

A photograph of an elderly couple sitting on a sandy beach at sunset. The woman is in the foreground, wearing a grey sweater and blue jeans, looking towards the ocean. The man is sitting behind her, wearing a plaid jacket and glasses, also looking out at the sea. The background shows a calm ocean and a line of trees under a soft, golden light. The image is framed by orange geometric shapes on the left and right sides.

# BerGenBio

*A world leader in exploring AXL biology –  
advancing lead program in front-line NSCLC 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

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# BerGenBio Highlights

- We are selectively targeting AXL biology, known to play a key role in the progression of cancer, respiratory diseases and fibrosis – and we are developing two proprietary clinical stage programs: bemcentinib (lead program) and tilvestamab
- Multiple Ph2 trials of bemcentinib validate clinical benefits of selective AXL inhibition in **NSCLC**, AML, MDS, and Mesothelioma
- Entirely focused on developing bemcentinib in 1L NSCLC where we have a strong competitive position, significant market opportunity and supportive pre-clinical and clinical data – NSCLC beyond 1L is pursued through partnering
- Recently raised NOK 250M through a Rights Issue with warrant element to potential secure additional financing of NOK 125M which may fund our planned activities into H2 2025
- 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)

A photograph of a group of people, likely in a clinical or research setting. A woman in a white lab coat is visible in the foreground, looking towards the right. Other people are blurred in the background. The image has a dark blue overlay and orange geometric shapes on the left and right sides.

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**Lead program - bemcentinib  
offers an attractive  
opportunity to address a  
significant unmet medical  
need in NSCLC**

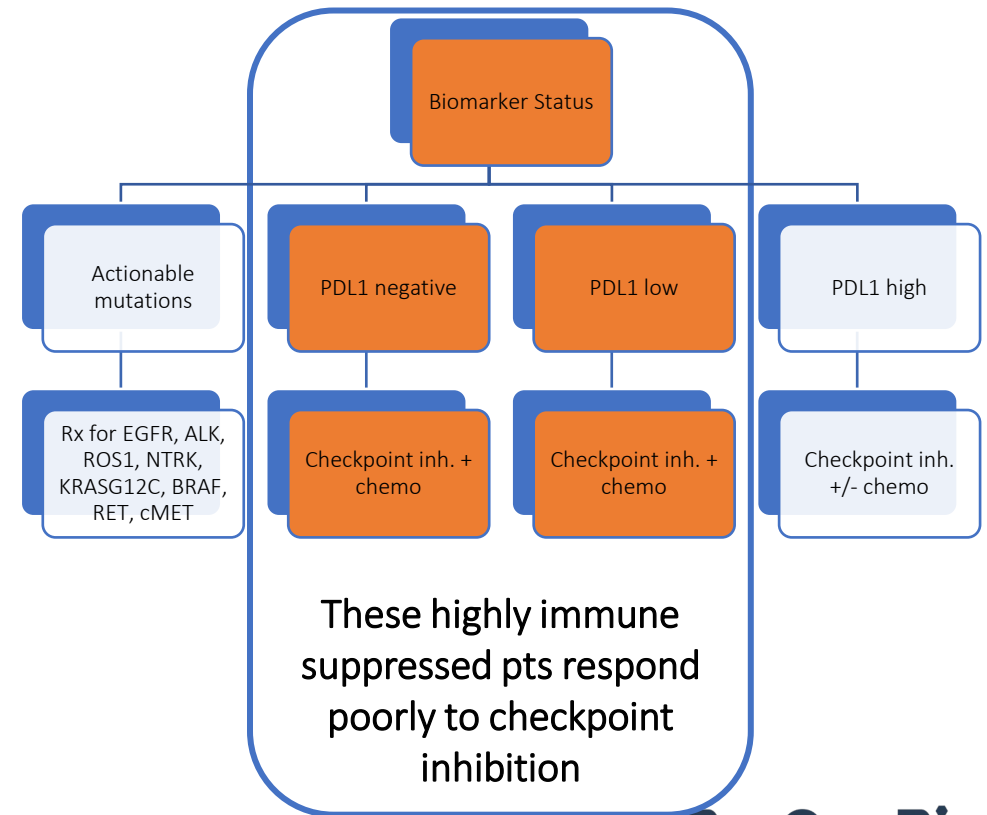
# Treatment of NSCLC requires new approaches for patients unresponsive to current therapies

## 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



# Bemcentinib, is 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" its 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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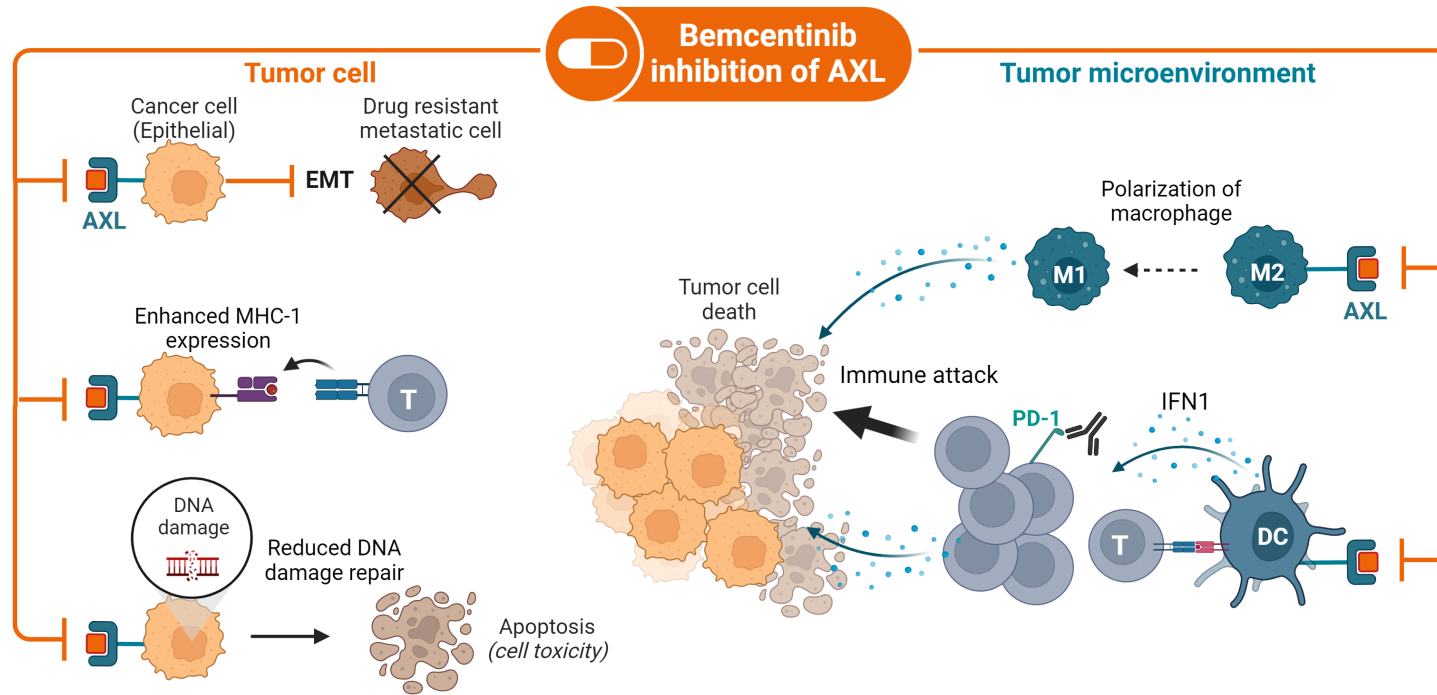
\*Checkpoint inhibition

# 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

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



- In NSCLC clinical trials of >100 patients suggest 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

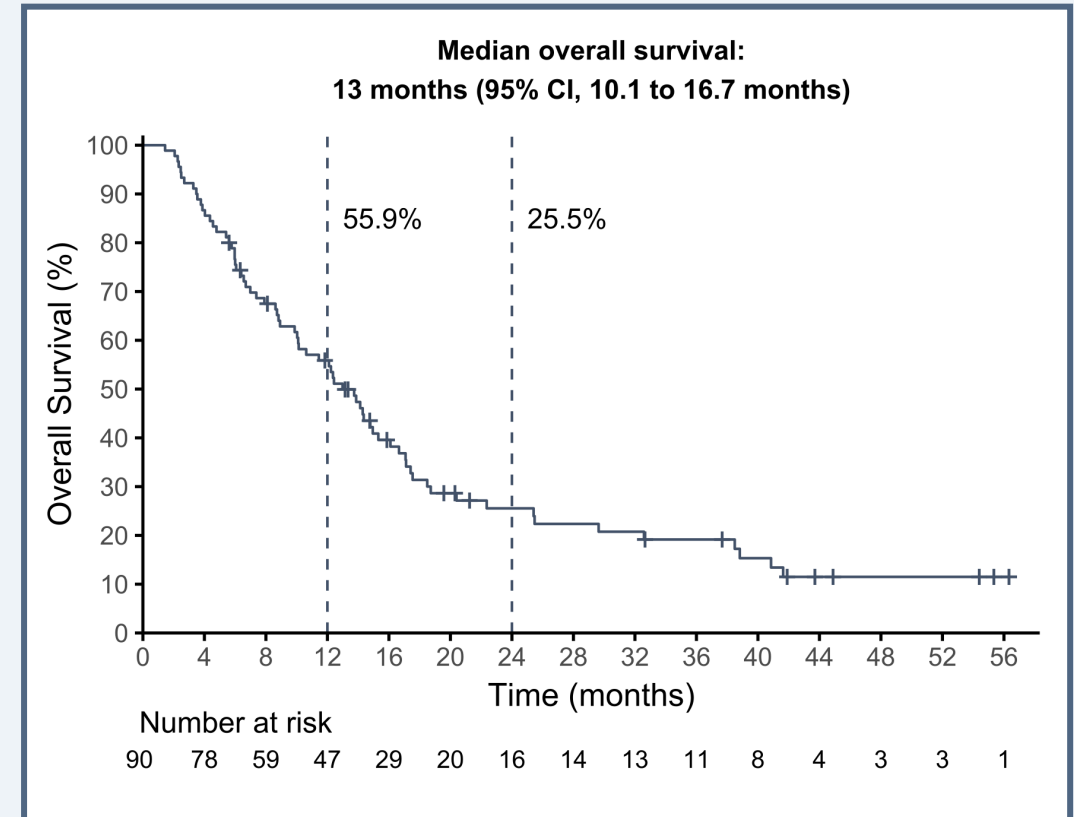
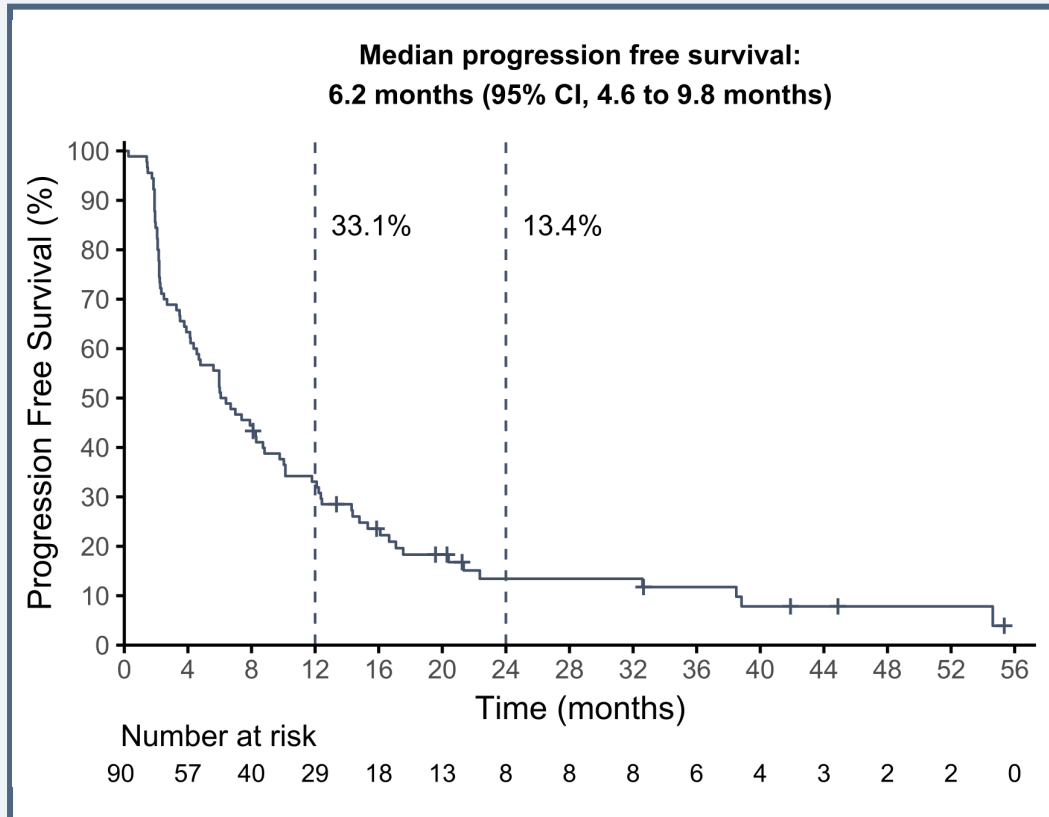
- Disease control on 1L for  $\geq 12$  wks. before progression
- 2<sup>nd</sup> or 3<sup>rd</sup> line metastatic Non-Squamous NSCLC

## 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

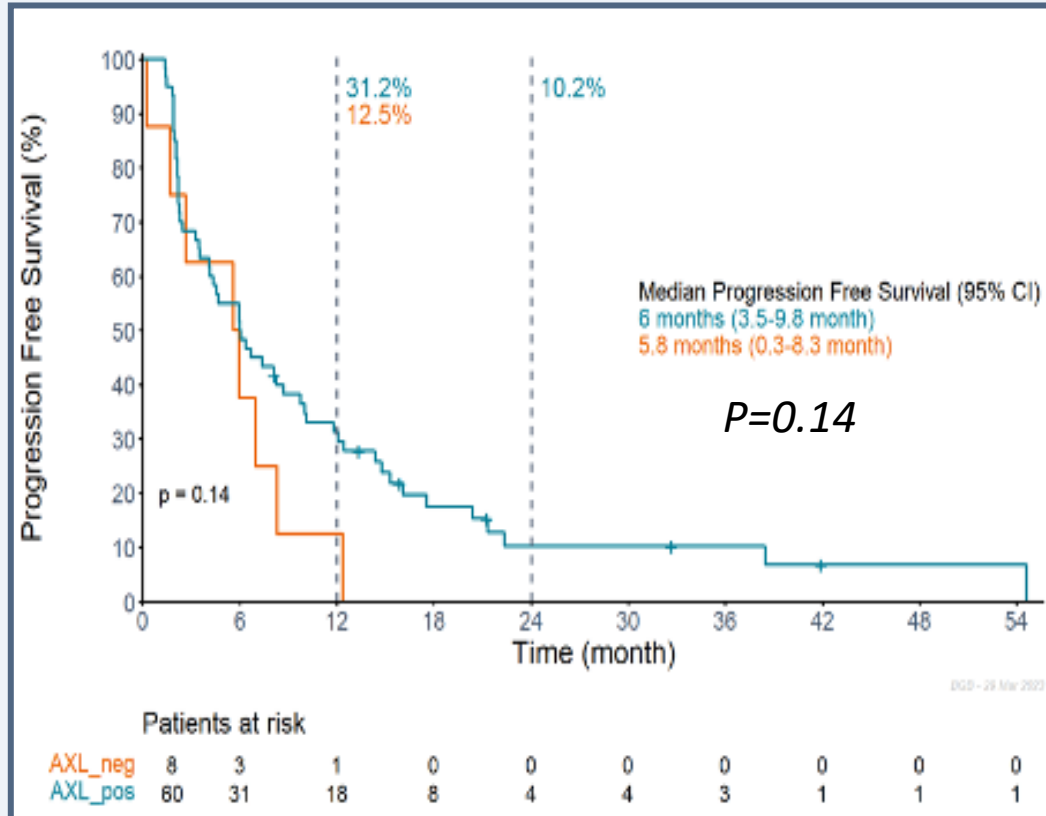
# Encouraging efficacy observed in all evaluable patients – 25% alive at 2 yrs



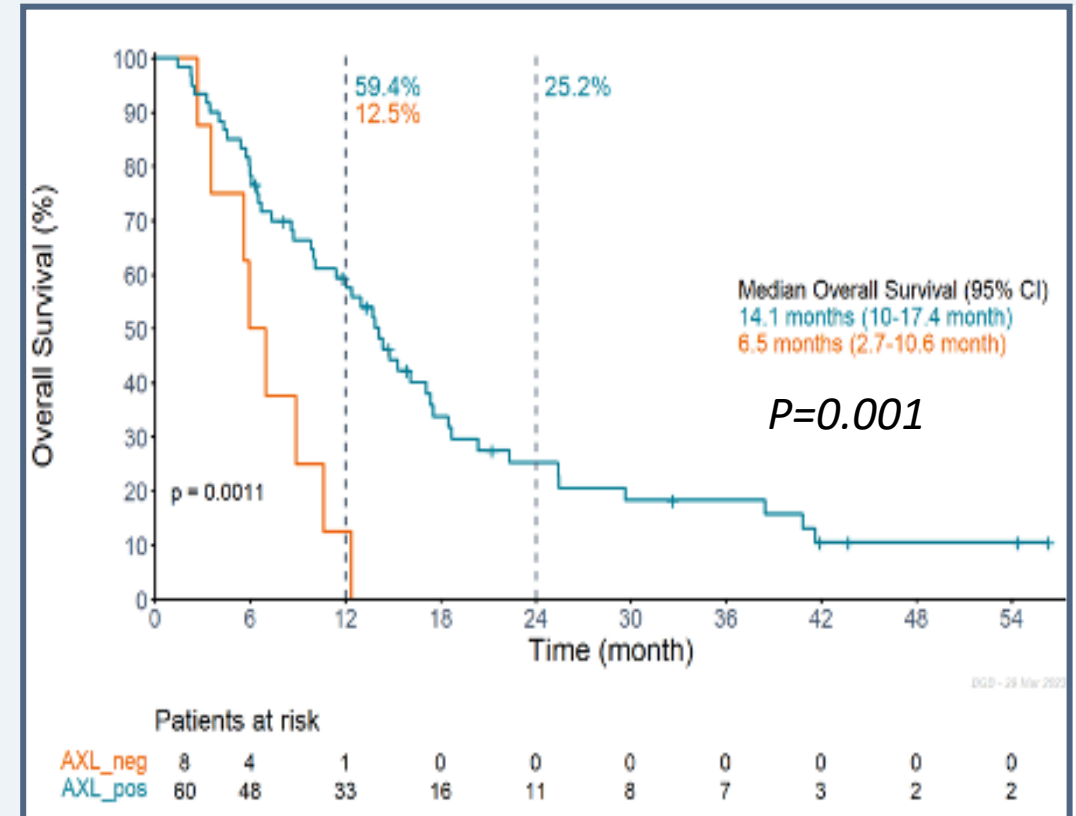
BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

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

Median progression free survival



Median overall survival



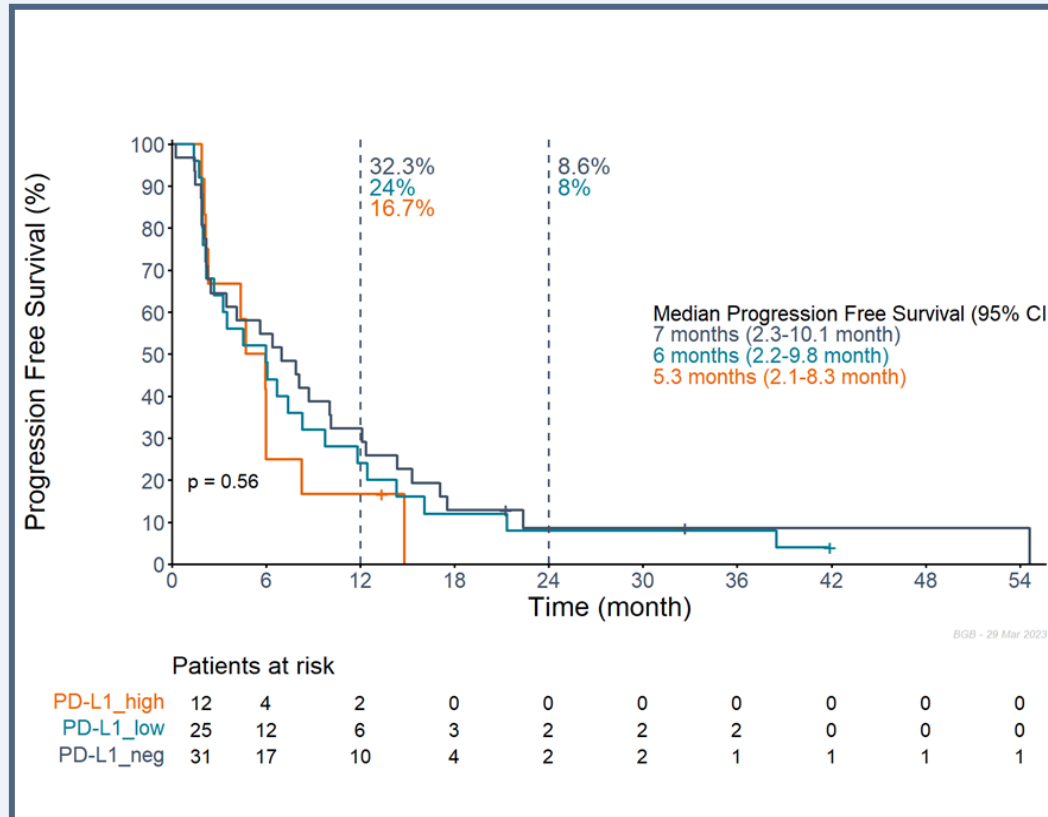
\*AXL positive in tumor cells (H=>5) /or immune cells (H>1) vs. pts with no or lower AXL levels

BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

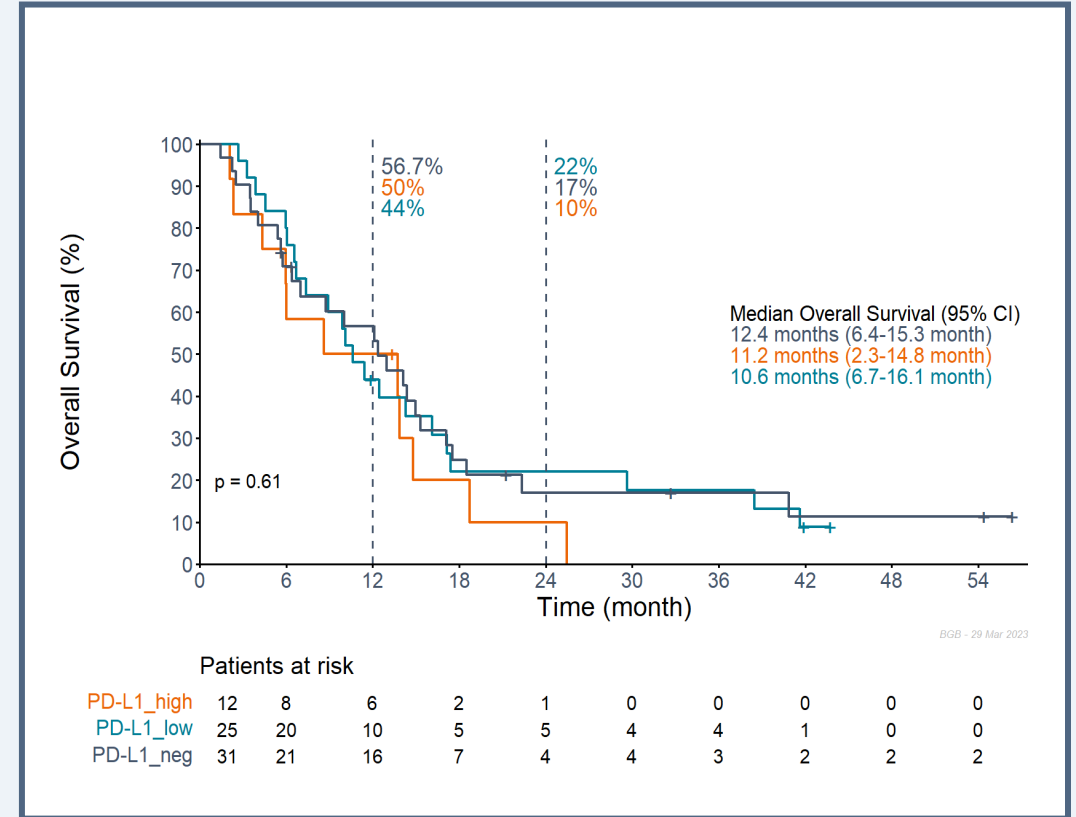
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# Benefit even in neg./low PDL1 pts who typically respond less well to checkpoint inhibition

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%

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

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\*\*
- 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<br><i>Bemcentinib + Pembrolizumab</i> | AXL>5<br><i>Bemcentinib + Pembrolizumab</i> | Pallis, 2010<br><i>Docetaxel + Carboplatin</i> | REVEL<br><i>Ramucirumab + Docetaxel</i> | KEYNOTE 189*<br><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

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

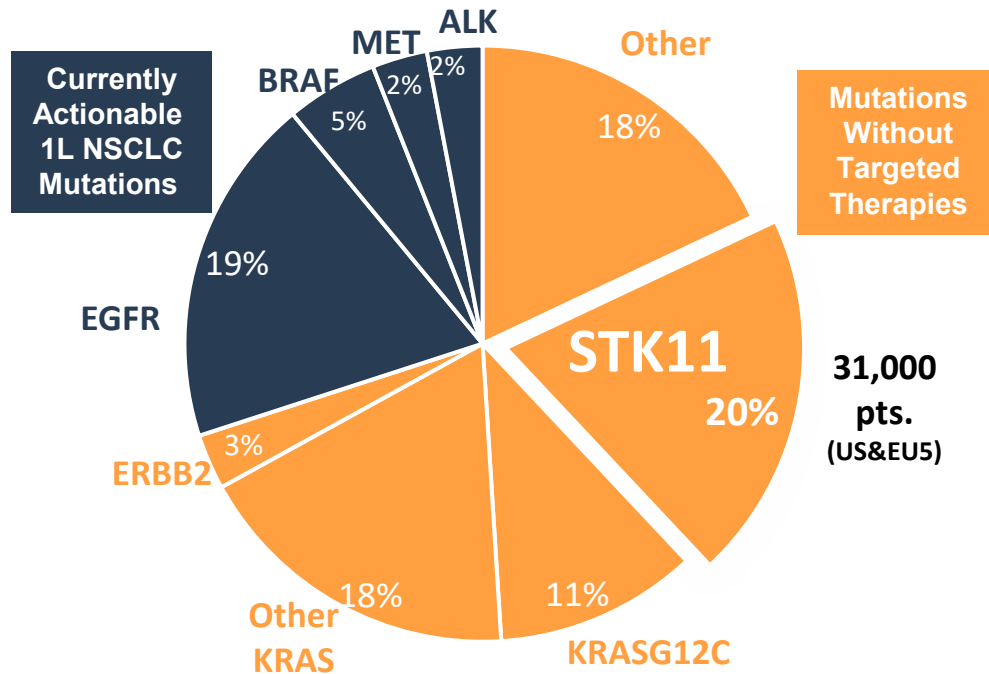
|                               | Bemcentinib 200mg fixed + pembrolizumab<br>BGBC008 | Pembrolizumab<br>Monotherapy<br>KEYNOTE-010 |
|-------------------------------|--|---|
| Population                    | 2L NSCLC   | 2L NSCLC                                    |
| <b>Top TRAEs , all grades</b> |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

# STK11<sup>mut</sup> NSCLC - a large underserved patient population in which AXL inhibition is critical

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

# 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<br>KRASG12C      | Ph2            | KRASG12Cm + STK11m 1L NSCLC       |
| Amgen/sotorasib<br>KRASG12C       | Ph2            | KRASG12Cm + STK11m<br>1L NSCLC    |
| Novartis/JDQ443                   | Ph2            | KRASG12Cm + STK11m<br>1L NSCLC    |
| JacoBio/<br>KRASG12C              | Ph1/2          | KRASG12Cm + STK11m<br>2L NSCLC    |
| Regeneron/anti-IL6R + anti-PD1    | Ph1/2          | EGFRm or STK11m NSCLC<br>any line |
| Tango/coREST inhibitor + anti-PD1 | Ph1/2          | STK11m 2L NSCLC                   |

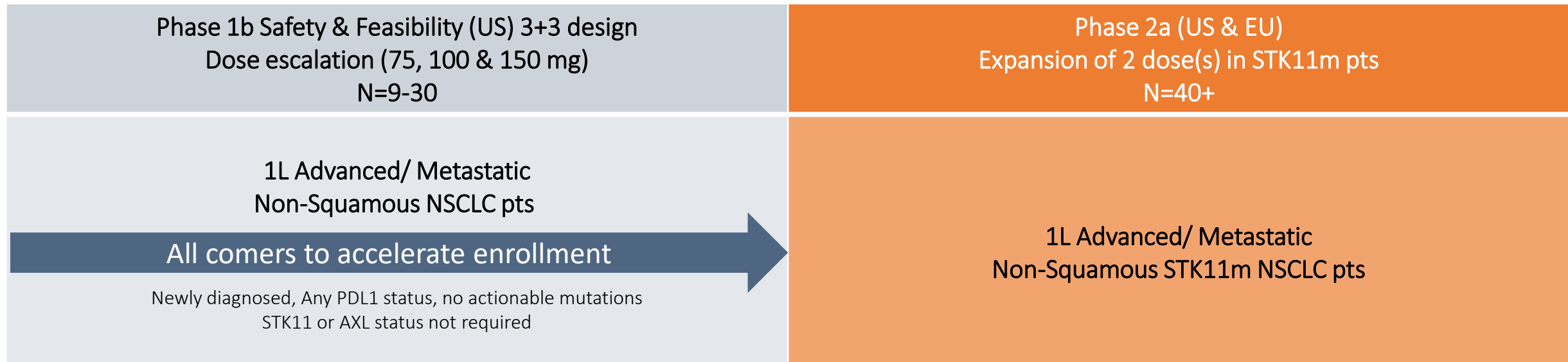
Sources: clinicaltrials.gov, EU clinical trials register, company websites

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

# News flow expected in 2023/2024

| Core Clinical Strategy                      | H1 2023   | H2 2023 / H1 2024   |
|---|---|---|
| <b>1L STK11m NSCLC</b>                      | <ul style="list-style-type: none"><li>✓ FPFV and additional sites activated for Ph1b/2a</li><li>✓ STK11 loss data presented at AACR</li><li>✓ Promising biomarker data from 2L study supports potential expansion of 1L NSCLC patient populations</li></ul> | <ul style="list-style-type: none"><li>• Ph1b data and selection of doses for Ph2a</li><li>• Initiation of Ph2a</li><li>• FDA advice to elucidate pivotal trial requirements in NSCLC</li><li>• Additional MoA data from BGBC008</li></ul> |
| <b>Severe Respiratory Infections (SRIs)</b> |   | <ul style="list-style-type: none"><li>• Preclinical data in SRIs</li></ul>  |
| Other News Flow                             | H1 2023   | H2 2023 / H1 2024   |
| <b>Other Clinical Data</b>                  | <ul style="list-style-type: none"><li>✓ Positive AML/MDS data (BGBC003) reported</li><li>✓ Data in mesothelioma presented at ASCO – primary end-point met</li><li>✓ Manuscript published by MD Anderson collaborator re: bem. + doce. in 2L NSCLC</li></ul> | <ul style="list-style-type: none"><li>• Presentation of data at major oncology conferences</li><li>• Potential clinical trial manuscript publications in major journals</li></ul>   |
| <b>Tilvestamab</b>                          | <ul style="list-style-type: none"><li>✓ Update on out-licensing progress (discussions on-going)</li></ul>   | <ul style="list-style-type: none"><li>• Complete out-licensing progress</li></ul>   |

# Implementing our vision for value creation

## Focused Indication Strategy

- ✓ Extensive clinical data provide confidence of efficacy/safety of bemcentinib
- ✓ 1L STK11m NSCLC selected as indication with strongest biological rationale, competitive position and market potential – potential beyond 1L STK11m NSCLC pursued through partnering

## Optimize Business Structure

- ✓ Focused on execution in 1L STK11m NSCLC – significant value potential
- ✓ Extended runway through reduced expenses and completed Rights Issue
- ✓ Enable partnering to capture value beyond 1L STK11m NSCLC

## The "Right" Partnership

- Partner at optimal point of value infection
- Goals: enable attractive investor return, maximize 1L NSCLC potential through expanded execution capabilities, financial resources and market validation



# BerGenBio



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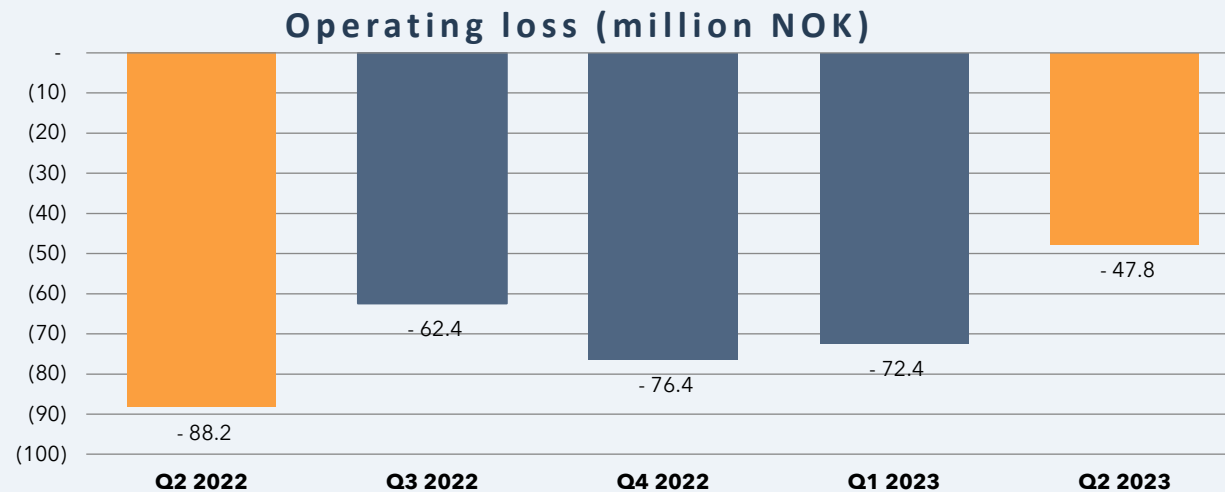
# Financials

Update of current financials

# Key financials Q2 2023

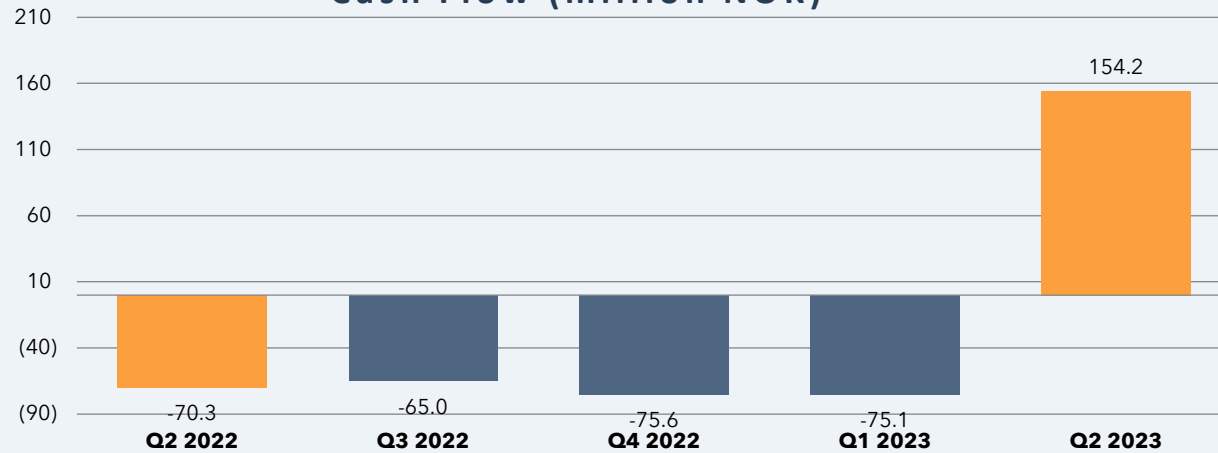
| (NOK million)                                     | Q2 2023 | Q2 2022 | YTD 2023 | YTD 2022 | FY 2022 |
|---|---------|---------|----------|----------|---------|
| Operating revenues                                | 0,0     | 0,0     | 0,0      | 0,0      | 0,4     |
| Operating expenses                                | 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



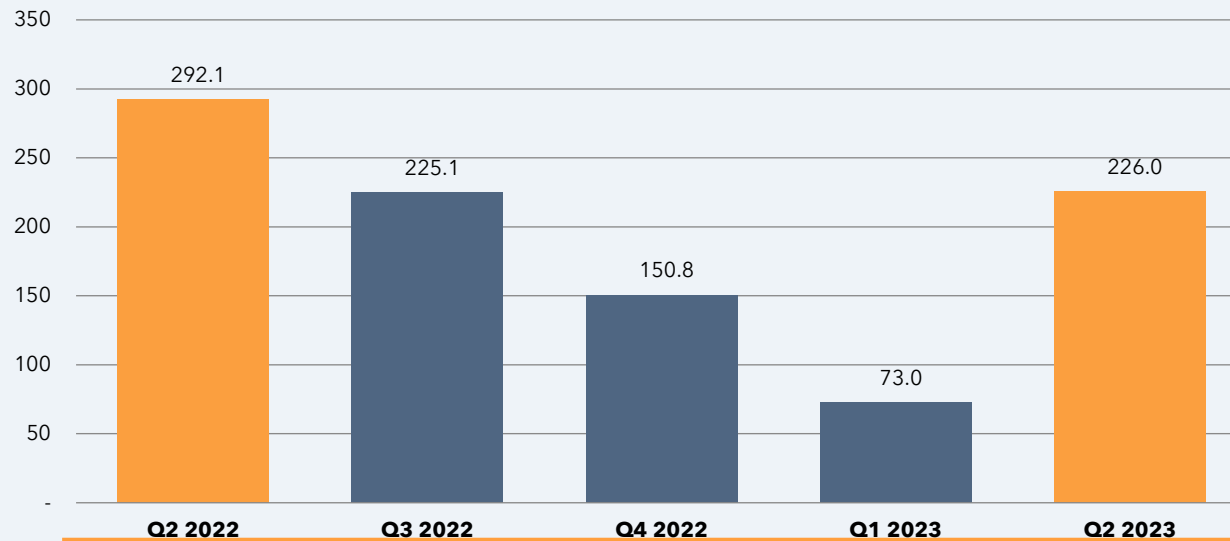
# Key financials Q2 2023

## Cash Flow (million NOK)



- Cash position end of Q2 2023:
  - 226 mNOK/21 mUSD
- Expected cash burn continuing operations going forward: 50 mNOK / 4.7 mUSD

## Cash position (million NOK)



# 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