DNB HealthCare Conference

15th December 2022

BerGenBio

www.bergenbio.com

Forward Looking Statements

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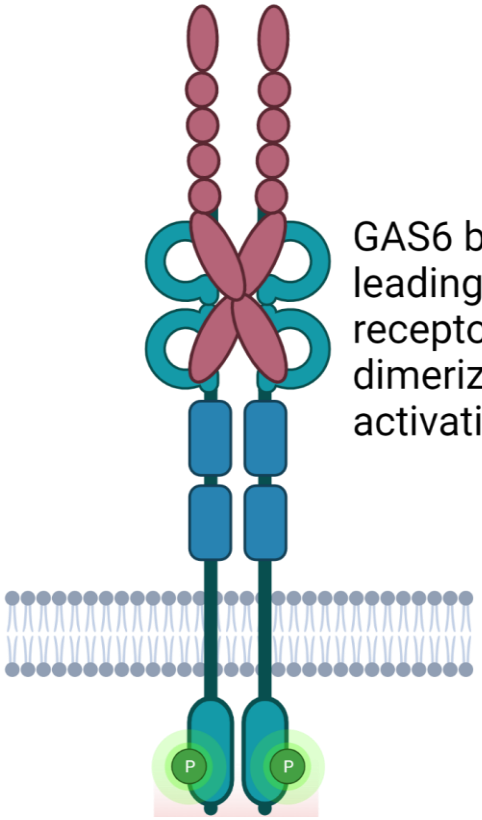
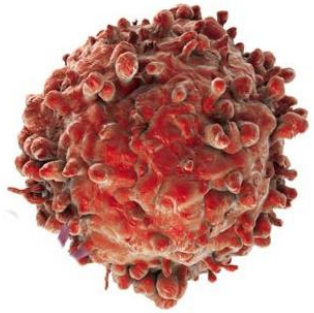
About BerGenBio

- The **leading company in targeting AXL** biology to prevent the progression of serious diseases
- Our 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**
    - **Hospitalized COVID-19**
- **Tilvestamab a highly selective mAb** has completed Ph1 – partnering process initiated
- Laser-focused to **deliver clear value drivers** within next 12-18 months

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



GAS6 binding leading to AXL receptor dimerization/ activation



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				
Oncology	Bemcentinib	2L NSCLC				MERCK
Oncology	Bemcentinib	R/R AML				
Oncology	Mipasetamab uzoptirine	Solid Tumors			Fully out-licensed mAb	ADC THERAPEUTICS
Viral	Bemcentinib	COVID-19				EU SOLIDACT Part of EU-RESPONSE
Fibrosis	Tilvestamab	Biomarker study in ovarian cancer				

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)

A significant opportunity for Bemcentinib to address a significant unmet medical need

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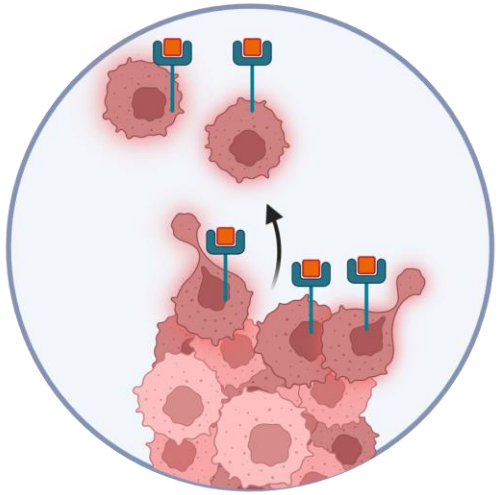
Clinical trials substantiate the relevance of key mechanisms in AXL inhibition by bemcentinib in NSCLC

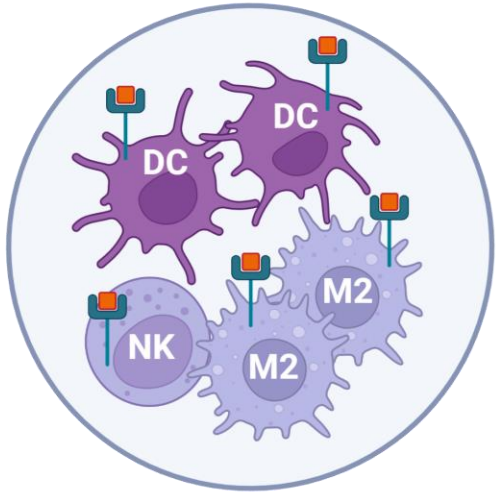


BGBIL005: 2L+ NSCLC

Reversal of cancer cell survival and escape

Ph2 (completed)
bemcentinib + docetaxel in 2L+ NSCLC

Anti-tumor activity in previously treated, advanced NSCLC
82% DCR: 35% PR and 47% SD rates



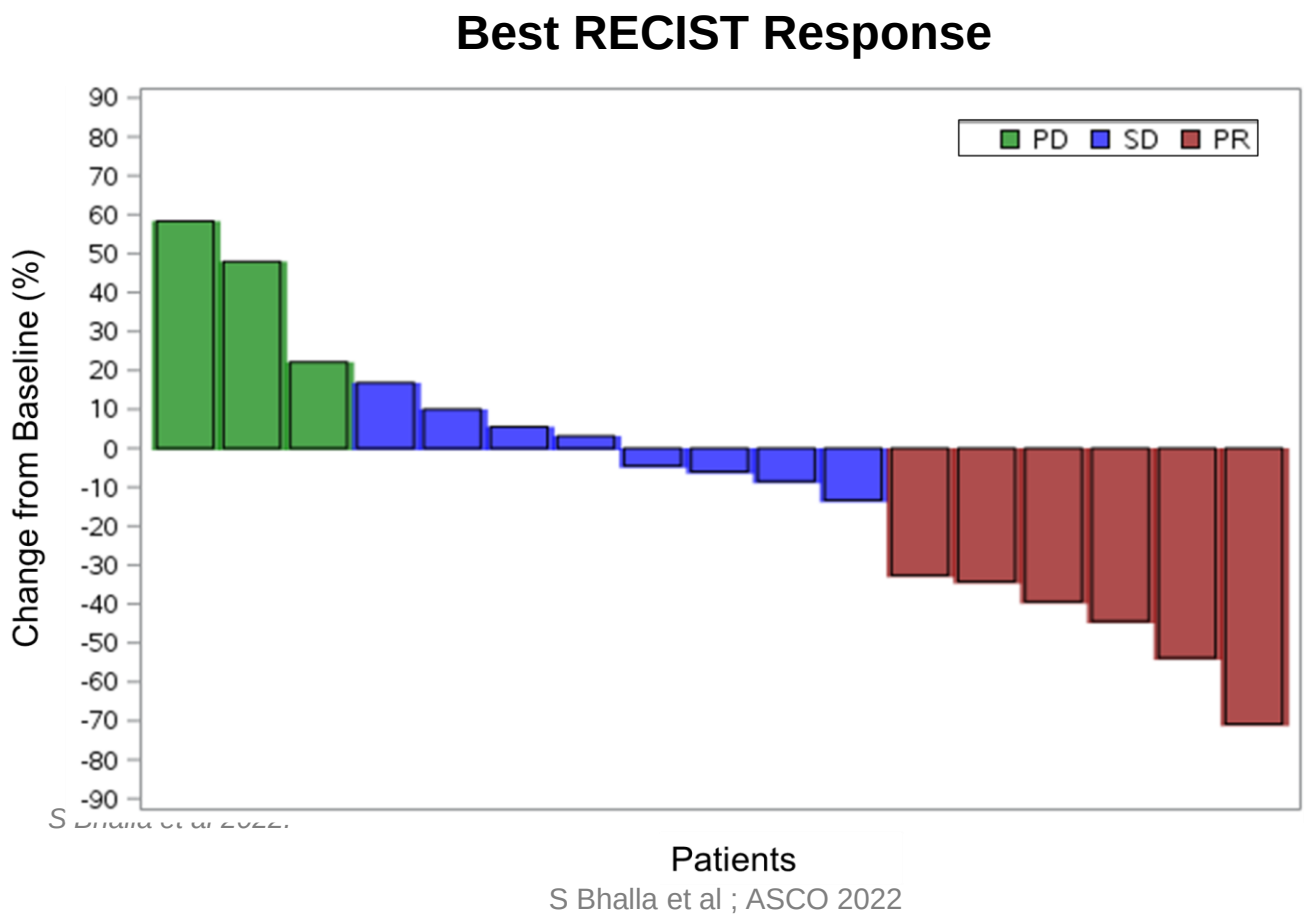
BGBC008: 2L NSCLC

Improved innate immune response

Ph2 (completed)
bemcentinib + pembrolizumab in 2L NSCLC

Immature data suggests suggest PFS & OS benefits in AXL+ pts

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



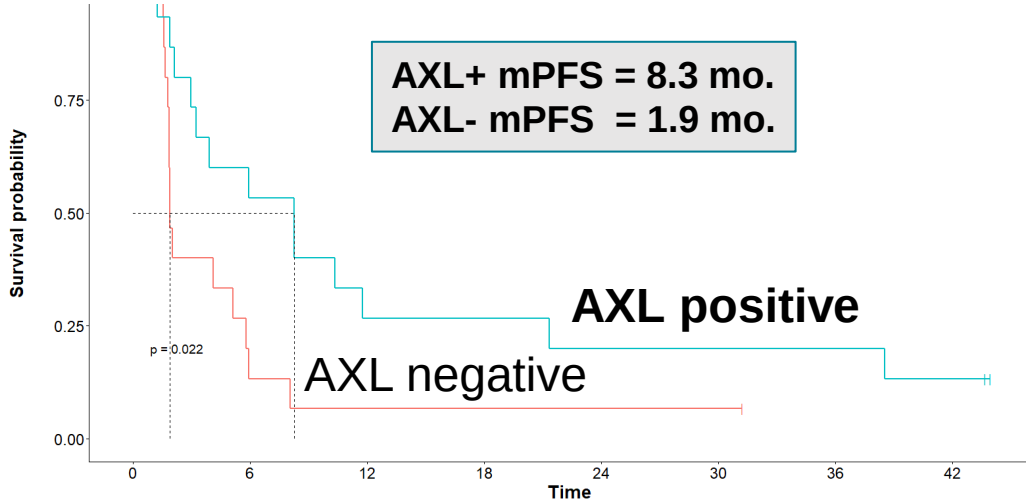
S Bhalla et al ; ASCO 2022

- **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**

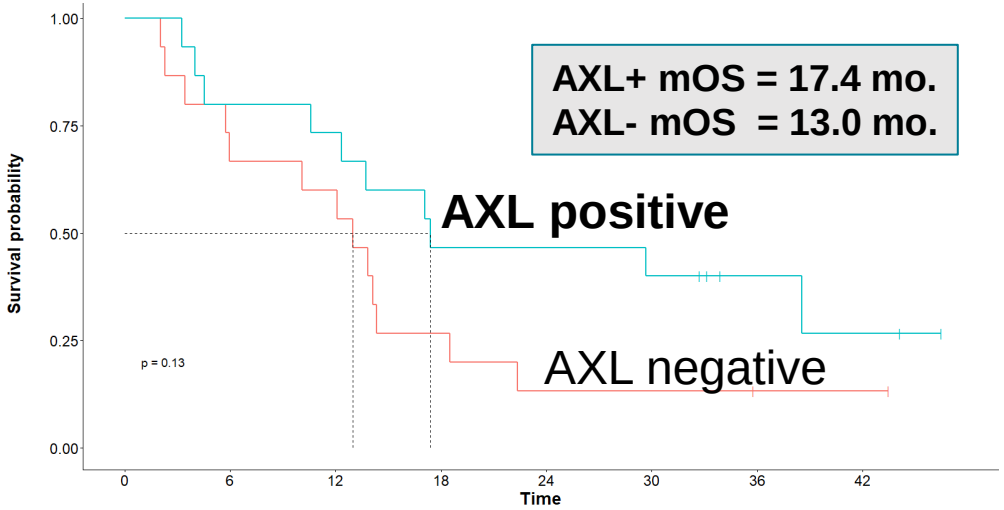
*Source: Besse, Eur Respir Rev 2015; 24: 582–593

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

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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%

*Keynote 42 – PDL1 >1

**Not reported

AXL activation reduces apoptosis and promotes an immune suppressed microenvironment

Cancer cell survival and escape

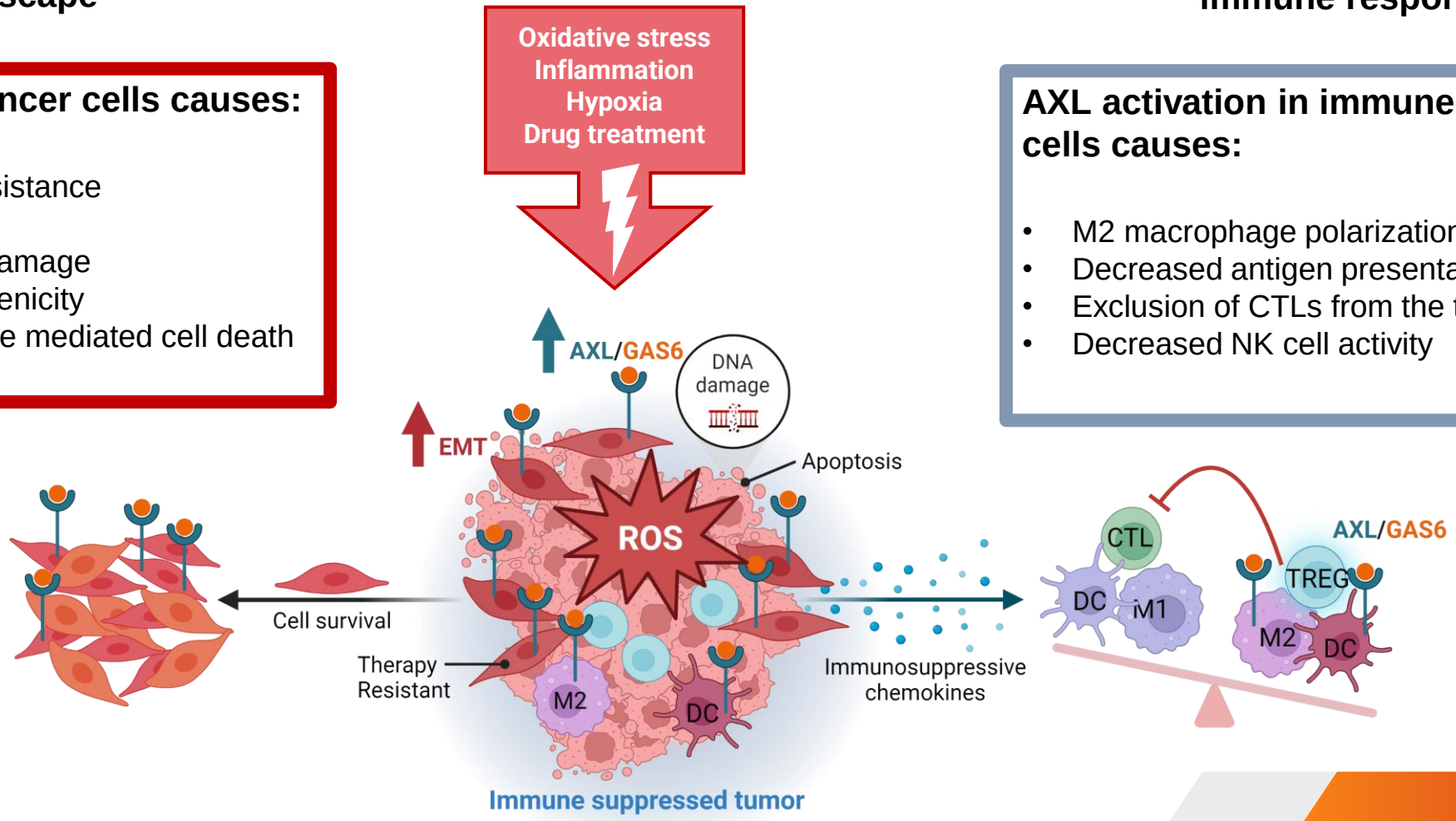
AXL activation in cancer cells causes:

- 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



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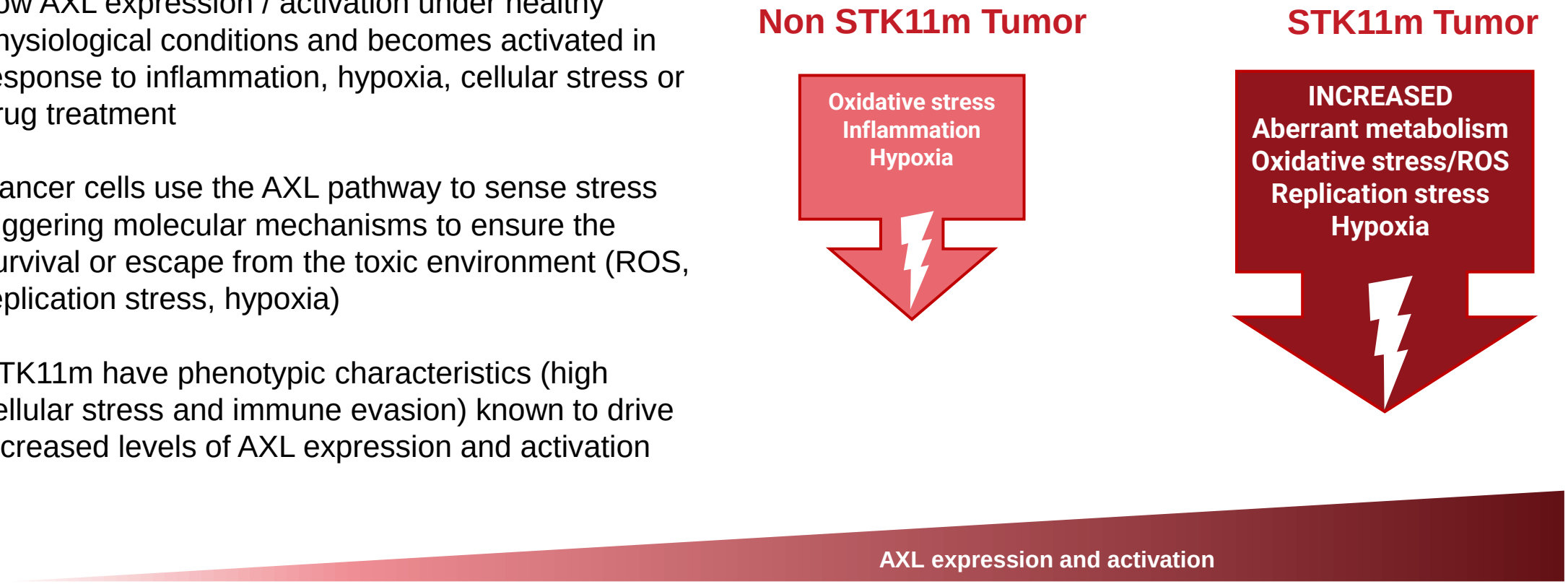
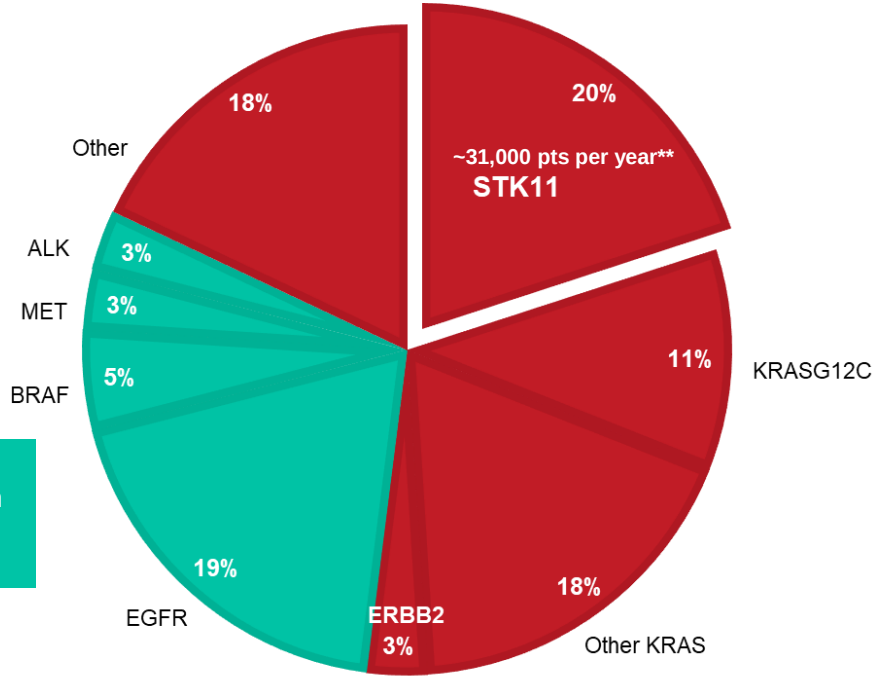
STK11m causes high oxidative stress, hypoxia, inflammation – resulting in almost universal AXL expression / activation

- 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



STK11m NSCLC a significant unmet medical need …

STK11m - The most common "non-actionable" mutation*



Actionable 1L NSCLC mutations with currently approved therapeutics

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 immuno-therapy
- No targeted therapy currently available

* 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

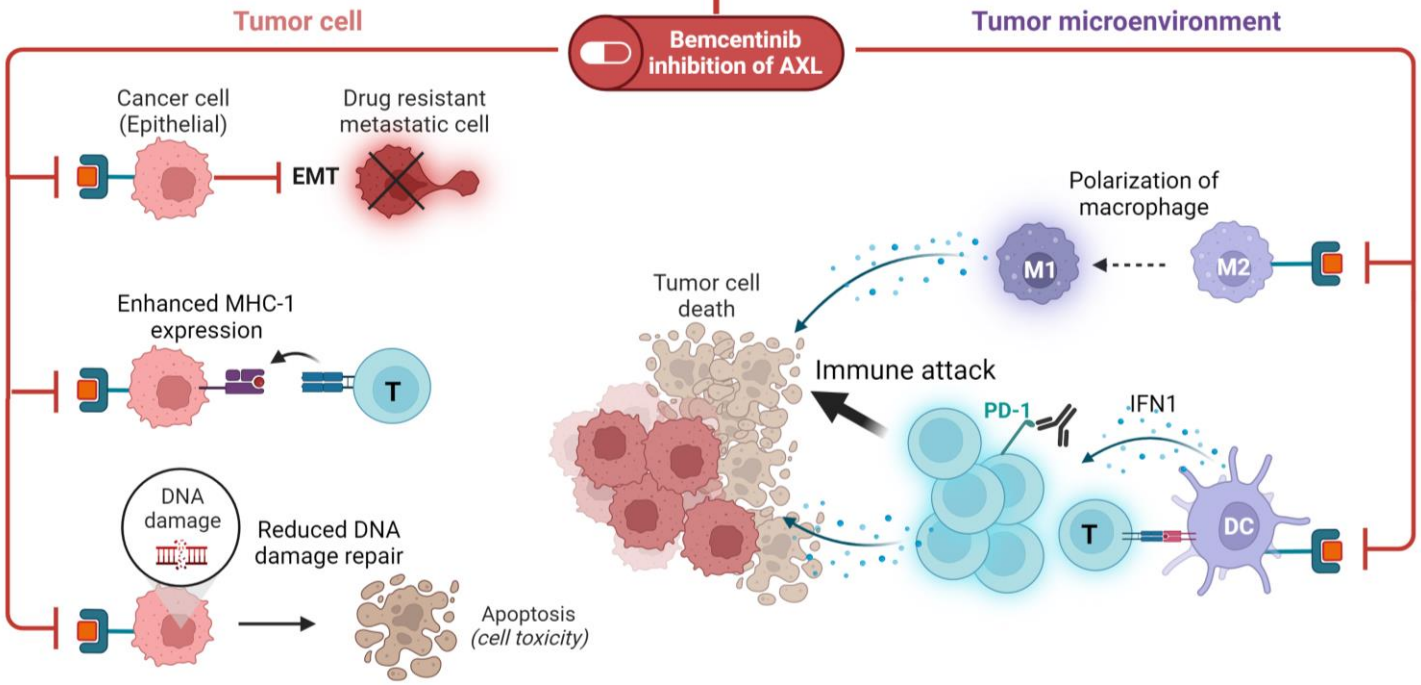
… which can be targeted by bemcentinib to potentiate current SOC efficacy in STK11m NSCLC

Aberrant metabolism and increased cellular stress/ROS

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

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

- **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**

Bemcentinib in 1L STK11m NSCLC

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

A significant unmet market with a strong rationale for AXL inhibition in combination with SOC

- STK11m represents a significant population within 1L NSCLC
- 1L STK11m NSCLC shows inferior survival outcomes on todays' 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

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 activated AXL -** showing PFS and OS outcomes similar to 1L patients – demonstrating the importance of AXL as a driver of disease progression
- Early retrospective **clinical data (BGBC008*) support benefit in STK11m patients**

*immature dataset; final data expected H1 2023

Hospitalized COVID-19

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

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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

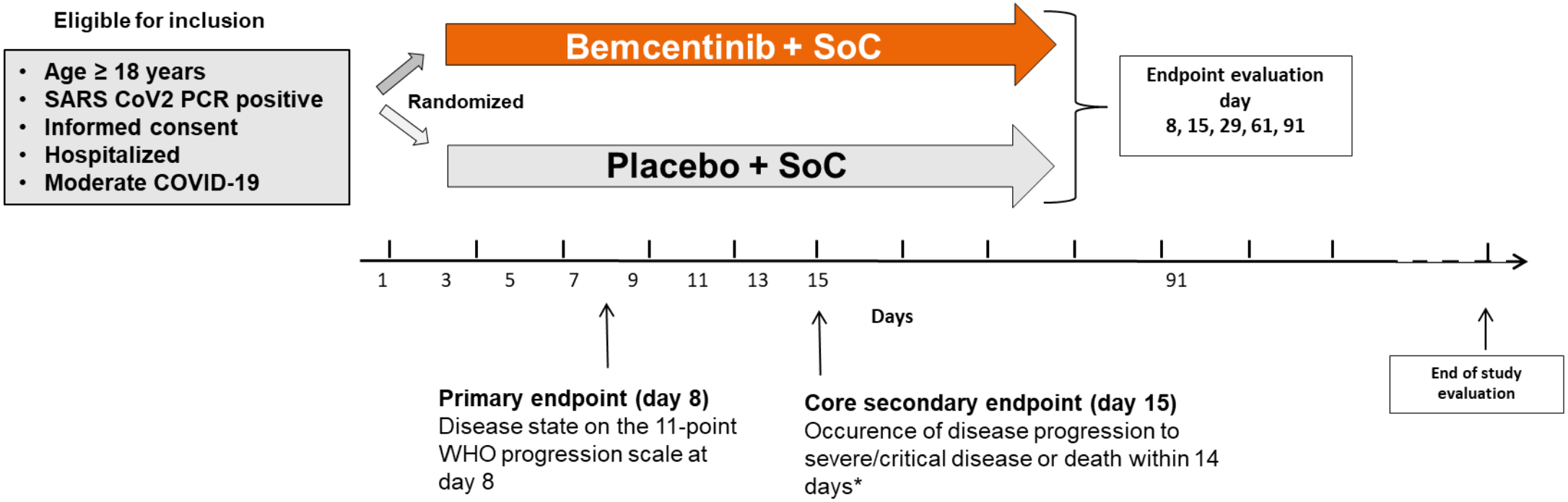
Phase 2b (EU-SolidAct platform) enrolling
Hospitalized COVID-19

Platform

- Demonstrated ability to 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



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Key Q3 2022 financials

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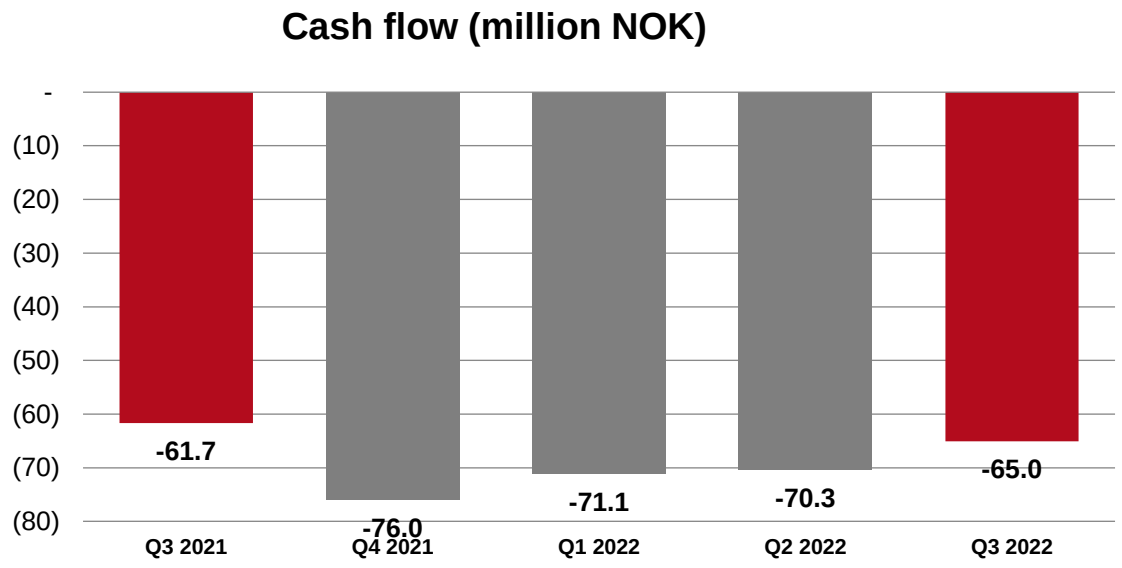
Cash flow and cash position Q3 2022



Cash burn operating activities Q3 2022

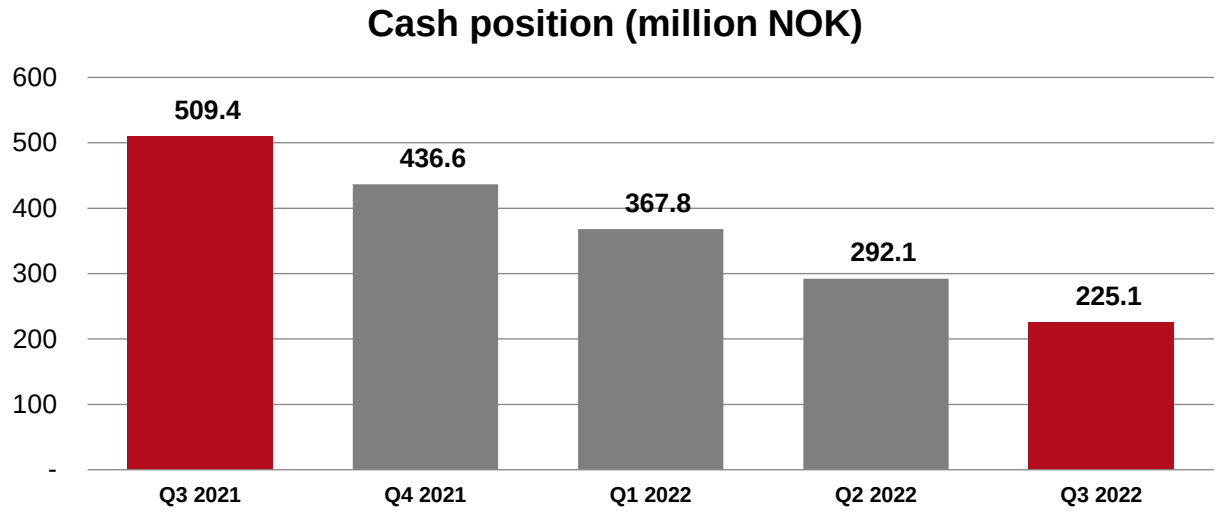
65.8 / 6.6

NOK million / USD million

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

71.5 / 7.8

NOK million / USD million



Cash position Q3 2022

225.1 / 20.7

NOK million / USD million

Post period:
Secured a NOK 100 (USD 9.5) million loan facility

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Key Catalysts

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Key catalysts

1L STK11m NSCLC

- 2L NSCLC (BGBC008) final data early H1 2023
- 2L+ NSCLC (BGBIL005) final data early H1 2023
- 1L NSCLC Ph 1b data H2 2023
- 1L NSCLC STK11m Ph 2a trial initiated H2 2023
- Additional pre-clinical data on STK11m (H1 2023)

Other

- 2L AML (BGBC003) final data early H1 2023
- Glioblastoma (BGBIL013) final data H2 2023
- Melanoma (BGBIL006) final data H2 2023

Hospitalized COVID-19 patients

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

Thank you!

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