
BerGenBio
A novel approach to address significant unmet medical needs in NSCLC
DNB Conference
December 14, 2023

Forward Looking Statements

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Laser focused on selective AXL inhibition to improve the outcome for NSCLC pts

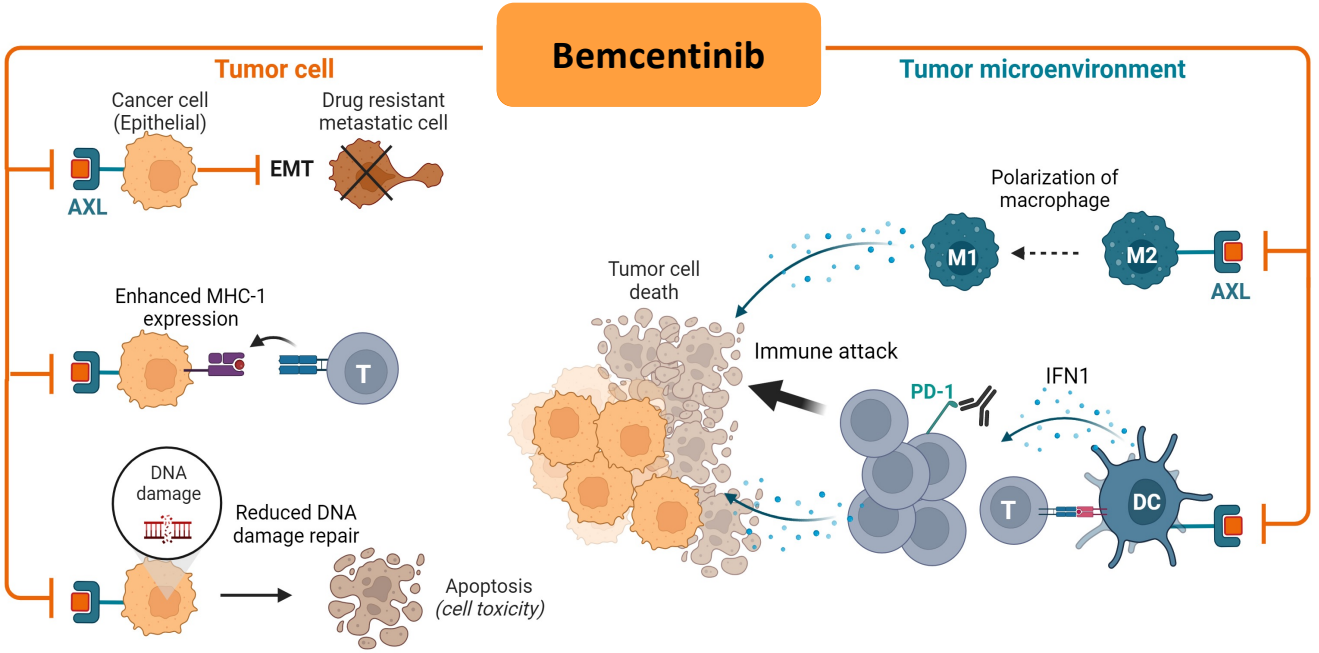
- ***Bemcentinib – our selective AXL inhibitor:*** demonstrated improved survival vs. expected outcome from current therapies in 2L NSCLC, particularly in:
    - AXL+ patients (the majority of pts studied)
    - Patients with low/negative PDL1 levels
    - Patients with difficult to treat mutations for which there are no targeted therapies today
- A strong dataset guides our focus on 1L STK11m NSCLC - a significant market opportunity with high unmet medical needs
- Potential upside from additional indications and out-licensed/earlier programs
- Current cash + potential proceeds from outstanding warrants provides runway into H2 2025 enabling key readouts from ongoing Phase 1b/2a trial in 1L STK11m NSCLC

AXL inhibition with bemcentinib sensitizes both the tumor and immune environment

Reduces immune evasion, drug resistance

Enhances antigen presentation

Reduces DNA damage repair



Reactivates innate immunity

Unique dual role of AXL inhibition expected to delay chemoresistance and improve checkpoint response in 1L NSCLC

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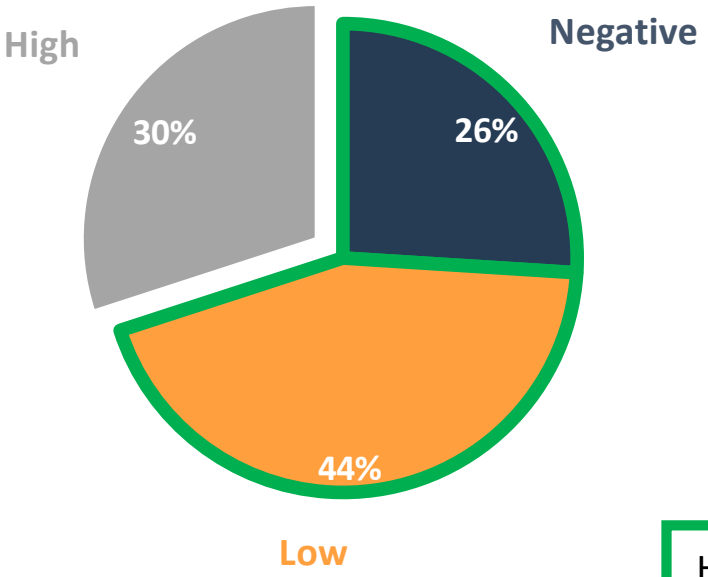
Bemcentinib: Differentiated AXL tyrosine kinase inhibitor

- High selectivity: precedent setting
- Improved potency: few off-target adverse events
- Concentrates in lung (40x) ; crosses BBB – brain mets common in NSCLC
- Monotherapy and combination activity seen in multiple indications
- Proven combinations: chemotherapy, targeted therapies and CPI*
- Fast Track Designation (FDA) in STK11m NSCLC
- Extensive IP through 2042

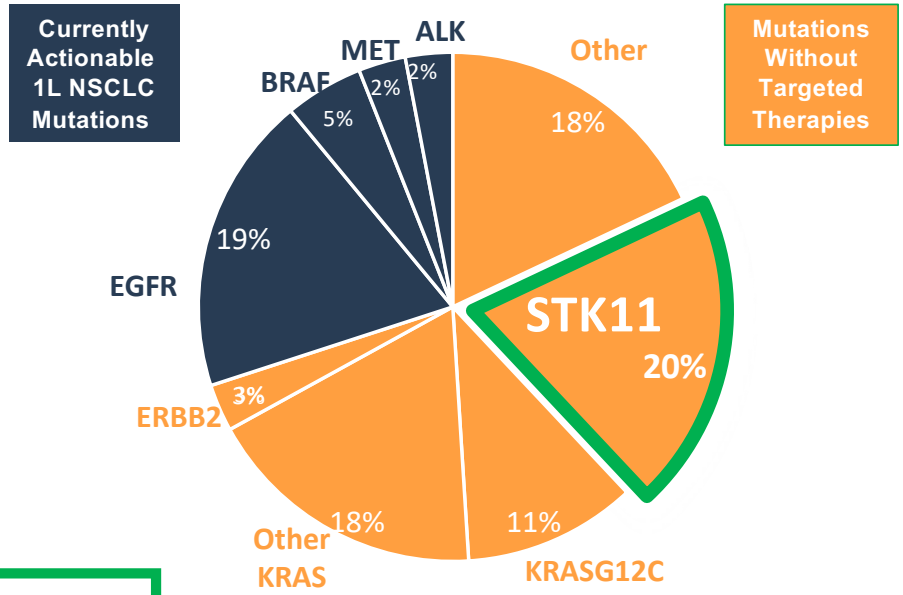
*Checkpoint inhibitors

1L NSCLC therapy today guided by molecular markers

1. PDL1 levels predict response to Immunotherapy



2. Mutational status predicts response to Targeted Therapies



Highest unmet needs

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Source: Holmes, 2019, JTO; TPS Scores Neg = <1; Low 1-49; High >50

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

~30,000 1L STK11m NSCLC pts in US/EU respond poorly to current therapies

A vast amount of data indicate poor prognosis in STK11m NSCLC

	Real World Data n = 707 Outcomes w/ 1L CPI + chemo		
	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

…and many factors support potential for bemcentinib in this population

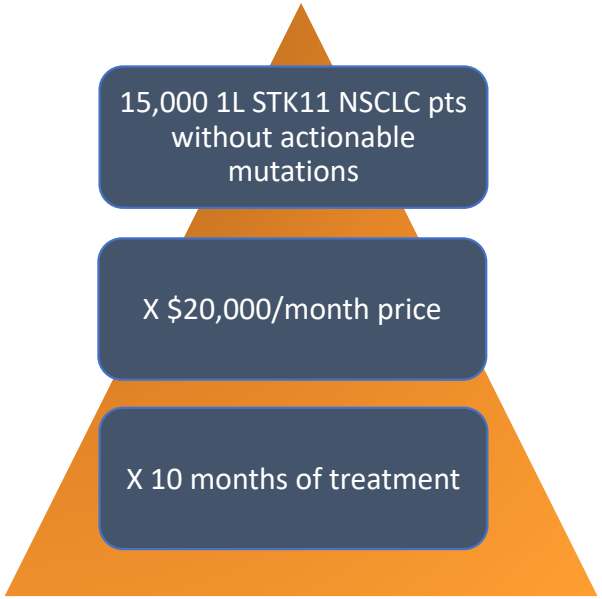
- No targeted therapies available today or in development
- STK11m pts "universally"* express AXL
- AXL inhibition improves response to checkpoint inhibition in preclinical models
- Early indications of clinical benefit of AXL inhibition in STK11m NSCLC

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

*Based on BGB data indicating at least 88% of patients express AXL in their tumors or on immune cells

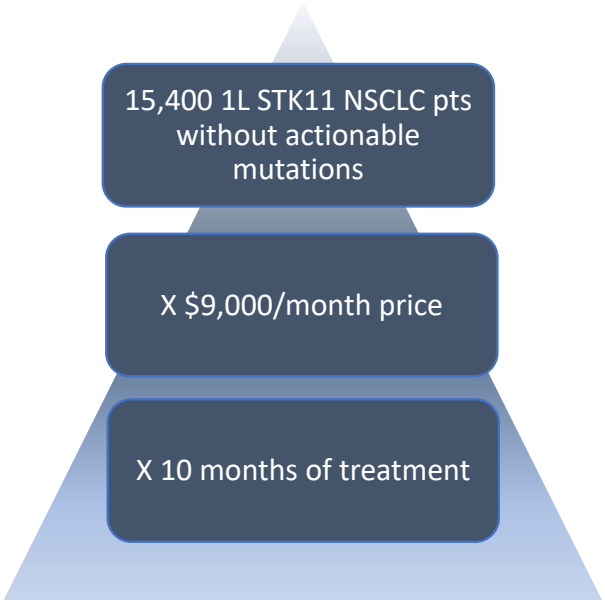
Translating into a significant potential for an effective 1L STK11m NSCLC treatment

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

BGB was one of the first to identify STK11m NSCLC as a new drug development frontier

Candidate/Company/Target	Current Phase*	Specific to 1L?	Specific to STK11m pts?	Comments
BGB/bemcentinib/AXL	**Ph 1b/2a**	✓	✓	**Entire STK11m population**
AZ/anti-PD1/CTLA4	Ph 3b	✓	✓	Also KEAP-1, KRASm
Mirati/adagrasib/KRASG12C	Ph 2	✓	No	KRASG12C+STK11m
Amgen/sotorasib/KRASG12C	Ph2	✓	No	KRASG12C+STK11m
Novartis/JDQ443/KRASG12C	Ph2	✓	No	KRASG12C+STK11m
JacoBio/KRASG12C	Ph 1/2	2L	No	KRASG12C+STK11m
Regeneron/anti-IL6R + PD1	Ph 1b	1L – 4L	✓	STK11m or EGFRm
Tango/coREST inhibitor + PD1	Ph 1/2	2L	✓	STK11m
Arcus / AXL inhibitor/AB-801	Ph1/1b	2L	No	Multiple solid tumors, STK11m expansion

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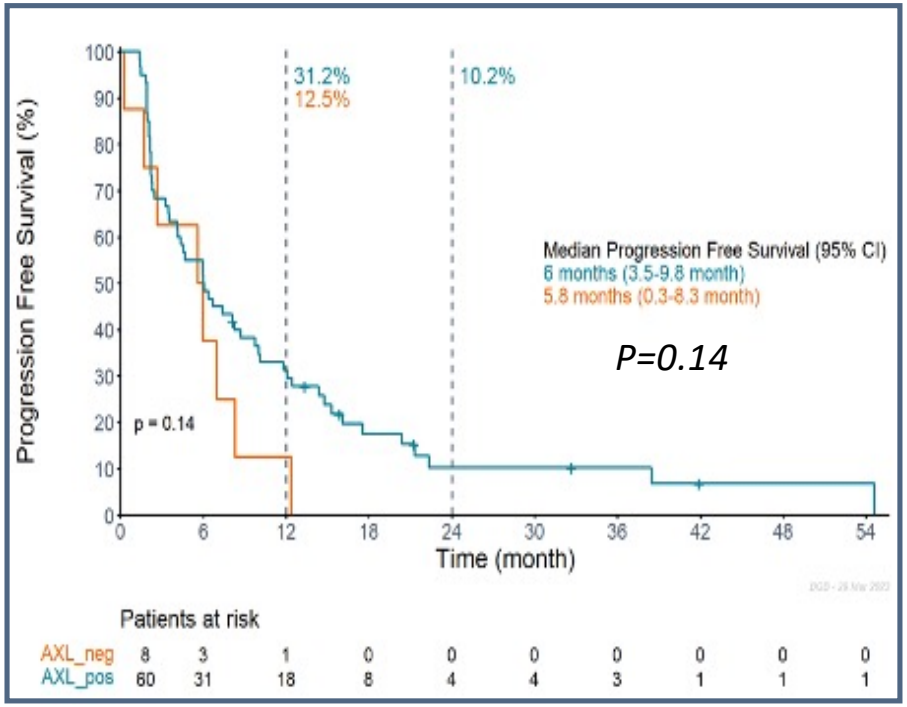
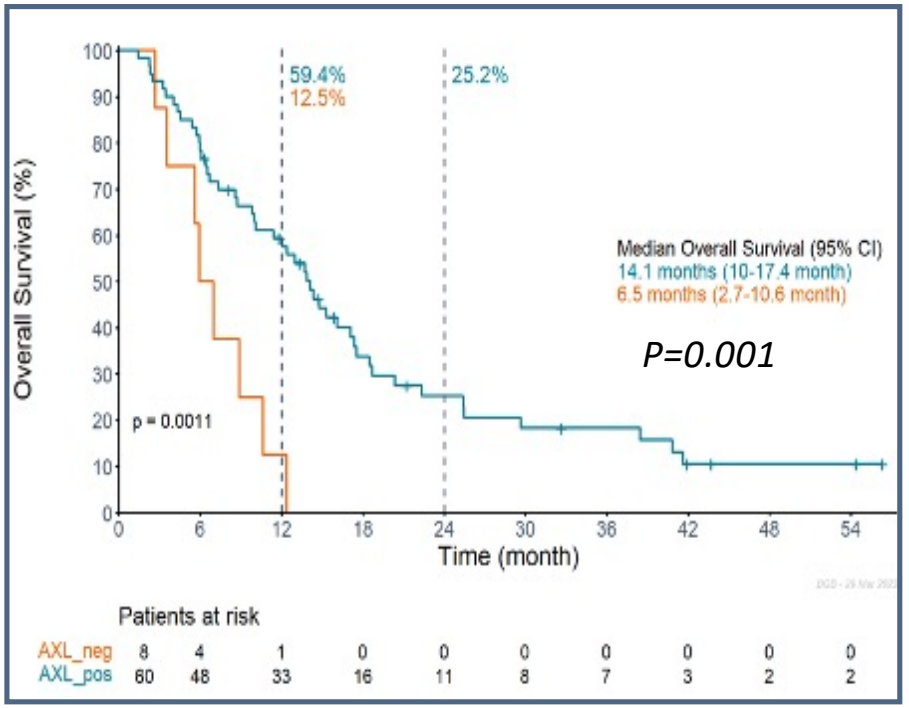
Sources: clinicaltrials.gov, EU clinical trials register, company websites
Note: does not include Investigator Sponsored Trials

BGBC008 (2L+NSCLC) bem. + pembrolizumab 88% AXL+ live significantly longer

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

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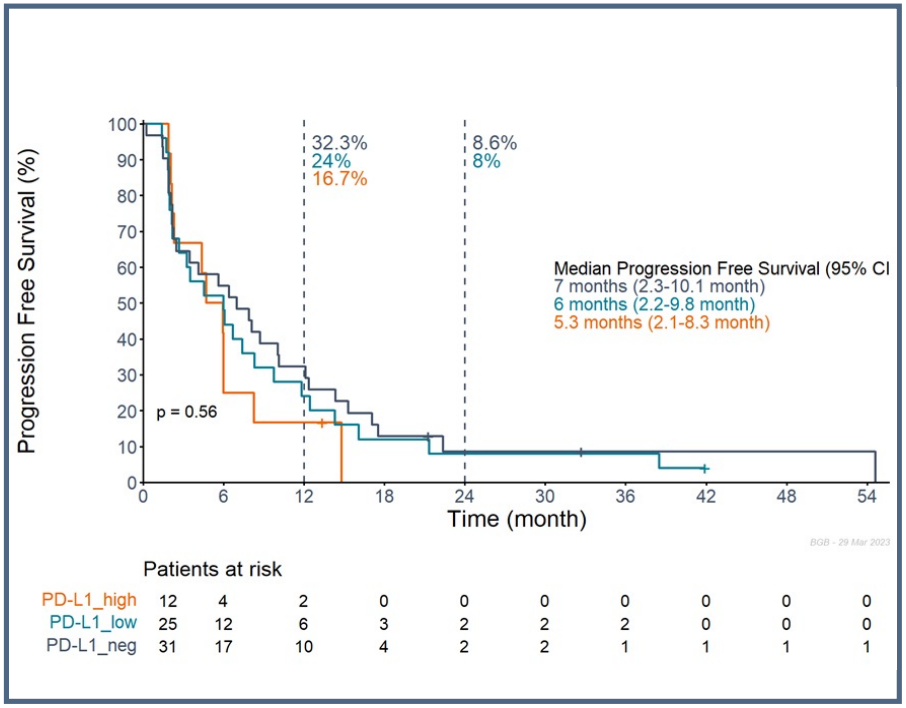
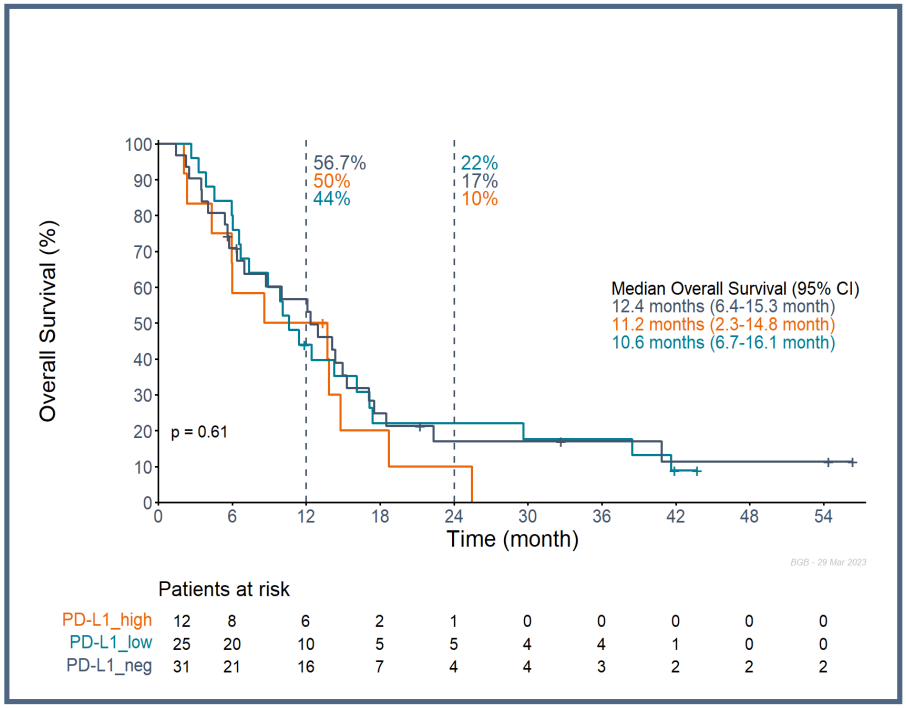
Benefit even in neg/low PD-L1 pts who typically respond less well

Median progression free survival



Median overall survival



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

BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

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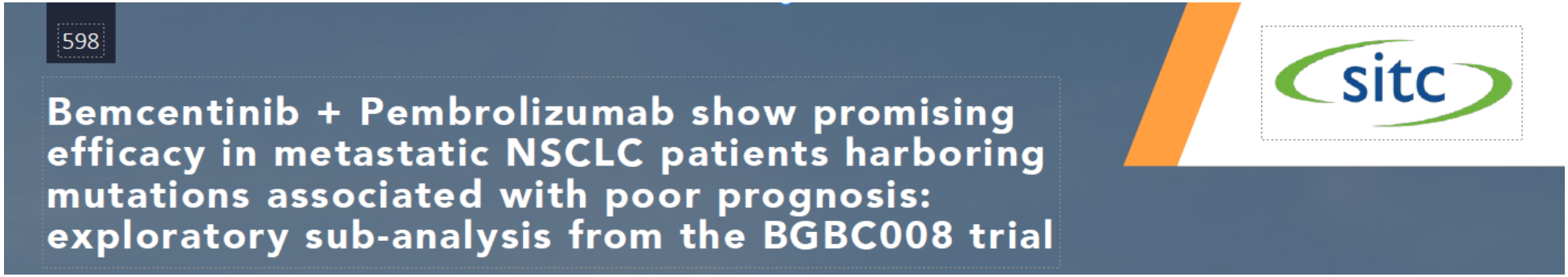
Recent SITC poster illustrates activity in difficult-to-treat mutations



Poster analyzed:

- BGBC008 results in 2L NSCLC vs.
- 2L NSCLC outcomes from Memorial Sloan Kettering MIND real-world database

Poster conclusions:

- Bemcentinib + pembrolizumab appears to eliminate liability of known poor responses to:
  - STK11m, KEAP1m, low/negative PD-L1 levels
- ~ Equal survival benefits vs. patients without these poor prognostic characteristics

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Recent ESMO data supports favorable BGBC008 survival vs. existing 2L NSCLC therapies

	BGBC008		2L Comparators	
	All Comers	AXL Positive*	KEYNOTE 189	SAPPHIRE
	Bemcentinib + Pembrolizumab	***Bemcentinib + Pembrolizumab***	***Pembrolizumab Monotherapy***	***Docetaxel following CIT***
ORR	**11.1%**	**16.4%**	**18%**	**17%**
mPFS, mos	**6.2**	**6.1**	**2.8**	**5.4**
mOS, mos	**13.0**	**14.1**	**6.9**	**10.6**

SAPPHIRE STUDY: New, highly relevant comparative data

- Prior to this, a lack of published data on 2L docetaxel (current SOC) after 1L I/O + chemo
- Docetaxel control arm after 1L I/O + chemo provides contemporary comparison supporting improved survival of bemcentinib + pembro vs. SOC

*AXL Positive = AXL H-score >5 in tumor &/or >1 in immune cells;
SOC= standard of care

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

	Bemcentinib 400mg Loading + 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: no loading dose + 100-150mg/qd with food

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

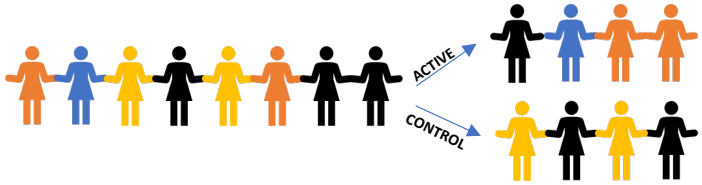
On-going global 1L STK11m NSCLC Ph1b/2a

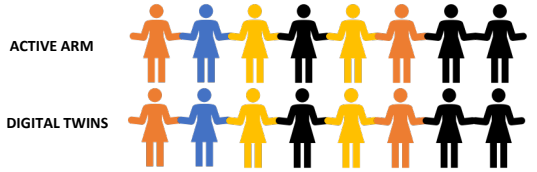
Open label study of bemcentinib + SoC (pembrolizumab + doublet chemo)

Phase 1b Safety & Feasibility (US) 3+3 design Dose escalation (75, 100 & 150 mg) N=9-30	Phase 2a (US & EU) Expansion of 2 dose(s) in STK11m pts N=40+
1L Advanced/ Metastatic **Non-Squamous NSCLC pts** Newly diagnosed, Any PDL1 status, no actionable mutations STK11 or AXL status not required	**40 pts. 1L Advanced/ Metastatic** **Non-Squamous STK11m NSCLC pts**
All comers to accelerate enrollment	vs. synthetic control arm ; pts with identical characteristics, mutational status

- US sites activated ; new European sites identified and coming on-line for Ph2a
- 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 may not be required as prospective biomarker given almost universal expression in STK11m pts

Benefits of a synthetic control arm in BGBC016





Traditional Control Arms

What: patients randomized at study entry to receive either active drug + SOC vs. placebo vs. SOC

Considerations for BGBC016:

- The regimen for bem + SOC vs SOC to be established before conducting a randomized study
- Balancing arms for STK11m co-mutational would require more time, patients, cost

Synthetic Control Arm

What: state-of-the-art outcomes database matches patients with same mutational/disease status profiles, creating **"digital twins"** for comparison

Benefits for BGBC016:

- Improved validation of activity in active arm and positioning for pivotal trial

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Bemcentinib: a unique opportunity in 1L NSCLC STK11m

High unmet medical need

- Common non-actionable mutation (> 30,000 patients in US and EU5); poor prognosis representing a significant commercial opportunity
- No available targeted therapies; limitations of SOC

High incidence of AXL expression which can be targeted by bemcentinib

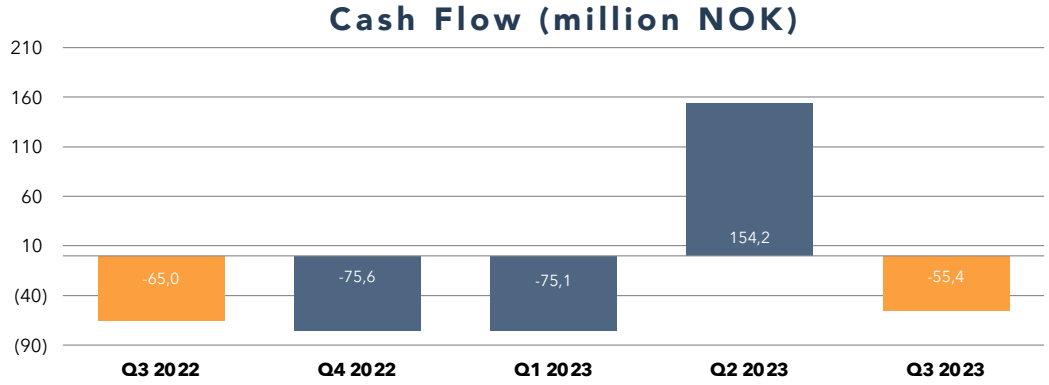
- A highly immunosuppressed and "toxic" tumor microenvironment
  - AXL expressed ~88% of patients
- AXL inhibition shown to delay chemo resistance and reactivate the anti-tumor immune response
- Strong proprietary position in STK11^{mut} NSCLC

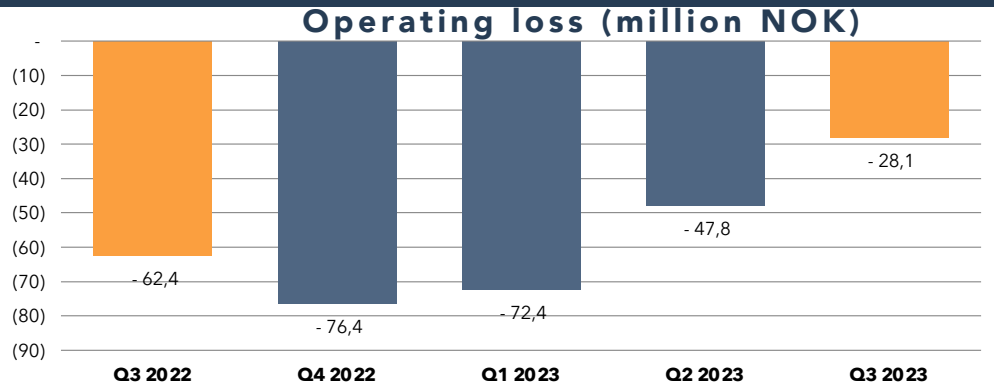
Confidence in 1L NSCLC benefit based on data in ~100 2L NSCLC

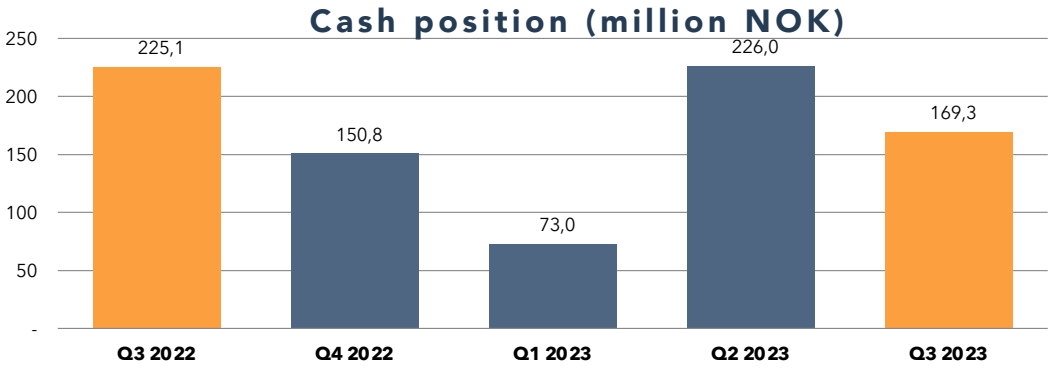
News flow expected in 2023/2024

Core Clinical Strategy	H1 2023	H2 2023 / H1 2024
1L STK11m NSCLC	✓ FPFV and additional sites activated for Ph1b/2a ✓ STK11 loss data presented at AACR ✓ Promising biomarker data from 2L study supports potential expansion of 1L NSCLC patient populations	• Ph1b data and selection of Ph2a doses • Initiation of Ph2a ✓ Additional MoA data from BGBC008 at SITC ✓ Final results from BGBC008 at ESMO 2023 • Data presentations at major oncology conferences (AACR, others)
Other News Flow	**H1 2023**	**H2 2023 / H1 2024**
	✓ Positive AML/MDS data (BGBC003) reported ✓ Data in mesothelioma presented at ASCO – primary end-point met ✓ Manuscript published by MD Anderson collaborator re: bem + docetaxel in 2L NSCLC ✓ (Bhalla et al. Lung Cancer 2023)	✓ BGBC003 final data to be presented at ASH 2023 • Clinical trial manuscript publications in major journals; presentations at oncology meetings (ASH, others)

Key financials Q3 2023







Operating loss Q3 2023
- 28.1 NOK million / - 2.7 USD million

Net cash flow Q3 2023
- 55.4 NOK million / - 5.3 USD million

Quarterly average operating cash burn (Q3 2022 – Q3 2023)
- 67.5 NOK million / - 6.5 USD million

Cash position Q3 2023
169.3 NOK million / 15.9 USD million

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April 2024 warrant window

- Rights Issue in June 2023 contained warrant component with final exercise window April 1-15, 2024
- Warrants are listed on Oslo Stock Exchange (ticker: BGBIS)
- Warrant component can provide additional funding to extend our runway into H2 2025 and allow announcement of key data from the BGBC016 trial and define next steps towards a registration trial

BerGenBio

Address
Mollendalsbakken 9, 5867 Bergen, Norway

Phone Number
+ 47 559 61 159

E-mail
post@bergenbio.com