

3rd Quarter Report 2022



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

Forward Looking Statements

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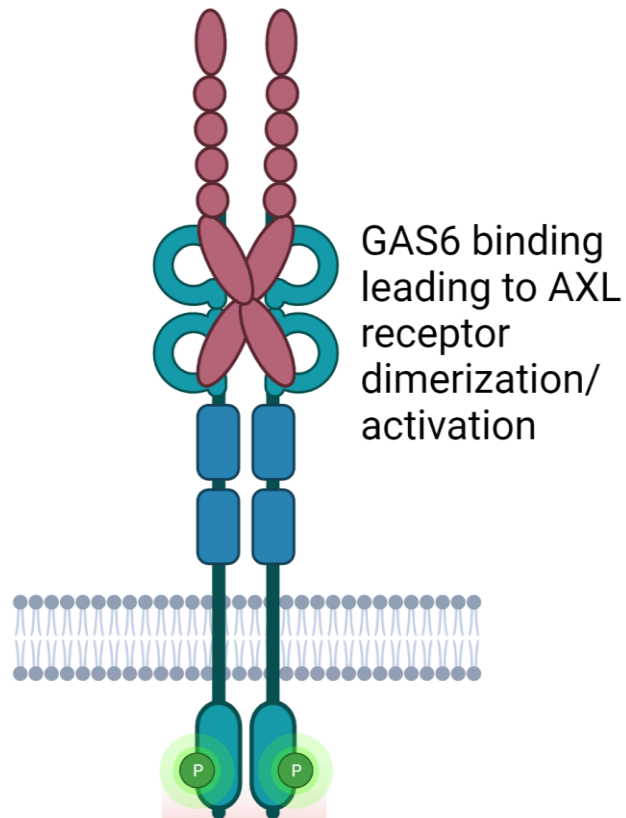
About BerGenBio

- Focused entirely on the development of **selective AXL inhibitors** for the treatment of aggressive diseases
- Lead compound **Bemcentinib** is an oral, potent and **highly selective inhibitor** of the receptor tyrosine kinase AXL
- **Bemcentinib** has been administered in more than 600 patients and is currently being advanced in two significant opportunities:
 - **1st line NSCLC STK11m - Ph 1b/2a**
 - **Hospitalized COVID-19 - Ph 2b**
- Laser-focused to **deliver clear value drivers** within next 12-18 months

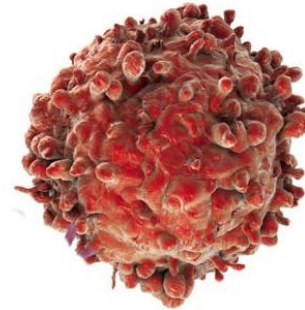
Recent Highlights

- ✓ **First patient dosed in COVID-19 Phase 2b trial conducted under the EU-SolidAct platform enrolling up to 500 hospitalized COVID-19 patients in Europe**
- ✓ **Initiated Phase 1b/2a trial evaluating bemcentinib in combination with standard of care (CPI + chemotherapy) in 1st line NSCLC patients harboring STK11 mutations. STK11 mutations occur in up to 20% of NSCLC patients and result in inferior survival outcomes with the current standard of care**
- ✓ **Ended period with NOK 225 million in cash and announced (post period) NOK 100 million loan facility from our largest shareholder, Meteva, enabling the execution of announced focused strategy within two significant opportunities: 1st line NSCLC STK11m and hospitalized COVID-19 patients**
- ✓ **BGBC003 (relapsed / refractory AML) had last patient last visit and BGBC008 (2L NSCLC) had last patient last visit in Q4 2022 allowing database lock and data analysis of both trials. Results to be reported in first part of H1 2023**
- ✓ **Partnership outreach for our AXL mAb tilvestamab initiated**

AXL activation results in several deleterious effects in both cancer and severe respiratory infections



CANCER






Invasion/Migration
Drug resistance
Proliferation
Survival
Immune suppression

RESPIRATORY



Viral entry, migration
Immune suppression
ECM production
Basal cell proliferation
Reduced cytokine signaling

BerGenBio Clinical Pipeline

	Candidate	Targeted Indication	Preclinical	Phase I	Phase II	Partner	
Oncology	Bemcentinib	1L STK11m NSCLC	[Progress bar in Phase I]				
	Bemcentinib	2L NSCLC	[Progress bar in Phase I]				
	Bemcentinib	R/R AML	[Progress bar in Phase I]				
	Mipasetamab uzoptirine	Solid Tumors	[Progress bar in Phase I]			Fully out-licensed mAb	
Viral	Bemcentinib	COVID-19	[Progress bar in Phase I]				
Fibrosis	Tilvestamab	Biomarker study in ovarian cancer	[Progress bar in Phase I]				

Note: Bemcentinib is also being studied in Investigator Led Trials in glioblastoma, 2L lung cancer, melanoma, pancreatic cancer and mesothelioma;

STK11 mutated Non-Small Cell Lung Cancer (STK11m NSCLC)

**Bemcentinib is well-positioned to
address a significant unmet medical need**

Bemcentinib in 1L STK11m NSCLC

A unique opportunity in a significant market with high unmet medical need

Data from our 2L NSCLC trials supports benefits of AXL inhibition with bemcentinib

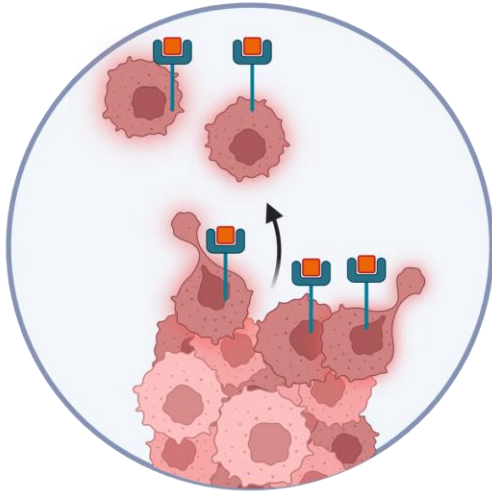
- **BGBIL005: Improved efficacy in combination with docetaxel** - demonstrates the potential for the delay of chemoresistance
- **BGBC008*: Improved efficacy in pts with overexpressed / activated AXL** - showing PFS and OS outcomes similar to 1L patients – demonstrating the importance of AXL as a driver of disease progression

... and supporting data identify a significant unmet market – 1L STK11m NSCLC

- 1L STK11m NSCLC shows inferior survival outcomes on today's SOC
- Data suggests that **1L STK11m pts almost universally have AXL overexpression/activation**
- **STK11m patients are characterized by: severely immuno-suppressed tumor environment**, high levels of ROS, EMT and oxidative stress, resulting in poor prognosis
- Early retrospective **clinical data (BGBC008*) support benefit in STK11m patients**

*immature dataset; final data expected H1 2023

Clinical trials substantiate the relevance of key mechanisms in AXL inhibition by bemcentinib in NSCLC

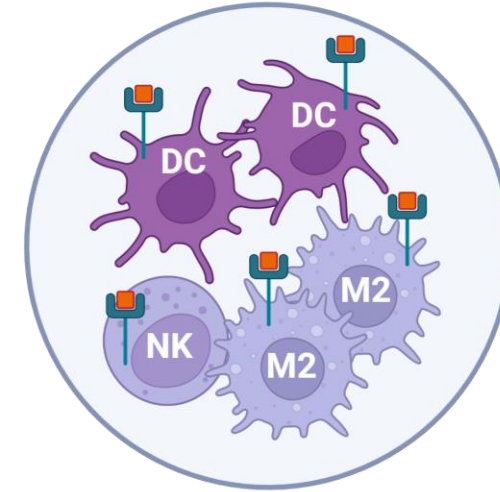


BGBIL005 2L+ NSCLC

Reversal of cancer cell survival and escape

Completed Ph2 study bemcentinib + docetaxel in 2L+ NSCLC

Anti-tumor activity in previously treated, advanced NSCLC
Reported 35% PR and 47% SD rates



BGBC008 2L NSCLC

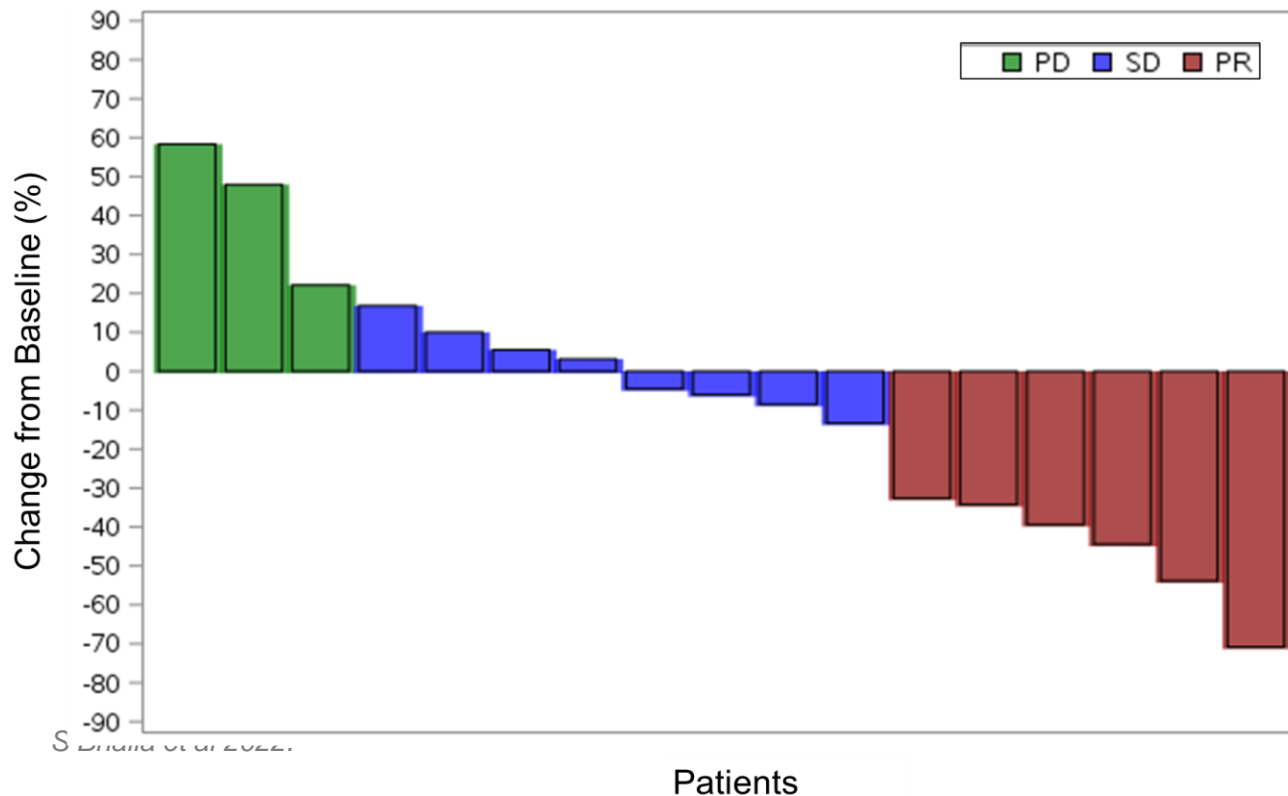
Improved innate immune response

On-going (fully enrolled) Ph2 study bemcentinib + pembrolizumab in 2L NSCLC

Immature data indicates PFS & OS benefits in AXL+ pts in 2L NSCLC

2L and beyond NSCLC (BGBIL005): bemcentinib + docetaxel compares favorably vs. historical docetaxel data

Best RECIST Response

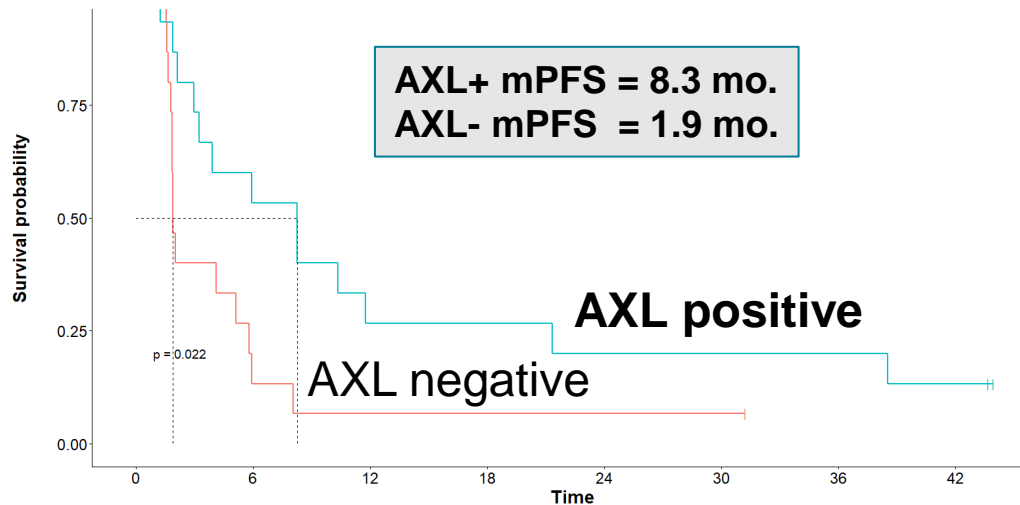


S Bhalla et al ; ASCO 2022

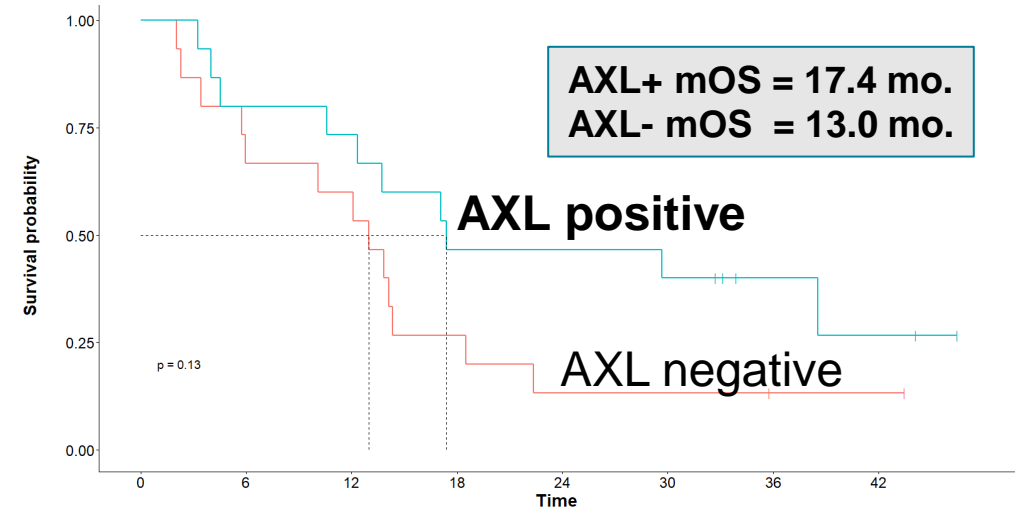
- Overall response rate (ORR) of 35% compared to docetaxel (6-8%)*
- 47% of patients had stable disease as the best radiographic response
- Most common TRAEs: neutropenia, diarrhea, fatigue and nausea; non-hematological grade ≥ 3 toxicities were rare

2L NSCLC (BGBC008): bemcentinib + pembrolizumab in AXL+ (50%) pts show benefit ~ equal to 1L NSCLC pts

Progression Free Survival
30 evaluable pts. (AXL status)



Overall Survival
30 evaluable pts. (AXL status)



End-point	2L Bem + pembro 2L (AXL+)	1L pembro + chemo Keynote-189*
PFS, mos.	8.3	9.0
OS, mos.	17.4	22.0

Note: immature data, study on-going

*Source: Merck press release September 2022

AXL activation reduces apoptosis and promotes an immune suppressed microenvironment

Cancer cell survival and escape

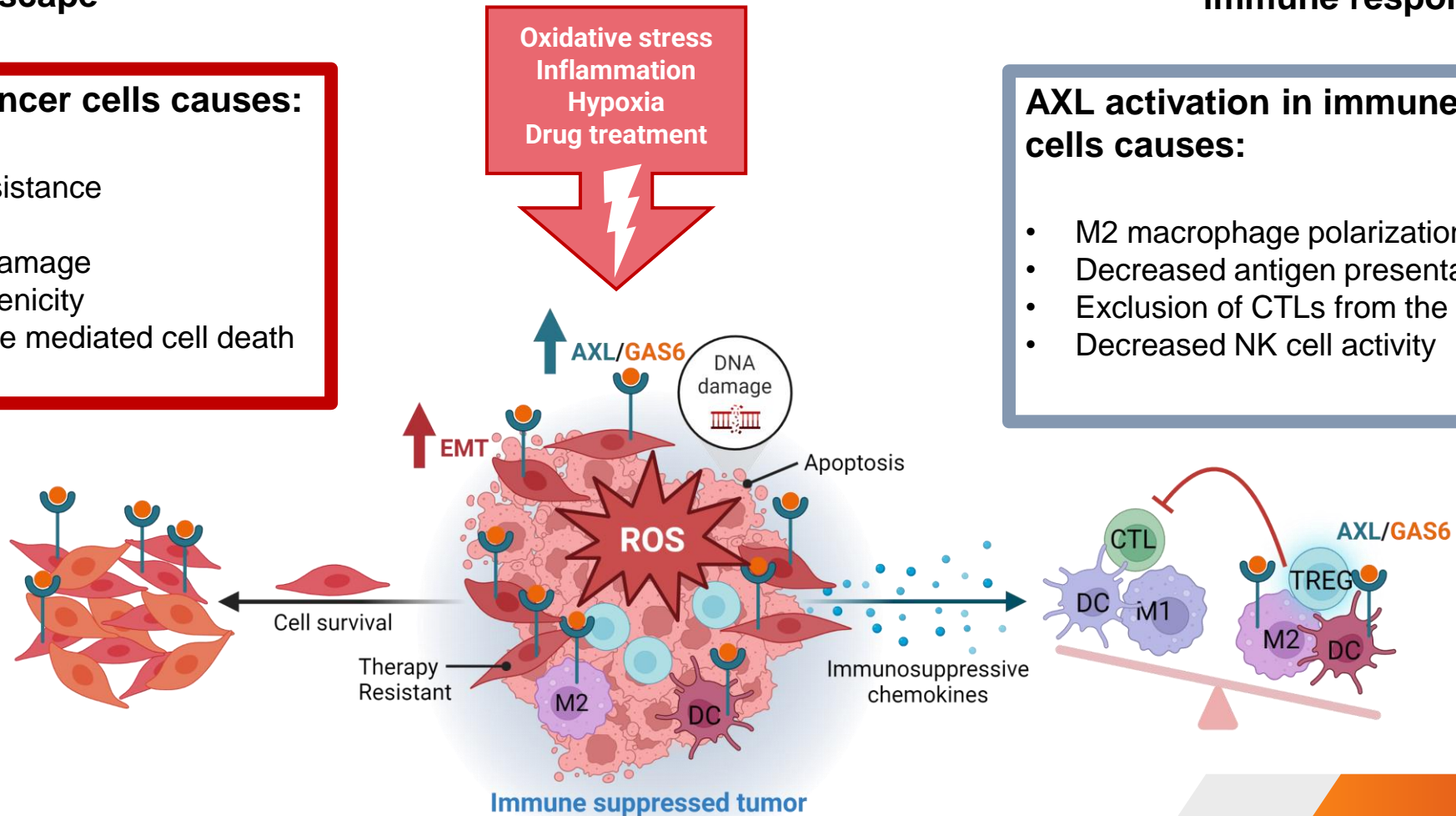
AXL activation in cancer cells causes:

- Survival and drug resistance
- EMT and Metastasis
- Resistance to DNA damage
- Decreased immunogenicity
- Resistance to immune mediated cell death

Suppression of innate immune response

AXL activation in immune suppressive cells causes:

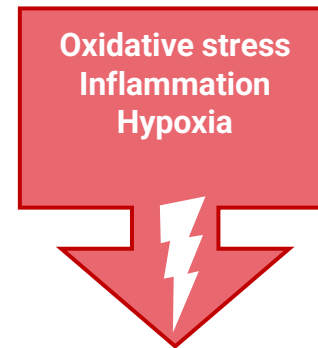
- M2 macrophage polarization
- Decreased antigen presentation by DCs
- Exclusion of CTLs from the tumor
- Decreased NK cell activity



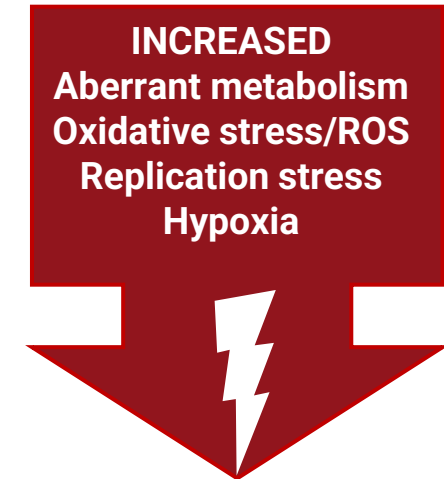
STK11m causes high oxidative stress, hypoxia, inflammation – resulting in almost universal AXL expression / activation

- Low AXL expression / activation under healthy physiological conditions and becomes 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)
- STK11m have phenotypic characteristics (high cellular stress and immune evasion) known to drive increased levels of AXL expression and activation

Non STK11m Tumor



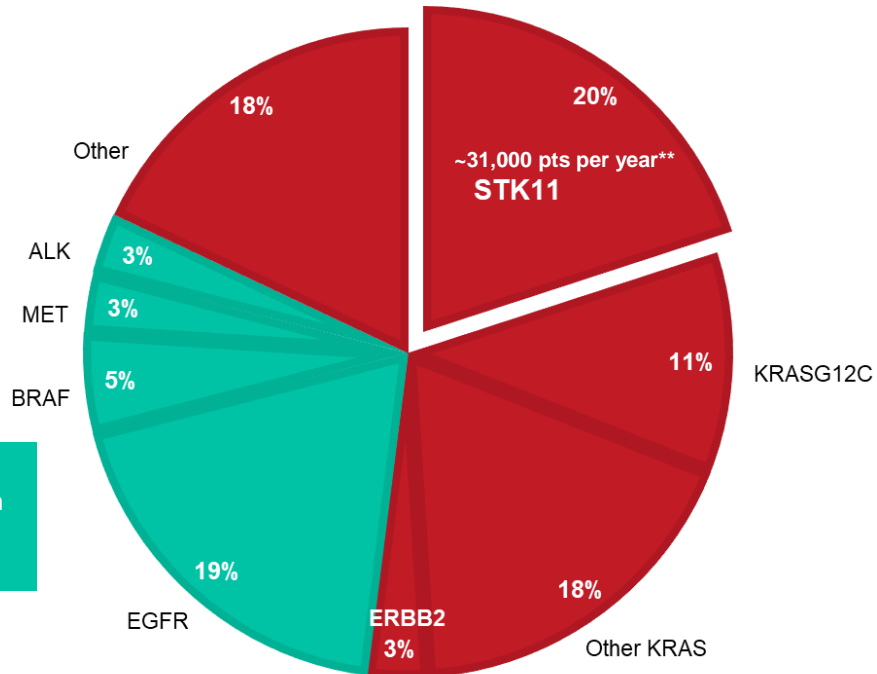
STK11m Tumor



AXL expression and activation

STK11m NSCLC a significant unmet medical need ...

STK11m - The most common “non-actionable” mutation*



Currently result in poor prognosis with anti-PD-1/L1 + chemo SOC

- ❖ Lower response rate
- ❖ Shorter overall survival and PFS
- ❖ Reduced response to current chemo and immunotherapy
- ❖ No targeted therapy currently available

Actionable 1L NSCLC mutations with currently approved therapeutics

* 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

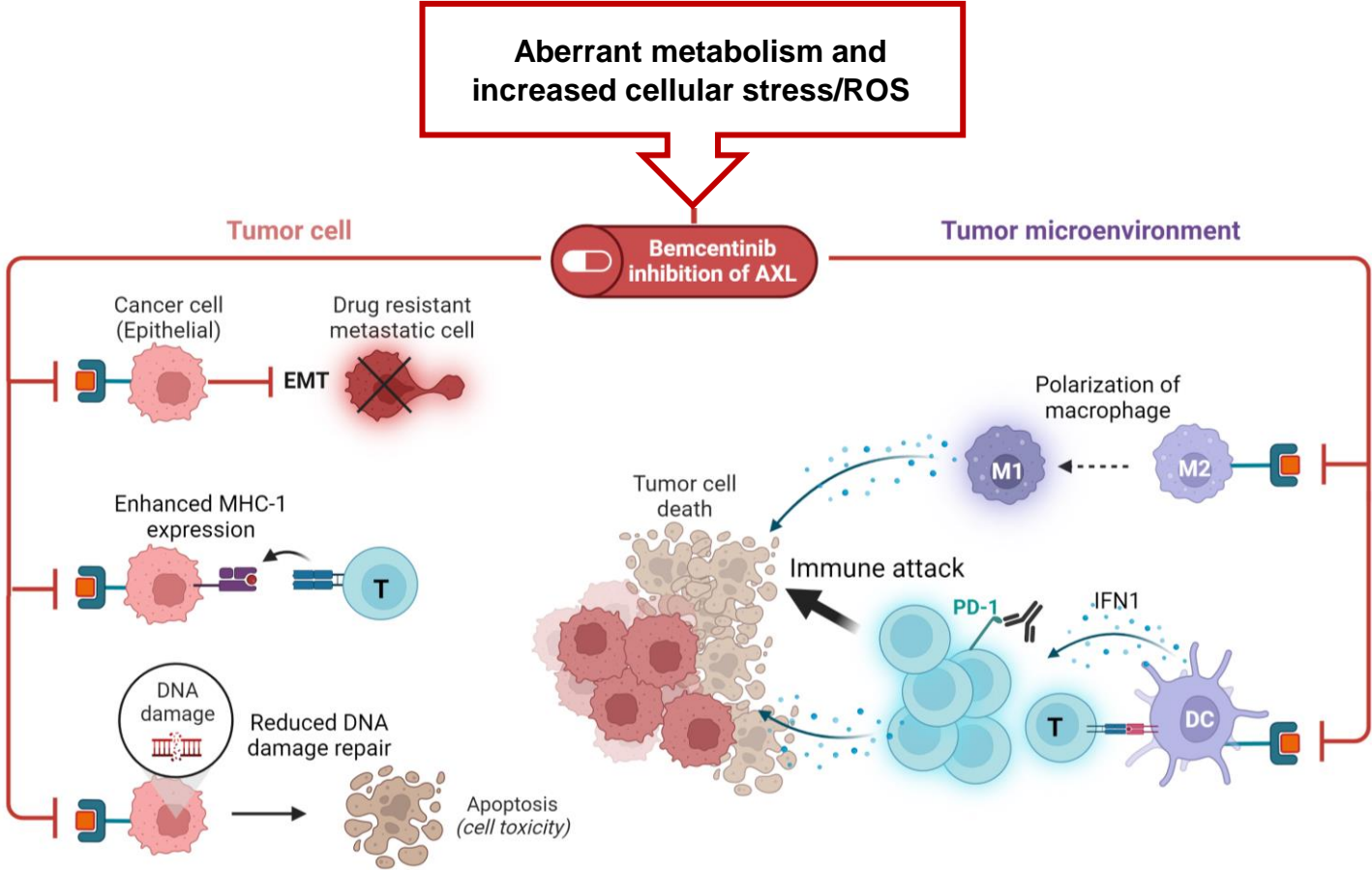
** Source: Global Data estimate in US, UK, Fr, Gr, Sp, It

... which can be targeted by bemcentinib to potentiate current SOC efficacy in STK11m NSCLC

Reduces EMT driven immune evasion, drug resistance

Enhances antigen presentation (MHC-1)

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

Bemcentinib has no significant safety issues vs. other relevant therapies

Existing 200mg/daily bemcentinib dose is ~ 2x the expected Ph2 dose

	Bemcentinib + pembrolizumab 200mg fixed	Pembrolizumab Monotherapy* 200mg fixed	Sotorasib monotherapy	Adagrasib monotherapy
Population	2L	1L	2L KRASG12C	2L KRASG12C
Dose Modifications				
Discontinuation rate	7%	9%	7%	7%
Dose reduction	14%	NR**	22%	52%
Dose interruption	25%	NR**	NR**	61%
Top TRAEs , all grades				
Diarrhea	39%	12%	32%	63%
Decreased appetite	30%	17%	NR	24%
AST increase	29%	31%	15%	25%
ALT increase	29%	33%	15%	28%
Blood creat. Incr.	29%	NR	NR	26%
Nausea	22%	12%	19%	62%
Vomiting	16%	13%	8%	47%

Significant “white space” to pursue broader 1L STK11m NSCLC population

- No known competitors studying broad STK11m NSCLC population
- KRASG12Cm inhibitors only target 20% of the STK11m population

Prospective Clinical Studies with STK11m Enrollment Requirement

Compound	Company	MoA	Population	Status
Sotorasib (LUMAKRAS) NCT04933695	Amgen	KRAS G12Cm inhibitor monotherapy	1L KRASG12C + STK11m co-mutated NSCLC	Have announced that they will be relooking at their strategy in 1L due to safety concerns
Adagrasib monotherapy NCT03785249	Mirati	KRAS G12Cm inhibitor monotherapy	1L KRASG12C + STK11m co-mutated NSCLC	Ph2
JAB21822 NCT05276726	Jacobio	KRAS G12Cm Inhibitor monotherapy	1L KRASG12C + STK11m/KEAP-1 WT	Ph1/2

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>1L Advanced/ Metastatic Non-Squamous NSCLC pts</p> <p>Newly diagnosed, Any PDL1 status, no actionable mutations STK11 or AXL status not required</p> <p>Traditional 3+ 3 design</p>	<p>1L Advanced/ Metastatic Non-Squamous STK11m NSCLC pts</p>
<p>Endpoints</p> <p>Primary: Safety/ Tolerability (DLT) Secondary: ORR, DCR, DOR, OS</p>	<p>Endpoints</p> <p>Primary: ORR Secondary: Safety, DOR, DCR, PFS, Time to Progression, OS, PK exposure</p>

- **Initiated Ph1b and planning for first patient in Q4 2022 (in all comers)**
- **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**

Hospitalized COVID-19

Bemcentinib offers a novel approach to effectively treat hospitalized COVID-19 patients



BerGenBio

Bemcentinib is a promising treatment modality in hospitalized COVID-19 in an evolving market

- Strong package of preclinical and clinical data supports bemcentinib's unique triple MoA's in severe respiratory diseases including COVID-19:
 - **Prevention of viral entry**
 - **Increased immune response to virus**
 - **Ability to repair lung tissue damage**
- Preclinical data points to "universal" efficacy regardless of SARS-CoV variant and in other severe respiratory diseases
- Two prior bemcentinib COVID-19 Ph2 studies show trends towards improved survival, delay of disease progression
- Recent events with potentially competitive hospitalized COVID-19 product candidates are supportive of BGB's approach to generate a robust dataset in the 500-patient hospitalized COVID-19 EUSolidAct study initiated in Q3 2022

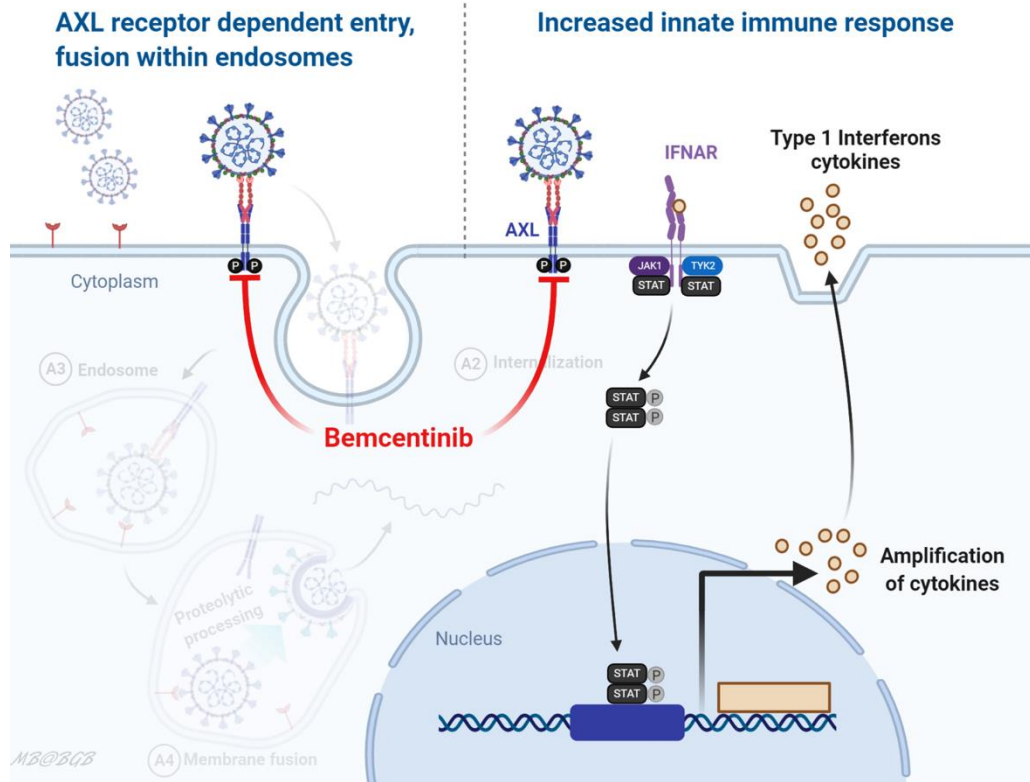
Unlike other anti-virals, bemcentinib acts through 3 mechanisms

Prevents viral entry, promotes innate immunity and repair of damaged epithelium

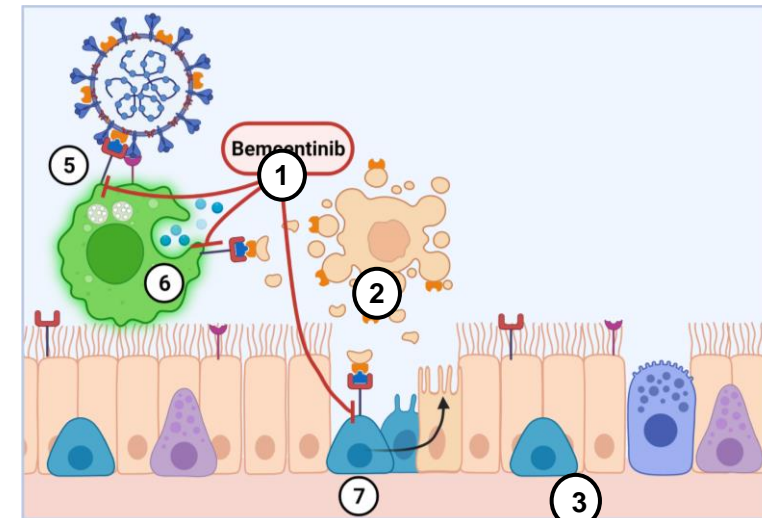
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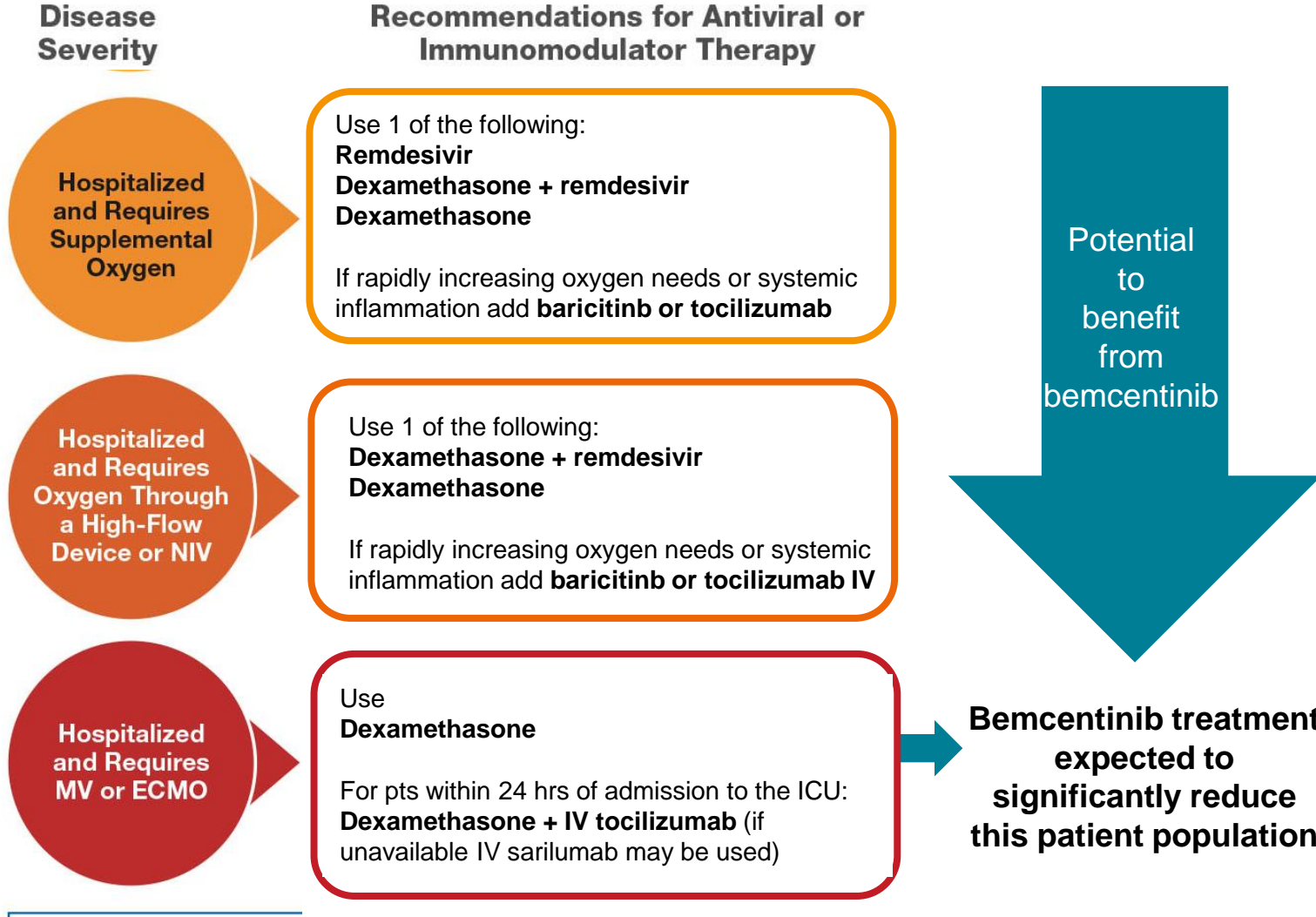
Repairs lung damage



Blocking AXL signaling:

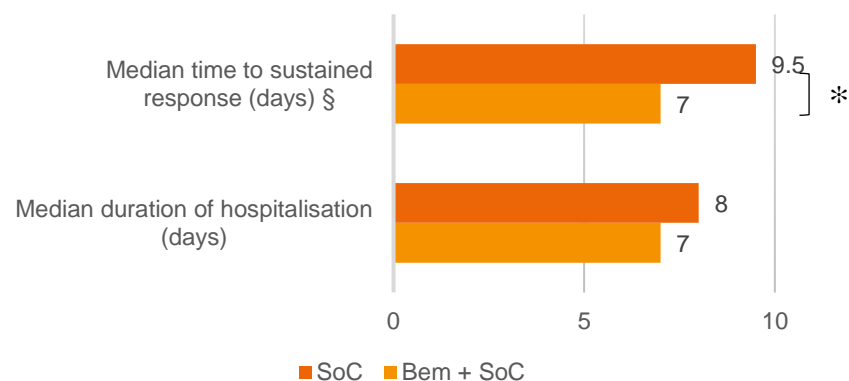
- 1 Prevents endosome acidification.
- 2 Restores mediator production.
- 3 Improves epithelial repair.

Current therapies are not positioned to treat across the spectrum of disease severity



ACCORD2 bemcentinib + standard of care (SOC) in hospitalized COVID met primary and key secondary endpoints

PRIMARY ENDPOINT §



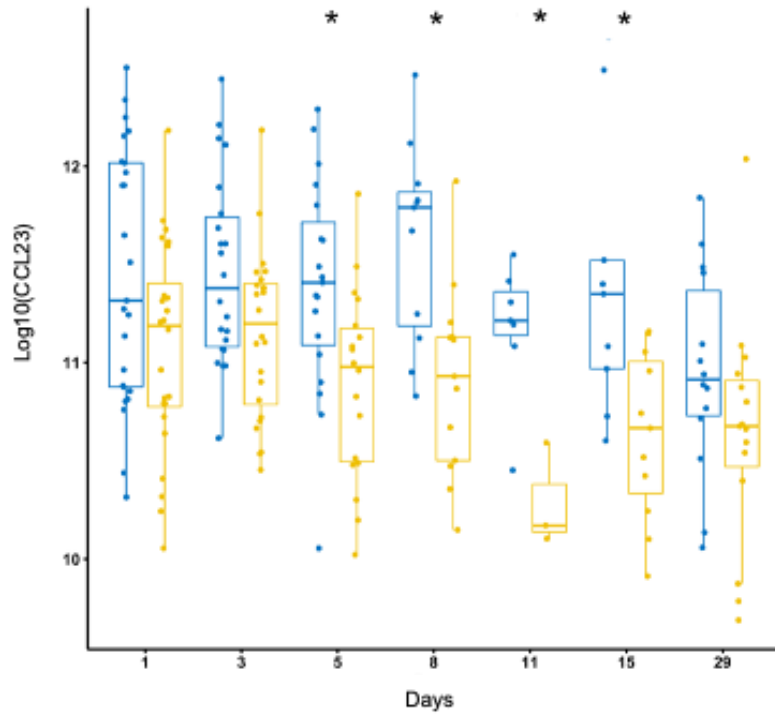
*, p-value ≤0.05

KEY SECONDARY ENDPOINTS

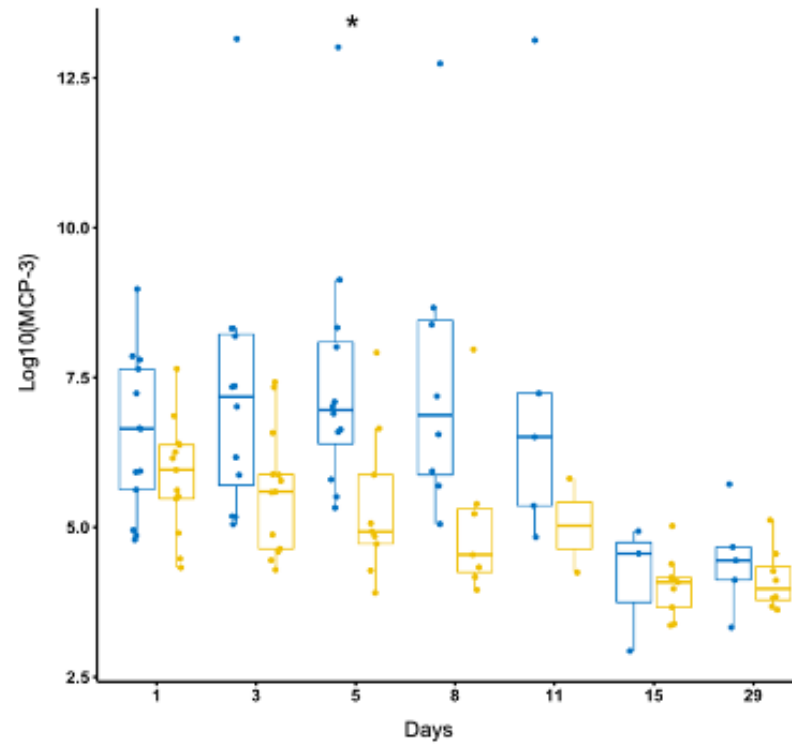
Endpoint	SoC + bemcentinib	SoC alone	Statistically significant*
Alive at day 29	97%	81%	<input checked="" type="checkbox"/>
Alive at day 60	97%	75%	<input checked="" type="checkbox"/>
% w/ sustained clinical benefit	90%	69%	<input checked="" type="checkbox"/>



ACCORD2 confirms MoA: markers of inflammation, profibrotic cytokines, increased expression of protective factors

High C-Reactive Protein



High neutrophil:lymphocyte ratio



Trt  SOC  SOC + Bemcentinib

Phase 2b (EU-SolidAct platform) enrolling

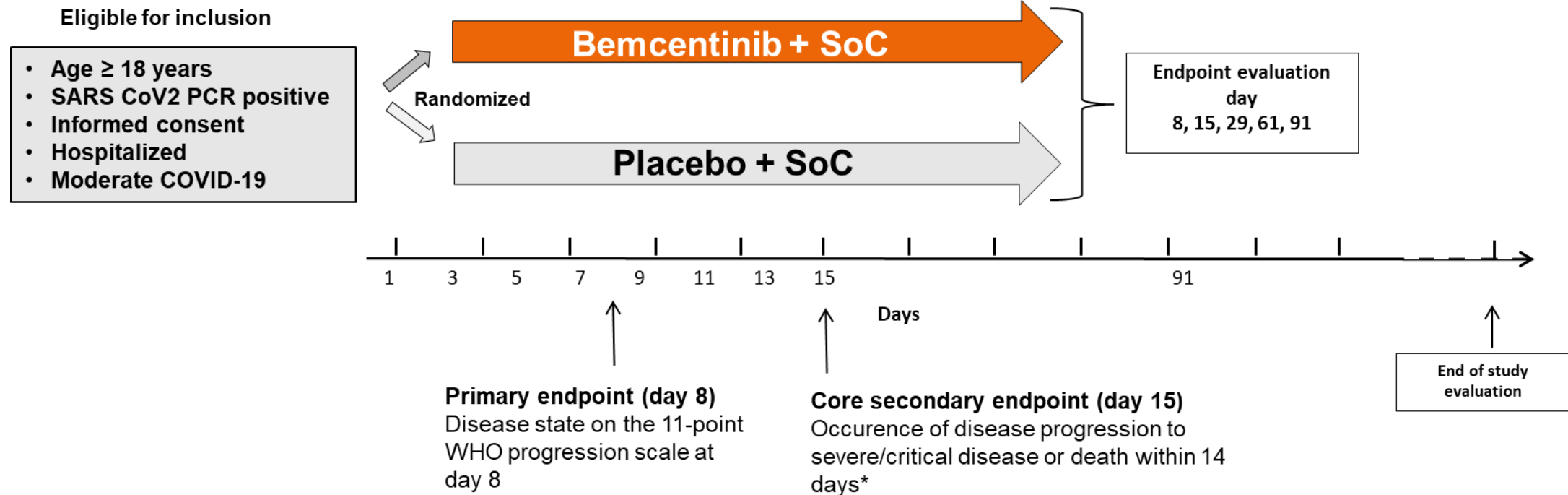
Established capability to recruit into hospitalized COVID-19 and captive study design

Platform

- Demonstrated ability to rapidly recruit hospitalized COVID-19 patients
- Baracitinib recently approved in COVID-19 was studied under the platform

Study design

- Reflects evolving nature of disease behaviour due to effect of vaccines and variants
- Primary endpoint selected with consultation with EU and informed by data generated in two previous COVID-19 studies



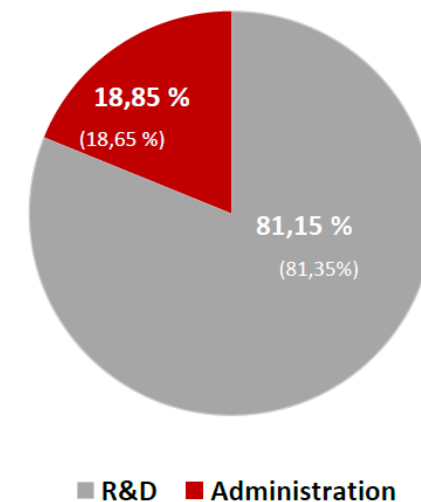
Key Q3 2022 financials



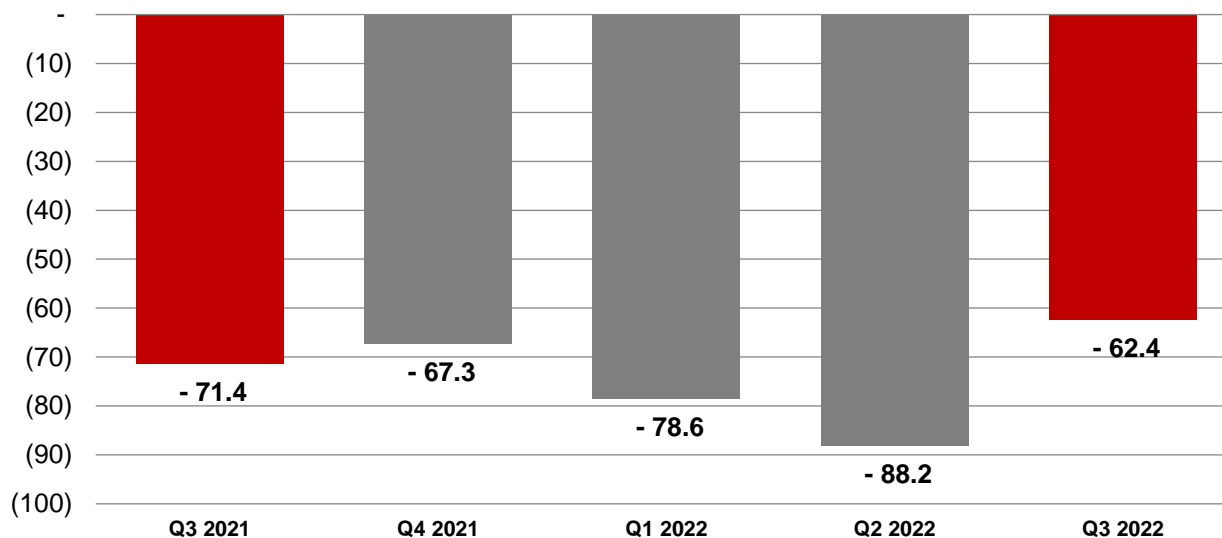
Key financial figures Q3 2022

(NOK million)	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
Operating revenues	0.0	0.0	0.0	0.0	0.8
Operating expenses	62.4	71.4	229.2	247.1	315.2
Operating profit (-loss)	-62.4	-71.4	-229.2	-247.1	-314.5
Profit (-loss) after tax	-59.8	-70.5	-224.9	-240.6	-309.4
Basic and diluted earnings (loss) per share (NOK)	-0.67	-0.80	-2.54	-2.74	-3.52
Net cash flow in the period	-65.0	-61.7	-206.5	-208.2	-284.2
Cash position end of period	225.1	509.4	225.1	509.4	436.6

Operating expenses Q3 2022
(YTD 2022)



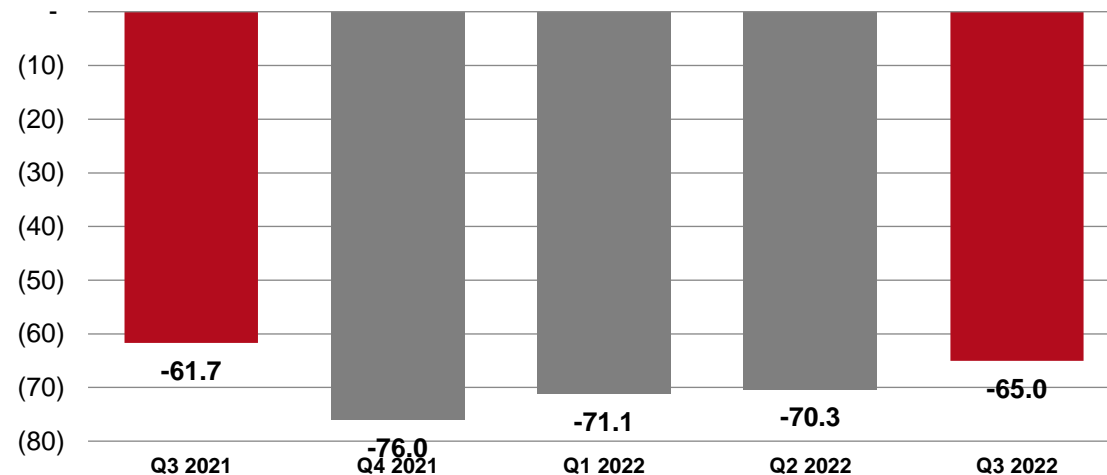
Operating loss (million NOK)



- Operating costs decreased from Q2 22 to Q3, mainly caused by decreased headcount due to rightsizing of the organization in connection with the company's focused strategy announced in May 2022.
- Year on year the decrease is related to severance payment to departing CEO in Q3 2021.
- Well managed overhead costs. 81% of operating expenses in Q3 and YTD is attributable to Research & Development activities.

Cash flow and cash position Q3 2022

Cash flow (million NOK)



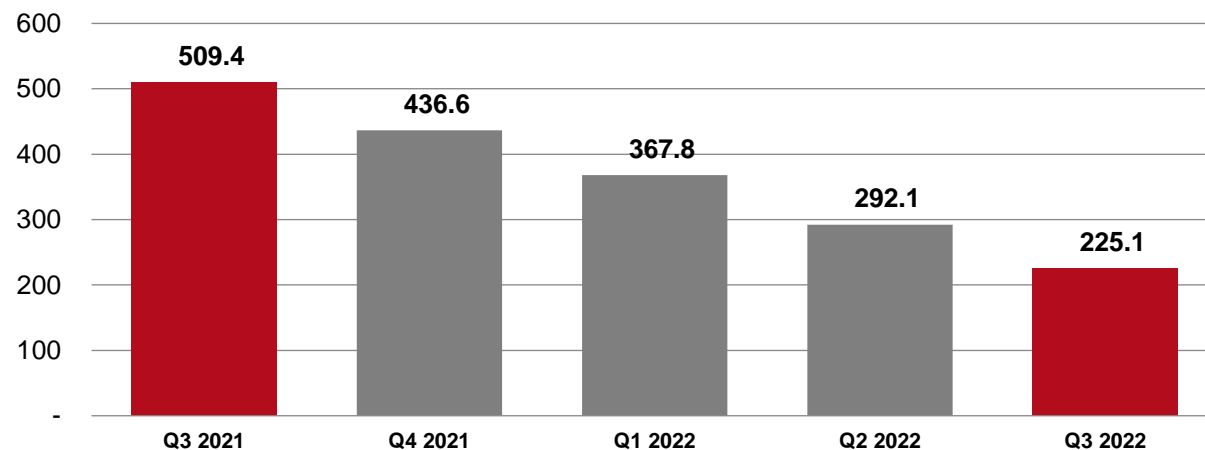
Cash burn operating activities Q3 2022

65.8 / 6.6
NOK million / USD million

Quarterly average net cash burn (Q3 2021 – Q3 2022)

71.5 / 7.8
NOK million / USD million

Cash position (million NOK)



Cash position Q3 2022

225.1 / 20.7
NOK million / USD million

Post period:

Secured a NOK 100 (USD 9.5) million loan facility

Key Catalysts

Key catalysts

1L STK11m NSCLC

- BGBC008 final data (H1 2023)
- Ph 1b data (H2 2023)
- Initiation of Ph 2a (H2 2023)
- Additional pre-clinical data on STK11m (H1 2023)

Hospitalized COVID-19 patients

- Phase 2b (EU-SolidAct) data (H2 2023)
- Additional preclinical data on respiratory infections (H2 2023)

Thank you!

