ph 2 ready
- Potential application in fibrotic diseases, cancer
- Out-licensing discussions ongoing

## **AXL inhibition matters**

***2L+ NSCLC topline data validates the clinical relevance of AXL inhibition***

### **BGBC008 Ph2 trial of bemcentinib + pembrolizumab in 2L+ NSCLC**

- Extended median overall survival vs. relevant historical comparators
- Particularly strong benefit seen in patients with AXL TPS >5 vs AXL TPS<sub>≤</sub>5
- Survival benefit observed regardless of prior therapy and PD-L1 status

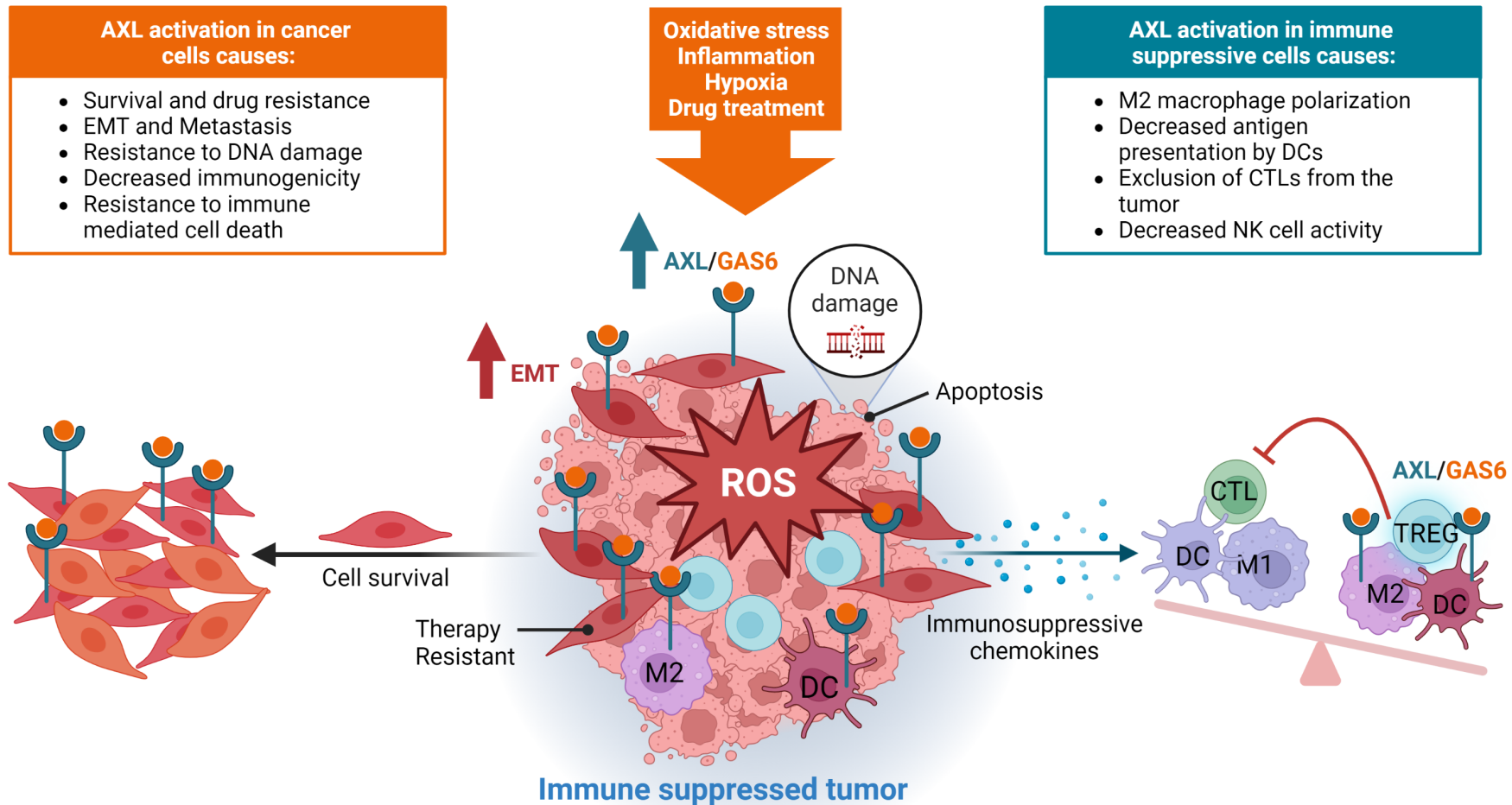
### **BGBIL005 Ph1 Investigator Led Study of bemcentinib + docetaxel in 2L+ NSCLC**

- Impressive ORR and median overall survival seen in combination with docetaxel (chemotherapy)

**Highly encouraging data confirming the relevance of AXL as a target**

**AXL inhibition in combination with chemo or immunotherapy provides clinically meaningful benefit and strongly support our strategy to pursue 1L STK11<sup>mut</sup> NSCLC**

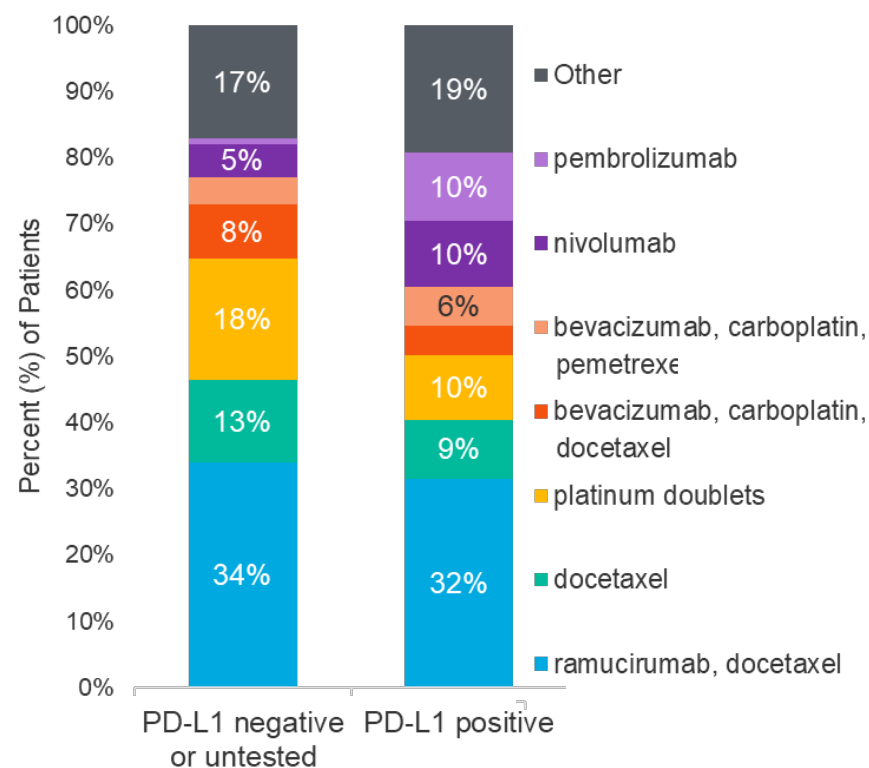
# Why does AXL inhibition matter in NSCLC?





## 2L NSCLC treatment - no single standard of care and poor prognosis

**Drug Regimen Use in US, 2022**  
**2L NSCLC Non-Actionable Mutations**



	Historical 2L Trial Comparators		
	Pallis, 2020	REVEL	KEYNOTE 189*
	<i>Docetaxel + Carboplatin</i>	Ramucirumab + <i>Docetaxel</i>	<i>Pembrolizumab</i>
<b>ORR</b>	<b>10.4%</b>	<b>23%</b>	<b>18%</b>
<b>PFS, mos</b>	<b>3.3</b>	<b>4.5</b>	<b>2.8</b>
<b>mOS, mos</b>	<b>10.3</b>	<b>10.5</b>	<b>6.9</b>

\* cross-over population

## BGBC008 (2L+ NSCLC) study design

### **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

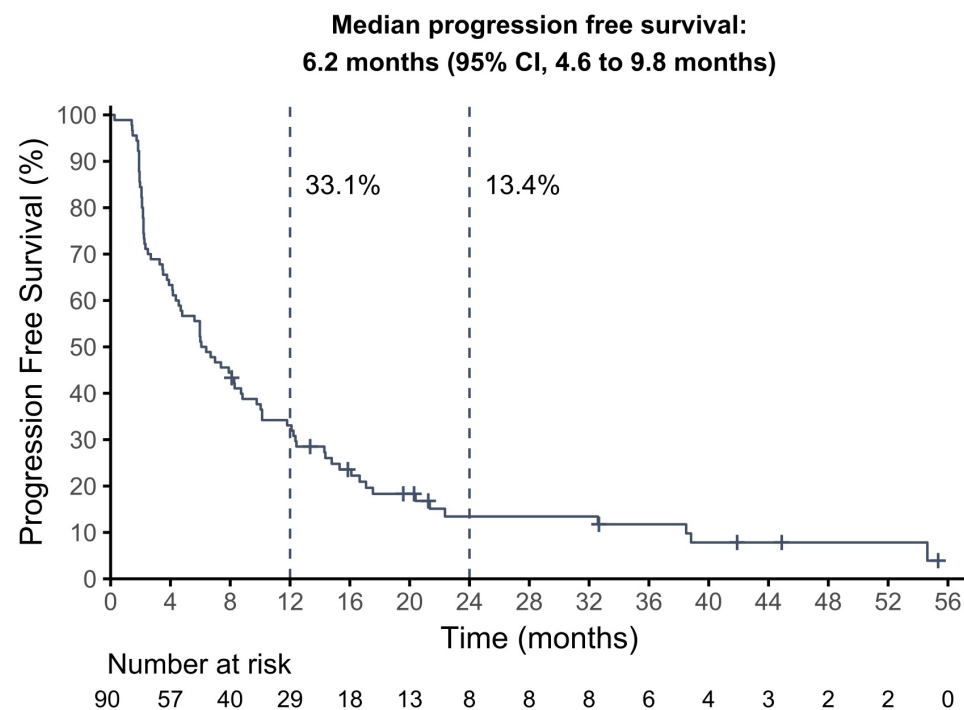
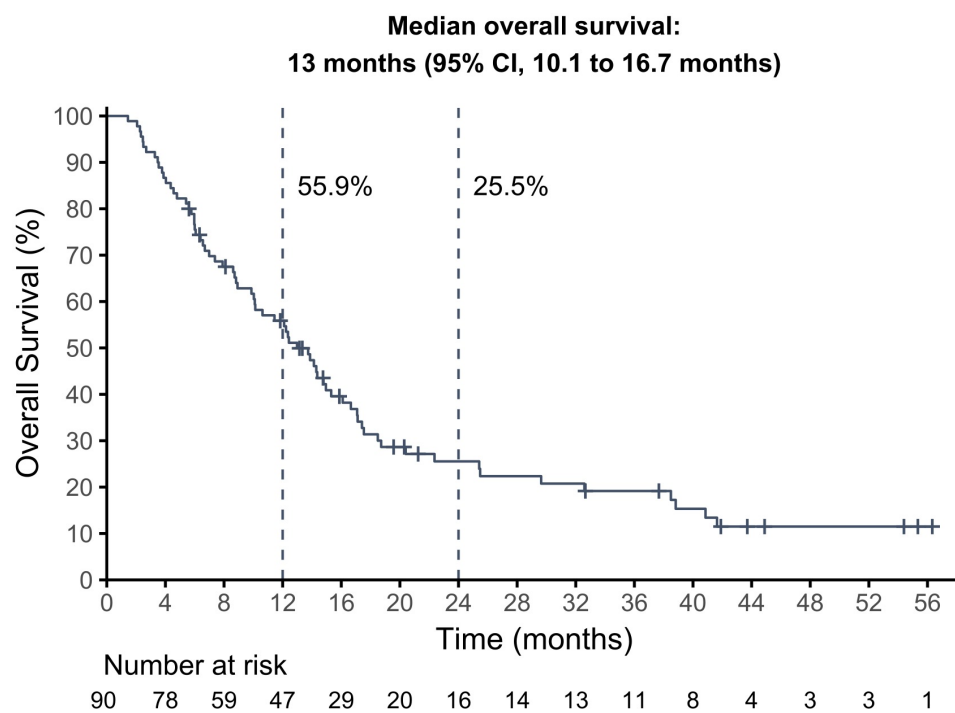
### **Cohort B (n=27)**

- **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)**

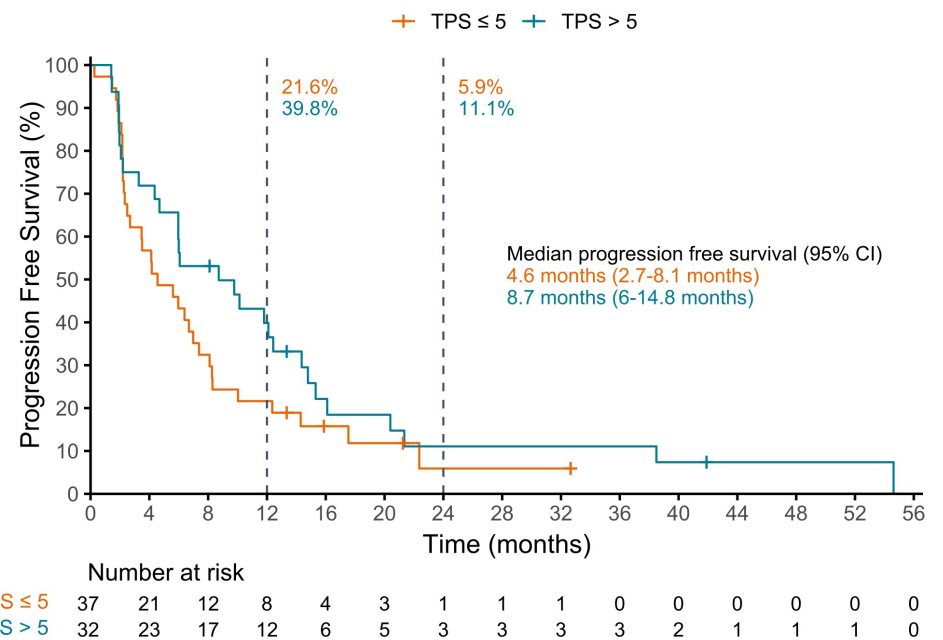
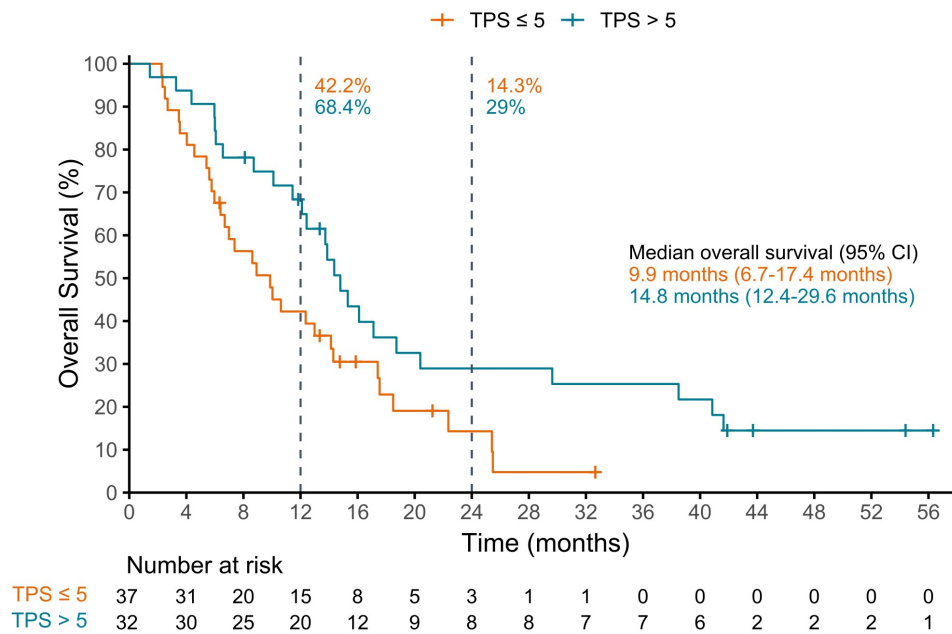
- **Prior 1L anti-PD-1/L1 + platinum-chemo treatment**
- Disease control on 1L for  $\geq 12$  wks. before progression
- 2<sup>nd</sup> or 3<sup>rd</sup> line metastatic Non-Squamous NSCLC

## BGBC008 – mOS and mPFS for all evaluable patients





## BGBC008: mOS and mPFS stratified by AXL status



## The combination of bemcentinib and pembrolizumab was well tolerated

	Bemcentinib + Pembrolizumab	
	Total (N = 99)	Grade ≥ 3
Number of Patients with	n (%)	n (%)
Any AE	98 (99.0)	-
Any Serious TEAE		49 (49.5)
AE Term (occurring in ≥ 20% of patients)		
Diarrhoea	41 (41.4)	1 (1.0)
Blood creatinine increased	30 (30.3)	0
Decreased appetite	30 (30.3)	0
Aspartate aminotransferase increased	29 (29.3)	5 (5.1)
Alanine aminotransferase increased	29 (29.3)	8 (8.1)
Asthenia	29 (29.3)	9 (9.1)
Nausea	24 (24.2)	0
Fatigue	23 (23.2)	1 (1.0)
Cough	22 (22.2)	0
Dyspnoea	21 (21.2)	5 (5.1)
Anaemia	21 (21.2)	4 (4.0)

### Conclusions:

- No new significant safety signals
- Majority of AEs grades 1-2
- Very rare treatment discontinuations due to TEAEs
- Bemcentinib studied w/ 400mg loading followed by 200mg/qd
- Future studies planned w/out loading & ~100mg/qd

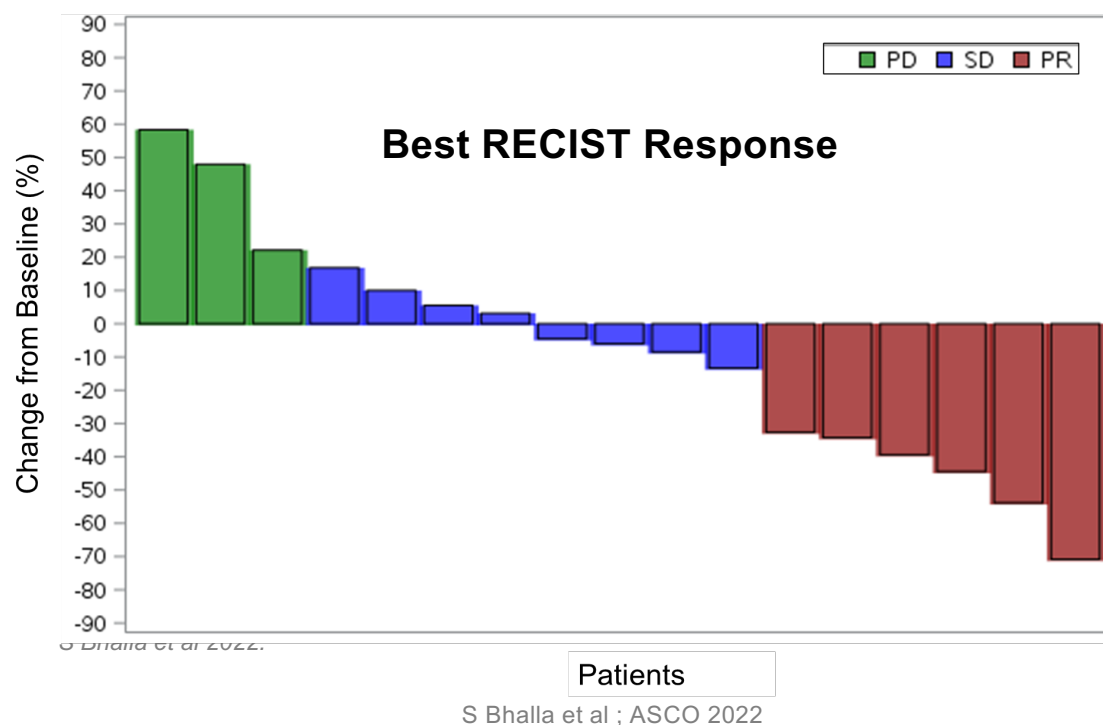
## Bemcentinib + pembrolizumab compares favorably to existing therapies in 2L NSCLC

	BGBC008		Historical 2L Trial Comparators		
	All Comers	AXL TPS>5	Pallis, 2020	REVEL	KEYNOTE 189*
	<i>Bemcentinib + Pembrolizumab</i>	<i>Bemcentinib + Pembrolizumab</i>	<i>Docetaxel + Carboplatin</i>	<i>Ramucirumab + Docetaxel</i>	<i>Pembrolizumab</i>
<b>ORR</b>	<b>11.1%</b>	<b>21.9%</b>	<b>10.4%</b>	<b>23%</b>	<b>18%</b>
<b>mPFS, mos</b>	<b>6.2</b>	<b>8.7</b>	<b>3.3</b>	<b>4.5</b>	<b>2.8</b>
<b>mOS, mos</b>	<b>13.0</b>	<b>14.8</b>	<b>10.3</b>	<b>10.5</b>	<b>6.9</b>

\* Cross-over population

## Update on 2L+NSCLC BGBIL005

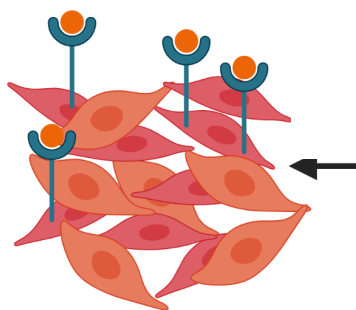
***Bemcentinib + docetaxel favorably compares vs. docetaxel even without AXL stratification***



	BCBIL005	Historical Trials*
	Bemcentinib + Docetaxel	Docetaxel**
ORR	35%	7-9%
PFS, mos	3.1	2.1-4.0
mOS, mos	12.3	7.7-10.1

**Most common TRAEs: neutropenia, diarrhea, fatigue and nausea; non-hematological grade  $\geq 3$  toxicities were rare**

## BGBC008 and BGBIL005 validate the importance of AXL inhibition in combination with chemo- or immunotherapy in NSCLC

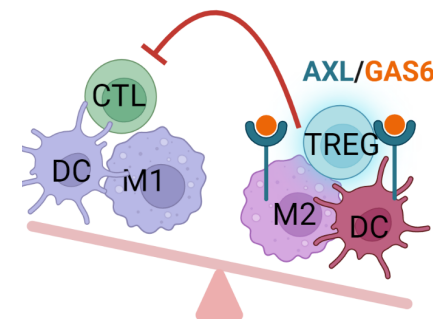


### BGBIL005 2L+ NSCLC

**Reversal of  
cancer cell  
survival  
and escape**

**Completed Ph2 study  
Bemcentinib + Docetaxel  
2L+ NSCLC**

Previously reported 35% PR and 47%  
SD rates  
**New data presentation: mPFS, mOS**



### BGBC008 2L NSCLC

**Improved  
innate  
immune  
response**

**Completed Ph2 study  
Bemcentinib + Pembrolizumab  
2L+ NSCLC**

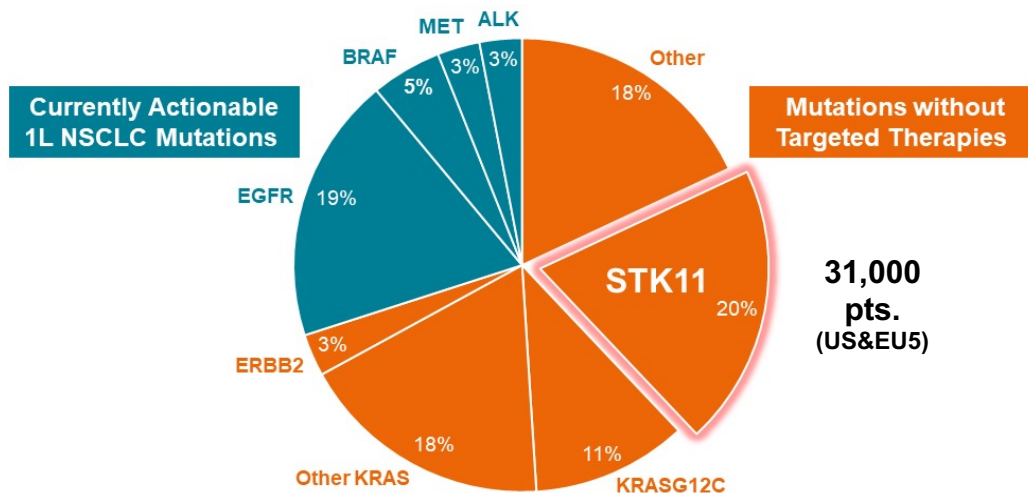
**Encouraging new topline data**

# 1L STK11<sup>mut</sup> NSCLC focus and update on progress



# STK11<sup>mut</sup> NSCLC a large, underserved patient population

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



**STK11<sup>mut</sup> result in poor prognosis  
with anti-PD-1/L1 + chemo SOC**

- Lower response rate
- Shorter overall survival and PFS
- No targeted therapy currently available

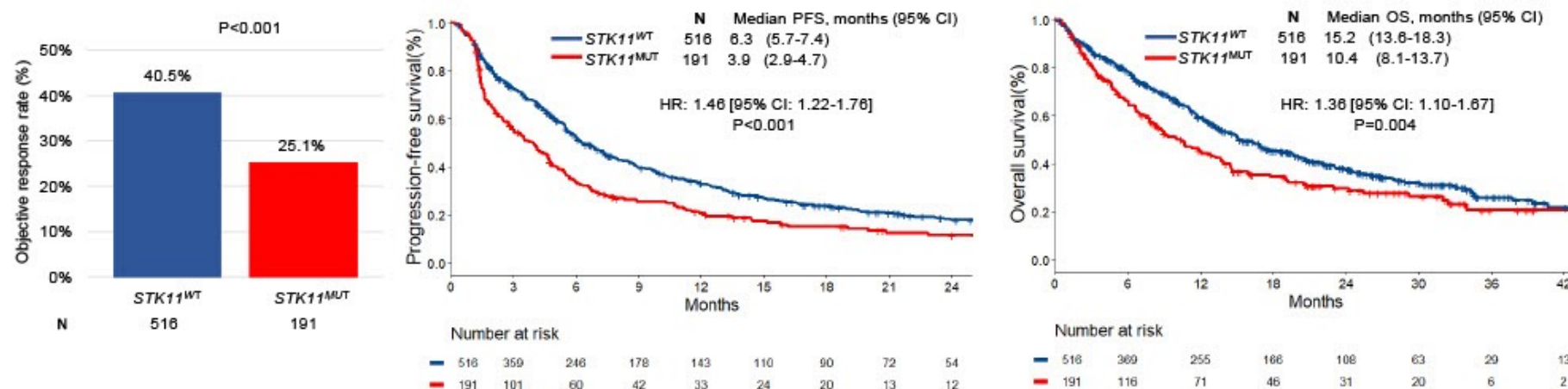
\* Sources: Oncogenic driver mutations in non-small cell lung cancer: Past, present and future, *World J Clin Oncol.* 2021 Apr 24; 12(4): 217–237

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

# Recent real-world evidence substantiates poor outcome in **STK11<sup>mut</sup>** pts with 1<sup>st</sup> line chemoimmunotherapy treatment

- 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
- **STK11<sup>mut</sup> vs. STK11wt pts: ORR of 25.1% vs. 40.5% ; mPFS of 3.9 mos vs. 6.3 mos; mOS of 10.4 vs. 15.2**



Alessi et al, Clinicopathologic & Genomic Factors Impacting Efficacy of First Line Chemoimmunotherapy in Advanced NSCLC, Journal of Thoracic Oncology, 2/9/23

# The 1L STK11<sup>mut</sup> NSCLC market potential can be compared with Tagrisso® sales experience



**Potential Tagrisso 1L Population Similar to STK11<sup>mut</sup> Yielding ~\$3B+**

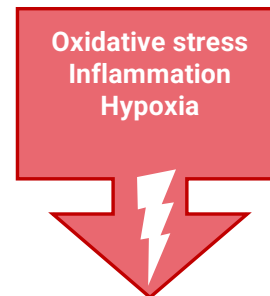
	EGFR 790 <sup>mut</sup> Pts.	STK11 <sup>mut</sup> Pts.
1L NSCLC Incidence of Mutation	17%*	20%
~2023 Eligible Patient Population**	26,500	31,000

- Tagrisso sales reached over \$1B globally based on 2L approval (2L population is ~50% of the size of 1L)
- Sales rapidly increased by an addtl. ~\$3B with 1L approval

# The unique phenotype of STK11<sup>mut</sup> cancers results in almost universal AXL expression/activation

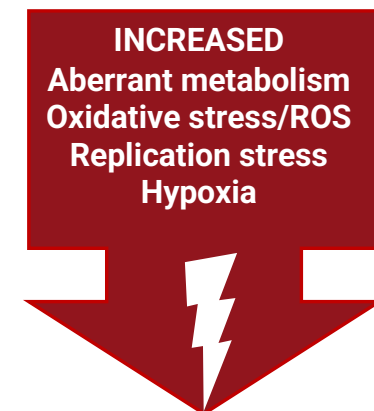
- AXL is activated in response to inflammation, hypoxia, cellular stress or drug treatment
- Cancer cells use the AXL pathway to sense stress triggering molecular mechanisms to ensure the survival or escape from the toxic environment (ROS, replication stress, hypoxia)
- STK11<sup>mut</sup> have phenotypic characteristics (high cellular stress and immune evasion) resulting in increased levels of AXL expression and activation

## Non STK11<sup>mut</sup> Tumor



~50% of pts.

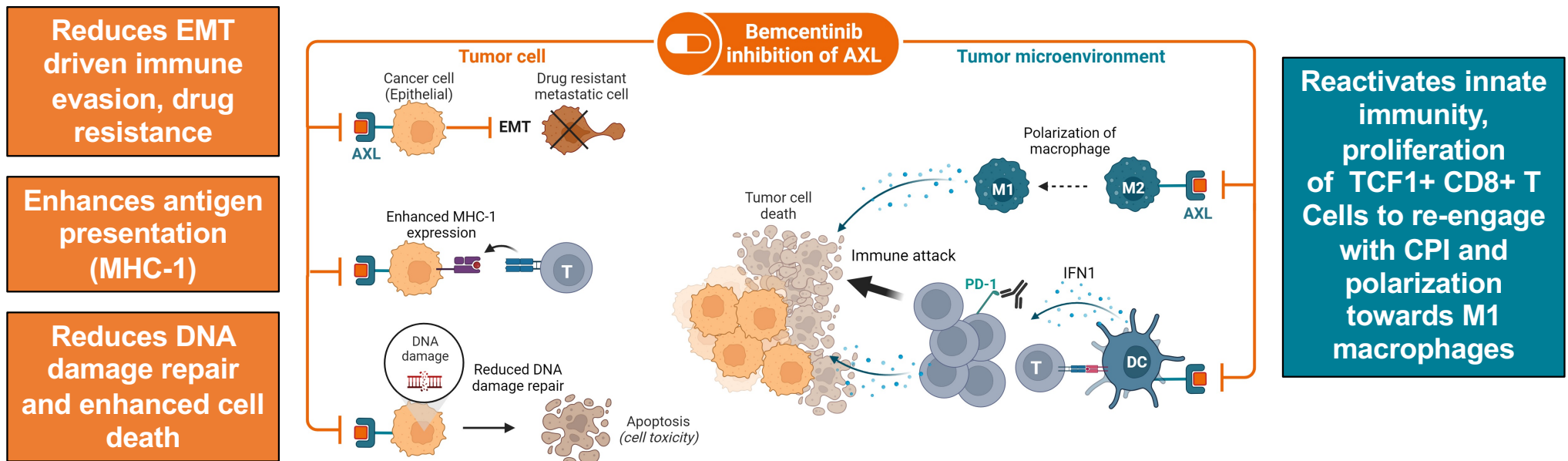
## STK11<sup>mut</sup> Tumor



~80% of pts.

AXL expression and activation

# AXL inhibition targets key survival and resistance mechanisms within the tumor microenvironment of STK11<sup>mut</sup> NSCLC



# Global, open-label 1L NSCLC Phase 1b/2a initiated

*Bemcentinib + SoC (pembrolizumab + doublet chemo)*

Phase 1b Safety & Feasibility (US) Dose escalation (75, 100 & 150 mg) n=9-30	Phase 2a (US & EU) Expansion of dose(s) identified in Ph 1b N=40+
<p><b>1L Advanced/ Metastatic Non-Squamous NSCLC pts</b></p> <p>Newly diagnosed, Any PDL1 status, no actionable mutations STK11 or AXL status not required</p> <p><b>Traditional 3+ 3 design</b></p>	<p><b>1L Advanced/ Metastatic Non-Squamous STK11m NSCLC pts</b></p>
<p><b>Endpoints</b></p> <p><b>Primary:</b> Safety/ Tolerability (DLT) <b>Secondary:</b> ORR, DCR, DOR, OS</p>	<p><b>Endpoints</b></p> <p><b>Primary:</b> ORR <b>Secondary:</b> Safety, DOR, DCR, PFS, Time to Progression, OS, PK exposure</p>

- **Multiple sites – 1<sup>st</sup> patient dosed**
- **Ph 2a expansion in STK11m patients may start while last dose cohort is on-going in Ph 1b**
  - **Primary endpoint – efficacy ; safety secondary**
- **Data from Ph 1b expected to be available 2H23**



# 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 3 billion

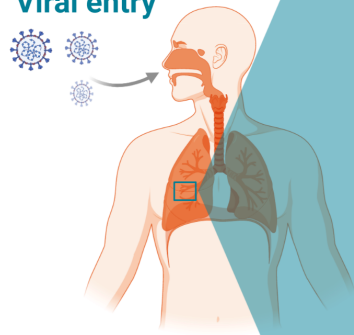
## High incidence of AXL expression which can be targeted by bemcentinib

- ✓ A highly immunosuppressed and "toxic" tumor microenvironment in which AXL is expressed in approx. 80% 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

# Severe Respiratory Infections (SRI's)

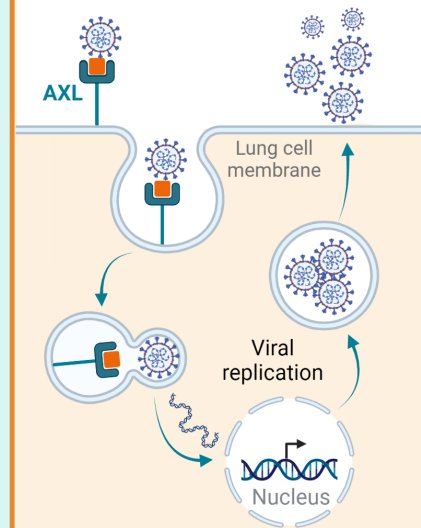
# Bemcentinib's multiple mechanisms of action make it an attractive treatment modality across important SRI's

## Viral entry



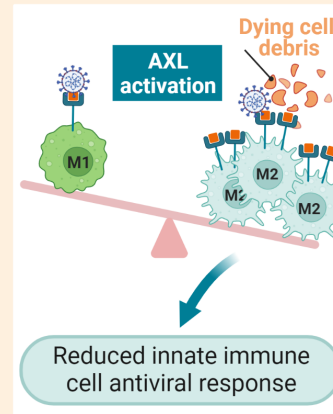
1

AXL dependent viral entry promotes viral replication



2

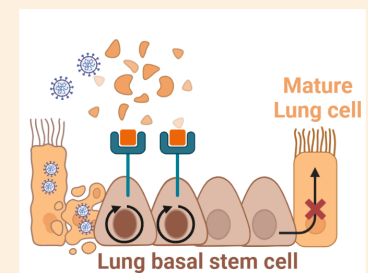
AXL modulates anti-viral inflammatory responses



- Dying cell debris and virus are sensed by AXL, causing it to be activated

3

AXL signaling contributes to ongoing lung injury and prevents healing



- Persistent AXL signaling on basal stem cells leads to overgrowth of immature lung cells

## Our strategy to exploit potential of bemcentinib in SRI's

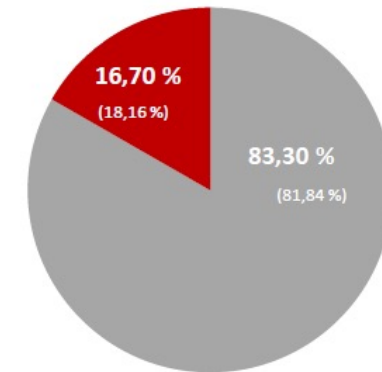
- Maximize understanding of bemcentinib activity and benefits in SRIs to inform future development path
  - Meta-analysis of previous COVID-19 studies
  - Studies in relevant SRI preclinical models in collaboration with leading academic institutions
- Utilize where possible, platform studies majority funded by governments/ institutions to rapidly assess clinical utility of bemcentinib at minimal cost
  - EUSolidAct platform Ph2b study initiated in up to 500 hospitalized COVID-19 patients
  - Ongoing activities to identify additional platform(s) to evaluate bemcentinib in other "re-emerging" SRIs, such as RSV and influenza
- Initiate "pathogen-agnostic" clinical trial for treatment of Acute Respiratory Distress Syndrome (ARDS)

# Financials

# Key financial figures Q4 2022

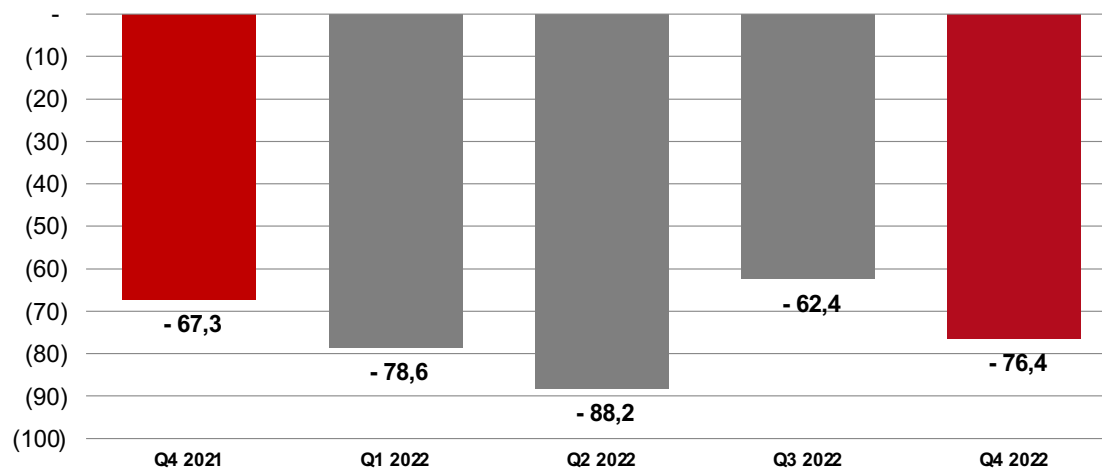
(NOK million)	Q4 2022	Q4 2021	FY 2022	FY 2021
Operating revenues	0.4	0.8	0.4	0.8
Operating expenses	76.8	68.1	306.0	315.2
Operating profit (-loss)	-76.4	-67.3	-305.6	-314.5
Profit (-loss) after tax	-77.2	-68.8	-302.1	-309.4
Basic and diluted earnings (loss) per share (NOK)	-0.87	-0.78	-3.41	-3.52
Net cash flow in the period	-75.6	-76.0	-282.1	-284.2
Cash position end of period	150.8	436.6	150.8	436.6

Operating expenses Q4 2022  
(YTD 2022)



■ R&D ■ Administration

Operating loss (million NOK)

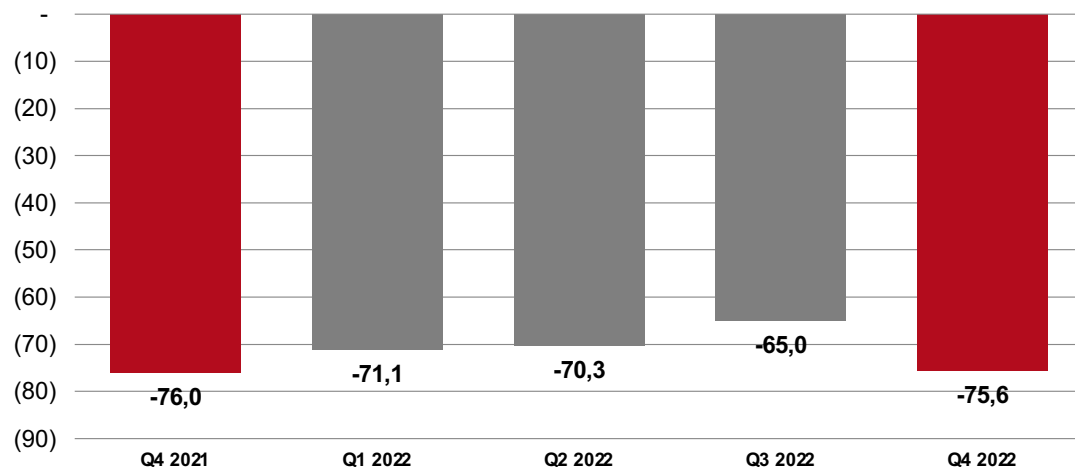


- Operating costs increased from Q3 22 to Q4 22, mainly caused by increased drug manufacturing activities in preparation for execution of new clinical trials.
- Well managed overhead costs. Above 80% of operating expenses in Q4 and YTD is attributable to Research & Development activities.



# Cash flow and cash position Q4 2022

Cash Flow (million NOK)



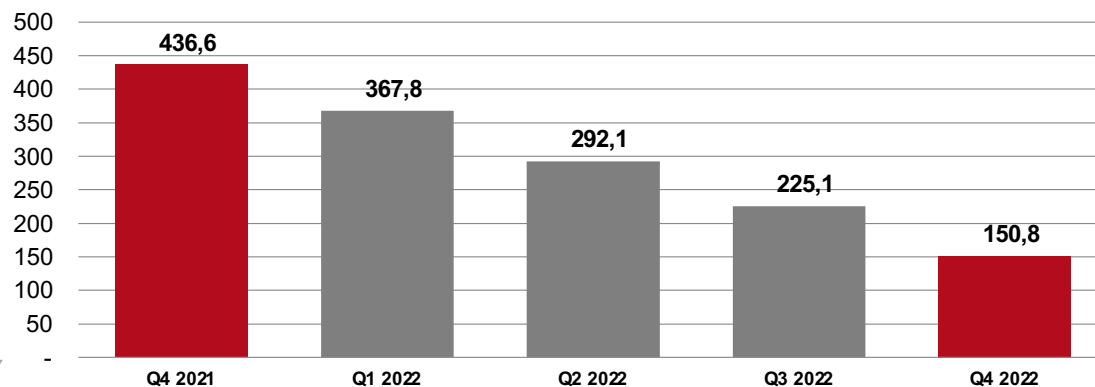
Net cash burn Q4 2022

**75.6 / 7.4**  
NOK million / USD million

Quarterly average net cash burn (Q4 2021 – Q4 2022)

**71.6 / 7.6**  
NOK million / USD million

Cash position (million NOK)



Cash position Q4 2022

**150.8 / 15.3**  
NOK million / USD million

In addition, a up to NOK 100 million loan  
Shareholder facility is secured from  
Meteva AS available from Q2 2023.

# News flow 2023



## News flow expected in 2023

Core Clinical Strategy		H1 2023	H2 2023
1L STK11m NSCLC	✓ FPFV in Ph1b		• Ph1b data
	• STK11m posters at major conferences		• Ph 2a initiation
	• Additional data analysis of BGBC008		
	• Additional preclinical data		
Severe Respiratory Infections (SRIs)			• EU-SolidAct data in hospitalized COVID-19
			• Preclinical/meta-analysis data in SRIs
Other News Flow		H1 2023	H2 2023
Bemcentinib clinical/biomarker data	• Ph2 AML (BGBC003) topline data		• Presentation of Trial data at major conferences
	• Presentation of trial data at major conferences		
Tilvestamab		• Update on out-licensing progress	