



# BerGenBio

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



# Forward Looking Statements

Certain statements contained in this presentation constitute forward-looking statements. Forward-looking statements are statements that are not historical facts and they can be identified by the use of forward-looking terminology, including the words "anticipate", "believe", "intend", "estimate", "expect", "will", "may", "should" and words of similar meaning. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements.

Accordingly, no assurance is given that such forward-looking statements will prove to have been correct. They speak only as at the date of the presentation and no representation or warranty, expressed or implied, is made by BerGenBio ASA or its affiliates ("BerGenBio"), or by any of their respective members, directors, officers or employees that any of these forward-looking statements

or forecasts will come to pass or that any forecast result will be achieved, and you are cautioned not to place any undue influence on any forward-looking statement.

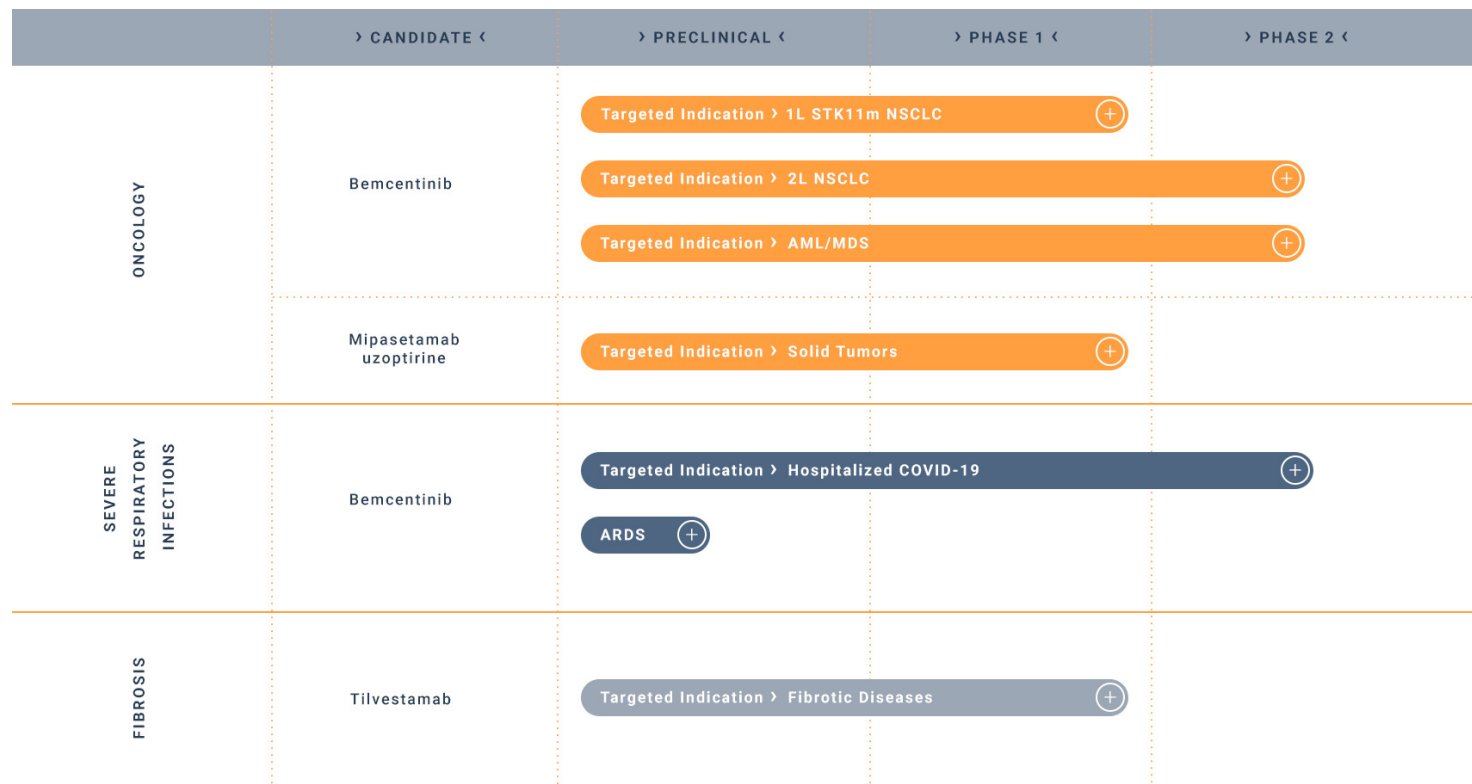
BerGenBio is making no representation or warranty, expressed or implied, as to the accuracy, reliability or completeness of this presentation, and neither BerGenBio nor any of its directors, officers or employees will have any liability to you or any other person resulting from the use of this presentation.

Copyright of all published material, including photographs, drawings and images in this presentation remain with BerGenBio and relevant third parties, as appropriate. Consequently, no reproduction in any form of the presentation, or parts thereof, is permitted without the prior written permission, and only with appropriate acknowledgements.

# A global leader in targeting AXL biology

- A leader in targeting AXL biology, which is known to play a key role in the progression of cancer, respiratory diseases and fibrosis, with two proprietary clinical stage programs: bemcentinib (lead program) and tilvestamab
- Top line data from multiple phase 2 trials of bemcentinib validate clinical benefits of selective AXL inhibition in NSCLC, AML, MDS and Severe Respiratory Infections (COVID-19)
- Strategic focus is development of bemcentinib in 1L NSCLC and Severe Respiratory Infections - each representing significant opportunities
- Potential incremental value from partnering of tilvestamab and out-licensed antibody utilized in ADCT's mipasetamab uzoptirine
- Newsflow to potentially unlock significant value and provide guidance for pivotal trials
- Seasoned leadership team, board, lean and focused business structure

# A diverse pipeline to exploit the multiple applications of AXL inhibition





**BerGenBio**

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

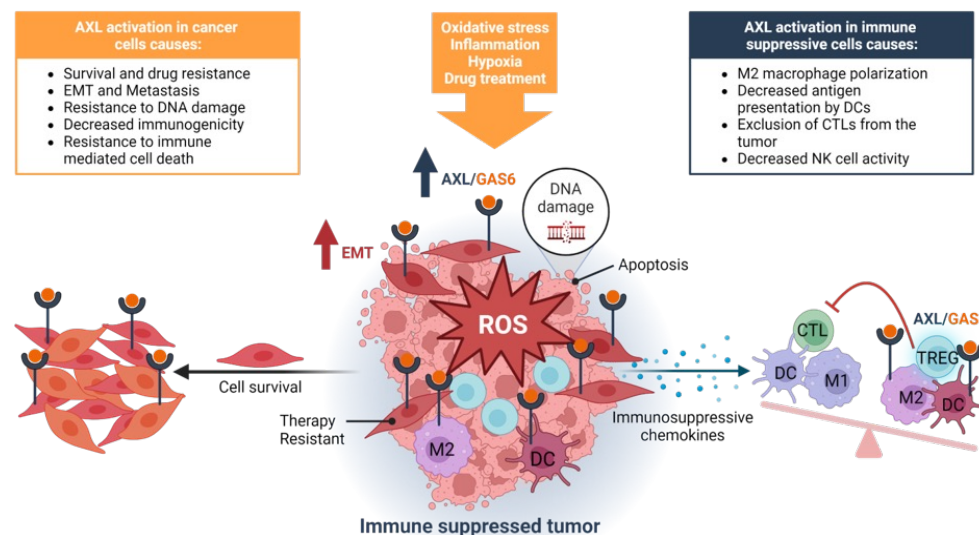
# NSCLC: a significant market with high unmet medical needs – AXL activation associated with poor prognosis



Lung cancer is one of the largest cancer killers and NSCLC represents approx. 85% of all lung cancers

NSCLC commonly spreads to other organs including bone and brain - significantly reducing survival

Significant unmet medical need for mutations without targeted therapies



# Recent NSCLC data validate the benefit of selective AXL inhibition with bemcentinib

- Promising clinical benefit of AXL inhibition in two 2L NSCLC trials
  - Topline data from more than 100 patients provide strong validation of AXL inhibition to substantially improve overall survival, particularly in patients with AXL IHC >5
- Data strongly support clinical rationale for 1L STK11m NSCLC indication selection
- Bemcentinib is the only selective AXL inhibitor in development in 1L STK11m NSCLC
  - 1L STK11m patients in combination with immune checkpoint inhibition + doublet chemotherapy where the Company has initiated a Ph1b/2a study

# 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

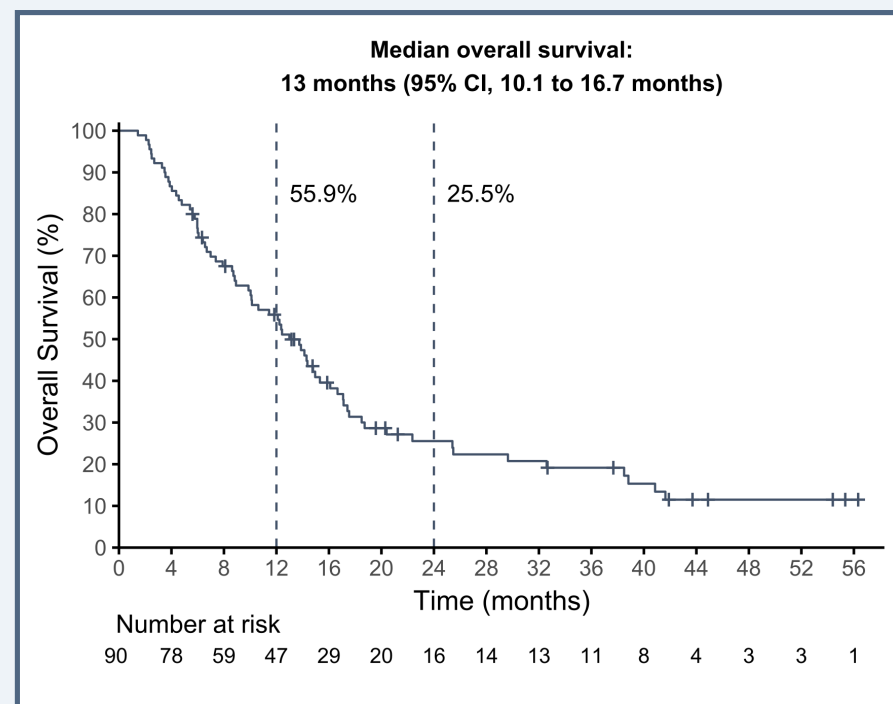
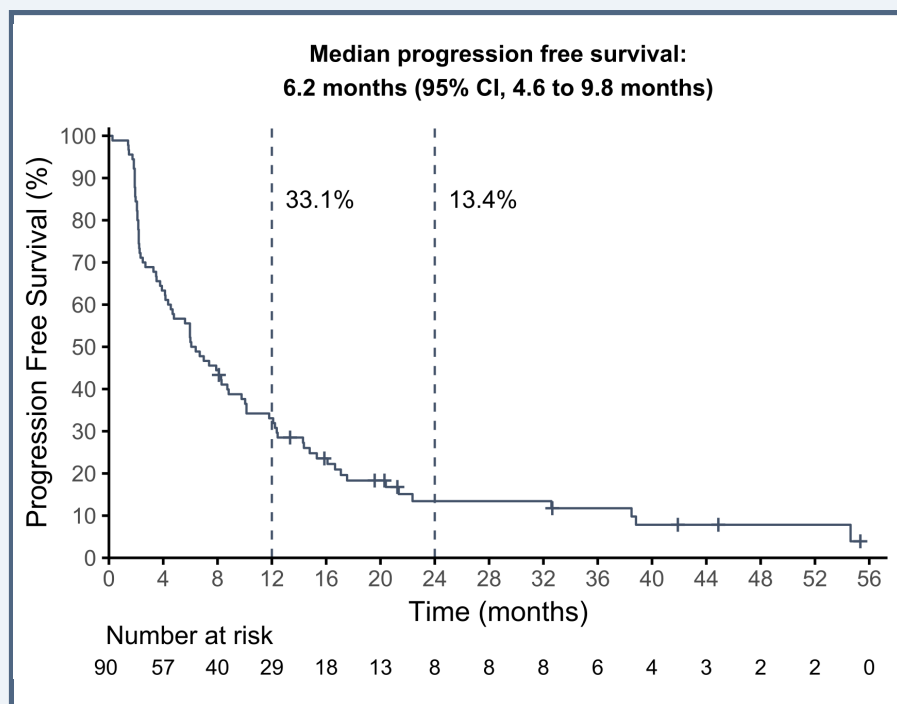
### Cohort C (n=19)

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



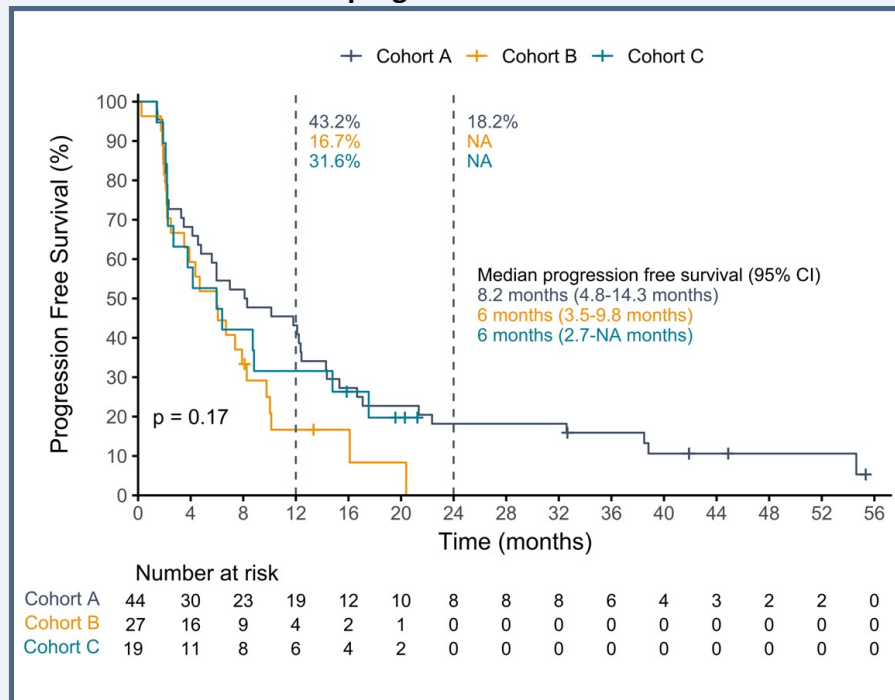
# BGBC008: encouraging efficacy observed in all evaluable patients – 25% alive at 2 yrs



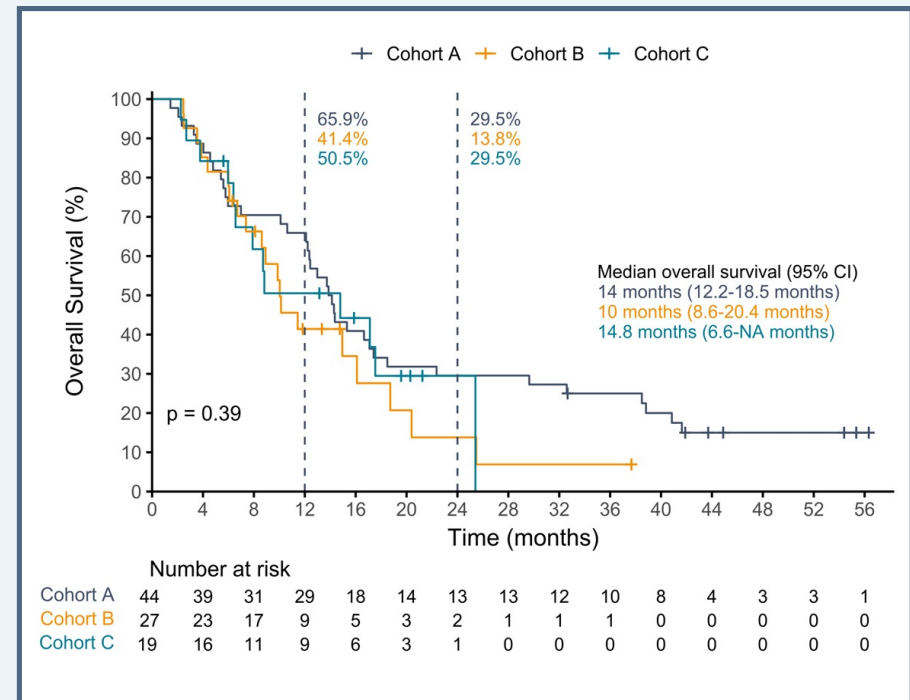
# BGBC008: analysis by cohort

## Long mOS regardless of prior therapy

Median progression free survival



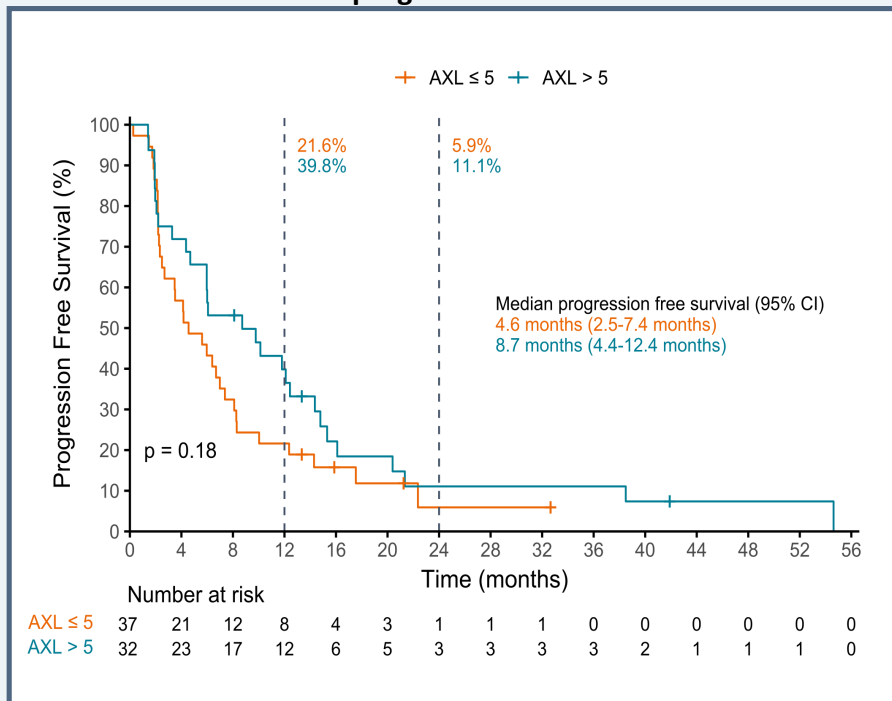
Median overall survival



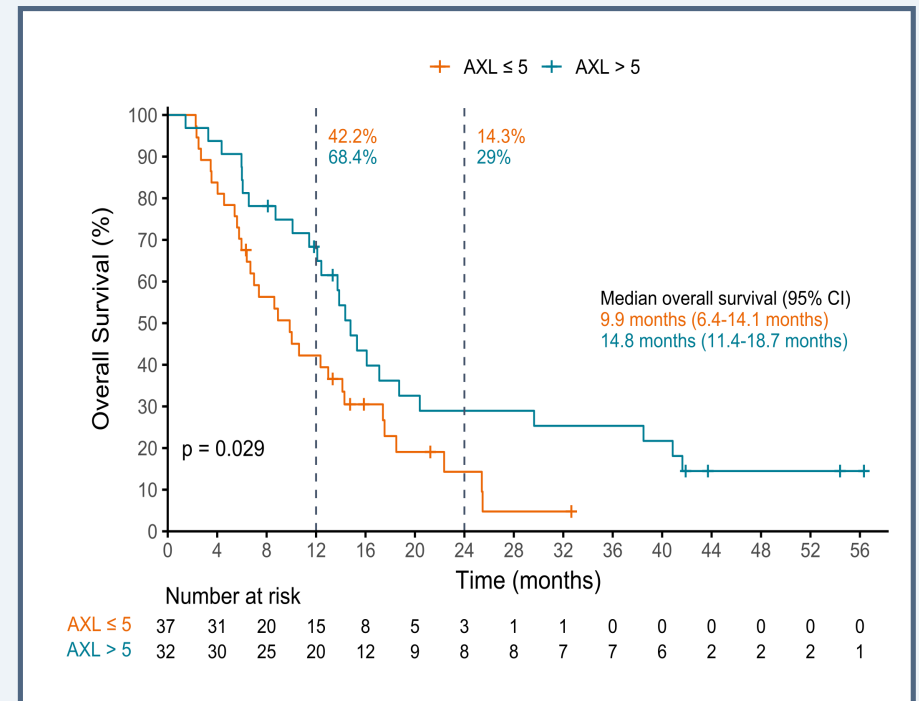
# BGBC008: stratification for AXL

## Statistically significant difference in mOS

Median progression free survival



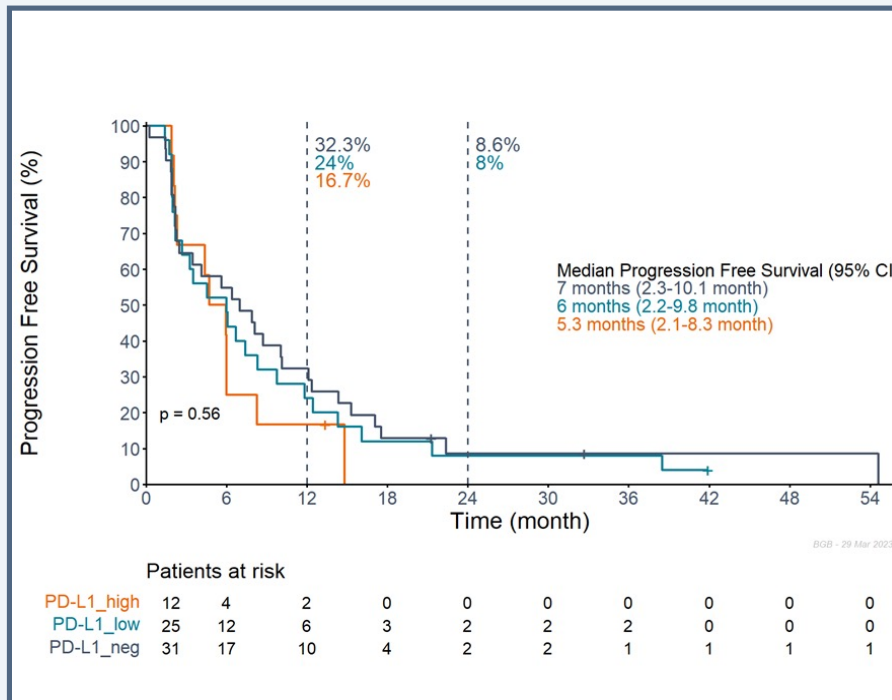
Median overall survival



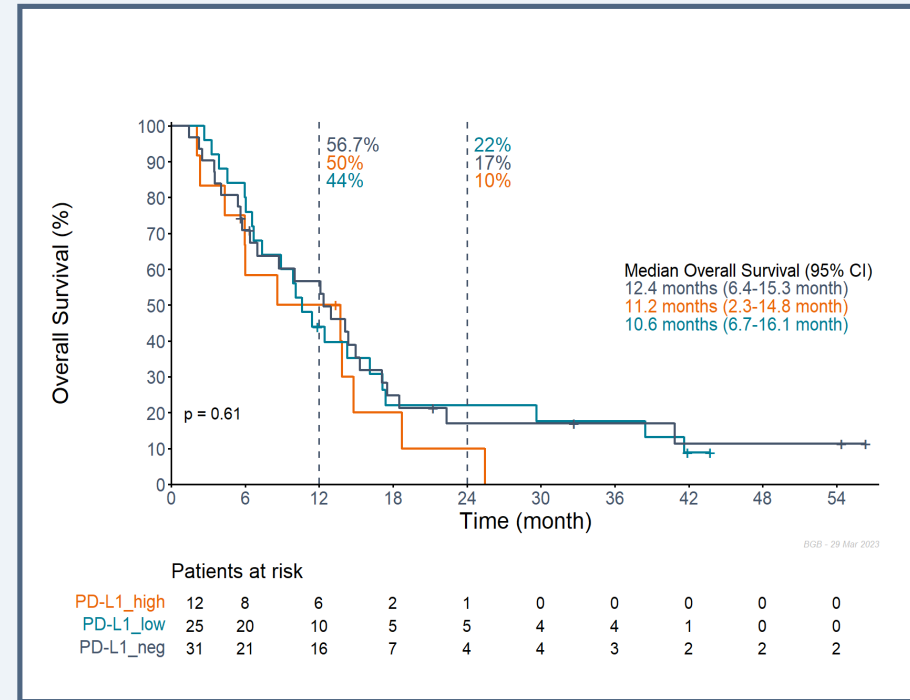
# BGBC008: analysis by PD-L1 status

## Clinical benefit regardless of PD-L1 status

Median progression free survival



Median overall survival

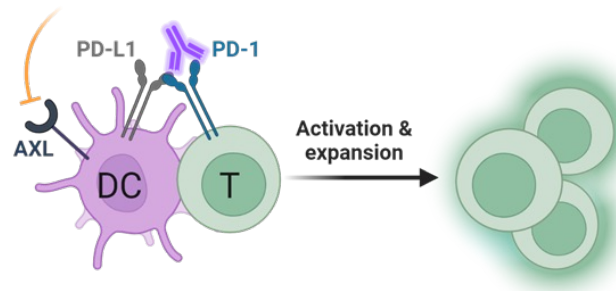


# Why bemcentinib potentiates check-point inhibitors in PD-L1 neg/low NSCLC

## AXL is heightened *regardless of tumor PD-L1 status*

- 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

**BerGenBio**

# Other NSCLC mutations with poor prognosis may benefit from bemcentinib (exploratory data)

Exploratory mutational analysis BGBC008

	% Mutated pts	PFS		mOS	
		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, and short overall survival\*\*
- Bemcentinib targets key mechanisms associated to these mutation within the tumor and TME
- Extensive biomarker analysis will be conducted in the 1L NSCLC STK11m study

\*Statistically significant at  $p=0.009$

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

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

	BGBC008		Historical 2L Trial Comparators		
	All Comers <i>Bemcentinib + Pembrolizumab</i>	AXL>5 <i>Bemcentinib + Pembrolizumab</i>	Pallis, 2020 <i>Docetaxel + Carboplatin</i>	REVEL <i>Ramucirumab + Docetaxel</i>	KEYNOTE 189* <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	14.8	10.3	10.5	6.9

\* Cross-over population following 1L CIT

# Bemcentinib+pembrolizumab safety comparable to pembrolizumab alone in 2L NSCLC

	Bemcentinib 200mg fixed + pembrolizumab BGBC008	Pembrolizumab Monotherapy KEYNOTE-010
Population	2L NSCLC	2L NSCLC
<b>Top TRAEs , all grades</b>		
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 pembrolizumab 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 & ~100mg/qd

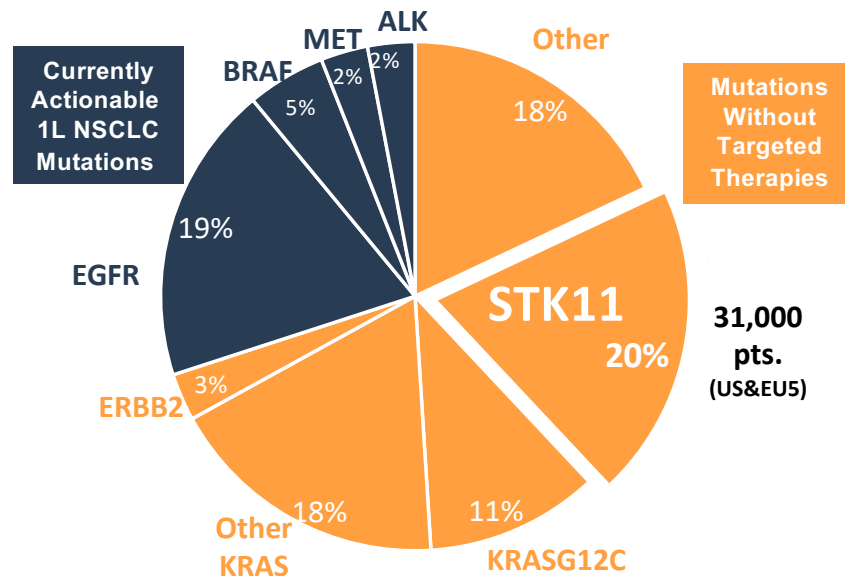
**BerGenBio**

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



# 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

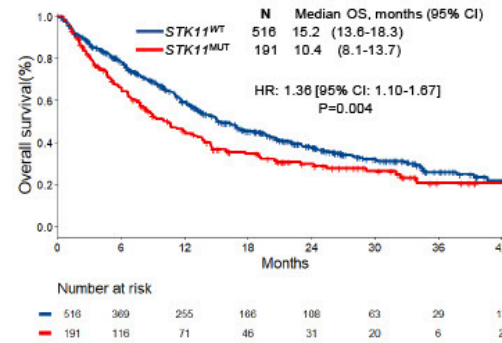
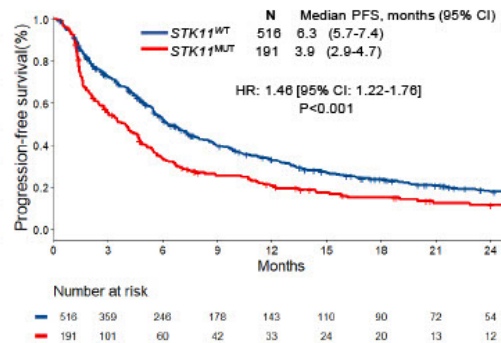
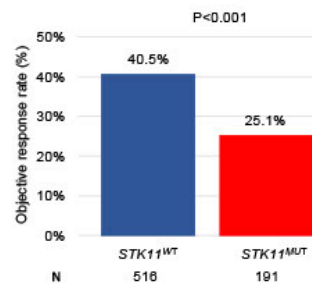
- Lower response rate, PFS and overall survival with SOC
- No targeted therapy currently available
- 1L STK11m pts have almost universal AXL expression
- Although unactionable today – STK11m are identified on all major NSCLC liquid tumor biopsy panels

\* 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

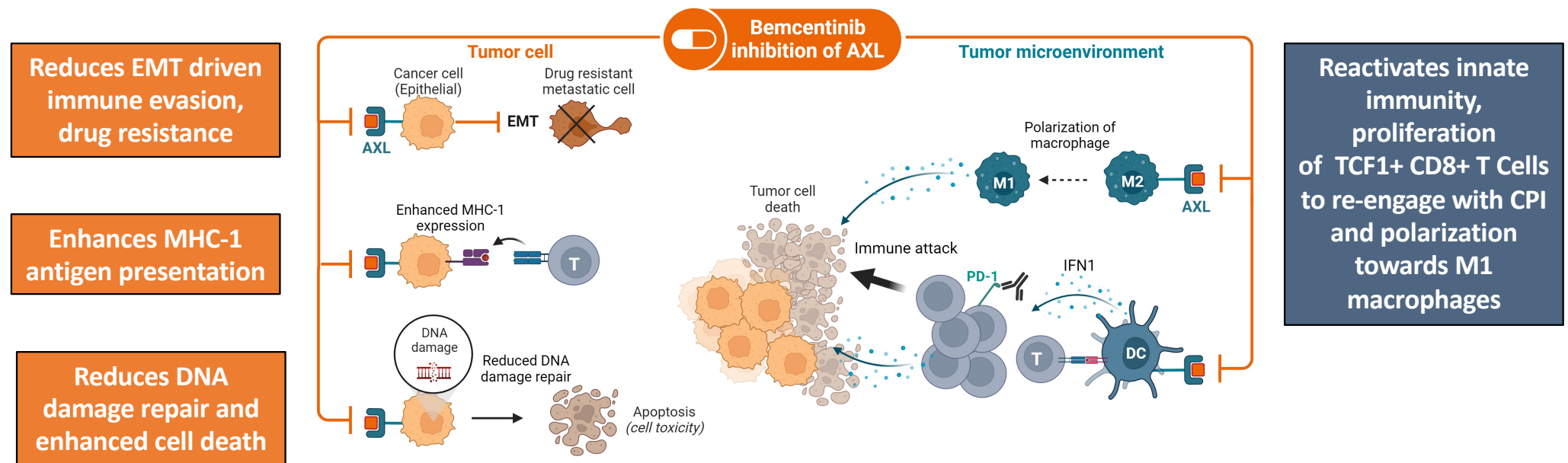
# Recent real-world evidence substantiates poor outcome in $STK11^{mut}$ pts with 1<sup>st</sup> line chemoimmunotherapy

- 707 patients at Dana Farber & Memorial Sloan Kettering treated with 1L immune checkpoint inhibition + chemotherapy in 1L NSCLC
- Outcomes document poor outcome in  $STK11^{mut}$  patients vs.  $STK11^{wt}$  patients



	STK11m	STK11wt
ORR	25.1%	40.5%
PFS, mos	3.9	6.3
OS, mos	10.4	15.2

# AXL inhibition targets key survival, resistance mechanisms in the TME of $STK11^{mut}$ NSCLC pts



# 1L STK11m NSCLC: unique "white space" and large market potential

Few Clinical Trials in STK11m NSCLC

Candidate/Company/Target	Current Phase	Patient Population
BerGenBio/bemcentinib/AXL	Ph1b/2a	STK11m 1L NSCLC
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

STK11<sup>mut</sup> Potential Similar to Tagrisso®,  
Yielding ~\$3B+

	EGFR790 <sup>mut</sup> Pts.	STK11 <sup>mut</sup> Pts.
1L NSCLC Incidence of Mutation	17%*	20%
~2023 Eligible Patient Population**	26,500	31,000

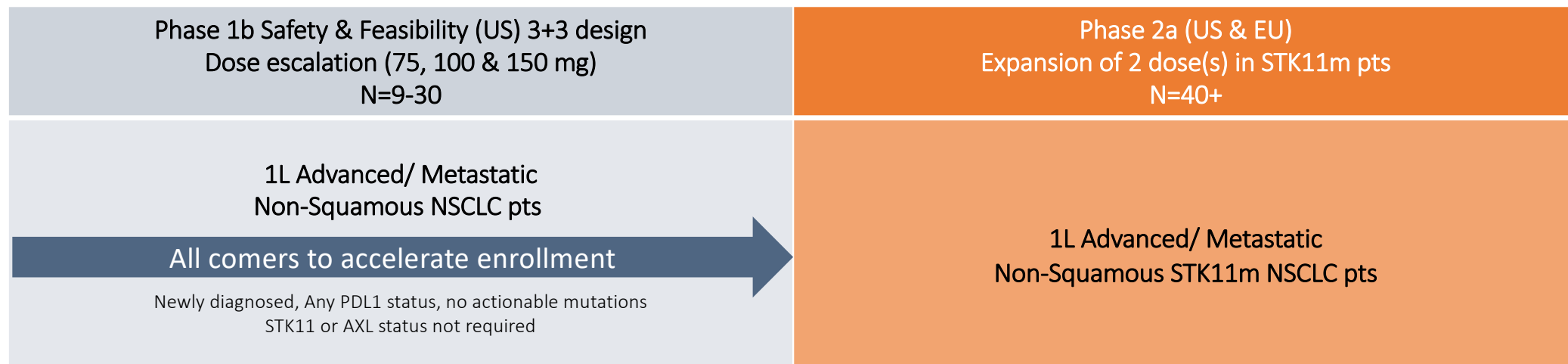
- Tagrisso sales reached over \$1B globally based on 2L approval (2L population is ~50% of the size of 1L)
- Sales rapidly increased by an addtl. ~\$3B with 1L approval

**BerGenBio**

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

# On-going global 1L NSCLC Phase 1b/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 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



**BerGenBio**

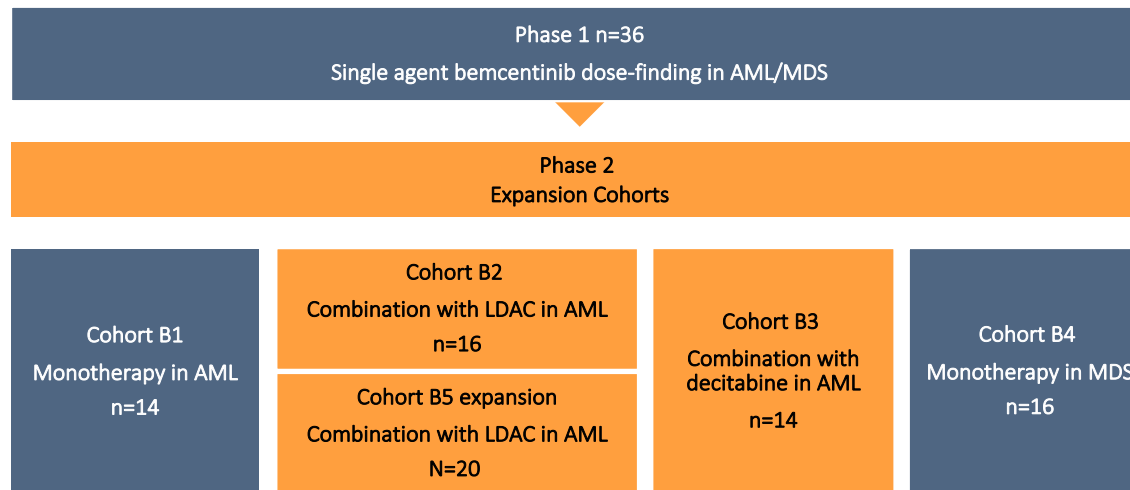
**Top line data from Ph 1b/2  
trial in AML & MDS  
(BGBC003)**

# BGBC003 PhIb/2 open label study of bemcentinib in AML and MDS

A Phase Ib/II multicenter open-label study of BGB324 (bemcentinib) as a single agent and in combination with cytarabine or decitabine in patients with acute myeloid leukemia or as a single agent in patients with myelodysplastic syndrome

## Key inclusion criteria

- Diagnosis of AML (except FAB M3)
- Ineligible for intensive chemotherapy
- Relapsed or refractory after at least 1 prior line of treatment (some cohorts)
- Suitable to receive treatment with LDAC or decitabine



## Endpoints

### Primary:

- Safety and tolerability

### Secondary:

- ORR (overall response rate)
- RFS (relapse-free survival)
- EFS (event-free survival)
- OS (overall survival)
- PK profile

LDAC = Low Dose Cytarabine; AML = Acute Myeloid Leukemia; MDS = Myelodysplastic syndromes



# Promising monotherapy activity of bemcentinib substantiates role of AXL inhibition

Cohort B1 Monotherapy in R/R AML pts. N=11	
ORR	18.2%
mOS	18 mos
<ul style="list-style-type: none"><li>All patients had relapsed or refractory AML</li><li><b><i>"A retrospective study by Zeicher et al showed that the median overall survival in relapsed and/or refractory AML patients is only 4 months"</i></b></li></ul>	

Cohort B4 Monotherapy in MDS pts N=16	
ORR	18.8%
mOS	9.2 mos
<ul style="list-style-type: none"><li>The majority of MDS patients were high-risk; all pts had relapsed following HMA chemotherapy</li><li><b><i>"...survival of refractory/relapsed patients [following HMA] is extremely short with median survival of 4 to 6 months"***</i></b></li></ul>	

\*Future Oncology Volume 18, Issue 16, May 2022, Pages 2029-2039

\*\*HemaSphere 3():p 138-140, June 2019. | DOI: 10.1097/HS9.0000000000000219

# Survival benefit observed in the combination of bemcentinib + LDAC

Cohort B2 + B5 Bemcentinib + LDAC in R/R AML pts. N=27	
ORR	18.5 %
mOS	<b>8.0 mos</b>
<ul style="list-style-type: none"><li>• The majority of patients had relapsed or refractory AML</li><li>• <b><i>"A retrospective study by Zeicher et al showed that the median overall survival in relapsed and/or refractory AML patients is only 4 months"</i></b></li></ul>	

- The combination of bemcentinib + LDAC appears superior to that of bemcentinib + decitabine
- The additive benefit of bemcentinib to LDAC mirrors preclinical findings
- The relatively lower benefit of bemcentinib + decitabine may be due to resistance from use of decitabine in 1L

# BGBC003 key findings

- Promising monotherapy efficacy, particularly in MDS patients
  - A key dataset confirming the role of AXL inhibition in cancer treatment
- Benefit seen by adding bemcentinib to LDAC (chemotherapy) in AML patients, consistent with preclinical findings
- Evidence of engagement with downstream markers, substantiating AXL inhibition
- Well tolerated as monotherapy and in combination with no new safety signals, even in these fragile patient populations
- *While intriguing in totality, the data is not applicable to future studies because standard of care in 1<sup>st</sup> line therapy has changed since the trial was conducted*



# Other potential value drivers

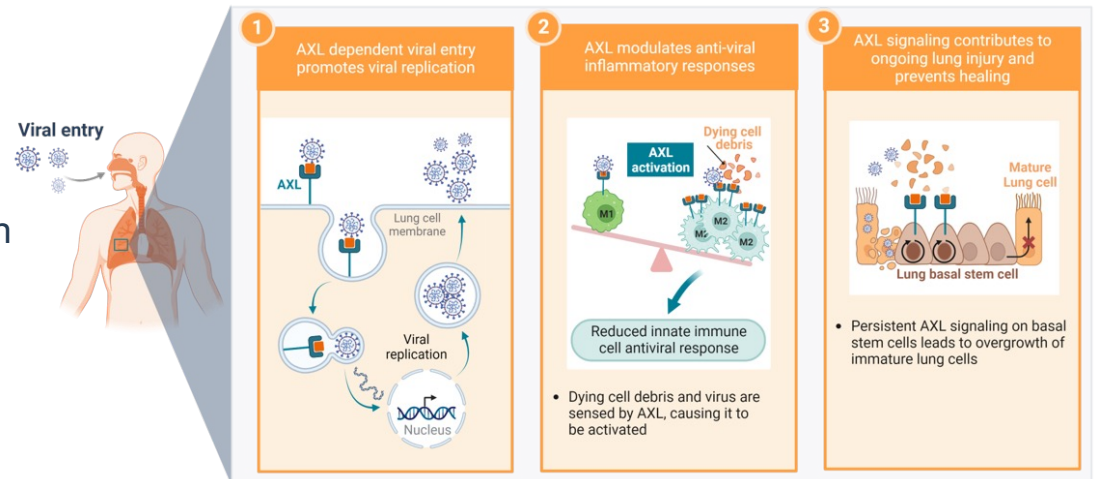
Severe respiratory infections, tilvestamab, AXL-ADC

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

While corporate focus remains centered on NSCLC, intriguing data with bemcentinib in hospitalized COVID supports further development in other SRIs in a cost-effective manner

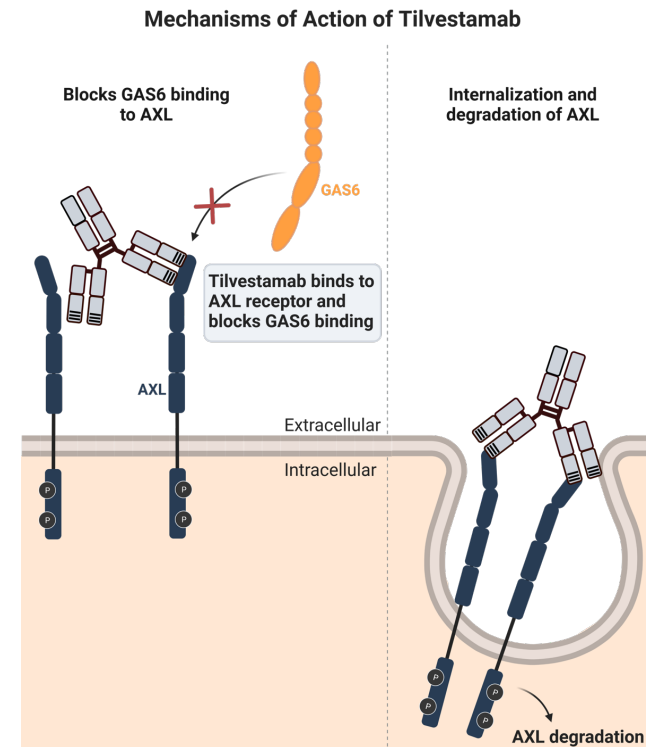
## Our strategy is centered on:

- Pausing, but maintaining, the EUSolidAct bemcentinib arm to be re-activated if an onset of new variants or pathogens
- On-going development of a new formulation explicitly designed for SRIs/ARDS
- Studies in relevant SRI preclinical models in collaboration with leading academic institutions
- Participation in low/no-cost “pathogen-agnostic” clinical studies majority funded by governments/institutions to rapidly assess utility of bemcentinib at minimal cost



# Tilvestamab update

- Preclinical and clinical data indicate potential application in progressive fibro-inflammatory diseases – with few current therapeutic options – and cancer
- Two Phase 1 safety studies completed in healthy volunteers and serous ovarian cancer patients
  - No dose-limiting toxicities identified; evidence of target engagement and downstream effects
- Licensing/collaboration discussions on-going



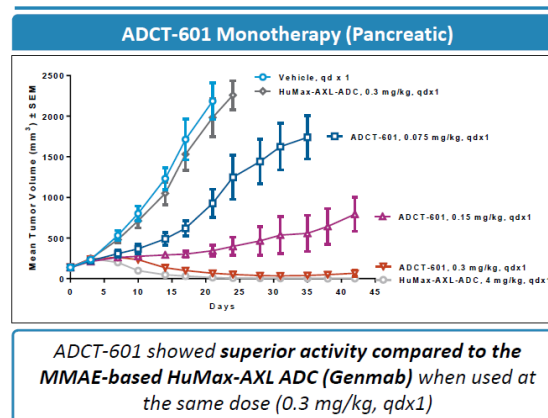
# AXL-ADC

## ADCT therapeutics advancing licensed anti-AXL mAb

- In 2014 BGB exclusively licensed to ADCT Therapeutics a selective anti-AXL monoclonal antibody (mAb) with a differing MoA from bemcentinib or tilvestamab
- ADCT's candidate mipasetamab uzoptirine (ADCT-601) consists of the BGB-developed mAb conjugated to ADCT's proprietary PBD-dimer toxin SG3199 employing GlycoConnect™ conjugation technology (licensed from Synaffix BV)

*ADCT has announced promising preclinical data potentially indicating a "best-in-class" position in the AXL-ADC field\**

### Pre-clinical Data



- Mipasetamab (ADCT-601) Status
  - Monotherapy study in sarcoma, NSCLC, AXL gene amplified tumors – *initial data expected 1H24\**

BGB is eligible to receive development and sales milestones and royalties on ADCT-601

**BerGenBio**

\*Source: ADCT statements at 43rd annual TD Cowen conference



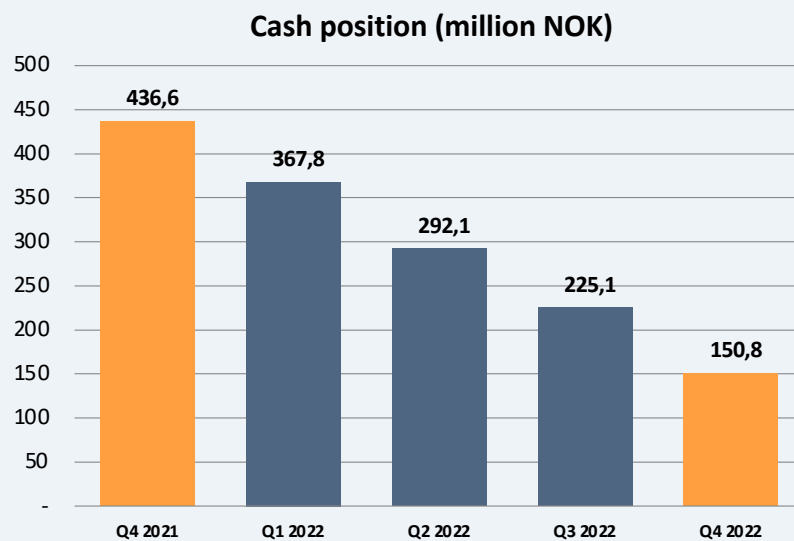
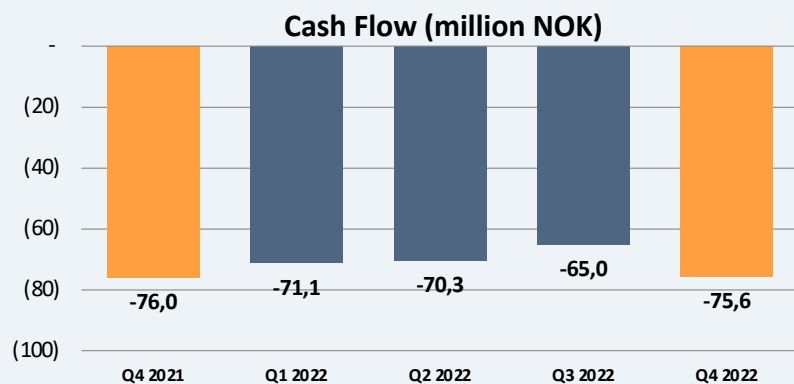
# Financials

Update of current financials & planned rights issue



# Key financials Q4 2022

# Financial update 2023



**Q1 2023 Finance report:** 22 June 2023

**Cash at end of Q1 2023:** NOK 73.0 million

**Shareholder loan facility:** Not drawn as of today, and NOK 100 million is available up to an equity issue is completed

# Key information of the planned rights issue

## Why is BerGenBio doing a rights issue?

- In accordance with previously communications, additional funding is required to pursue the strategy and further development of BerGenBio's main asset bemcentinib
- The current capital market is challenging, and the company has assessed alternative opportunities to raise capital
- A rights issue is deemed as the best opportunity to secure the capital needs and ensure that all current shareholders are given an equal opportunity to participate pro-rata in the offering
- With a focused strategy, tight cost control and a partly underwritten and guaranteed right issue the company will be able to secure the required capital to pursue the strategy

## Key dates for the rights issue:

- 21 May 2023 - Price of the offering
- 22 May 2023 - Annual general meeting, approval
- 26 May 2023 - Expected publication of prospectus
- 30 May 2023\* - Subscription period starts
- 7 June 2023\* - Last trading day of subscription rights
- 13 June 2023\* - Last day of the subscription period

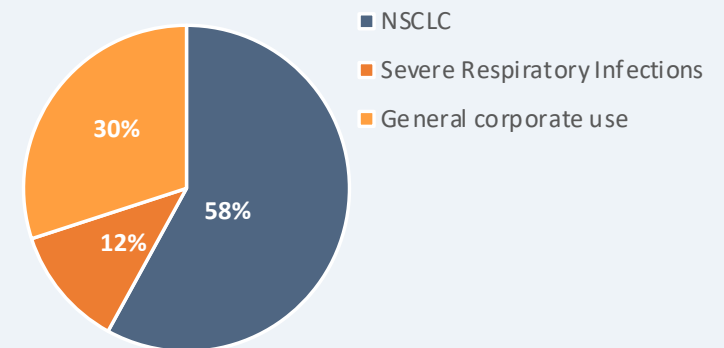
*\* Dates are subject of approval of a prospectus 26 May 2023*

# Key information of the planned rights issue

## Proposed rights issue

- A rights issue with subscription rights for all existing shareholders
  - Subscription rights equal to share holding 22 May 2023
  - Subscription rights will be tradable on Oslo Stock Exchange
- Gross proceeds of up to NOK 250 million of which NOK 175 million is underwritten and guaranteed
- Price agreed to theoretical ex-rights price (TERP) less a discount of 37.5%, based on share price (VWAP) last three days before the AGM 22 May 2023
- Subscriber in the rights issue will receive one free warrant for every second share subscribed in the right issue. The warrant can be exercised in pre-defined future subscription periods in a set price interval.
- The rights issue is subject to General Meeting approval and approval of a prospectus

## Use of Proceeds



Additional information: <https://www.bergenbio.com/investors/general-meetings/>

- BerGenBio website in the Investors/general meetings section
  - Q&A
  - Annual General Meeting invite
- Prospectus, expected to be approved 26 May 2023

# News flow expected in 2023

<b>Core Clinical Strategy</b>	<b>H1 2023</b>	<b>H2 2023</b>
<b>1L STK11m NSCLC</b>	<ul style="list-style-type: none"><li>✓ FPFV in Ph1b</li><li>✓ STK11m posters at major conferences</li><li>✓ Additional data analysis of BGBC008</li><li>• Additional preclinical data</li></ul>	<ul style="list-style-type: none"><li>• Ph1b data</li><li>• Ph 2a initiation</li></ul>
<b>Severe Respiratory Infections (SRIs)</b>		<ul style="list-style-type: none"><li>• Preclinical/meta-analysis data in SRIs</li><li>• Potential pathogen agnostic trial in ARDS</li></ul>
<b>Other News Flow</b>	<b>H1 2023</b>	<b>H2 2023</b>
<b>Bemcentinib clinical/biomarker data</b>	<ul style="list-style-type: none"><li>✓ Ph2 AML (BGBC003) topline data</li><li>✓ Presentation of trial data at major conferences</li></ul>	<ul style="list-style-type: none"><li>• Presentation of trial data at major conferences</li></ul>
<b>Tilvestamab</b>	<ul style="list-style-type: none"><li>• Update on out-licensing progress</li></ul>	

# Unlocking the promise of AXL inhibition

- Data from multiple phase 2 trials provide substantial evidence of clinical benefits by selective AXL inhibition of bemcentinib across cancer and severe respiratory infections – a unique and promising dataset
- Bemcentinib's route of administration, mode-of-action and safety profile makes it an excellent combination agent
- Applying a focused strategy with clear value drivers to unlock significant value potential of AXL inhibition in two major opportunities: 1L NSCLC STK11m and Severe Respiratory Infections
- Additional incremental value potential from partnering of tilvestamab, out-licensed mAB
- Proposed rights issue provides capital to continue the execution of the focused strategy

# BerGenBio



## **Address**

Mollendalsbakken 9, 5867 Bergen,  
Norway

## **Phone Number**

+ 47 559 61 159

## **E-mail**

[post@bergenbio.com](mailto:post@bergenbio.com)