



BerGenBio

Q4 2021 REPORT, HIGHLIGHTS AND FINANCIALS

16th February 2022

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AGENDA

1. Q4 and recent highlights
2. Role of AXL targeting in serious diseases
3. Strategic priorities - three shots on goal:
 - 1L STK11 mutated Non-Small Cell Lung Cancer (NSCLC)
 - 2L relapsed Acute Myeloid Leukemia (AML)
 - Hospitalized COVID-19 patients (Respiratory Infections)
4. Finance report
5. 2021 highlights & outlook

Q4 and recent highlights

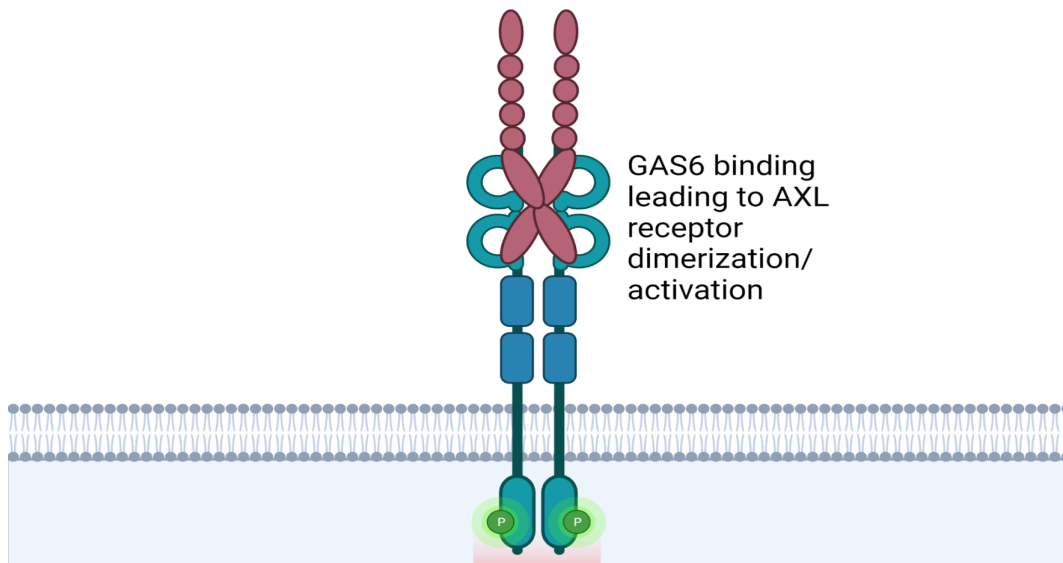
- Strategic review: three “shots on goal” for near-term clinical development of bemcentinib
 - 1st line (1L) STK11 Mutated NSCLC
 - 2nd line (2L) Relapsed AML Patients
 - Hospitalized COVID-19 Patients
- Further strengthened the opportunity for bemcentinib in 1L NSCLC patients harboring STK11 mutations:
 - Obtained exclusive license to STK11m IP from UTSW Medical Center
 - Fast Track designation received for bemcentinib as treatment for patients harboring STK11*
- Post-period announcement of bemcentinib’s entry into the EUSolidAct Phase II platform study in hospitalized COVID-19 patients

• ⁴ * In combination with anti-PD1/L1 therapy in advanced/metastatic NSCLC pts without other actionable mutation

AXL mediates aggressive disease

Very low expression under healthy physiological conditions

AXL-GAS6 SIGNALLING UPREGULATED IN SERIOUS DISEASES



IMPACT OF AXL ACTIVATION

Cancer

Cancer progression, immune evasion, drug resistance and metastasis

Respiratory

Mediates viral entry into cells, dampens viral immune response

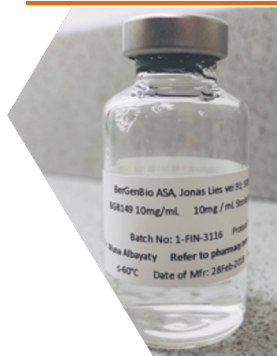
Two first-in-class, potent, highly selective AXL inhibitors in clinical development

BEMCENTINIB



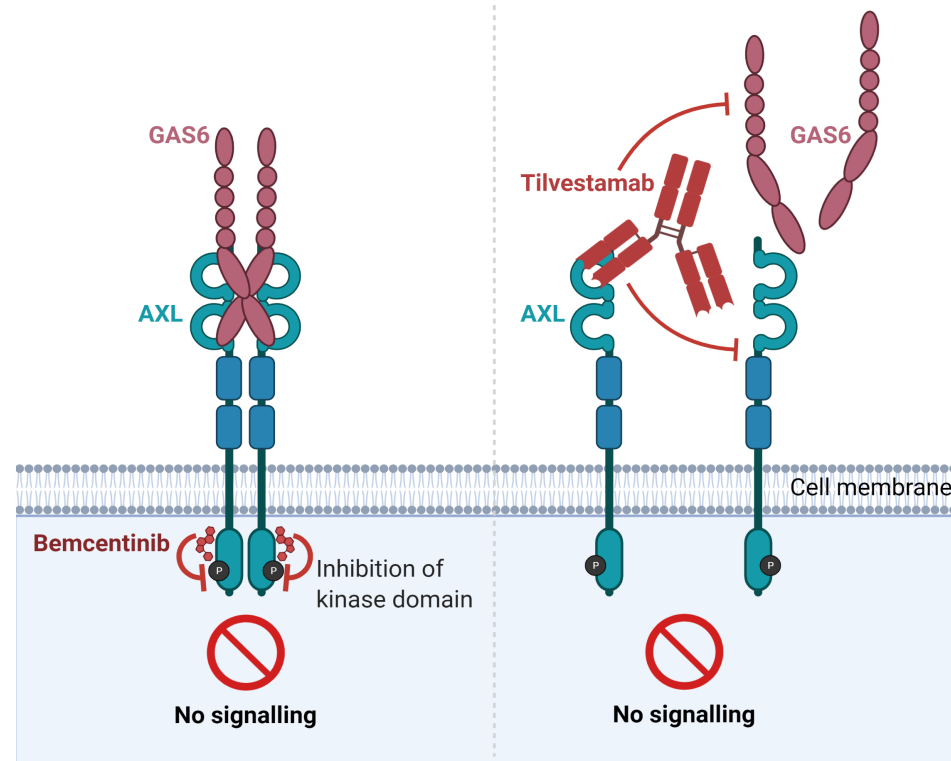
- Oral capsule, once a day
- Extensive clinical dataset – over 600 pts treated to date:
 - Favorable benefit:risk profile
 - Combines well with other drugs
- In Phase II in multiple indications

TILVESTAMAB



- Fully humanized mAb – displaces GAS6
- Phase Ib trial on-going
 - Serial biopsies to confirm PK-PD

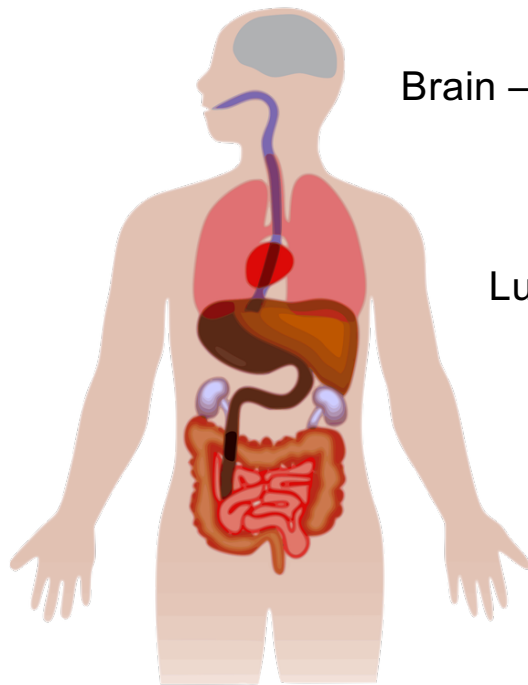
Bemcentinib - small molecule tyrosine kinase inhibitor



Bemcentinib is well distributed and accumulates in targeted organs

PRIMARY AREAS OF BEMCENTINIB ACCUMULATION

POTENTIAL THERAPEUTIC IMPLICATIONS



Brain – 26 fold*



- Bemcentinib crosses the blood brain barrier
- May be particularly important to treat metastases

Lungs – 48 fold*




- Relevant to both lung cancer and respiratory infections

Bone Marrow
– 16 fold*



- Relevant to engagement in hematological cancers, including AML

BerGenBio has built a significant dataset within oncology and respiratory infections

	Candidate	Targeted Indication	Preclinical	Phase I	Phase II	Registrational
Oncology	Bemcentinib Monotherapy & in combination	AML & MDS (multiple cohorts)				
	Bemcentinib	2L NSCLC (multiple cohorts)				 MERCK
	Tilvestamab	Ovarian Cancer Phase Ia / Ib				
	Mipasetamab uzoptirine*	Solid Tumors				
Viral	Bemcentinib	COVID-19				

*Mipasetamab uzoptirine under development by ADC Therapeutics is composed of an AXL monoclonal antibody (licensed from BerGenBio), conjugated using GlycoConnect™ technology (licensed from Synaffix BV) to a linker with a PBD-dimer toxin.

On-going investigator led trials may expand potential opportunities

	Candidate	Targeted Indication	Preclinical	Phase I	Phase II	Registrational
Oncology	Bemcentinib + chemo	≥2L NSCLC				
	Bemcentinib with CPI* or dabrafenib/trametinib	Metastatic melanoma				
	Bemcentinib +/- chemo	Metastatic pancreatic				
	Bemcentinib + CPI	Relapsed Mesothelioma				
	Bemcentinib	Recurrent Glioblastoma				

*CPI = checkpoint inhibitor.

Strategic focus: three shots-on-goal for bemcentinib with potential to unlock significant value

STK11 MUTATED NSCLC

- Large commercial opportunity: STK11 mutation represents large identifiable subgroup (c. 20% of NSCLC patients) with poor prognosis
- 2L STK11 mutated patients in Phase II (BGBC008) trial showed encouraging clinical benefit.

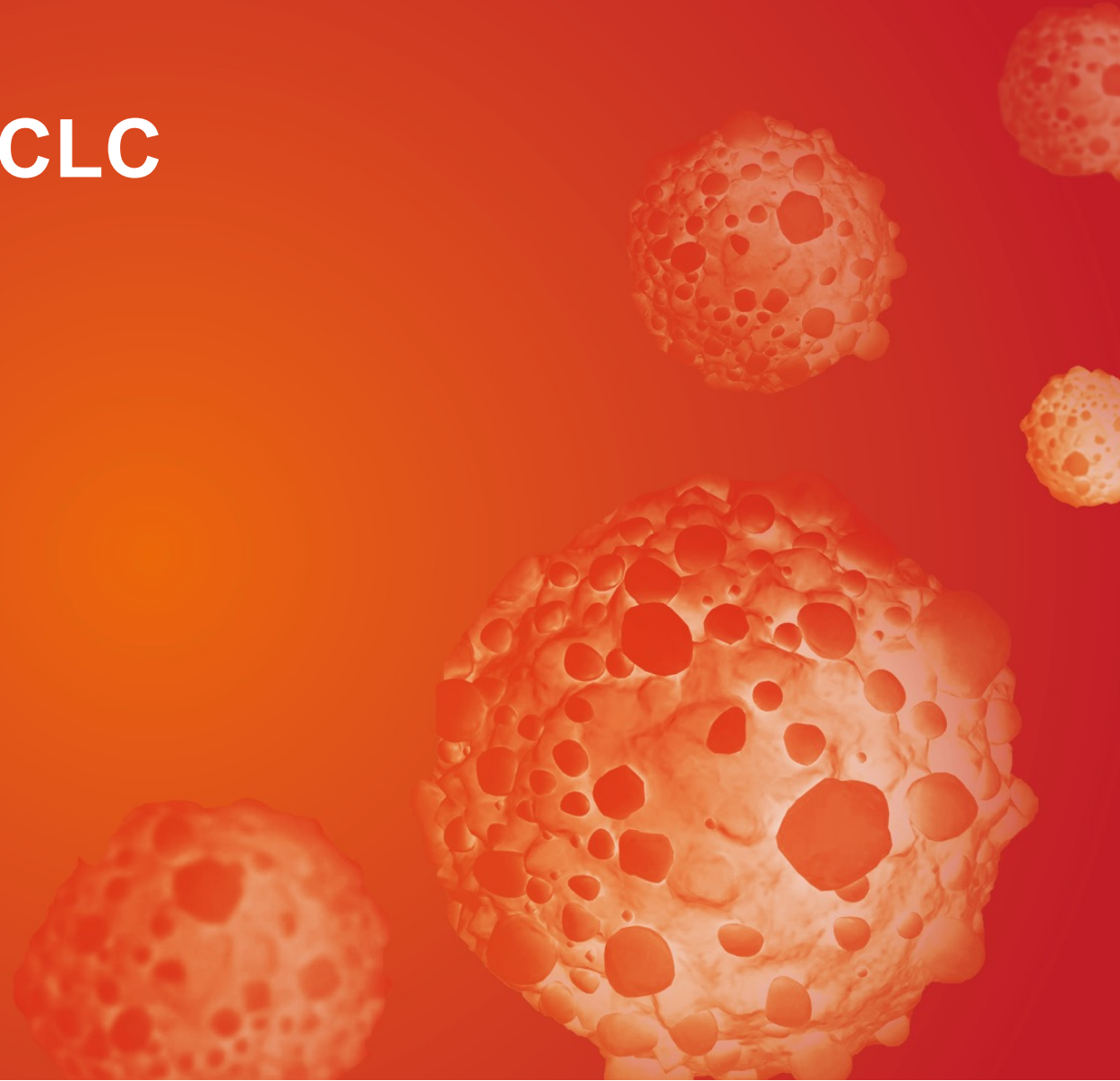
2L RELAPSED AML

- Despite change in standard of care, 2L AML represents a significant unmet medical need
- Immature Phase II data (BGBC003) in relapsed AML patients warrants further development

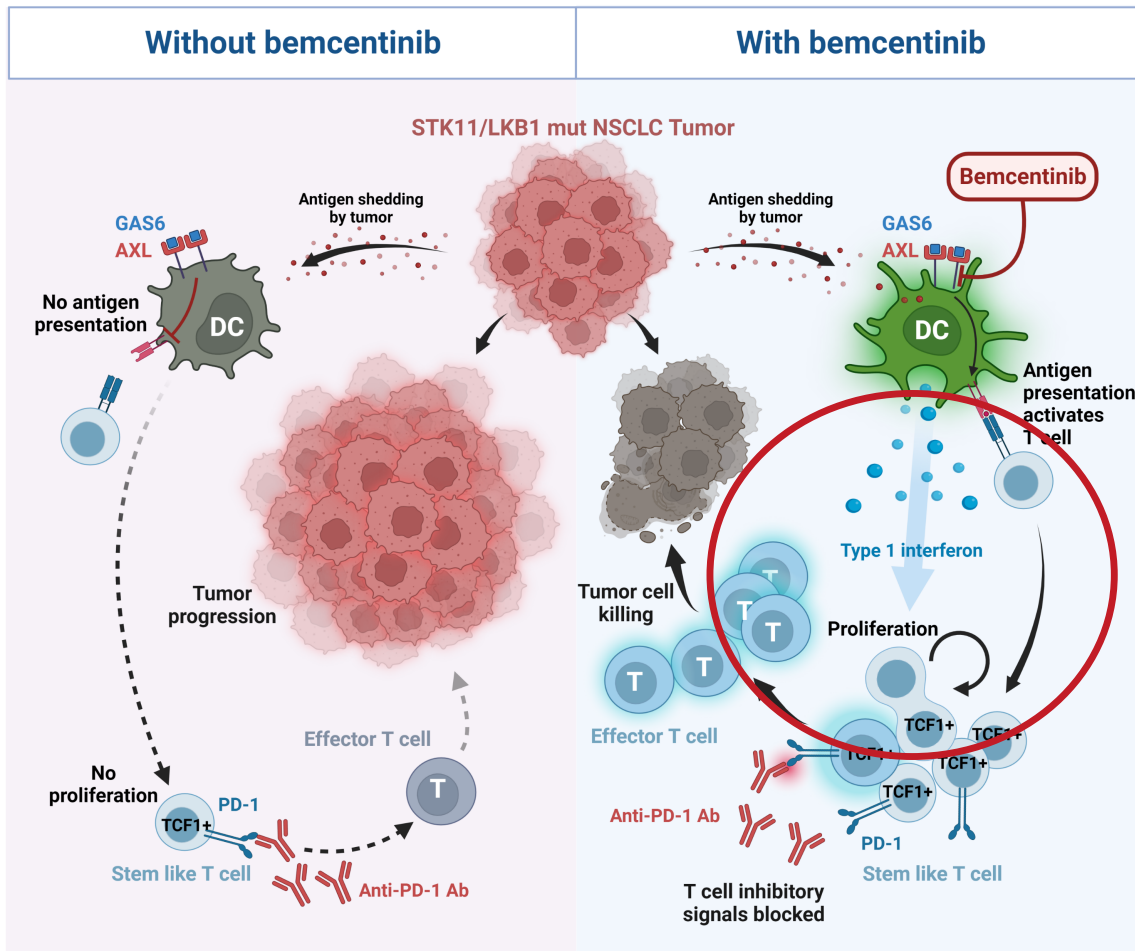
COVID-19

- Unmet medical need for severe hospitalized patients
- Encouraging data from two Phase 2 trials
- EU-SolidAct trial; Phase II adaptive, multi-centre trial, in up to 500 hospitalised COVID-19 patients

Bemcentinib in NSCLC



Bemcentinib restores checkpoint inhibitor sensitivity in STK11m NSCLC

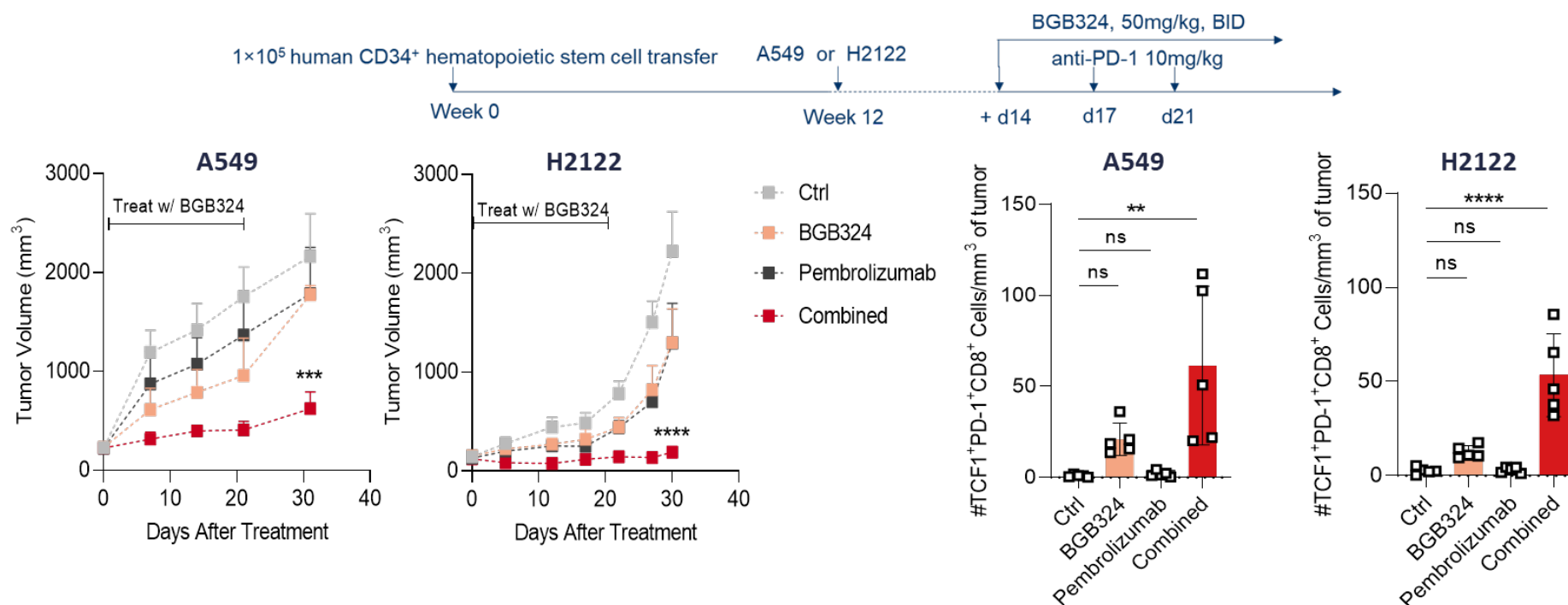


Bemcentinib MoA:

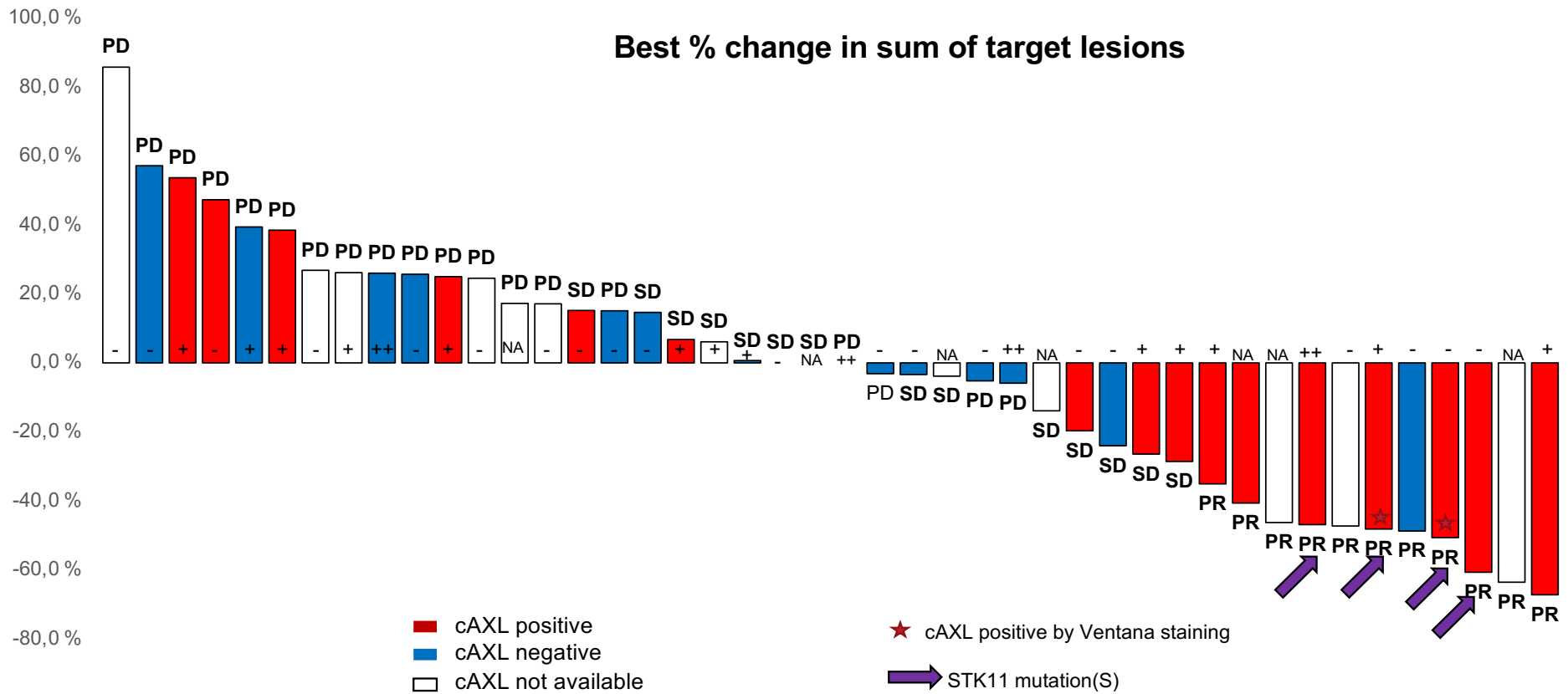
- Mutations in the tumor suppressor STK11 associated with poor response to immune checkpoint inhibition
- STK11m NSCLCs lack T cells to respond to checkpoint inhibition
- AXL inhibition with bemcentinib **increases Type I interferon secretion from dendritic cells** expanding T cells, restoring therapeutic response to PD-1

2021 SITC data shows compelling activity of bemcentinib in STK11m

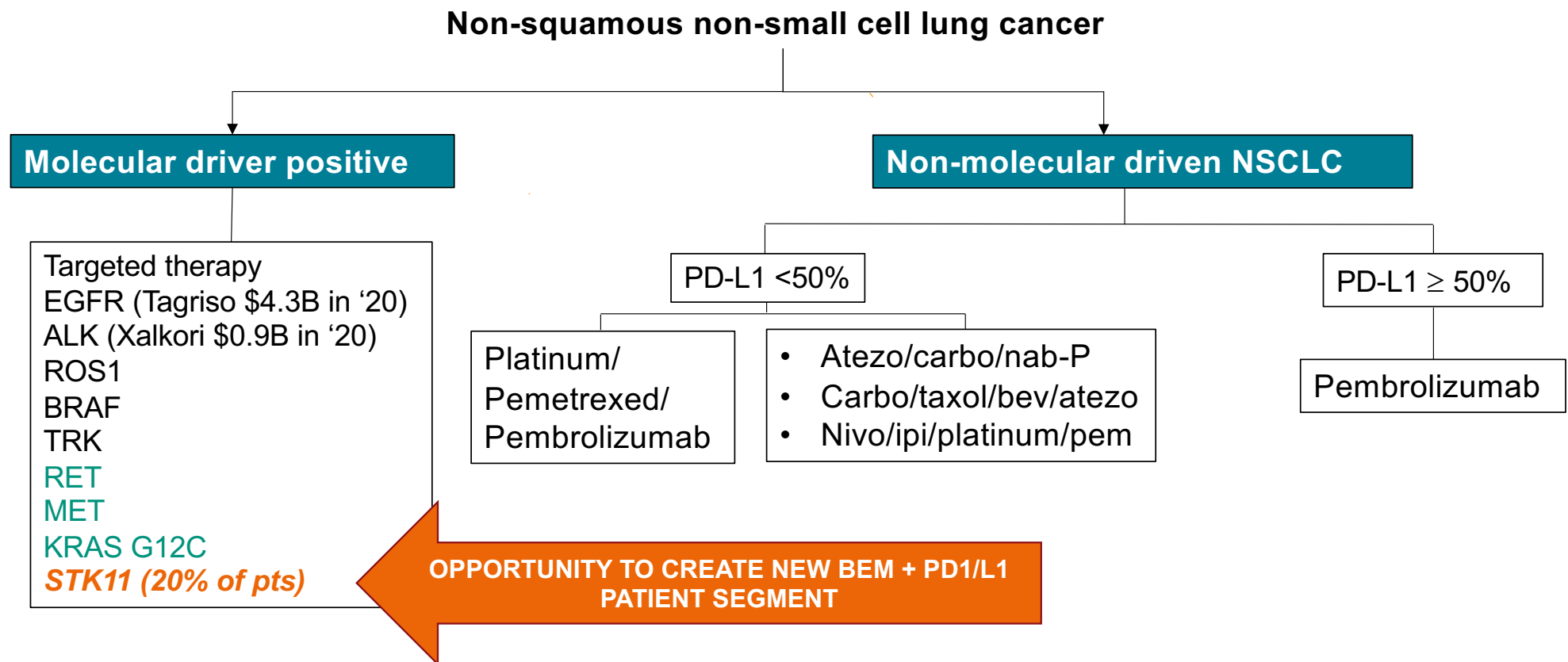
THERAPEUTIC EFFECTS IN NSCLC XENOGRAFTS & PATIENTS



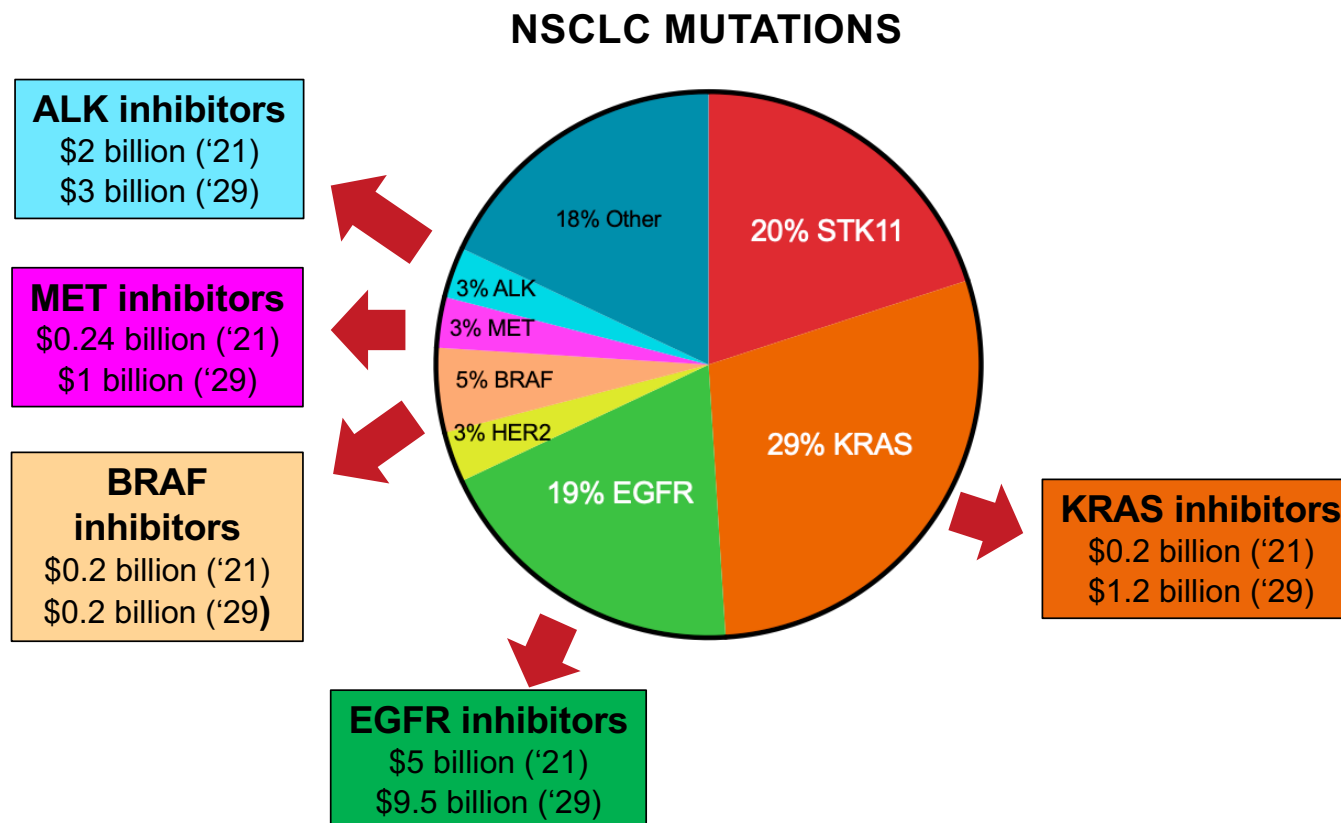
Data from on-going 2L NSCLC trial (BGBC008) indicates anti-tumor activity of bemcentinib in STK11 mutated patients



STK11m represent a poor prognosis for current therapies and bemcentinib represent a new significant treatment option for 1L NSCLC



Actionable mutation markers in 1L NSCLC represent significant markets

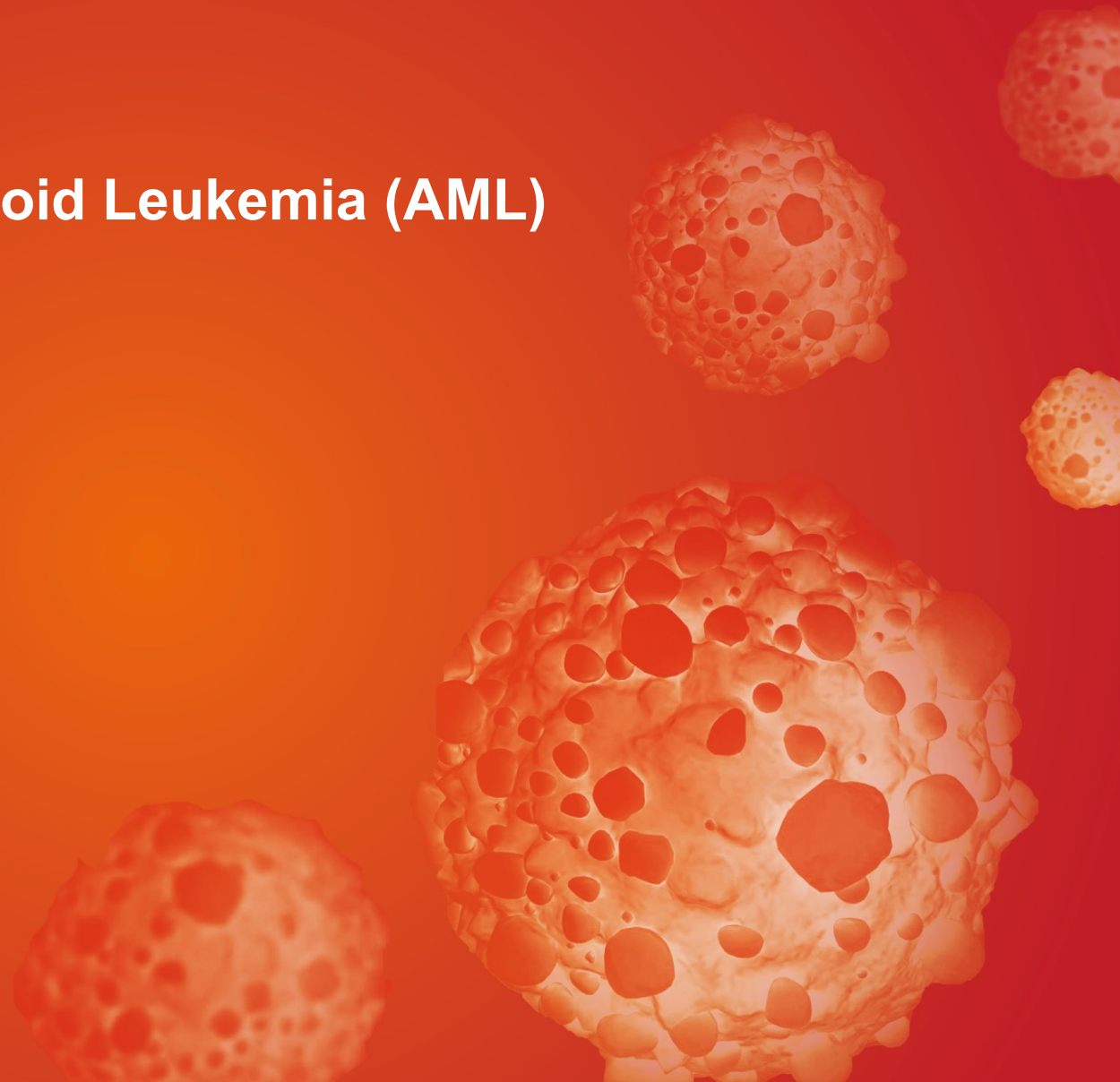


Source 2021 Global Data G8 sales and 2029 Projections (US, EU5, Japan & China)

Summary of bemcentinib in NSCLC

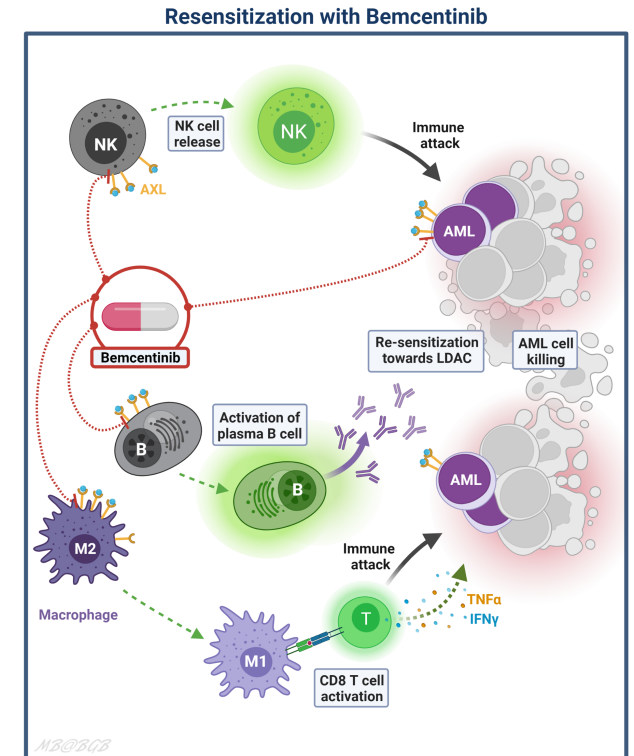
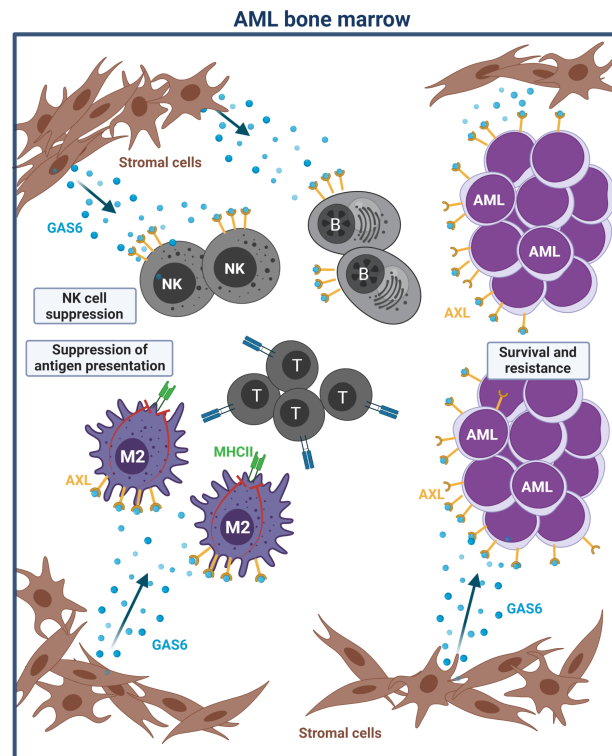
- **NSCLC treatment determined by presence/lack of molecular drivers**
- **STK11m patients respond poorly to anti-PD1/L1 treatment; no approved molecular targeted treatments**
- **STK11m represents a multi-billion dollar opportunity with favourable competitive position**
- **Bemcentinib shown to restore PD1-blockade sensitivity of STK11 mutations**
- **2L NSCLC trial (BGBC008) indicates response in STK11m patients, even in advanced lines of treatment**
- **Next step: Phase IB/II trial start (H1 2022), FDA granted Fast Track Designation**
- **Data from 2L NSCLC (BGBC008) not yet matured – expected in H1 2022**

Bemcentinib in Acute Myeloid Leukemia (AML)



AXL inhibition reverses the immune-suppressive microenvironment and sensitizes AML blasts to cytarabine

- AXL overexpressed in AML tumour cells
- AXL signalling in macrophages, NK cells leads to suppression of immune activity
- Blockade of the GAS6/AXL signalling axis by bemcentinib leads to:
 - ✓ re-sensitization of AML blasts to LDAC and apoptosis
 - ✓ innate immune cell antigen presentation and T-cell activation
 - ✓ NK activation



Phase I/II trial: elderly AML 2L+ patients unfit for intensive chemo provides rationale for continued development

Phase 2 Expansion Cohorts Data (unmatured) Presented at 2021 ASH Meeting

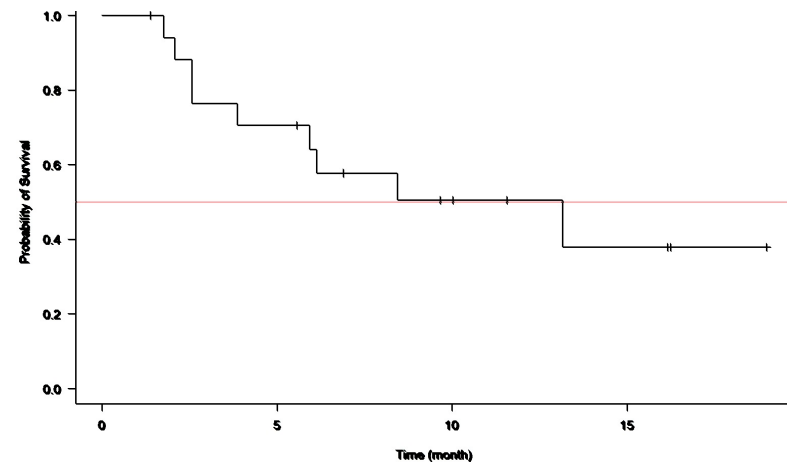
Cohort B2 n=16

Combination with LDAC in newly diagnosed, refractory/relapsed AML

Cohort B5 n=20

Combination with LDAC in refractory/relapsed AML

**Survival of 2L+ AML: Bemcentinib + LDAC
13.3 mOS vs. 4.7 mOS Historical Control***



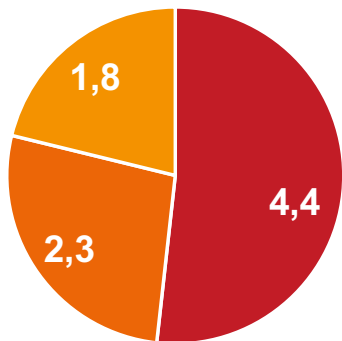
n=18

Time (month)

2L Relapsed AML Opportunity

TARGETED, GROWING 2L RELAPSED PATIENT POPULATION

2025 Incidence 2L AML
'000s of pts



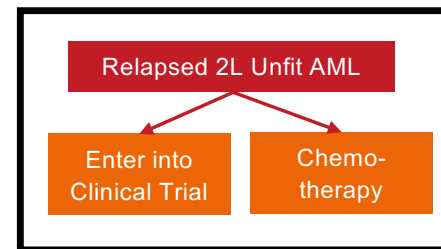
■ US ■ EU ■ Japan

Source: Global Data, 2022

Market Growth Drivers

- ↑ Aging population
~80% of pts >60 yrs
- ↑ Entry of Venetoclax® in 1L with improved response rate results in more 2L relapse pts
- ↑ Entry of novel, premium-priced drugs in orphan indications

CURRENT PROGNOSIS & TREATMENTS



*Adapted from Annals of Hematology
Chemotherapy includes: LDAC, HMA
and hydroxyurea*

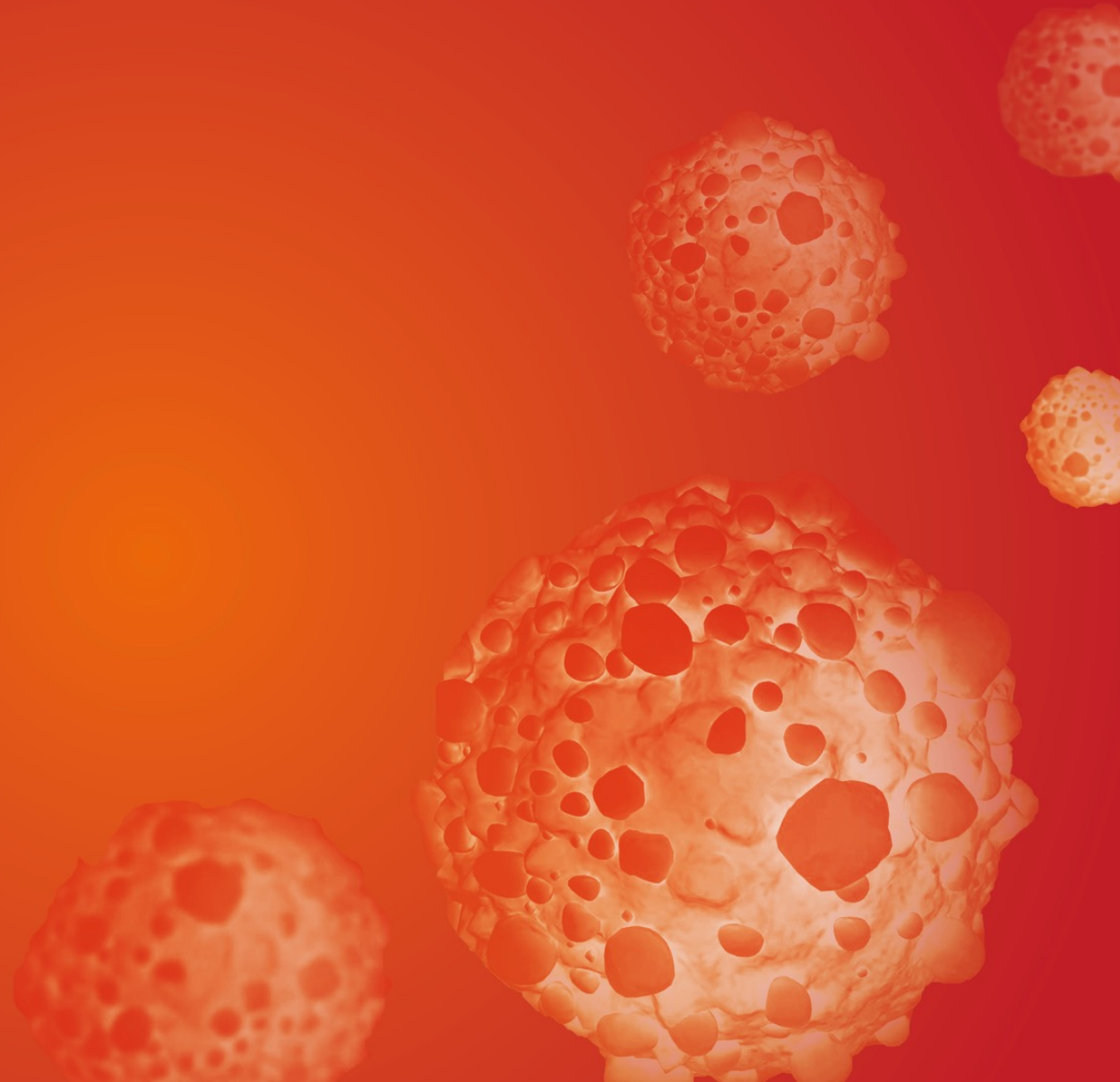
High Unmet Needs

- No single standard of care
- Current therapies do not provide lasting responses
- Clinical trial entry is often offered to patients
- Median overall survival of only 4-5 mo ; post Venetoclax/HMA 2.4 mos*

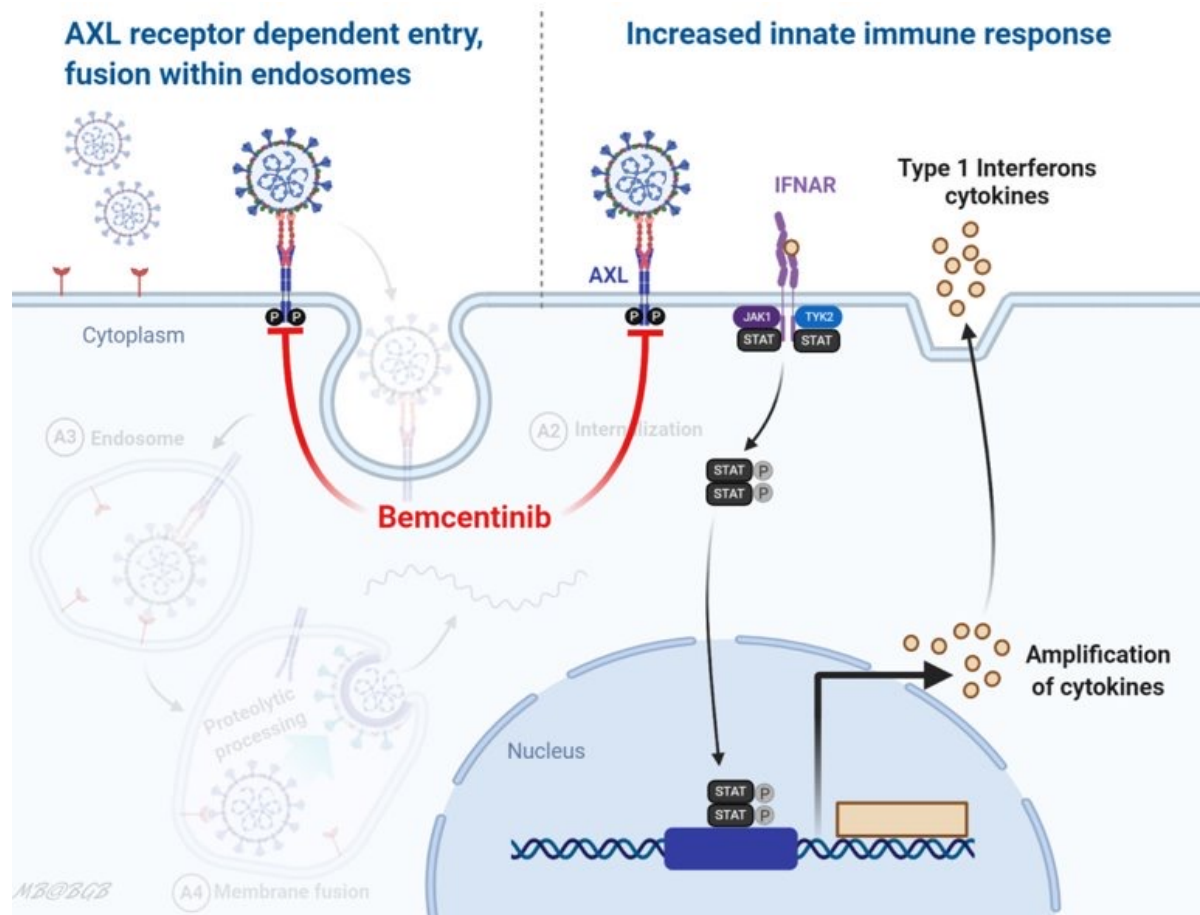
Summary of bemcentinib in AML

- Profound high unmet medical need in relapsed, unfit 2L AML patients
- Bemcentinib mediates anti-AML immune response through NK and T cell activation
- Bemcentinib is well tolerated (mono- and combination) and accumulates in bone marrow tissue
- Encouraging non-matured mOS benefits in relapsed 2L unfit AML patients
- Granted Orphan Drug Designation and Fast Track by US FDA in 2L AML (patients unfit for intensive chemotherapy)
- Next step: Phase II trial start (H2 2022)

Bemcentinib in COVID-19



Role of AXL and potential of bemcentinib in SARS-CoV-2 infection



- AXL receptors contribute to viral entry
- AXL signaling suppresses the Type1 IFN response contributing to lung injury and prevention of healing
- Inhibition of AXL through bemcentinib:
 - Increases the innate immune response to infection
 - Decreases inflammation, promotes normal healing

Unmet need persists for new COVID-19 hospital treatments

Need for effective treatment active across variants

Dynamics point to continued need for new therapies

	Vaccines	At-home Treatments	Hospital Treatments
Approved Products	mRNA vaccines Traditional vaccines	Paxlovid* Molnupiravir*	Corticosteroids Antibody therapy* Remdesivir (anti-viral) Baricitinib*
Current Situation	60.8% of adults W/W have ≥ 1 vaccine Vaccine aversion continues	Shown to reduce hospitalizations by 50-90%	Death rate still ~10% Current SOC has modest activity, variant coverage issues
Impact on Hospital. Rate	Breakthrough infections, vaccine adversity continues to drive hospitalizations	Limited impact; for vulnerable pts only, need to dose w/in 5 days; requires rapid testing	Significant # of hospitalizations expected to continue ; level dependent on variant, seasonality

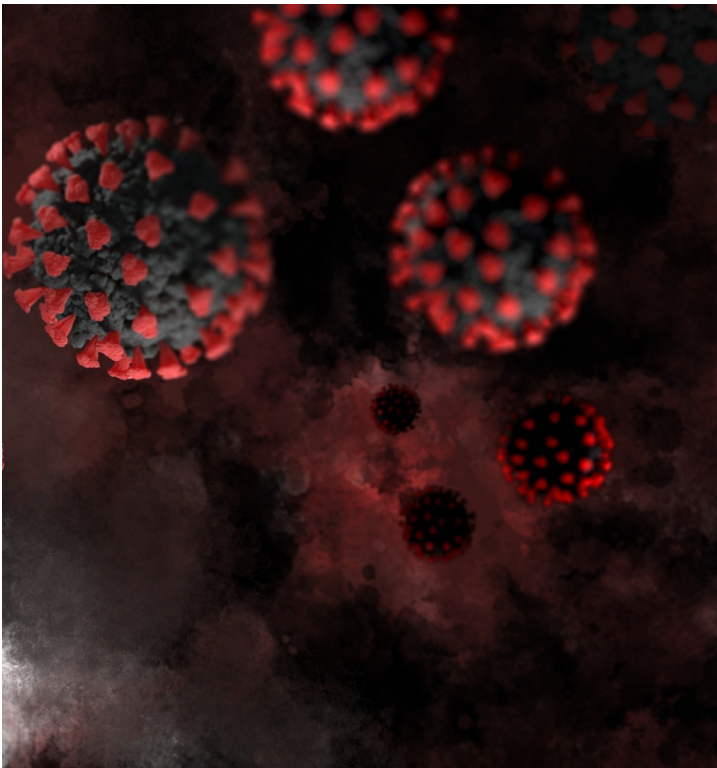
*approved under Emergency Use Authorization(s)

Bemcentinib will be studied in the EU funded EU-SolidAct trial in hospitalized COVID-19 patients



- EU-SolidAct trial – provides BerGenBio access to an establish clinical protocol and infrastructure in Europe through a multi-center, randomized, adaptive platform trial
- Bemcentinib will be studied in up to 500 patients
- BerGenBio will provide drug material and incremental funding of costs related to the bemcentinib sub-protocol
- Opportunity for BerGenBio to efficiently confirm previously encouraging clinical data

Strong scientific and clinical rationale for bemcentinib as a potential therapy for severe respiratory infections like COVID-19



- In spite of recent approvals, a high unmet medical need remains to treat hospitalized patients requiring oxygen
- In two Phase 2 trials bemcentinib in combination with SOC reduces acute COVID-19 inflammation and enhanced cellular repair signalling
- Bemcentinib has been shown to be effective in variants of concern and irrespective of mutations in the spike protein
- Bemcentinib included in EU-SolidAct trial; Phase II adaptive, multi-center trial in up to 500 hospitalized COVID-19 patients
- Further data will enable BerGenBio to assess potential of AXL inhibition in a broad range of respiratory indications

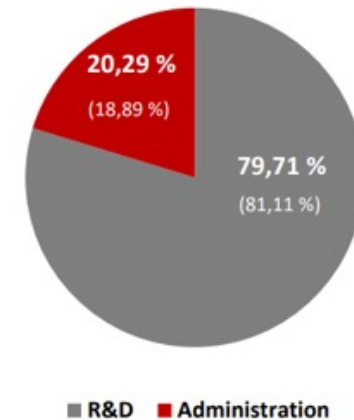
Finance Report – Key Q4 and FY 2021 financial highlights



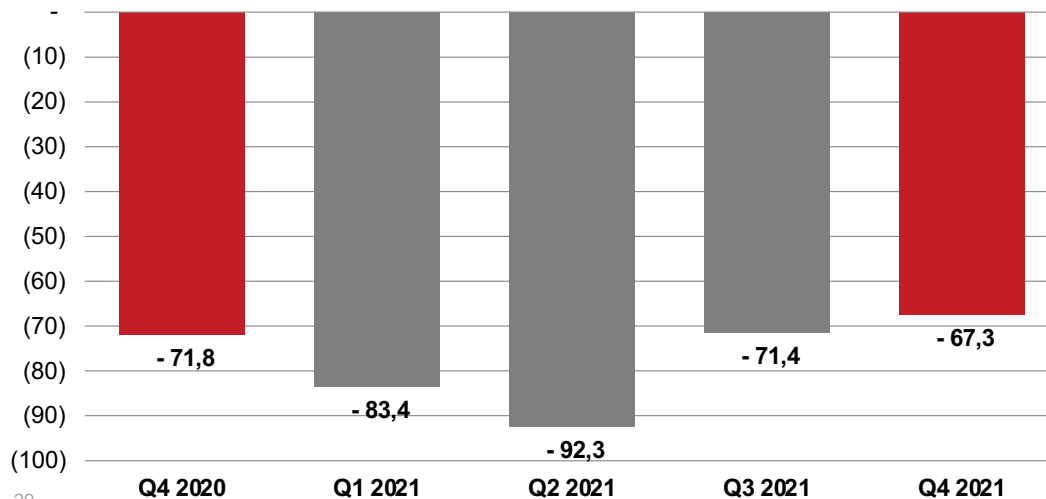
Key financial figures

(NOK million)	Q4 2021	Q4 2020	FY 2021	FY 2020
Operating revenues	0,8	0,6	0,8	0,6
Operating expenses	68,1	72,4	315,2	261,7
Operating profit (-loss)	-67,3	-71,8	-314,5	-261,1
Profit (-loss) after tax	-68,8	-73,9	-309,4	-257,0
Basic and diluted earnings (loss) per share (NOK)	-0.78	-0.85	-3.52	-3.43
Net cash flow in the period	-76,0	-53,1	-284,2	468,8
Cash position end of period	436,6	721,6	436,6	721,6

Operating expenses Q4 2021
(YTD 2021)



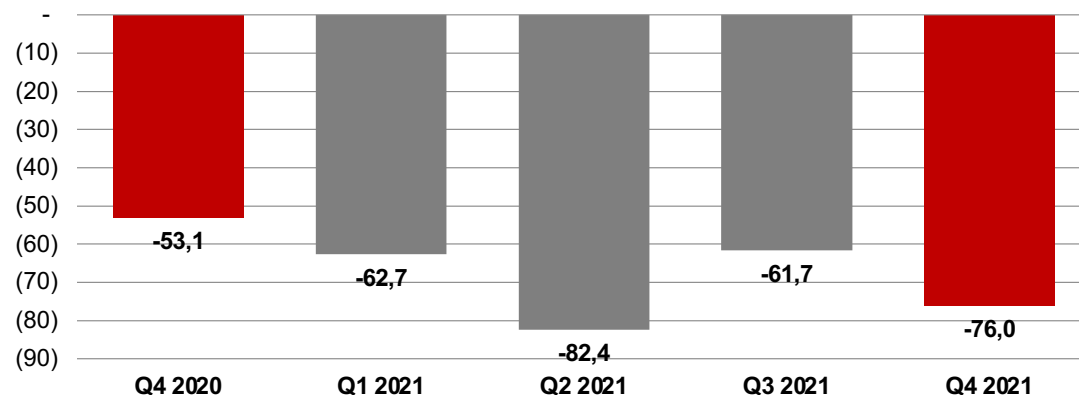
Operating loss (million NOK)



- Operating costs decreased to an average level after peak patient recruitment in Q1-Q2, mostly related to COVID-19 clinical trial
- Year on year cost increase in line with clinical trial activities.
- Organisational development continuing with increased headcount compared to Q4 2020.
- Well managed overhead costs. 80% of operating expenses in Q4 and the FY 2021 is attributable to Research & Development activities.

Cash flow and cash position

Cash flow (million NOK)



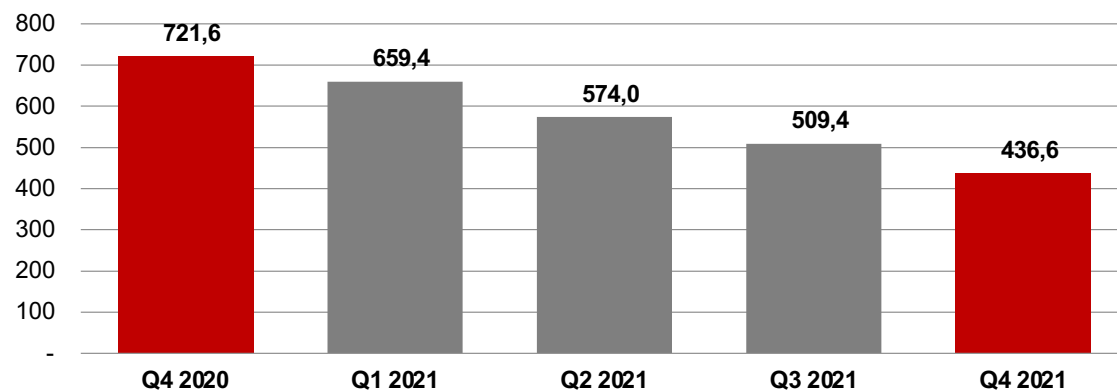
Cash burn operating activities Q4 2021

79,5 / 9,1
NOK million / USD million

Quarterly average cash burn (Q4 2020-Q4 2021)

67.2 / 7.8
NOK million / USD million

Cash position (million NOK)



Cash position Q4 2021

436.6 / 49.5
NOK million / USD million

2021 highlights & outlook



BerGenBio – investment highlights



Pioneering biology

World leaders in understanding AXL biology, as a mediator of aggressive disease such as cancer and respiratory infections



Two first in class selective AXL inhibitors

Bemcentinib - oral once-a-day capsule

Tilvestamab – functionally blocking mAb



Three shots on goal within significant market

NSCLC

AML

COVID-19

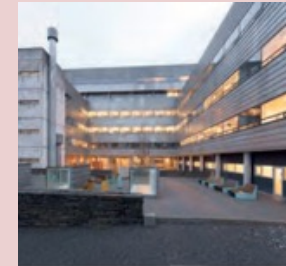


Potential to unlock significant value

1L NSCLC STK11m

2L AML

Hospitalized COVID-19



Strong balance sheet and fit-for-purpose organisation

Experienced R&D team

Industry & academic partnership and collaborations