



# BerGenBio

*A focused strategy of selective AXL inhibition to address  
unmet needs in NSCLC*  
**Q4 2023 report**

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# Highlights: focused strategy gathers momentum

## BGBC016 (1L STK11m NSCLC) progressing as planned

- No new safety signals observed to date
- Regulatory approval progress in EU enabling initiation of Phase 2a sites in H1 2024
- Strong support from oncology community

## Focused strategy has significantly reduced operating expenses

- 2023 FY operating expenses of NOK 192.2M represents a reduction of 37% compared to 2022 FY (NOK 306.0M)
- Year-end cash position of NOK 156.4M projected to fund operations until end of 2024
- If exercised outstanding warrants will extend runway to H2 2025

## Bemcentinib data continues to support its significant potential

- Multiple Phase 2 bemcentinib studies presented at prestigious oncology meetings
- New preclinical data continues to support the potential of bemcentinib beyond NSCLC

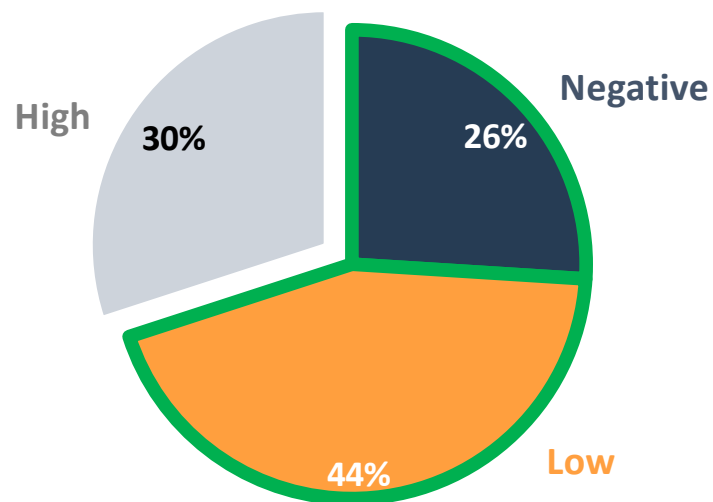
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**1L STK11m NSCLC:  
A Significant Opportunity**

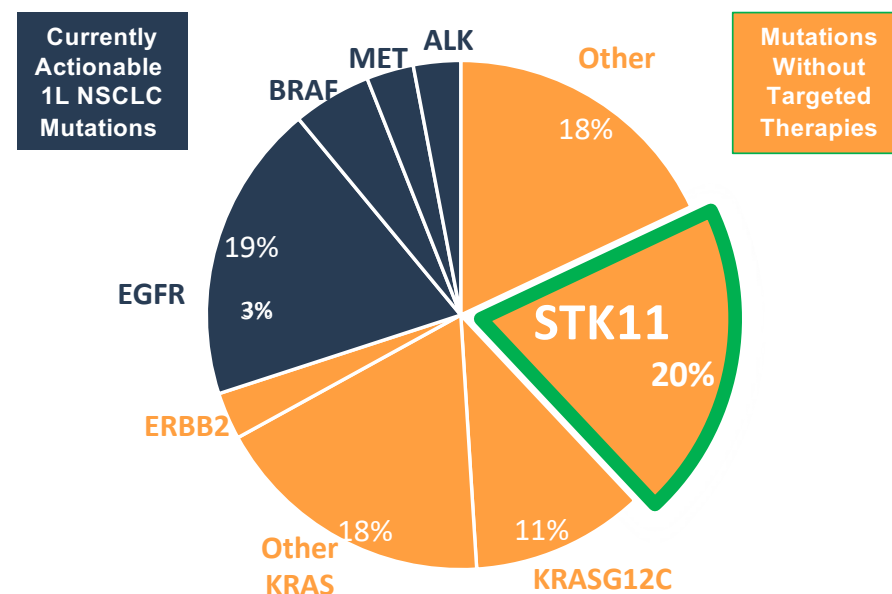
# Highest unmet 1L needs today: neg/low PD-L1 ; STK11m

Bemcentinib expected to address NSCLC patients with the highest unmet needs

## 1. PD-L1 levels predicts response to Immunotherapy



## 2. Mutational status predicts response to Targeted Therapies



# Large potential in >30,000 1L STK11m NSCLC pts US/EU5

## 2024 US Market Potential



= \$2.9B USD/yr

## 2024 Market Potential in EU5



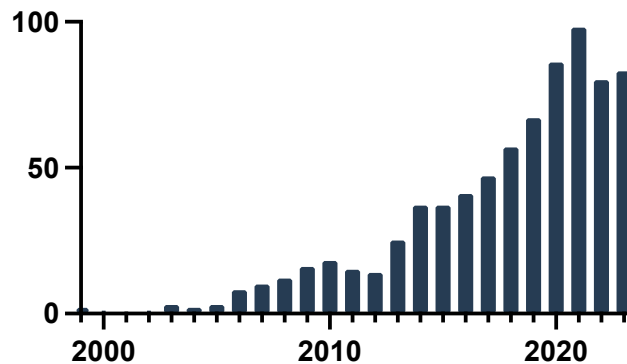
= \$1.4B USD/yr.

**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

# Increasing focus on STK11m in oncology

STK11 Lung Cancer Scientific Publications  
by Year



Source: PubMed 1999-2023

ELSEVIER

European Journal of Cancer  
Volume 172, September 2022, Pages 85-95

Original Research

## Clinical impact of *STK11* mutation in advanced-stage non-small cell lung cancer

Pietro Rosellini<sup>a</sup>, Samuel Amintas<sup>a, b</sup>, Charline Caumont<sup>a</sup>, Rémi Veillon<sup>a</sup>,  
Sigolène Galland-Girodet<sup>c</sup>, Alain Cuguillière<sup>d</sup>, Laurent Nguyen<sup>e</sup>, Charlotte Domblides<sup>f, g</sup>,  
Amandine Gouverneur<sup>a, b</sup>, Jean-Philippe Merlio<sup>a, b</sup>, Julien Bezin<sup>a, b</sup>,  
Pierre-Olivier Girodet<sup>a, b</sup>

ORIGINAL REPORTS | January 05, 2023

## *STK11* Inactivation Predicts Rapid Recurrence in Inoperable Early-Stage Non-Small-Cell Lung Cancer

Authors: Rohan R. Katipally, MD, Liam F. Spurr, BS, Stanley I. Gutiontov, MD, William Tyler Turchan, MD, Philip Connell, MD, Aditya Juloori, MD, Renuka Malik, MD, ... [SHOW ALL](#) ... and Sean P. Pitroda, MD

Publication: JCO Precision Oncology • Volume 7, Number 7 • <https://doi.org/10.1200/PO.22.00273>

January 11, 2024

## Cancer Cell

### Clinical and molecular features of acquired resistance to immunotherapy in non-small cell lung cancer

*STK11m identified as resistance mechanism to immunotherapy*

# BGB's role as AXL inhibition leader is garnering notice

Phase 1b/2a safety and tolerability study of bemcentinib (BEM) with pembrolizumab/carboplatin/pemetrexed in subjects with untreated advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) without/with a STK11 mutation



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Final results of the BGBC008 Phase 2, multicenter study of bemcentinib and pembrolizumab (bem+pembro) in 2nd line (2L) advanced non-squamous (NS) non-small cell lung cancer (NSCLC) (NCT03184571)

MADRID, SPAIN  
20-24 OCTOBER 2023



<sup>1</sup> Memorial University of Newfoundland, St. John's, NL, Canada; <sup>2</sup> The Cancer Research and Biotechnology Institute, Manchester, UK; <sup>3</sup> Medical Research Service, National Institutes of Health, Bethesda, MD, USA; <sup>4</sup> University of Colorado Cancer Center, Aurora, CO, USA; <sup>5</sup> University of Texas MD Anderson Cancer Center, Houston, TX, USA; <sup>6</sup> University of California, San Francisco, CA, USA; <sup>7</sup> University of Colorado, Aurora, CO, USA; <sup>8</sup> BerGenBio Ltd, Oxford, UK

Bemcentinib + Pembrolizumab show promising efficacy in metastatic NSCLC patients harboring mutations associated with poor prognosis: exploratory sub-analysis from the BGBC008 trial



2023 Publications and Scientific Presentations



AXL as a therapeutic target in STK11 mutant NSCLC

Magnus Ble<sup>1</sup>, Austin Rayford<sup>1,2</sup>, Noëly Madeleine<sup>3</sup>, Fabian Gärtner<sup>4</sup>, Dana Bohan<sup>5</sup>, Natalie Ruggio<sup>6</sup>, Huiyu LP<sup>7</sup>, Luc Girard<sup>8</sup>, Rolf Brekken<sup>9</sup>, John Minna<sup>10</sup>, Marianne Aunerud<sup>11</sup>, Wendy Maury<sup>12</sup>, Michael Chisamore<sup>13</sup>, Claudia Gorcea-Carson<sup>14</sup>, Gro Gausdal<sup>15</sup>, David Micklem<sup>16</sup>, Nigel McCracken<sup>17</sup>  
<sup>1</sup>BerGenBio ASA, Bergen, Norway; <sup>2</sup>Department of Biomedicine, University of Bergen, Norway; <sup>3</sup>Department of Thoracic Medicine, Haukeland University Hospital, Bergen, Norway; <sup>4</sup>University of Iowa, Iowa City, IA, USA; <sup>5</sup>UT Southwestern Medical Center, Dallas, TX, USA; <sup>6</sup>Merck & Co., Inc., Rahway, NJ, USA; <sup>7</sup>BerGenBio Ltd, Oxford, UK



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4287

Phase Ib/II Study (NCT02488408 / BGBC003) of Bemcentinib Monotherapy or in Combination With Cytarabine or Decitabine in Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS): FINAL RESULTS

SAN DIEGO, CALIFORNIA  
9-12 DECEMBER 2023



<sup>1</sup> Dana-Farber Cancer Institute, University Medical Center, Boston, MA, USA; <sup>2</sup> Memorial Sloan-Kettering Cancer Center, New York, NY, USA; <sup>3</sup> University of Colorado Cancer Center, Aurora, CO, USA; <sup>4</sup> University of Texas MD Anderson Cancer Center, Houston, TX, USA; <sup>5</sup> University of California, San Francisco, CA, USA; <sup>6</sup> University of Colorado, Aurora, CO, USA; <sup>7</sup> BerGenBio Ltd, Oxford, UK

Phase 1 trial of bemcentinib (BGB324), a first-in-class, selective AXL inhibitor, with docetaxel in patients with previously treated advanced non-small cell lung cancer

LUNG  
CANCER

# Bemcentinib: highly differentiated AXL inhibitor



Selective, potent – improved AXL inhibition with fewer side effects

Concentrates in lung (40x) ; crosses blood-brain barrier

Extensive safety data base: studied in over 600 patients

Monotherapy activity seen in multiple indications

Proven combinations: chemotherapy and checkpoint inhibition

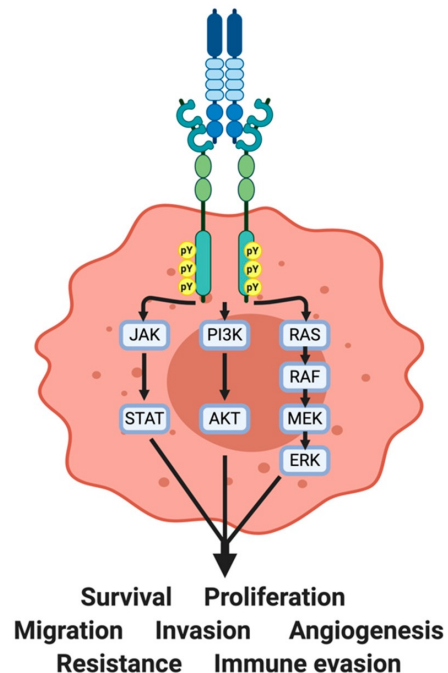
Fast Track Designation (FDA) in STK11m NSCLC and 2L NSCLC

Extensive IP through 2042

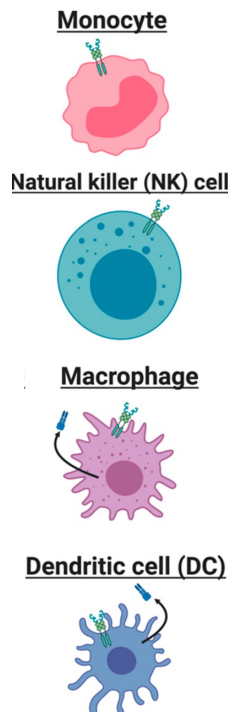
## The case for AXL inhibition with bemcentinib in 1L STK11m NSCLC

# AXL on tumor and immune cells critical for survival and disease spread

AXL on tumor cells

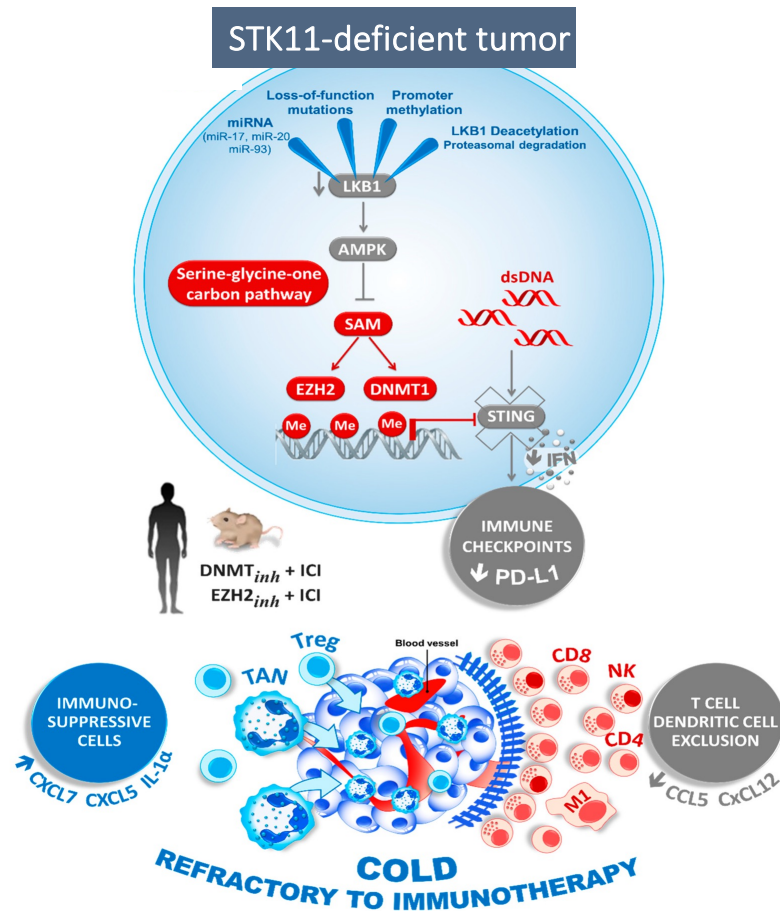


AXL on immune cells



- Bemcentinib inhibition of AXL expected to play a dual role in the tumor and immune system
- Bemcentinib adds benefit in combo with both chemotherapy and CPI
- Treating 1L pts *before* they develop resistance may significantly delay disease progression and extend survival

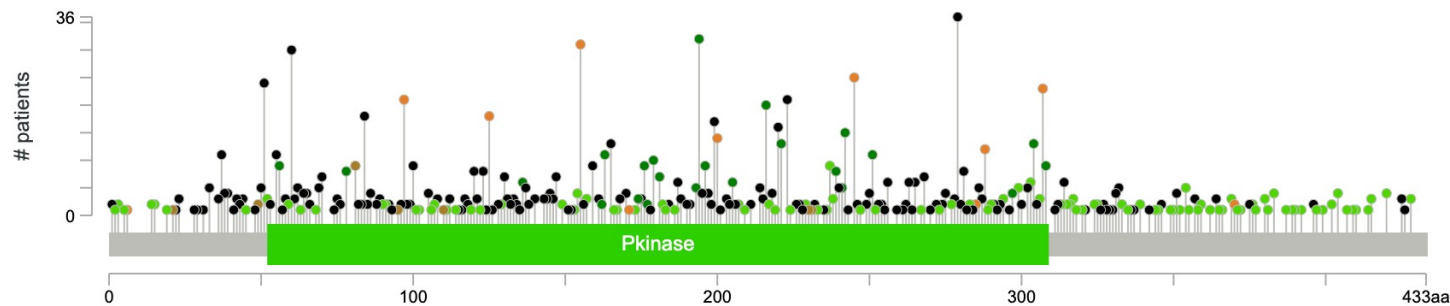
# STK11m creates “immune desert” with AXL expression



- STK11m NSCLC patients have a highly immunosuppressive immune system with:
  - Striking infiltration of immunosuppressive cells
  - Exclusion of inflammatory immune cells
- AXL expressed in  $\geq 80\%$  of STK11m NSCLC reflective of AXL's key role in “immune deserts”
- Targeting AXL restores anti-PD-L1 response in STK11m<sup>1</sup> and reduce resistance to chemotherapy

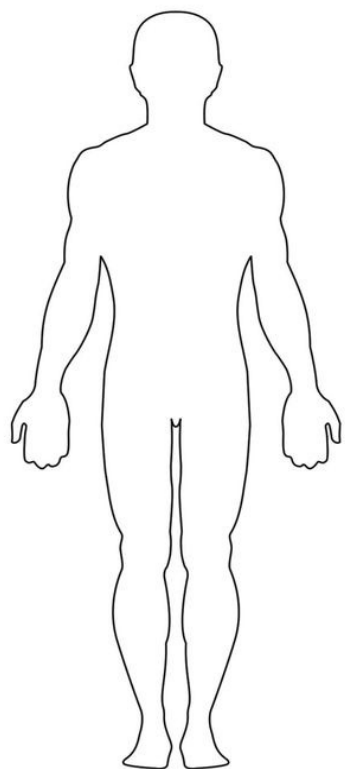
# STK11m attractive target, but not amenable to targeted therapy

STK11/LKB1 gene mutations



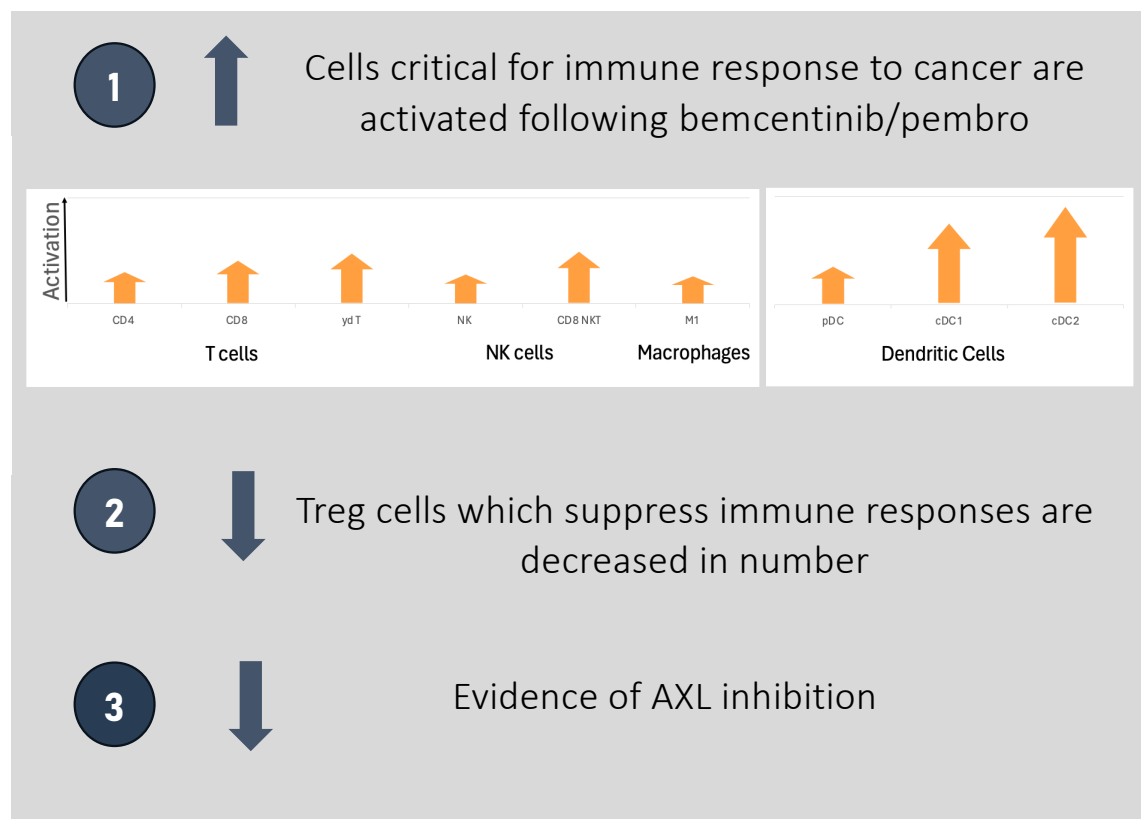
- Study of the STK11 gene indicates ~1,300 mutations can occur
- ~83% of all STK11 mutations result in a loss of STK11 expression, making drug targeting impossible
- Improving the immune response in STK11m patients is the most promising approach

# Immune cell changes support bemcentinib mechanism



## BGBC008 Patient Case Study

- STK11m/KRASm
- Prior 1L therapy: CPI + chemotherapy
- BGBC008 2L bemcentinib/pembrolizumab provided OS >16 mos.
- Immune cells (PBMCs) were studied prior to and post cycle 1 of bemcentinib/pembrolizumab



# BGB leading AXL inhibitor for 1L STK11m NSCLC

*Bemcentinib earliest entry into clinic in 1L STK11m patients*

Company/MoA	Current Phase*	Specific to 1L?	Specific to STK11m pts?	NSCLC Population
BGB/AXL inhibitor + anti-PD1+ chemo	Ph 1b/2a	✓	✓	STK11m
AZ/anti-PD1+anti-CTLA4	Ph 3b	✓	✓	STK11m, KEAP-1m, KRASm
Regeneron/anti-IL6R + anti-PD1	Ph 1b	1L – 4L	✓	STK11m or EGFRm
Tango/coREST inhibitor + anti-PD1	Ph 1/2	2L	✓	STK11m
Arcus / AXL inhibitor +/- anti-PD1	Ph1/1b	2L	No	Multiple solid tumors, STK11m expansion

Note: table excludes KRASG12C inhibitors in development for KRASG12Cm/STK11m pts which represent only ~22% of the STK11m pt pool

# 2L NSCLC data support potential for added benefit with CPI and chemo in 1L STK11m

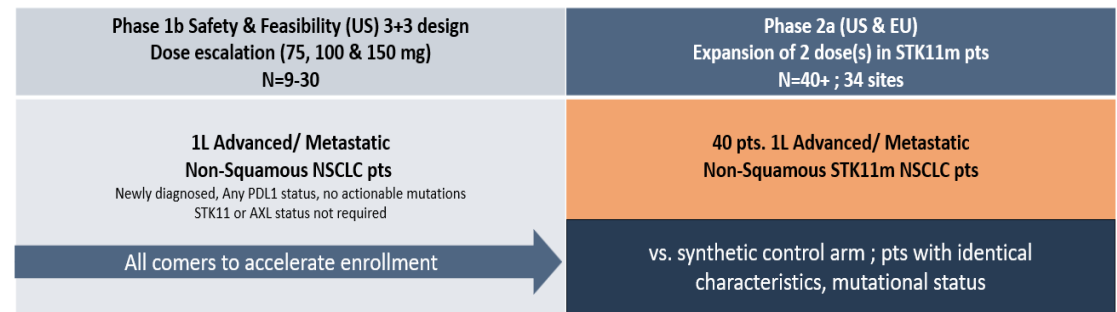
## Ph2 trial in ~ 100 pts 2L NSCLC

- Encouraging PFS, OS benefit vs. comparators
- While overall population benefited, AXL "high" patients live even longer
- Clinical benefit regardless of PD-L1 status
- Potential benefit in hard-to-treat mutations characteristic of immune deserts (STK11m, KRAS, KEAP-1)

		2L Comparators	
	AXL Positive*	KEYNOTE 189 Trial	SAPPHIRE Trial
	<i>Bemcentinib + Pembrolizumab</i>	<i>Pembrolizumab Monotherapy</i>	<i>Docetaxel following CIT</i>
ORR	16.4%	18%	17%
mPFS, mos	6.1	2.8	5.4
mOS, mos	14.1	6.9	10.6

# BGBC016 in 1L STK11m NSCLC progressing well

- BGBC016 Phase 1b “run-in” studying bemcentinib + IO + chemotherapy
  - Progressing per plan
  - No new safety signals identified to date
- BGBC016 Phase 2a in 1L STK11m NSCLC pts
  - High-volume regional oncology centers
  - European approvals obtained in all countries
  - Strong interest, active participation on part of investigators given medical need for STK11m pts
- Key expected newsflow: Ph2a start H1 2024 ; interim analyses (ORR, PFS) H2 2024-H1 2025



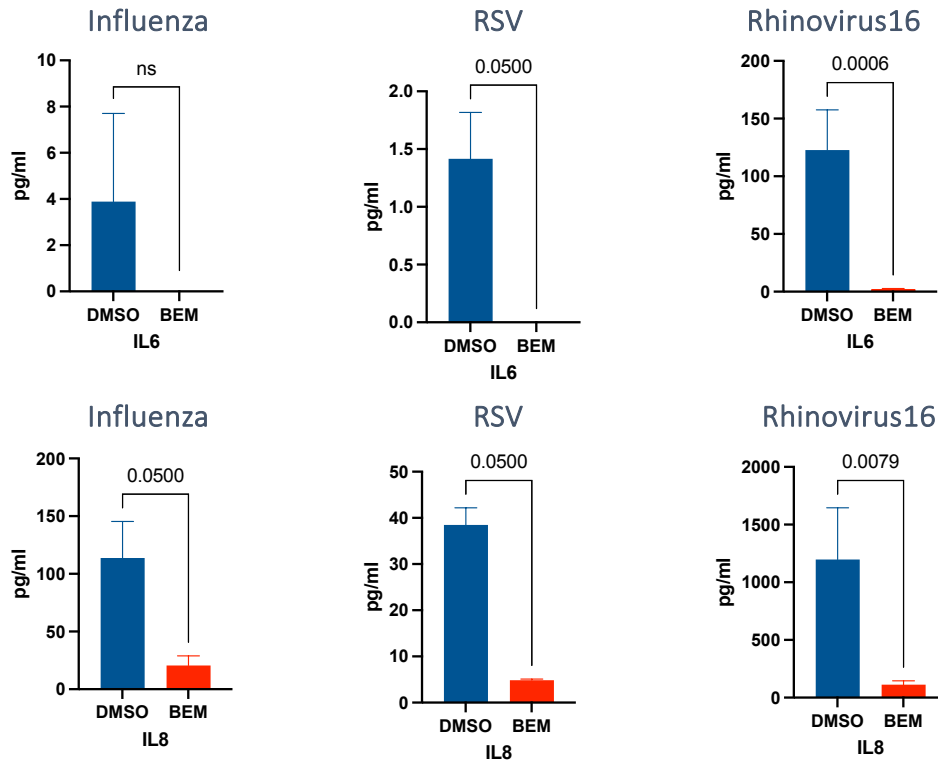
# Summary of AXL inhibition by bemcentinib in 1L STK11m NSCLC

- Growing MD awareness of need for STK11m treatment
- Extensive AXL expression in STK11m patients reflective of immune suppressed environment
- AXL expression is relevant on the immune cell and tumor cell
- Early evidence (PBMC) of immune activation induced by bemcentinib supporting the MoA
- Efficacy of bemcentinib validated in two Ph2 studies (chemo/CPI) in 2L NSCLC
- Monotherapy activity observed in difficult-to-treat patients
- Early intervention in 1L prior to development of resistance is expected to provide better efficacy
- Ongoing BGBC016 progressing in accordance with guidance allowing initiation of Ph2a in H1 2024

## **New data supports bemcentinib role in SRIs**

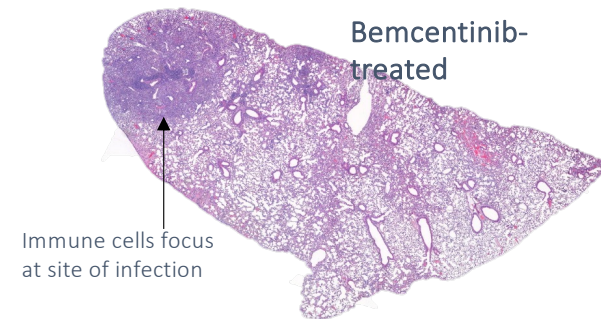
# Reduced cytokine induction limits lung tissue damage

*In vitro*

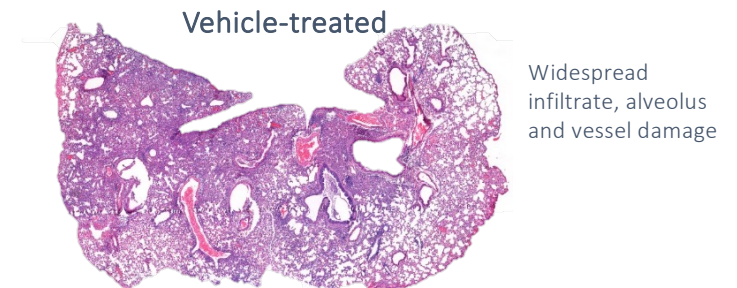


Bemcentinib prevents induction of inflammatory cytokines in bronchial epithelial cells infected by **influenza**, **respiratory syncytial virus** or **rhinovirus**

*In vivo*

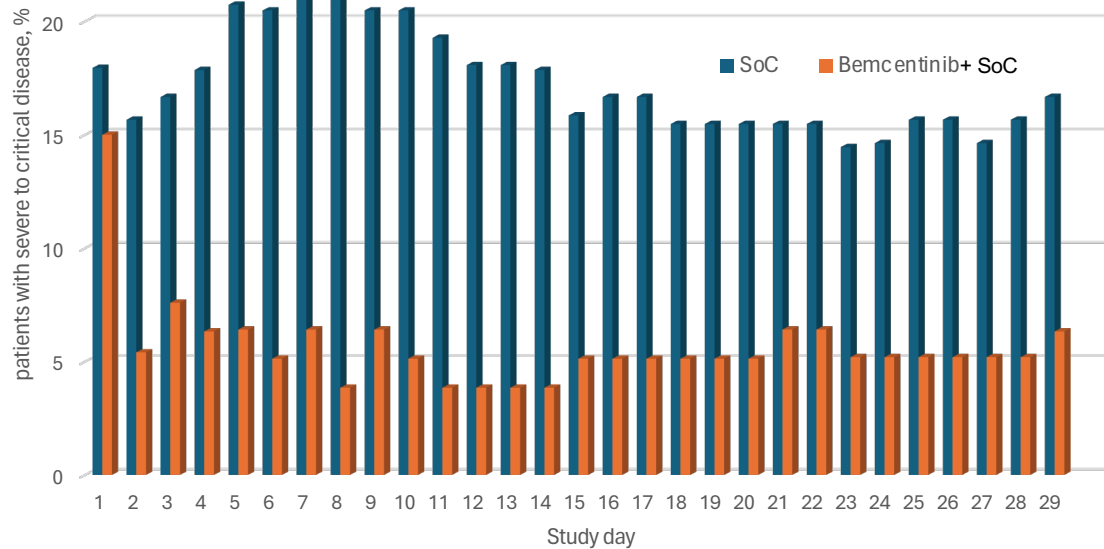


Bemcentinib limits infection-driven lung damage in influenza model, supporting tissue healing and repair



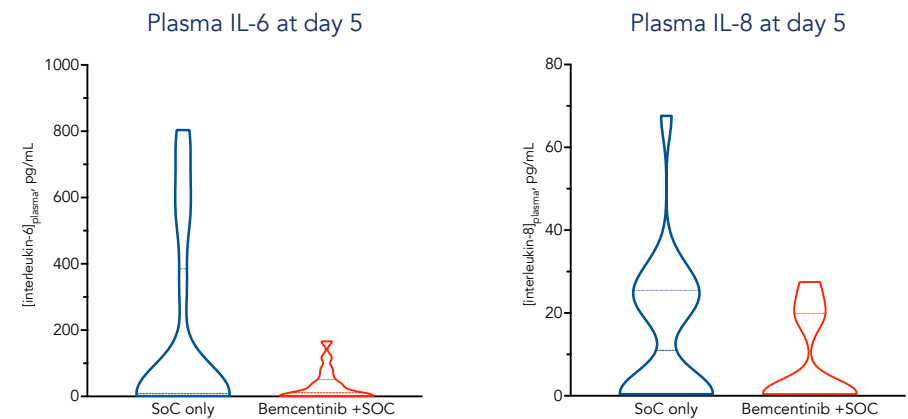
# Reduction in COVID-19 severity with bemcentinib

% of Pts with Severe Disease\* or Death  
Across Two Studies



\*Pts in studies BGBIL019 and BGBC020 requiring oxygen or non-invasive ventilation at baseline

Bemcentinib addition to SoC reduces  
cytokines associated with COVID19 disease  
severity



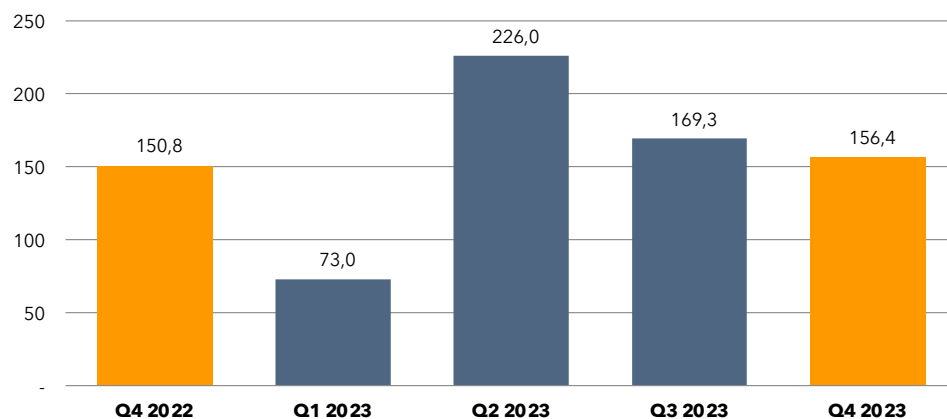
BGBIL019 ACCORD-2 study

## Key financials and newsflow

# Key financials Q4 2023

(NOK million)	Q4 2023	Q4 2022	FY 2023	FY 2022
Operating revenues	0.4	0.4	0.4	0.4
Operating expenses	43.9	76.8	192.2	306.0
Operating profit (-loss)	(43.5)	(76.4)	(191.8)	(305.6)
Profit (-loss) after tax	(41.6)	(77.2)	(190.4)	(302.1)
Basic and diluted earnings (loss) per share (NOK)	(0.02)	(0.87)	(0.13)	(3.41)
Net cash flow in the period	(11.8)	(75.6)	2.8	(282.1)
Cash position end of period	156.4	150.8	156.4	150.8

Cash position (million NOK)



## Focused strategy, cost saving initiatives have reduced cash use

- Net cash flow Q4 2023:  
NOK -11.8M/USD -1.1M
- Operational loss in Q4 2023:  
NOK 43.5M/USD 4.1M
- Stable cash use ~ NOK 40m /USD 4m per quarter expected to support on-going study
- Cash position end of 2023:  
NOK 156.4 million/USD 15.4 million  
Runway to end of 2024
- Warrant exercise April 2024 may extend runway – into 2H 2025

# Newsflow expected in 2024

Core Clinical Strategy	H1 2024	H2 2024
1L STK11m NSCLC	<ul style="list-style-type: none"><li>• Ph1b enrollment completion</li><li>• Initiation of Ph2a study in US &amp; EU</li><li>• Additional PBMC MoA data</li><li>• Establishment of synthetic control arm</li></ul>	<ul style="list-style-type: none"><li>• Interim analysis of Ph1b/2a data</li><li>• Publications at major medical meetings</li></ul>
Other Newsflow	H1 2024	H2 2024
	<ul style="list-style-type: none"><li>• Warrant exercise period (April 1-15, 2024)</li><li>• Additional SRI data presentations</li><li>• Potential new clinical trial(s) funded by 3<sup>rd</sup> parties</li><li>• Update on ADCT partnered mAb (ADCT-601)</li></ul>	<ul style="list-style-type: none"><li>• Update on tilvestamab out-licensing</li><li>• Manuscripts from completed studies published</li></ul>

# Clear focus to unlock significant value potential

- Focused approach in 1L STK11m NSCLC
- Ph1b enrolment completion and initiation of Ph2a in H1 2024
- Interim data from Phase 2a H2 2024 / H1 2025 to potentially unlock significant value
- Cash position end of 2023 NOK 156.4m - significantly reduced burn; runway through 2024
- Warrant element extends runway into H2 2025

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