



# BerGenBio

## Q4 2020 REPORT, HIGHLIGHTS AND FINANCIALS

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10<sup>th</sup> Feb 2021

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# AGENDA

1. Introduction & recent highlights
2. AXL Biology & Bemcentinib
3. Bemcentinib clinical trial update:
  - Relapse Acute Myeloid Leukaemia (AML)
  - Relapse Myeloid Dysplastic Syndrome (MDS)
  - Refractory Non-Small Cell Lung Cancer (NSCLC)
  - COVID-19
4. Tilvestamab
5. Finance Report
6. 2020 Highlights & Outlook

# BerGenBio Corporate Overview



## World leaders in understanding AXL biology

AXL tyrosine kinase mediates aggressive disease: immune evasion, therapy resistance & metastatic cancer, fibrosis and viral infection

Selective AXL inhibitors have the potential to treat many serious unmet medical needs

**Pipeline opportunities in multiple aggressive diseases**



## 2 selective AXL inhibitors in clinical development

Bemcentinib (oral once a day pill)  
Tilvestamab (mAb)

Bemcentinib broad Phase II program  
Monotherapy and combos with CPI, targeted & chemo

Biomarker correlation,  
parallel CDx development

Bemcentinib clinical data points 2020:  
**AML** (chemo-combo)  
**NSCLC** (KEYTRUDA combo) **COVID19** (mono)



## Resourced to deliver milestones

Listed on Oslo Børs: BGBIO

Clinical trial collaborations  
Merck, UKRI, and leading academic centres EU & USA

49 staff at two locations:  
HQ & R&D in Bergen, Norway;  
Clinical Development in Oxford, UK

**Cash Q4'20 NOK 722m**

# Q4 and recent highlights

Oct  
2020

First patient enrolled in BerGenBio's sponsored Phase II clinical trial in South Africa and India assessing bemcentinib as a potential treatment of hospitalised COVID-19 patients.  
Presented pre-clinical data on humanized anti-AXL antibody Tilvestamab at 32nd ENA Symposium

Oct  
2020

First patient dosed in MiST3 trial assessing bemcentinib in combination with pembrolizumab in relapsed malignant pleural mesothelioma patients, the world's first molecularly stratified umbrella study in mesothelioma.

Nov  
2020

Hosted a virtual R&D Day with prominent expert independent KOLs presenting recent AXL/bemcentinib data  
Selected for oral presentation at SITC 35th Annual Meeting; presented clinical translational research updates from Phase II bemcentinib and pembrolizumab combination study in refractory NSCLC

Dec  
2020

Updated clinical data from two Phase II studies of bemcentinib in AML and MDS patients presented at ASH 2020  
Presented at the Nordic-American Life Science Conference and DNB Nordic Healthcare Conference  
ACCORD 2 reinitiated recruitment of COVID-19 patients in the UK

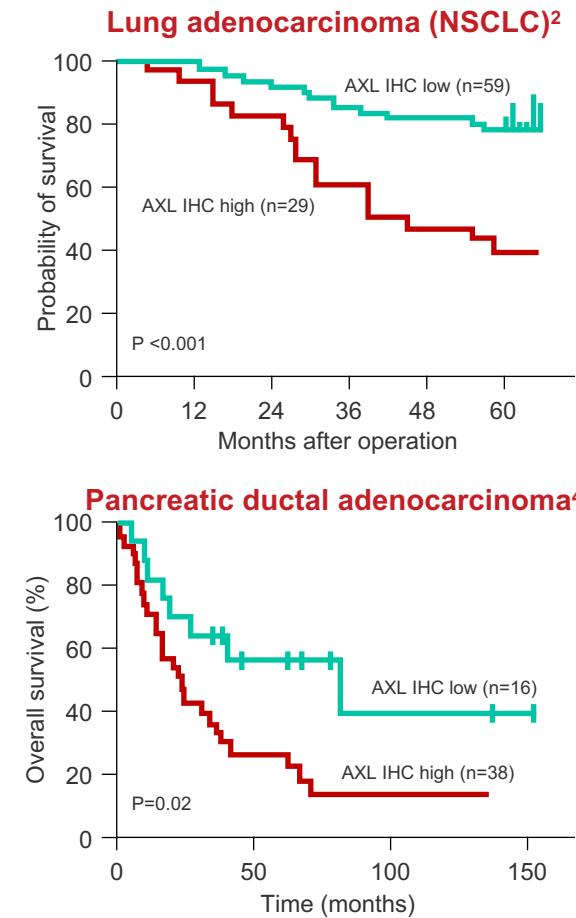
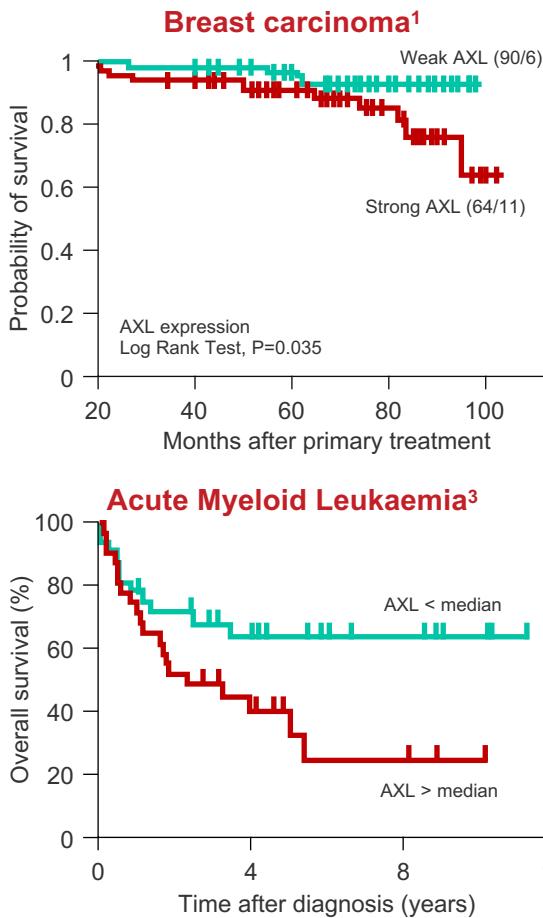
Jan  
2021

Selected for oral presentation at WCLC 2020; presenting translational data updates from ongoing Phase II bemcentinib and pembrolizumab combination study in refractory NSCLC  
Presented at H.C. Wainwright Bioconnect 2021 and SEB Virtual Nordic Healthcare Conference

# AXL Biology

# AXL is an independent negative prognostic factor in many cancers

## Strong AXL expression correlates with poor survival rate



## Broad evidence of AXL linked with poor prognosis<sup>5</sup>

Astrocytic brain tumours

Breast cancer

Gallbladder cancer

GI

- Colon cancer
- Oesophageal cancer
- Gastric cancer

Gynaecological

- Ovarian cancer
- Uterine cancer

HCC

HNC

Haematological

- AML
- CLL
- CML

Melanoma

Mesothelioma

NSCLC

Pancreatic cancer

Sarcomas

- Ewing Sarcoma
- Kaposi's sarcoma
- Liposarcoma
- Osteosarcoma

Skin SCC

Thyroid cancer

Urological

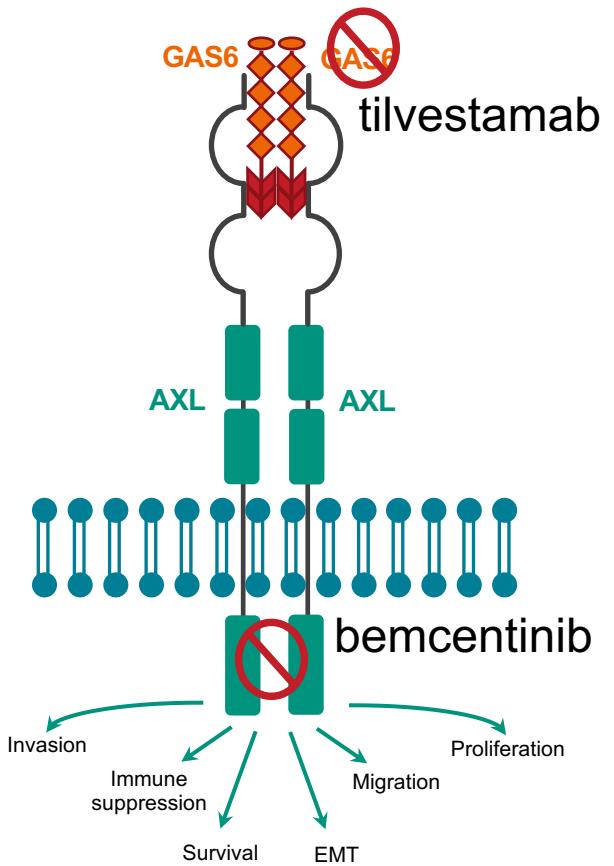
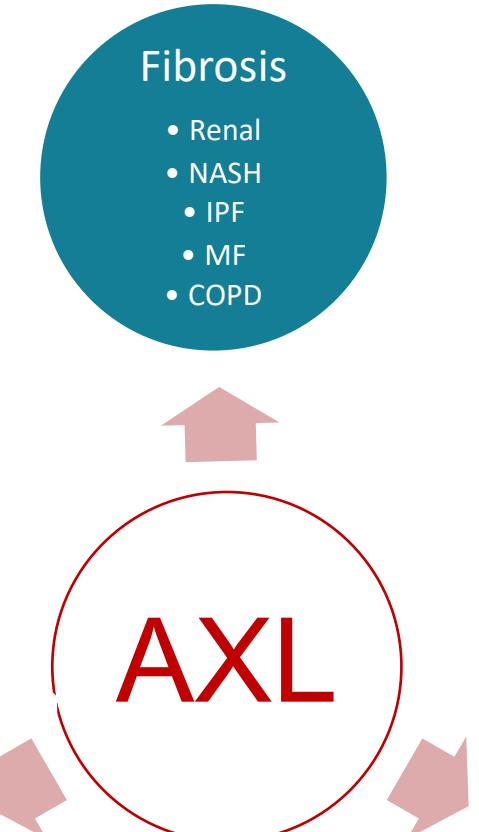
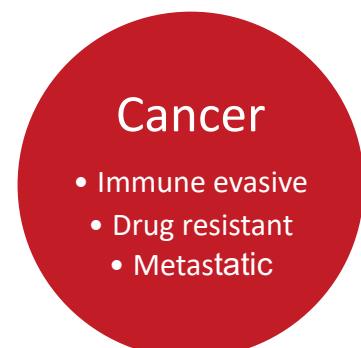
- Bladder cancer
- Prostate cancer
- RCC

# Our drugs selectively inhibit AXL signaling

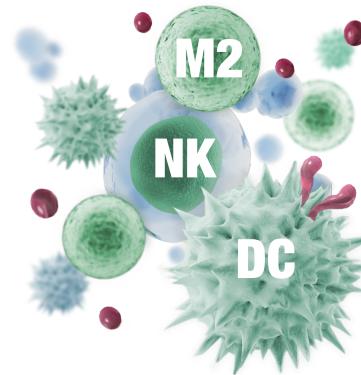
Axl regulates cellular plasticity implicated in **fibrotic** pathologies e.g. EMT, EndMT, Macrophage polarity

Elevated AXL signaling strongly associated with **cancer** progression, immune evasion, drug resistance and metastasis

AXL mediates **viral** entry to host cells and dampening of viral immune response

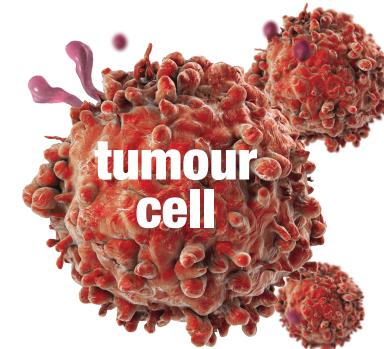
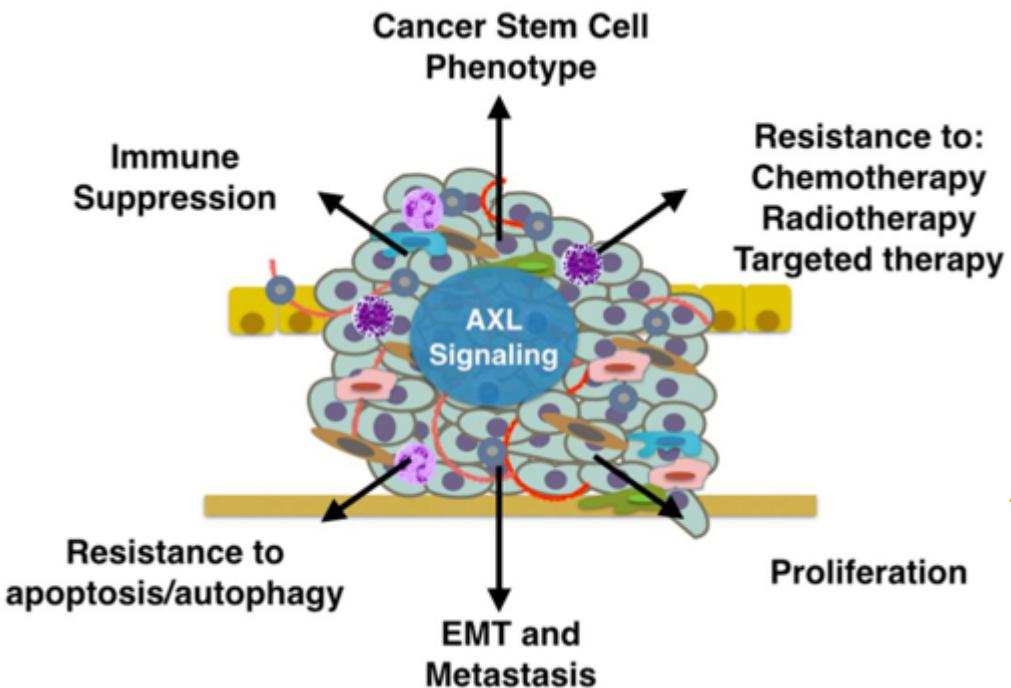


# AXL is a key survival mechanism ‘hijacked’ by aggressive cancers and drives drug resistance, immune-suppression & metastasis



AXL increases on immune cells and suppresses the innate immune response

- M1 to M2 macrophage polarisation<sup>1</sup>
- Decreased antigen presentation by DCs<sup>2</sup>
- Prevent CD8+ T cell mediated cell death<sup>3</sup>
- Activates Treg cells



AXL increases on the tumour cell and causes cancer escape and survival

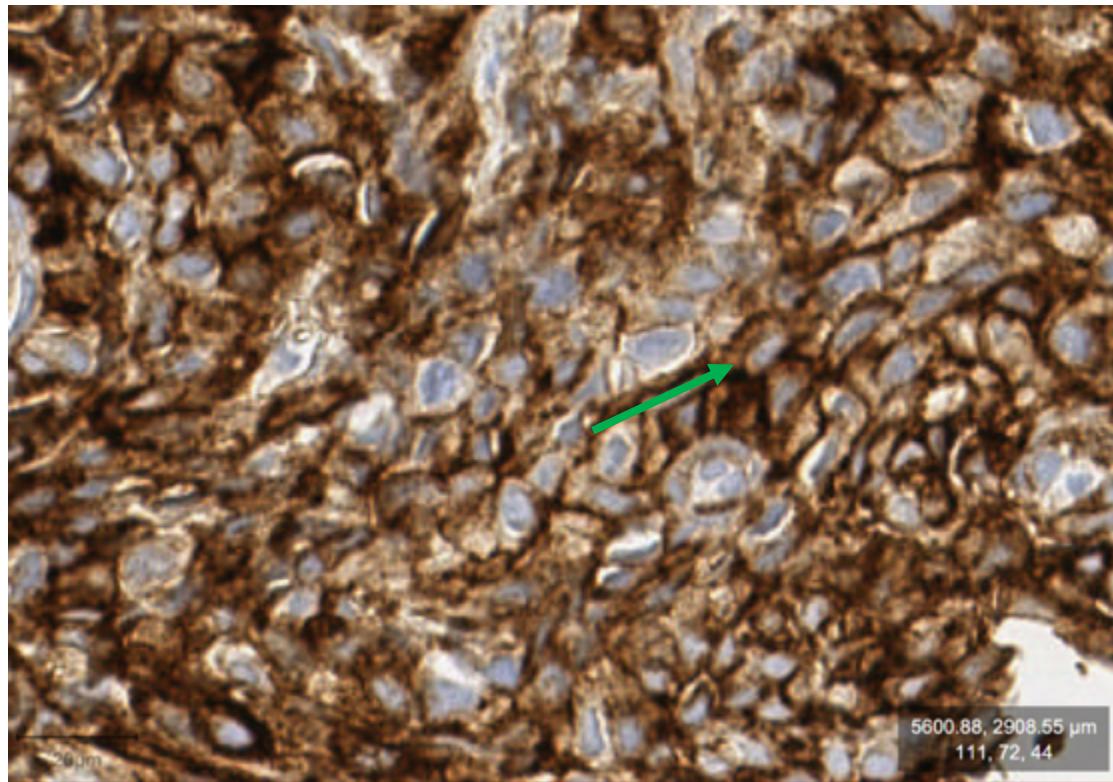
- AXL is a unique type I interferon (IFN) response checkpoint
- Acquired drug resistance
- Immune cell death resistant
- Metastasis

<sup>1</sup> DC- dendritic cells Treg – Regulatory T Cell

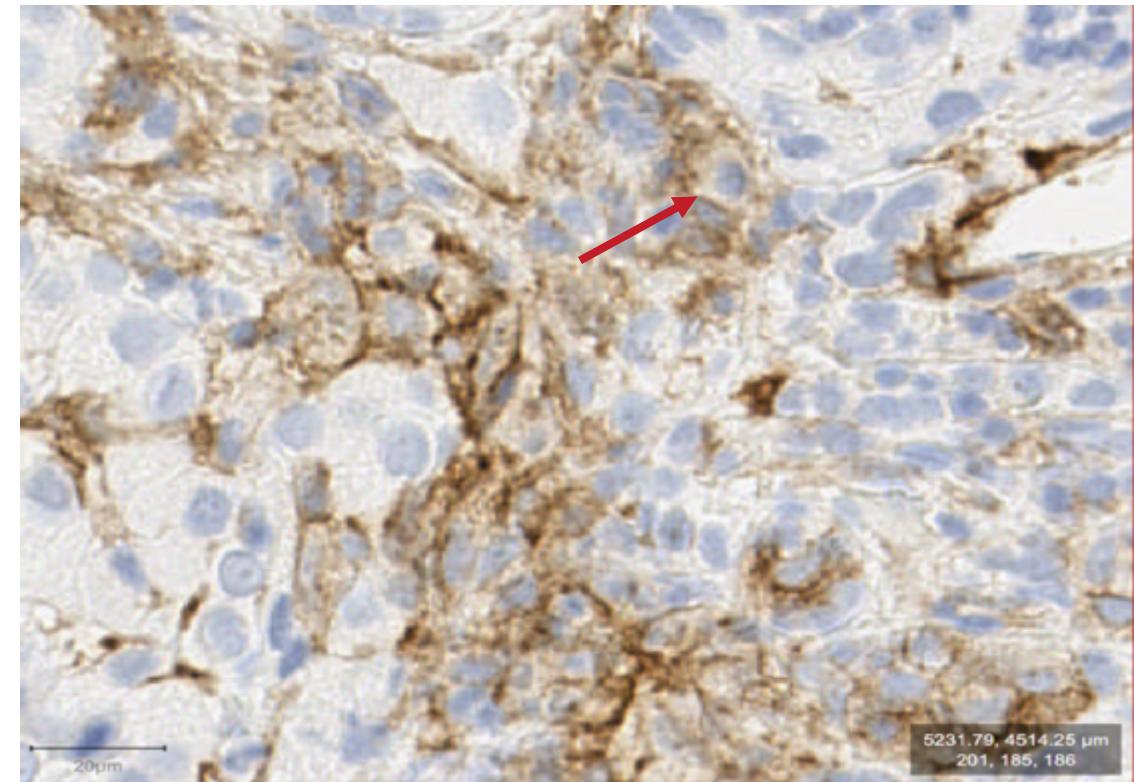
<sup>2</sup> 1.Ludvig et al Can Res, 2018; Davidsen et al., submitted 2.Kurowska-Stolarska et al Nature Comm 2017; Rothlin et al Cell 2007 3.Ludvig et al Can Res, 2018; Davidsen et al., submitted

# Composite AXL score (cAXL) - status defined by presence of AXL on membranes of tumour + immune cells

Example of high AXL expression on tumour cells: cAXL status of this patient is positive



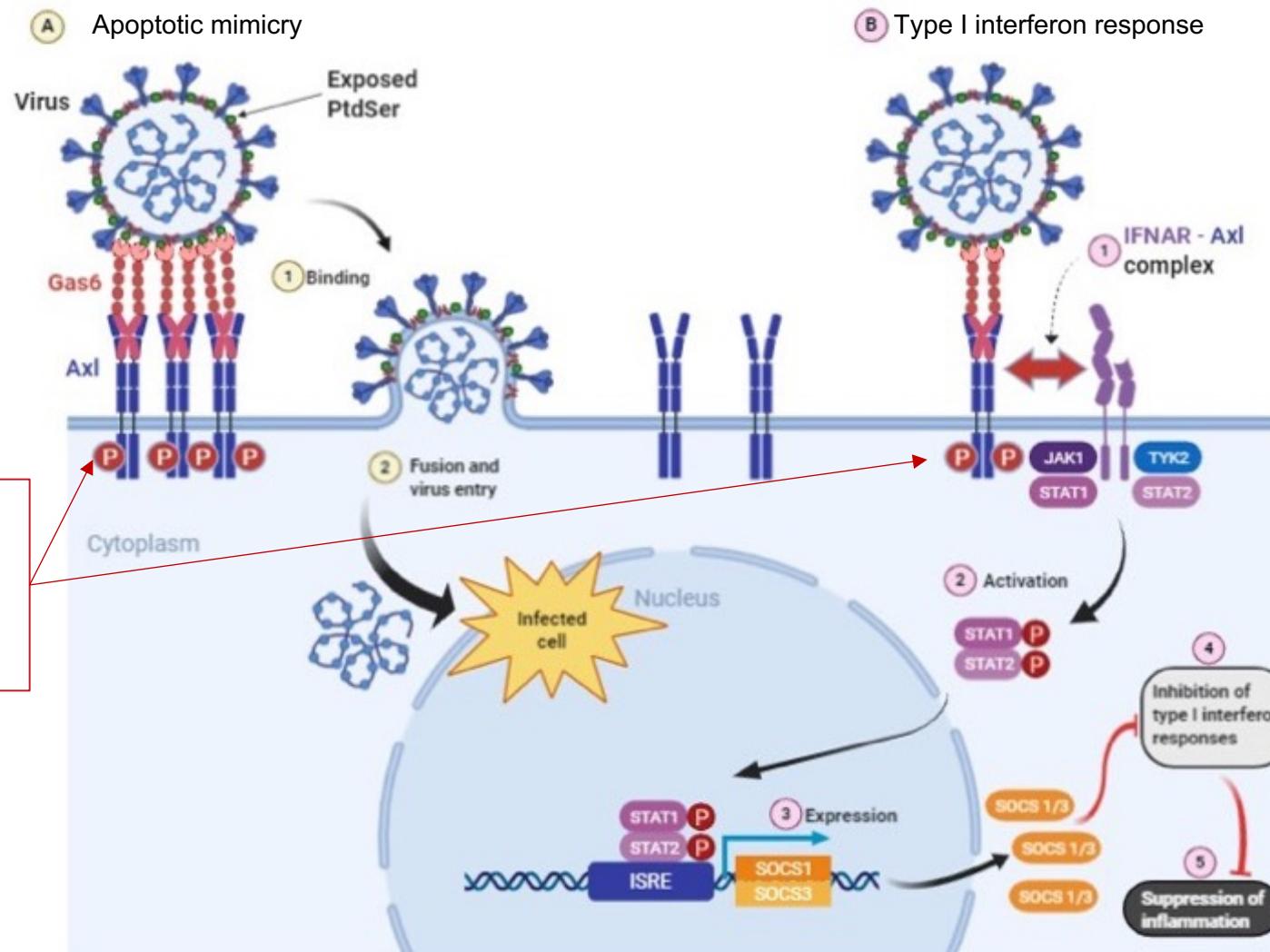
Example of tumour with a high number of AXL positive immune cells: cAXL status of this patient is positive



- Arrows directed at examples of positively-stained **tumour** and **immune** cell, respectively
- Both patients experienced significant tumour shrinkage on bemcentinib + pembrolizumab treatment combination

# AXL is targeted by enveloped viruses to enter cells and dampen the viral immune response

Enveloped viruses display phosphatidylserine that is recognized by GAS6, the AXL receptor ligand, that mediates viral entry through “apoptotic mimicry”.



# BerGenBio R&D Day with prominent independent expert Key Opinion Leaders



## Professor Wendy Maury, PhD

Department of Microbiology and Immunology, University of Iowa, Iowa, USA

### A novel approach for controlling SARS-CoV-2 infection: Bemcentinib inhibition of AXL signaling

- Utilization of AXL contributes to ACE2-dependent entry
- AXL enhances virus infection by facilitating virus entry via an endosomal pathway
- Bemcentinib control of virus infection likely involves both reduced viral entry and enhanced interferon responses



THE UNIVERSITY  
OF IOWA



## Cory M. Hogaboam, PhD

Professor of Medicine, Department of Medicine, Cedars-Sinai Medical Center, Los Angeles, USA

### The Role of AXL in Fibrosis

- Gas6, AXL and pAXL are increased in severe IPF
- Targeting AXL with bemcentinib abolishes synthetic and functional properties of primary IPF fibroblasts *in vitro* assays
- Targeting AXL ameliorates fibrotic responses in an *in vivo* model of IPF



## Dr. Matthew Krebs, ChB, FRCP, PhD

Clinical Senior Lecturer in Experimental Cancer Medicine, The University of Manchester & Consultant in Medical Oncology, The Christie NHS Foundation Trust, Manchester, UK

### Targeting AXL with Bemcentinib in Lung Cancer

- AXL expression highly prevalent in mesothelioma
- Bemcentinib reverses EMT, repolarizes TAMs and potentiates efficacy of immunotherapy in murine cancer models
- cAXL selects for 2L immunotherapy relapse NSCLC patients that benefit from bemcentinib + pembrolizumab combination



## Professor Sonja Loges, MD, PhD

Director, Department of Personalised Oncology, University Hospital Mannheim and Division of Personalised Medical Oncology, German Cancer Research Center – DKFZ, Germany

### AXL by Bemcentinib – a novel opportunity to treat AML and MDS

- Bemcentinib inhibits AML/MDS cell survival and enhances anti-leukemic immunity
- Bemcentinib mode of action is most like most blockade of immune suppression.
- LDAC + Bemcentinib is well tolerated and effective in unfit/elderly AML patients



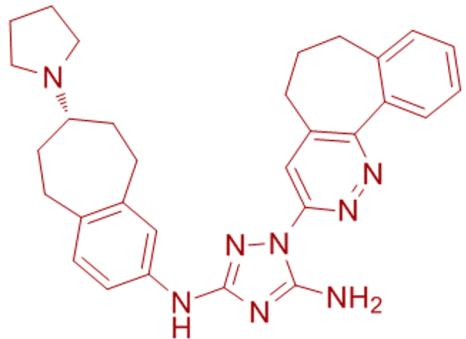
# Bemcentinib

First-in-class, selective, potent, oral AXL inhibitor

# Bemcentinib, a first-in-class, potent, oral, highly selective AXL inhibitor

- ✓ Nanomolar in vitro potency ( $IC_{50} = 14 \text{ nM}$ )
- ✓ Uniquely selected for AXL
  - ✓ 50-100-fold selective cf. TAM kinases
- ✓ Manufacturing at increased scale for late-stage regulatory filing
- ✓ Size 0 100mg HPMC capsules
- ✓ 3 years stability confirmed
- ✓ Once daily oral dosing





- ✓ MOA is synergistic with other therapies, enhancing response
- ✓ Extensive Phase I & II experience
  - ✓ >400 patients
- ✓ Safety and tolerability profile supports use in combination with other drugs

# BerGenBio pipeline of sponsored clinical trials

Candidate	Targeted Indication	Preclinical	Phase I	Phase II	Registrational
Bemcentinib monotherapy	>2L AML & MDS				
Bemcentinib combination with LDAC	>2L AML				
Bemcentinib combination with Pembrolizumab 	2L NSCLC chemo refractory				
	2L NSCLC CPI refractory				
	2L NSCLC CPI+chemo refractory				
Bemcentinib monotherapy	Hospital COVID19 patients				
Tilvestamab (BGB149)	Phase I				

# BerGenBio pipeline of Investigator Sponsored Trials (ISTs)

Candidate	Targeted Indication	Phase I	Phase II	Registrational	Sponsor
Bemcentinib	COVID-19	Monotherapy			Uni. Hospital Southampton/UKRI funded 
	2L AML	Monotherapy			European MDS Cooperative Group
	2L HR-MDS	Monotherapy			European MDS Cooperative Group
	Recurrent Glioblastoma	Monotherapy			Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
	Relapsed Mesothelioma	+ pembrolizumab			University of Leicester 
	1L Metastatic Melanoma	+ pembrolizumab or +Dabrafenib/Trametinib			Haukeland University Hospital
	2-4L Stage 4 NSCLC	+ docetaxel			UT Southwestern Medical Center
	1L metastatic or recurrent PDAC	+ Nab-paclitaxel +Gemcitabine +Cisplatin			UT Southwestern Medical Center

Ongoing Trial

Completed Trial

# Bemcentinib is most advanced and broadly developed selective AXL inhibitor

Selective

ARCUS  
BIOSCIENCES

SIGNALCHEM  
LIFESCIENCES  
AnHeart  
therapeutics

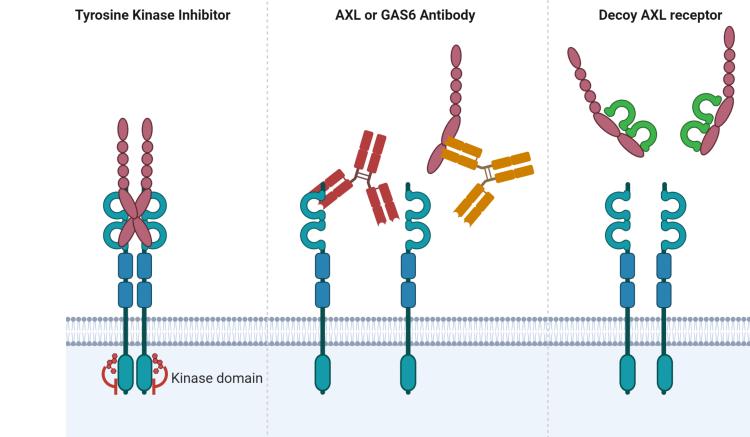
BerGenBio  
bemcentinib

Celldex  
therapeutics  
Anti-AXL MAB  
biatla

ADC  
THERAPEUTICS

BerGenBio  
tilvestamab

Small  
molecule



Non-selective

aravive  
BIOLOGICS  
AVB-S6-500  
(decoy receptor)

Biologic

Biologic

BETTA  
藥業  
Qurient  
therapeutics  
Incyte  
Sumitomo Dainippon  
Pharma

Lilly

MIRATI  
THERAPEUTICS

astellas  
EXELIXIS

Small  
molecule

ONO  
ONO PHARMACEUTICAL CO.,LTD.

preclinical

Phase I

Phase II

Phase III

Approved

## Clinical Trial Update:

### Relapsed AML with bemcentinib/LDAC combination

FDA granted Orphan status in AML

FDA granted Fast Track Designation in AML

# Acute Myeloid Leukaemia (AML)

*Most common type of acute leukaemia in adults<sup>1</sup>*

AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018<sup>2</sup>

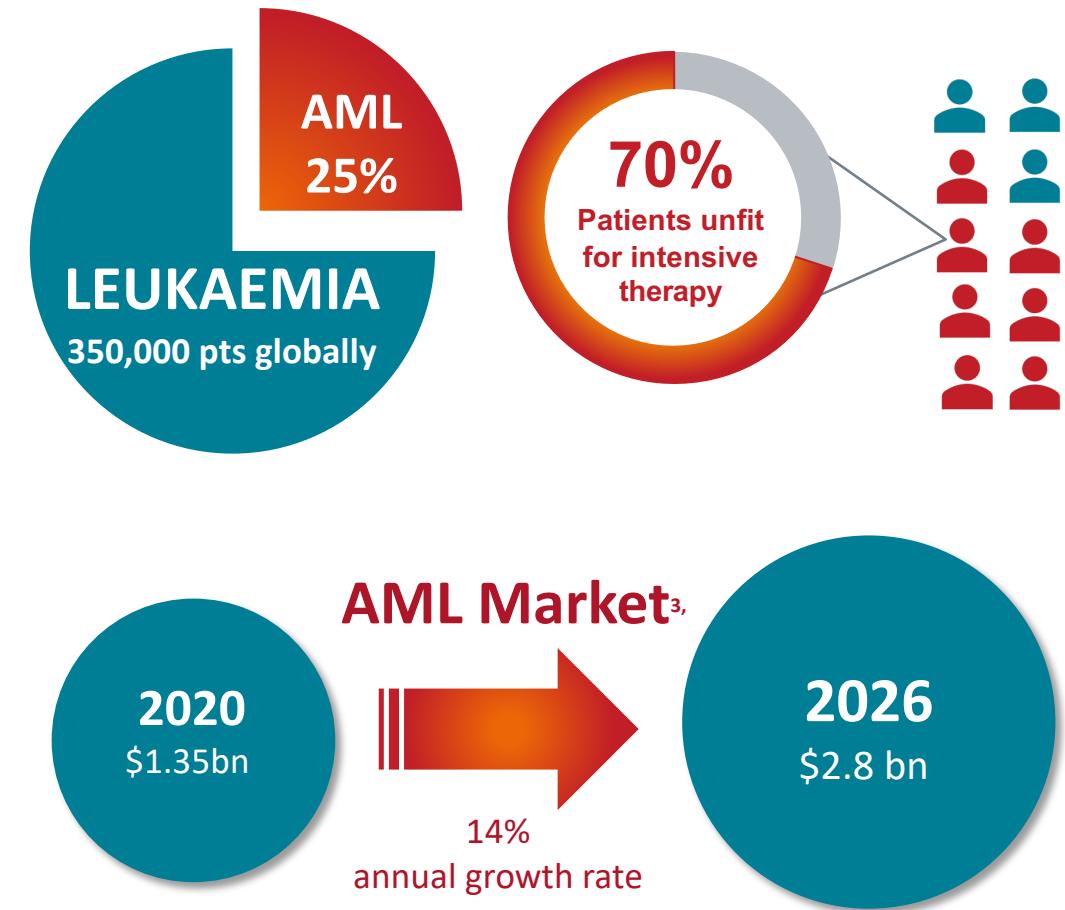
AML makes up 32% of all adult leukaemia cases

Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years<sup>6</sup>

Standard of care<sup>8</sup>

1L Venetoclax+HMA: CR/CRI 66.4% v 28.3% mOS 14.7 v 9.6mo  
1L Venetoclax+LDAC: CR/Cri 27% v7.4% mOS no benefit

5-year survival rates of 3-8% in patients over 60 years old<sup>7</sup>

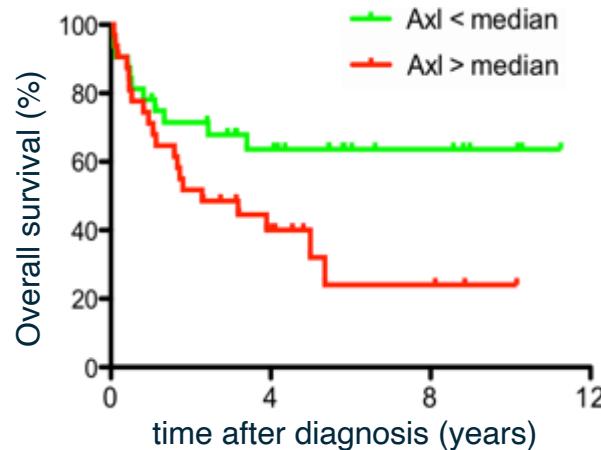


(1) Cancer.gov; (2) SEER; (3) 360marketupdates, Nov 2020.

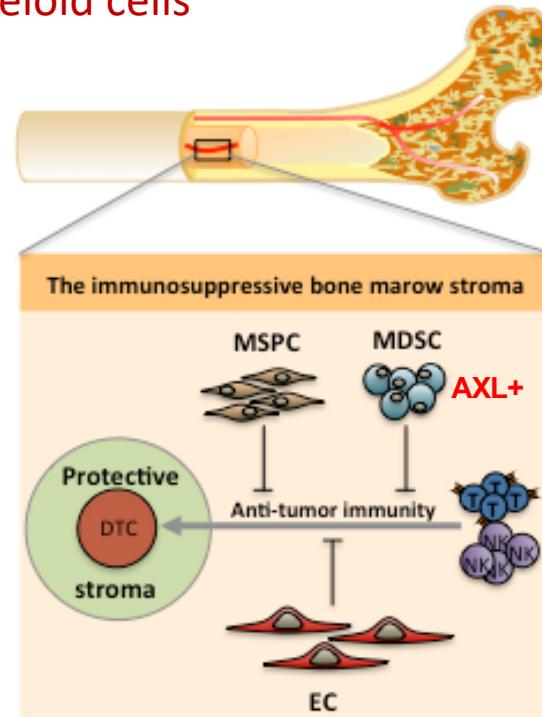
(4) <https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics> (5) <https://www.businesswire.com/news/home/20190319005442/en/> (6) <http://asheducationbook.hematologylibrary.org/content/2010/1/62.long>, (7) <https://www.ncbi.nlm.nih.gov/books/NBK65996/> (8) VIALE A & C

# Bemcentinib inhibits AML/MDS cell survival and enhances anti-leukemic immunity

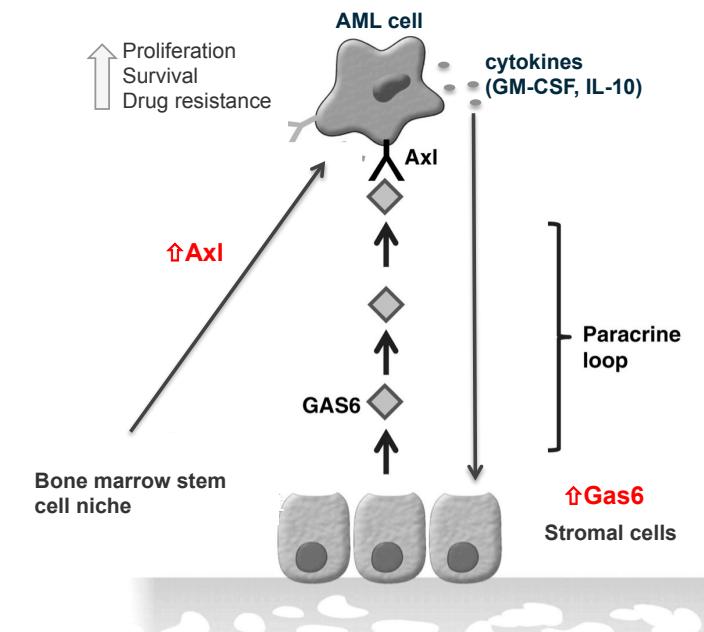
Axl is associated with therapy resistance and poor overall survival in AML patients.



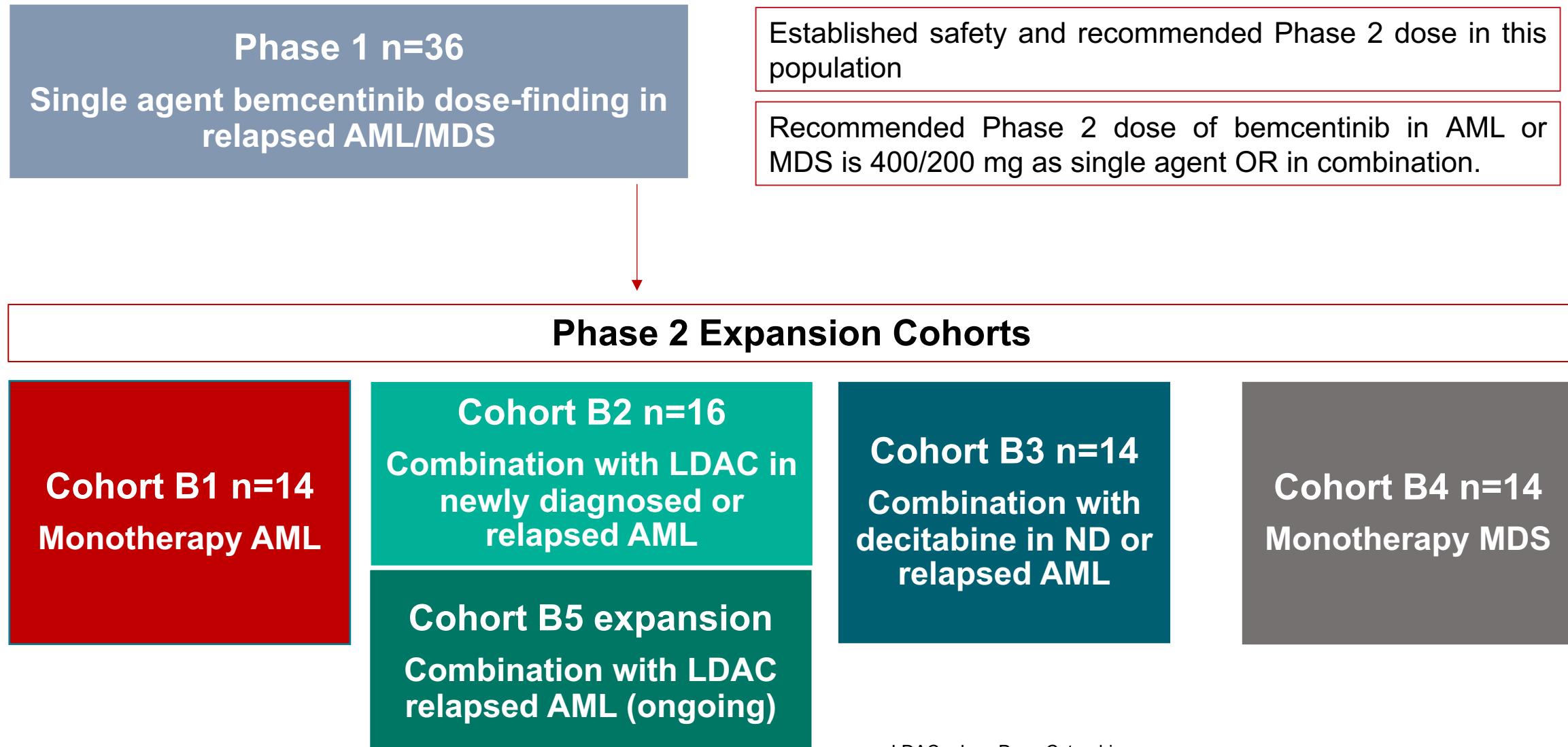
Immunosuppressive niches in the bone marrow show enhanced AXL on AML, MDS progenitor and myeloid cells



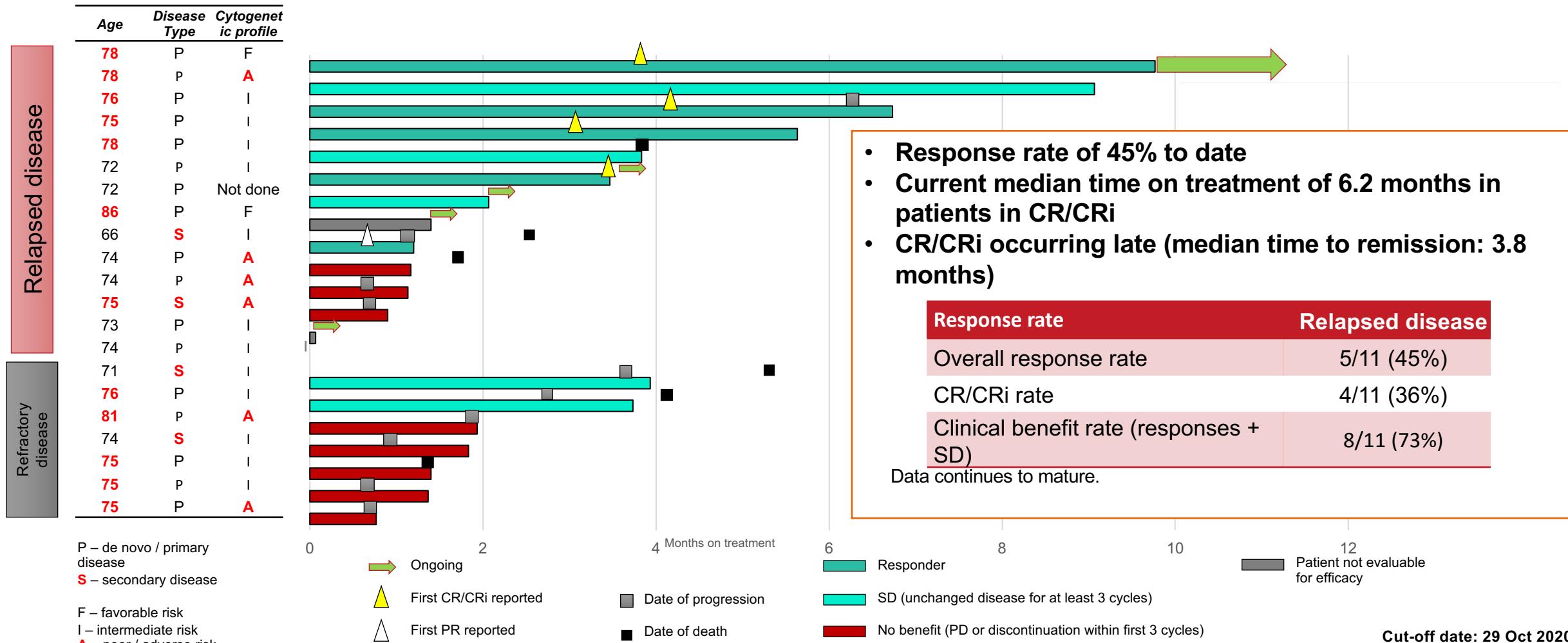
A paracrine axis between AML cells and the BM stroma establishes an immune and therapy-protective tumor cell niche



# Study BGBC003 conducted in two parts: Phase 1 and Phase 2



# Encouraging clinical activity observed in bemcentinib + LDAC combination in relapsed AML (Recruitment is ongoing)



Response assessed according to IWG revised recommendations in reporting AML (Cheson, et al. 2003)

**Efficacy-evaluable:** subjects completed 1 cycle of treatment and have bone marrow blast count at screening and at Cycle 2 or after

Clinical Trial Update:

**Relapsed HR-MDS with bemcentinib monotherapy**

# Myelodysplastic Syndromes (MDS)

*A heterogeneous group of closely-related clonal hematopoietic disorders*

All are characterized by one or more peripheral blood cytopenia.

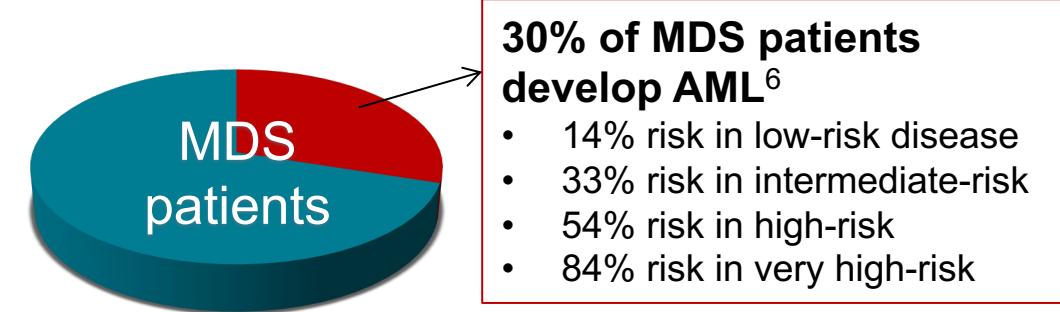
The incidence of MDS is estimated to be 4 in 100,000.<sup>1</sup>

The incidence in those aged  $\geq 80$  years is 50-75 in 100,000, sometimes estimated to be higher.<sup>1,2,5</sup>

Average age of diagnosis is 60 years<sup>3</sup>, and only 10% of patients are less than 50 years old.<sup>2,4</sup>

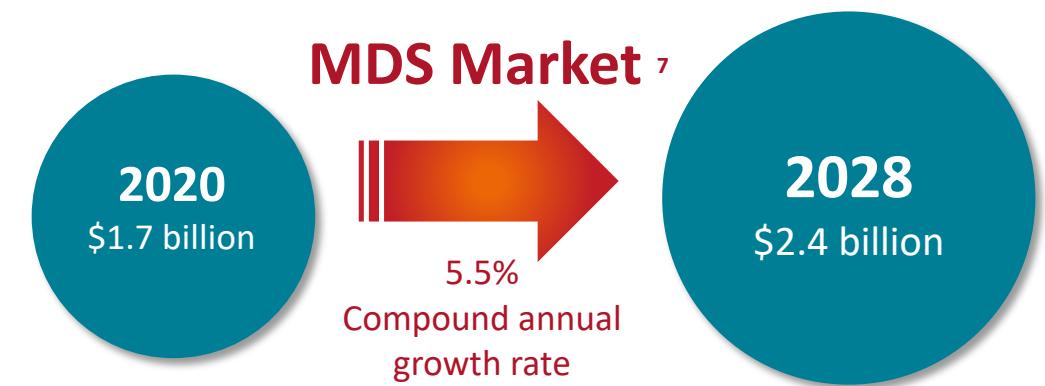
Approx. 30% of patients with MDS **will develop AML**, rates of transformation dependent on risk classification (IPSS-R, WPSS)

Median Overall Survival for HMA failure HR-MDS: 5.4mo<sup>7</sup>.



**30% of MDS patients develop AML<sup>6</sup>**

- 14% risk in low-risk disease
- 33% risk in intermediate-risk
- 54% risk in high-risk
- 84% risk in very high-risk



(1) SEER; (2) Neukirchen et al., 2011 (3) Greenberg et al., 2012, (4) Lubeck et al., 2016, (5) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3143554/>, (6) WPSS, (7) GlobalData, June 2020. (7) Komrokji et al

# Rationale for targeting AXL in MDS with bemcentinib

1

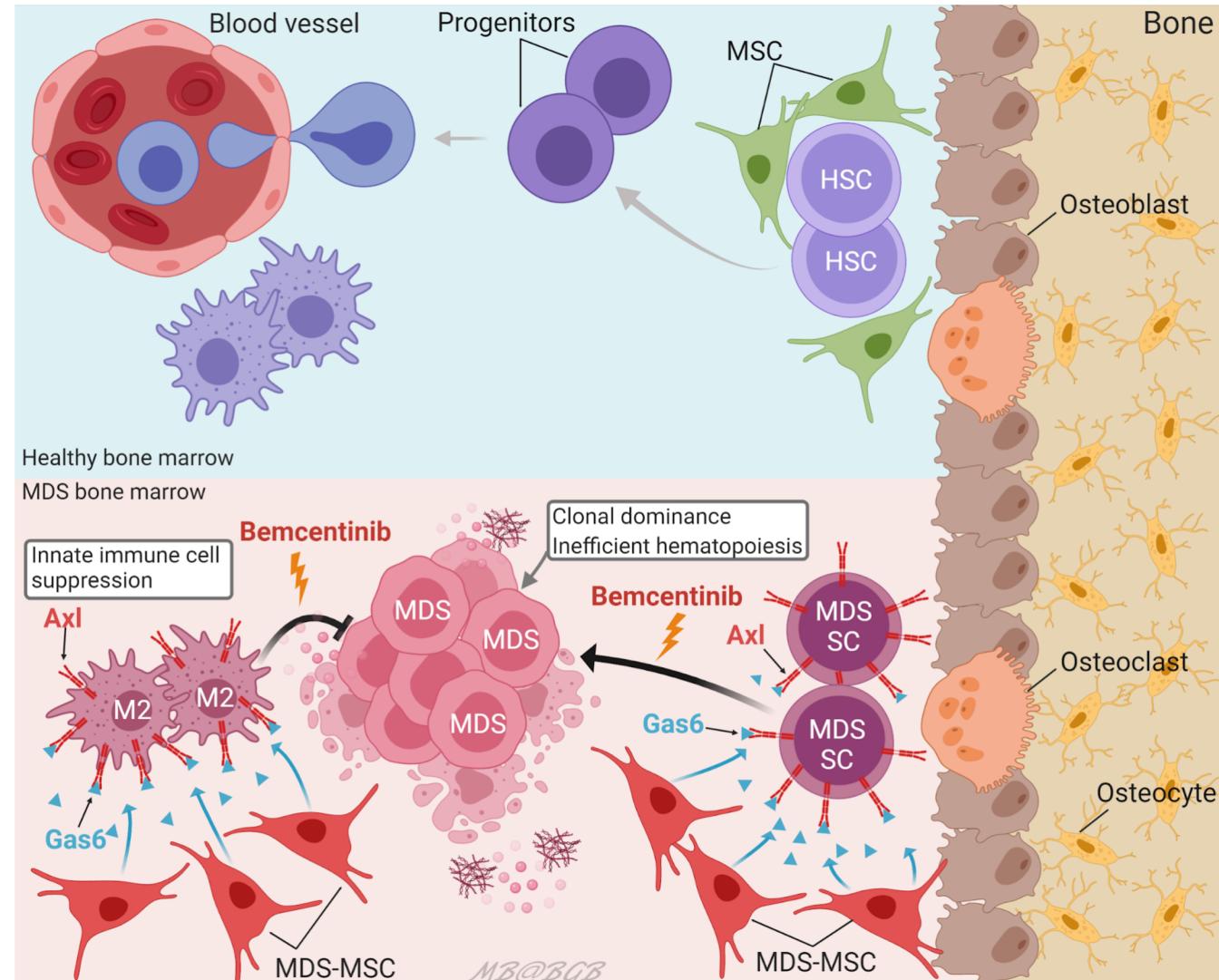
Patients failing HMA still have a dismal outcome with median survivals of less than 6 months<sup>1,2</sup> and very limited available treatment options

2

AXL mediates proliferation and survival of leukemic cells, innate immune cell suppression and resistance to chemotherapeutic agents<sup>3</sup>

3

Bemcentinib (BEM) is a selective small molecule inhibitor of AXL, a surface membrane protein kinase receptor overexpressed on leukemic (stem) cells<sup>3</sup>



Abbreviations: HMA: Hypomethylating agents, AXL: Axl Receptor Tyrosine Kinase Gas6: Growth arrest-specific Protein 6, SC: stem cell, MSC: mesenchymal stem cells

1 Prebet et al. American Society of Clin. Onc. (2011);  
2 Komrokji et al., Clin. Lymphoma Myeloma Leuk., 2015  
3 Medyoub H, Annals of Oncology, 2018, Abstract 5735

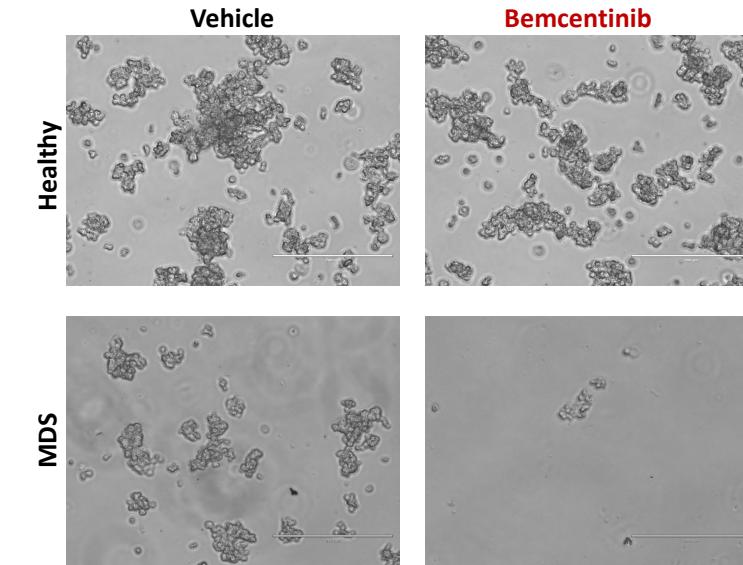
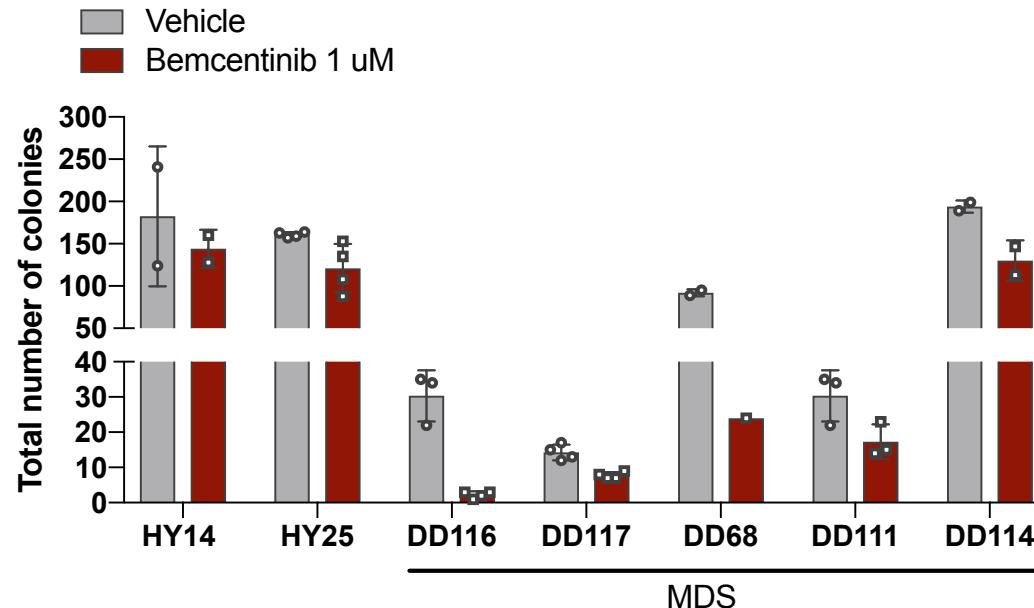
Figure: BerGenBio, Bergen, Norway

# Bemcentinib: Background and Rationale

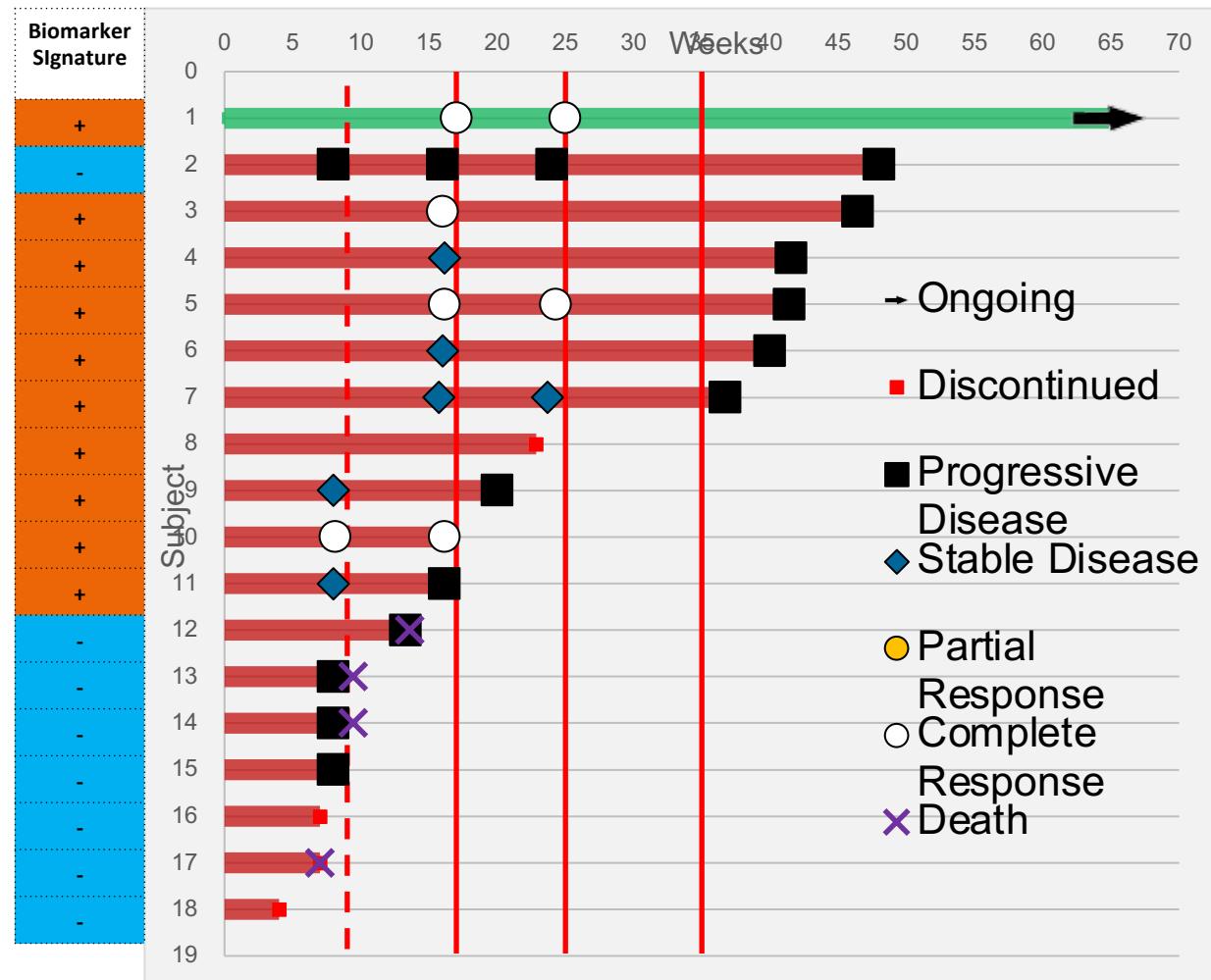
4

Blockade of the Gas6/AXL signalling axis selectively impaired MDS growth in an ex-vivo stroma-dependent co-culture setting

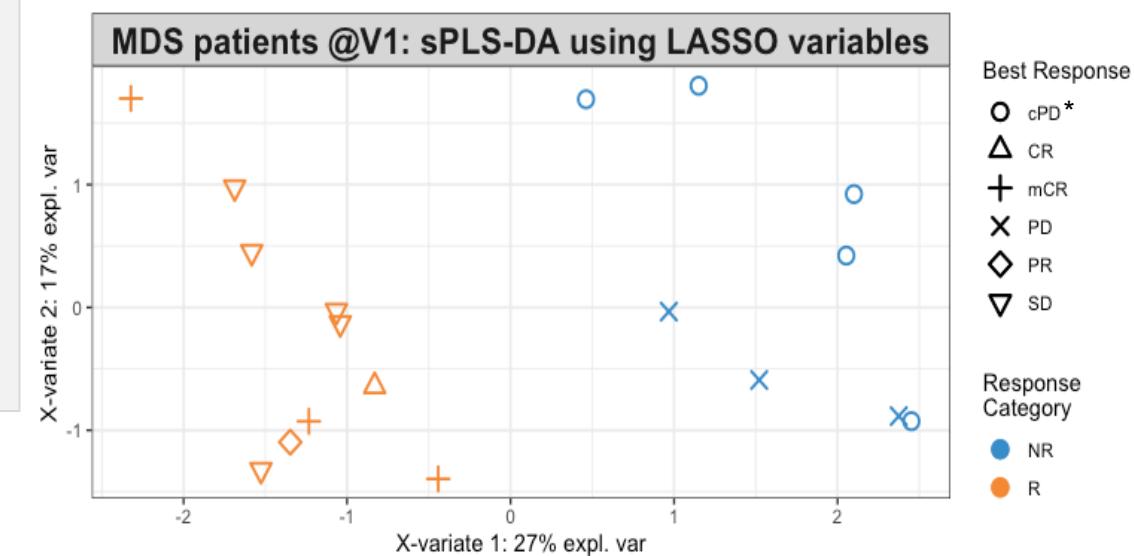
→ Effects were especially observed in the CD34+ MDS stem cell compartment



# Encouraging clinical activity observed with bemcentinib in relapsed HR-MDS



Best Response	Number (%); Median [range]
ORR (CR, CRI, PR, SD) (n=22)	8 (36%)
CR/CRI HR-MDS	4 (18%) CR:1 (4%); CRI:3 (14%)
Duration of response (immature)	269 days (9mo)
Biomarkers (predictive)	sAXL + immune mediators



Clinical Trial Update:

Refractory NSCLC with  
bemcentinib/pembrolizumab combination

# 2L NSCLC study: bemcentinib + pembrolizumab

## Open-label multi-center single arm phase II study

### Regimen

- Pembrolizumab**  
200mg fixed dose  
IV
- Bemcentinib** oral  
400mg loading  
dose X3/7, then  
200mg OD

### Cohort A

- Previously treated with a platinum-containing chemotherapy
- CPI-naïve
- Demonstrable PD

### Interim Analysis

#### Cohort A

#### Stage 1

**N=22 patients**

(each patient has the potential for at least 24 weeks follow-up)

### Final Analysis

#### Cohort A

#### Stage 2

**N=48 patients**

(each patient has the potential for at least 24 weeks follow-up)

### Cohort B

- Previously treated with PD-L1 or PD-1 inhibitor mono- therapy
- ≥12 weeks clinical benefit followed by PD

### Interim Analysis

#### Cohorts B

#### Stage 1

**N=16 patients**

(each patient has the potential for at least 24 weeks follow-up)

### Final Analysis

#### Cohorts B

#### Stage 2

**N=29 patients**

(each patient has the potential for at least 24 weeks follow-up)

Recruitment on-going

### Cohort C

- Previous 1<sup>st</sup> line combination checkpoint inhibitor + platinum doublet
- ≥12 weeks clinical benefit on 1<sup>st</sup> line therapy followed by PD

### Interim Analysis

#### Cohorts C

#### Stage 1

Recruitment on-going

**N=13 patients**

(each patient has the potential for at least 24 weeks follow-up)

### Final Analysis

#### Cohorts C

#### Stage 2

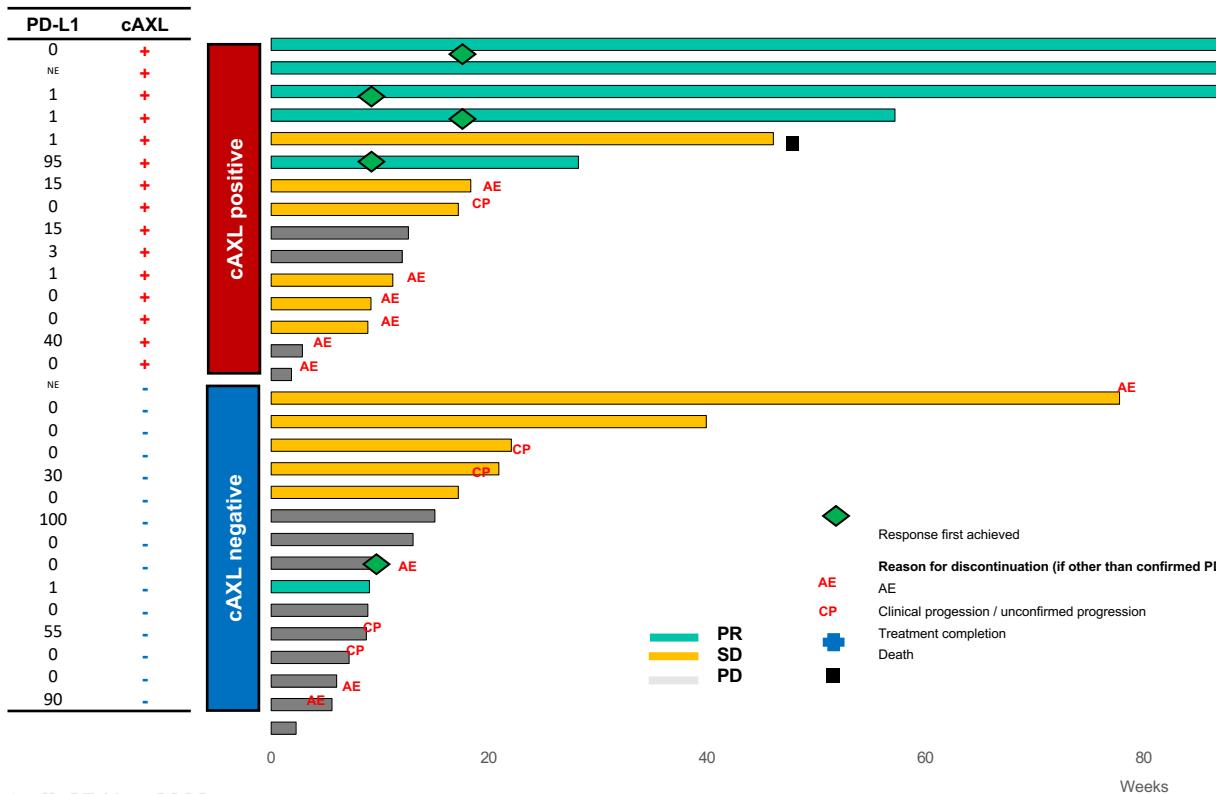
**N=29 patients**

(each patient has the potential for at least 24 weeks follow-up)

# Clinical Outcomes: Cohort A

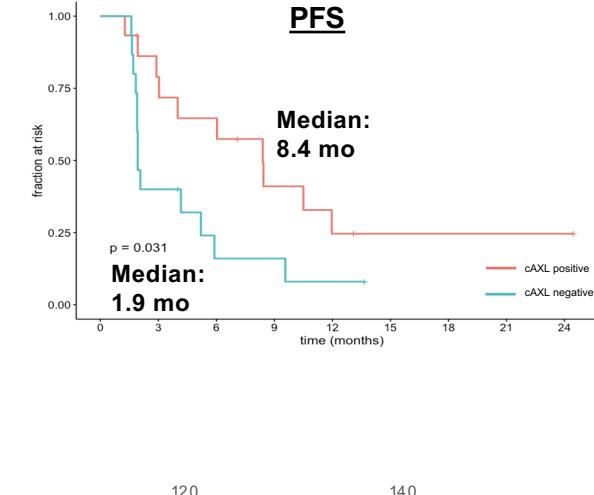
Informs potential 1L patient population

Time on treatment in radiologically evaluable patients by cAXL status



	ORR	CBR
cAXL positive (n=15)	5 (33%)	11 (73%)
cAXL negative (n=15)	1 (7%)	6 (40%)

Survival benefit cAXL +ve patients

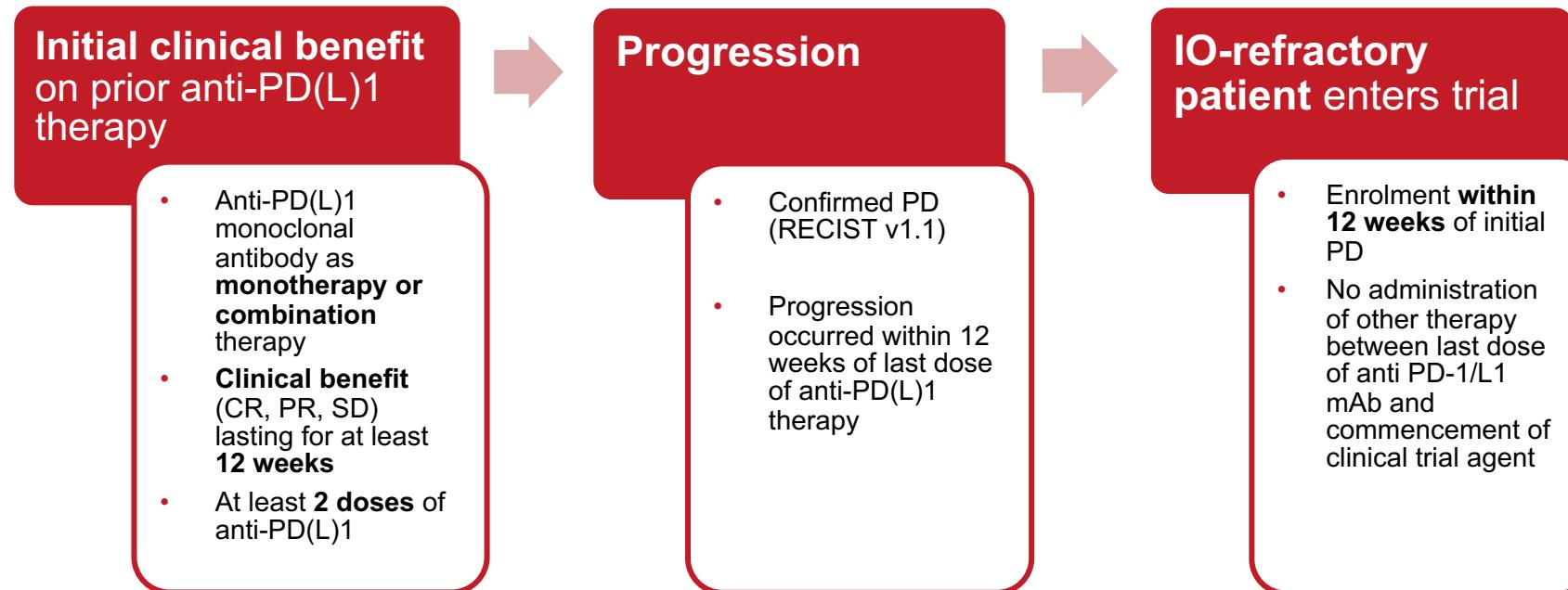


Survival outcomes (still maturing at cut-off)		
Cohort	mOS	12-mo OS
cAXL +ve	17.3 mo	79%
cAXL -ve	12.4 mo	60%

Cut-off: 27 Nov 2020

# Bemcentinib + KEYTRUDA in CPI refractory patients

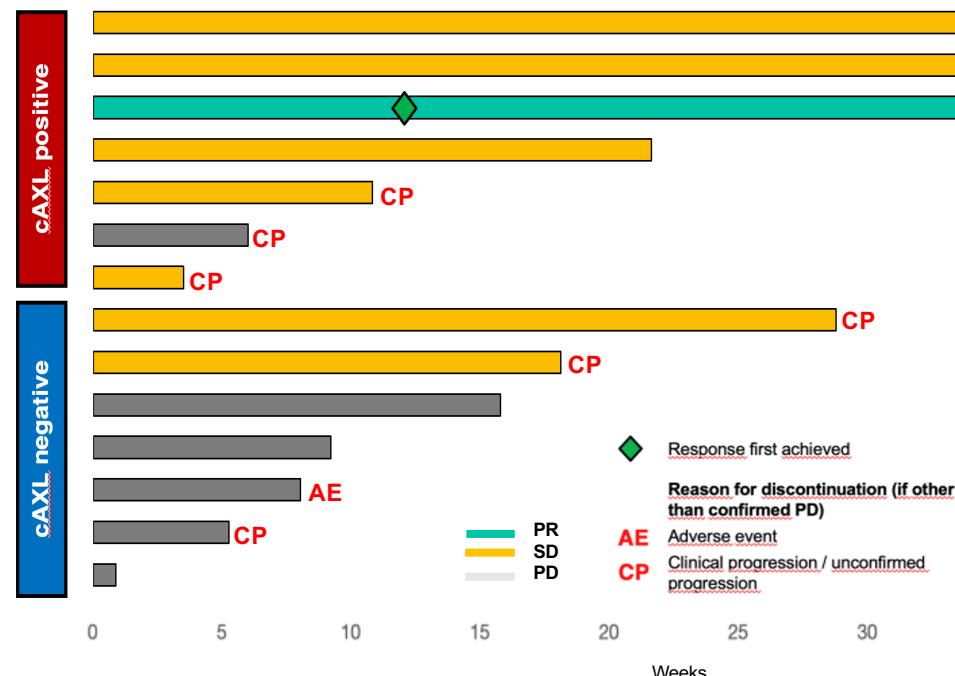
CHECK POINT INHIBITOR REFRACTORY PATIENTS: precise and specific definition



# Update On Clinical Outcomes: Cohort B

## Time on treatment in radiologically evaluable patients by cAXL status

Number pre Tx	Immediate prior treatment	PD-L1	cAXL
2	A + O	65	+
1	P	20	+
1	A	95	+
2	P	15	+
2	N	100	+
2	P	95	+
1	N+I	2	+
1	A	NA	-
1	A	NA	-
2	P	35	-
3	N	30	-
2	A	0	-
2	O	NA	-
2	O	0	-

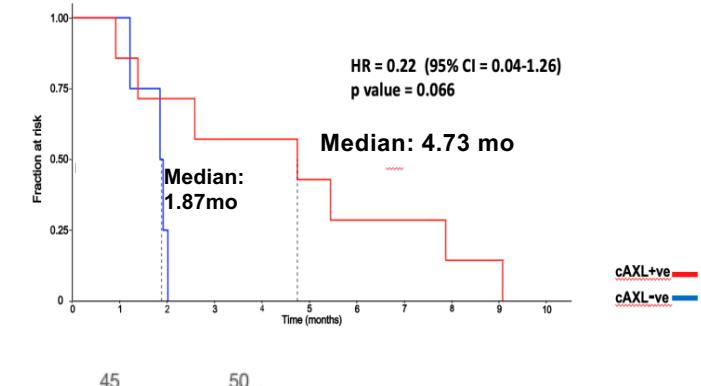


### Immediate prior therapy

P: pembrolizumab; A: atezolizumab; N: nivolumab; I: ipilimumab; O: other

Ongoing – rates at cut-off	ORR	CBR
cAXL positive (n=7)	1 (14%)	6 (86%)
cAXL negative (n=7)	0 (0%)	2 (29%)

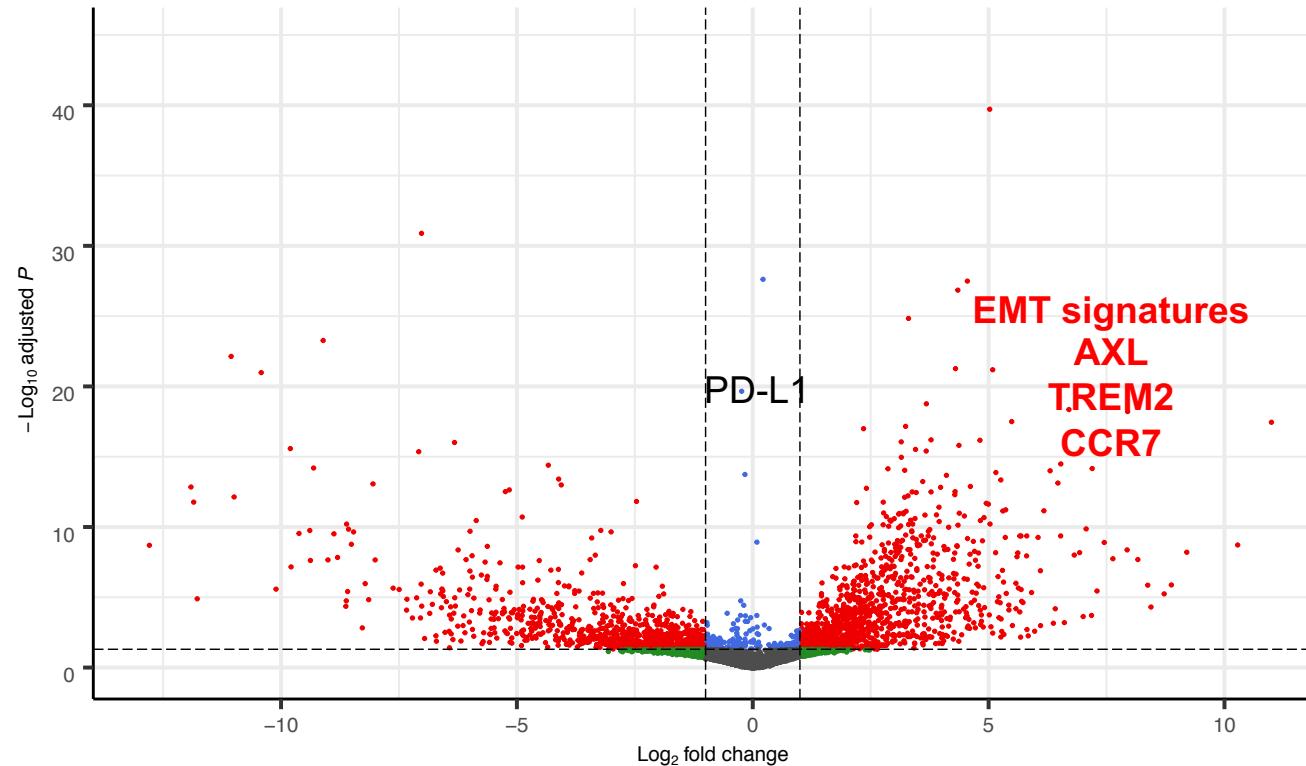
Previously reported PFS, Cohort B1 (Gabra, et al. Next Gen IO Congress, 2020.):





# Clinical translational findings

Whole tumour gene expression of Cohort B1 patients benefiting from bemcentinib-pembrolizumab



**Volcano Plot:** Differential gene expression analysis of patients showing benefit (n=5) vs patients with PD (n=3)

**RNAseq analysis** identifies gene signatures from benefiting patients:

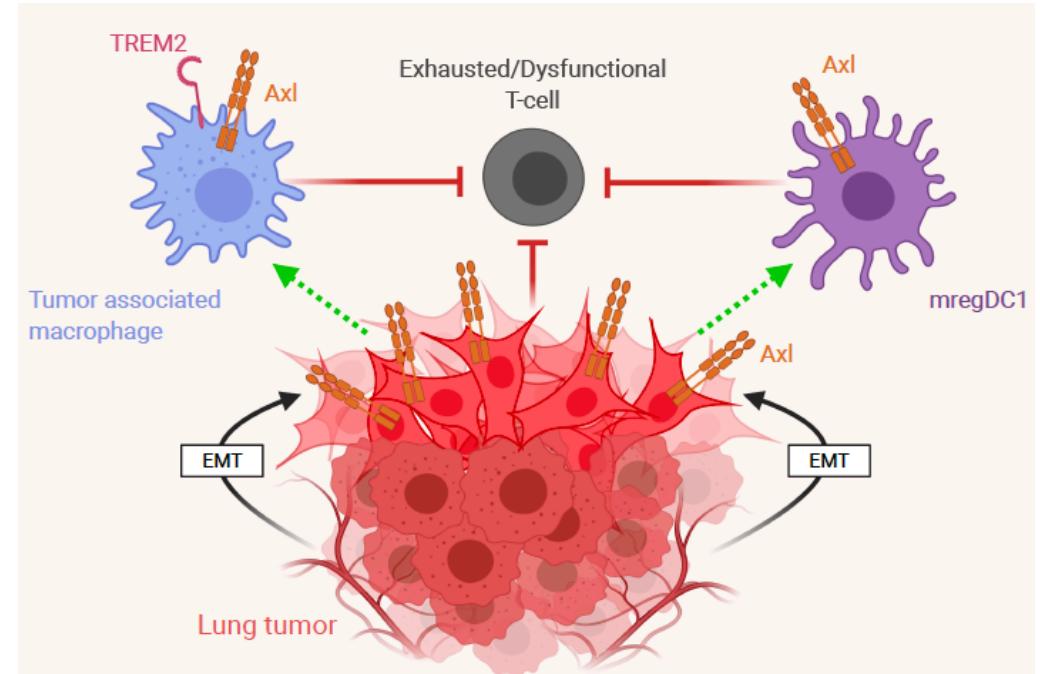
- Increased AXL expression
- Genes associated with tumor cell EMT<sup>1</sup>
- Presence of TREM2+ TAMs<sup>#,2</sup>
- Presence of CCR7+ mregDC1<sup>##,3</sup>

# tumor-associated macrophages  
##regulatory dendritic cells

# Proposed mechanism of acquired resistance to CPI

## AXL+ suppressive myeloid cells drive T cell dysfunction

- AXL promotes tumour-cell EMT and recently-described regulatory myeloid cells:
  - AXL<sup>+</sup> TREM2<sup>+</sup> Tumour Associated Macrophage<sup>1,2</sup>
  - AXL<sup>+</sup> CCR7<sup>+</sup> mregDC1<sup>3</sup>
- AXL expression in these cells promotes T cell dysfunction/exhaustion<sup>2</sup>
- Bemcentinib-pembrolizumab combination well tolerated and clinically active in CPI-naïve and CPI-refractory cAXL+ NSCLC
- Bemcentinib may reverse acquired resistance to checkpoint inhibition by targeting AXL<sup>+</sup> TREM2 macrophages and regulatory DCs
- Recruitment ongoing in CPI-refractory and chemo-CPI-refractory patient populations, cohorts B & C



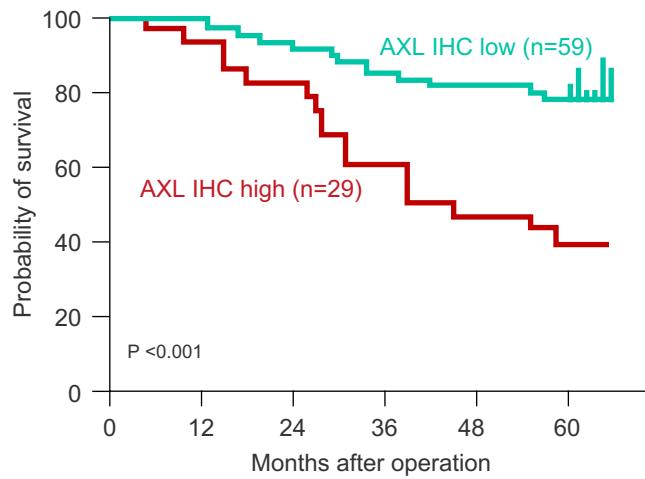
**Proposed mechanism (Spicer, et al. SITC, 2020):** AXL+ suppressive myeloid cells drive T cell dysfunction/exhaustion; bemcentinib inhibition of AXL reverses this state of immune suppression in the microenvironment, and promotes checkpoint inhibitor re-engagement

TREM – Triggering receptor Expressed on Myeloid Cells  
CCR7 - CC Chemokine receptor 7

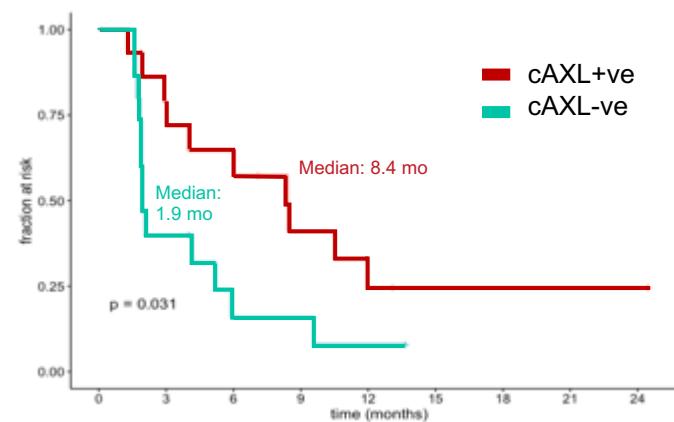
# AXL expression defines a poor prognosis subgroup of NSCLC

cAXL+ patients have significantly enhanced survival with bemcentinib + pembrolizumab in CPI-naïve and refractory patients

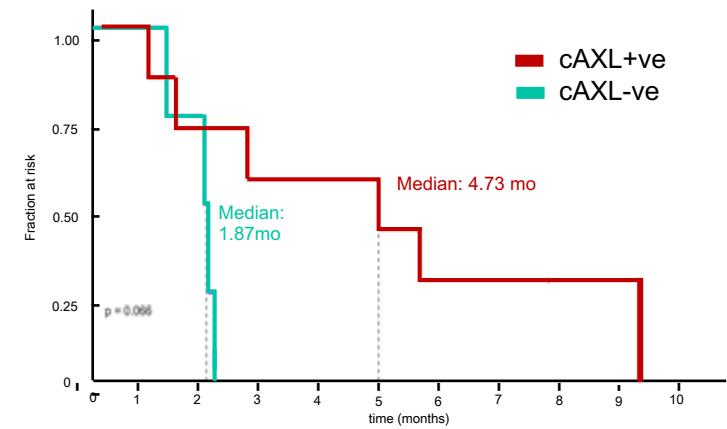
In NSCLC, the AXL expression encodes poor-prognosis<sup>1</sup>: defines expectations of the control arm



Cohort A PFS : CPI-naïve



Cohort B1 PFS: CPI-refractory



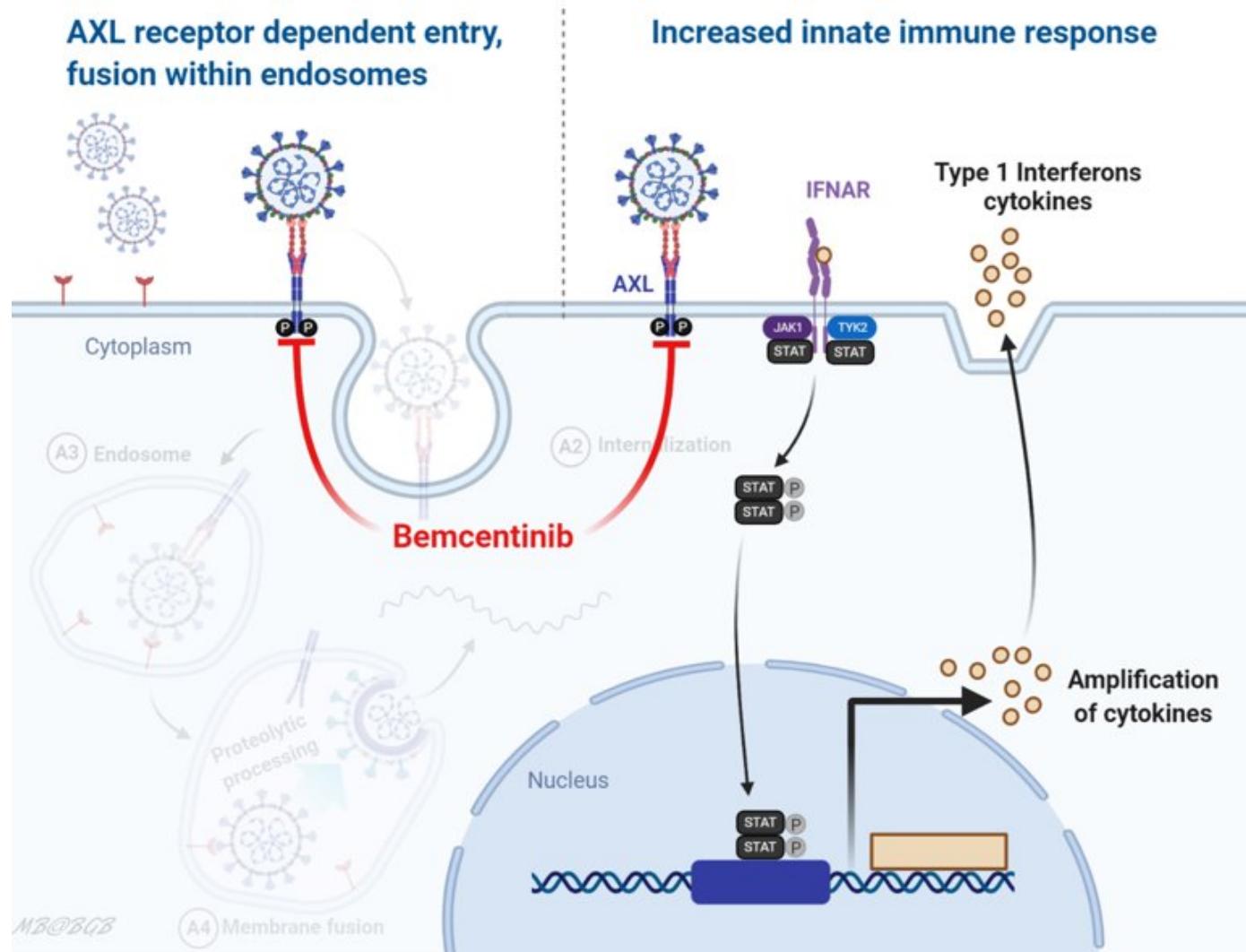
BIOLOGY = RATIONALE = OUTCOME

# Bemcentinib clinical development in COVID-19

ACCORD-2 trial

BGBC020 trial

# Potential of Bemcentinib on SARS-CoV-2 infection of host cells



- Utilization of AXL contributes to ACE2-dependent entry
- AXL enhances virus infection by facilitating virus entry via an endosomal pathway
- Bemcentinib control of virus infection likely involves both reduced viral entry and enhanced interferon responses

# Two rPh II trials in hospitalised COVID-19 patients

## BGBC020

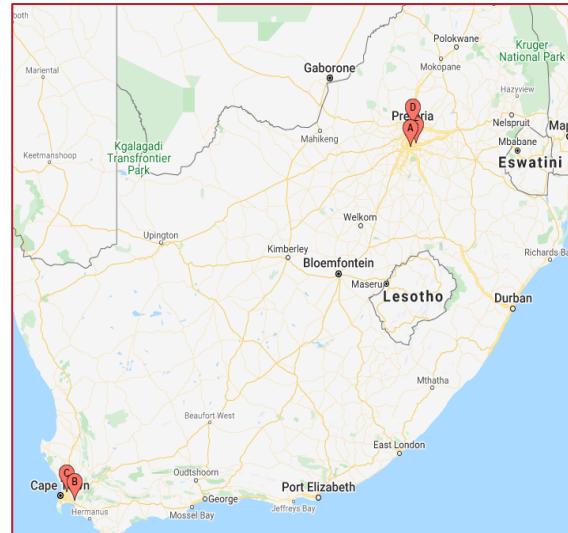
- Strong recruitment
- Well-tolerated; 2 iDMC meetings recommend continued patient recruitment
- Anticipate top line clinical efficacy data Q1'21

### ACCORD II STUDY



- Multicentre, seamless, Phase II adaptive randomisation platform trial
- Assessing the safety and efficacy of three candidate agents
- Up to 25 sites across the UK
- 60 patients will receive bemcentinib and 60 patients in a control group will receive standard of care treatment.

### BGBC020 – SOUTH AFRICA



- Company sponsored randomises Phase II trial
- 60 patients will receive bemcentinib and 60 patients in a control group will receive standard of care treatment
- Assessing the safety and efficacy of bemcentinib
- 5 sites across South Africa
- 7 sites across India.

### BGBC020 - INDIA



# Bemcentinib randomised Phase II Studies in COVID-19

COVID: BGBC020

## Primary objective

To evaluate the efficacy of bemcentinib as add-on therapy to standard of care (SoC) in patients hospitalised with coronavirus disease 2019 (COVID-19).



## Primary endpoint

Time to sustained clinical improvement of at least 2 points (from randomisation) on a 9-point category ordinal scale, live discharge from the hospital, or considered fit for discharge (a score of 0, 1, or 2 on the ordinal scale), whichever comes first, by Day 29 (this will also define the “responder” for the response rate analyses).

## Key Secondary objectives

- To evaluate the ability to prevent deterioration according to the ordinal scale by 1, 2, or 3 points
- To evaluate the number of oxygen-free days
- To evaluate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral load



## Key Secondary objectives

- The proportion of patients not deteriorating according to the ordinal scale by 1, 2, or 3 points on Days 2, 8, 15, and 29
- Duration (days) of oxygen use and oxygen-free days
- Qualitative and quantitative polymerase chain reaction (PCR) determination of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in oropharyngeal/nasal swab while hospitalised on Days 1, 3, 5, 8, 11, 15, and 29

## Exploratory objectives

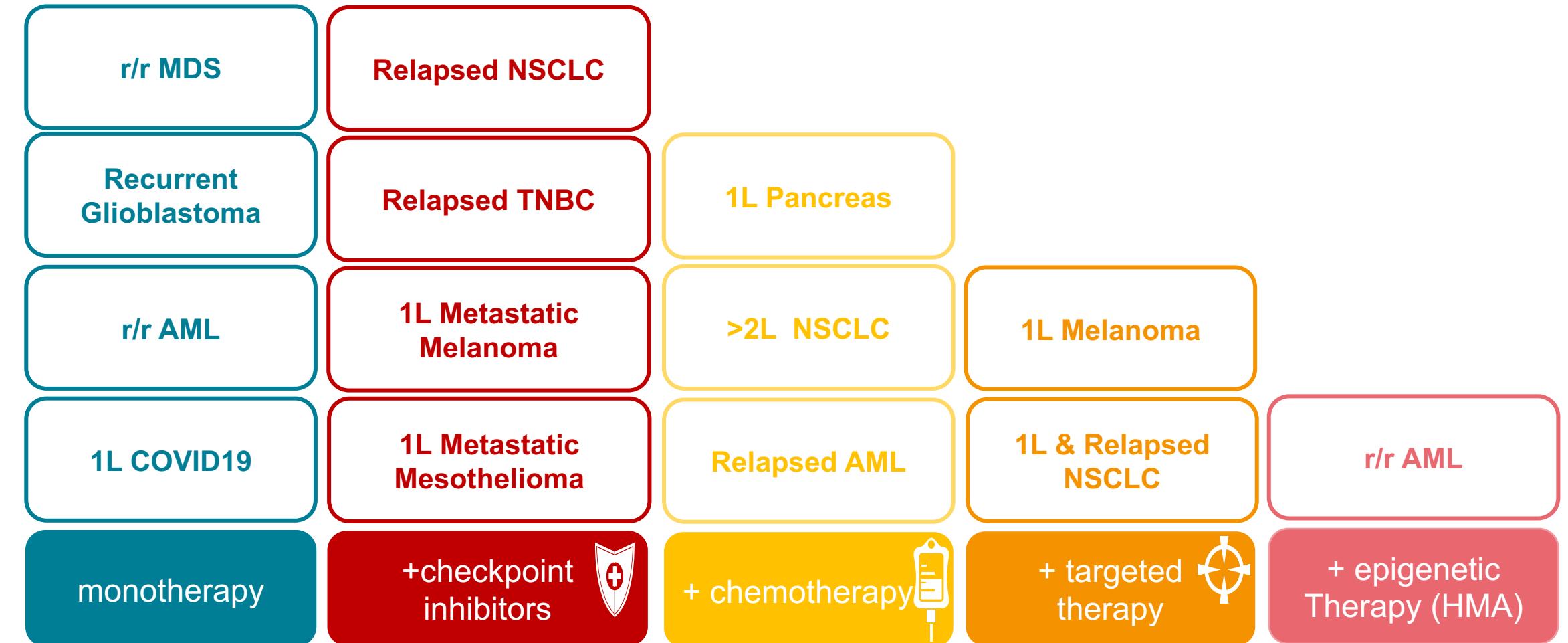
- To evaluate PK of bemcentinib
- To evaluate SARS-CoV-2 viral load
- To collect samples for serology research, viral genomics, serum antibody production, and COVID-19 diagnostics



## Exploratory objectives

- PK concentration and parameters
- Qualitative and/or quantitative PCR determination of SARS-CoV-2 in blood (on Day 1) and saliva
- Analysis of samples collected at baseline prior to treatment and at specific time points

# Executing a broad development program for Bemcentinib



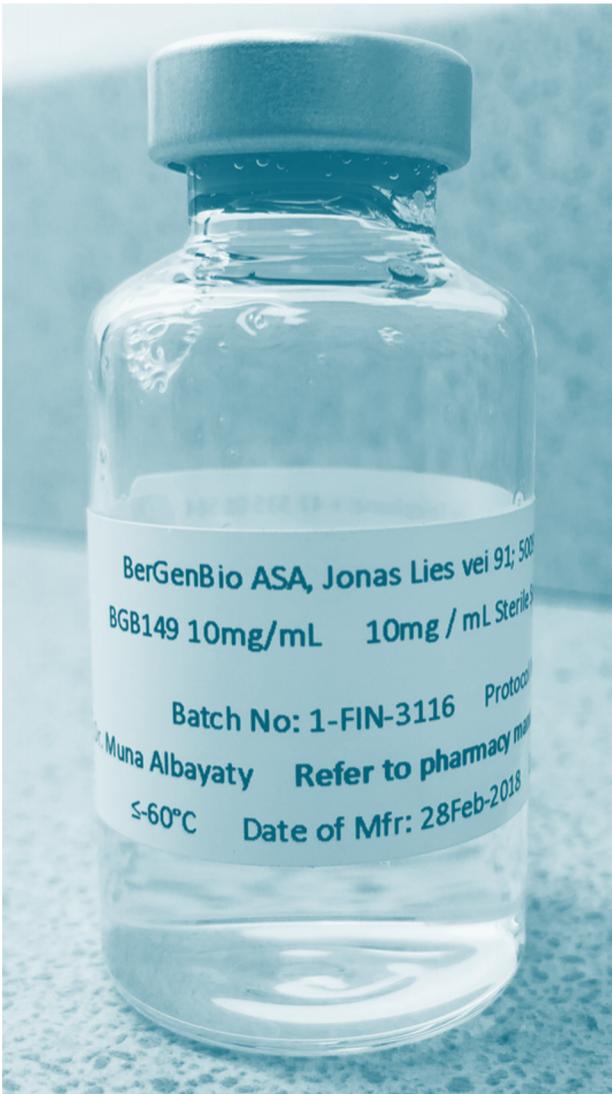
**Bemcentinib foundation for cancer therapy**

# Tilvestamab (BGB149)

## Anti-AXL monoclonal antibody

# TILVESTAMAB: Anti-AXL monoclonal antibody

## Phase I clinical trial ongoing



Functional blocking fully-humanised IgG1 monoclonal antibody

Binds human AXL, blocks AXL signalling  
Anti-tumour efficacy demonstrated *in vivo*

High affinity (KD: 500pM), displaces GAS6

Robust manufacturing process & formulation established, 18 months stability

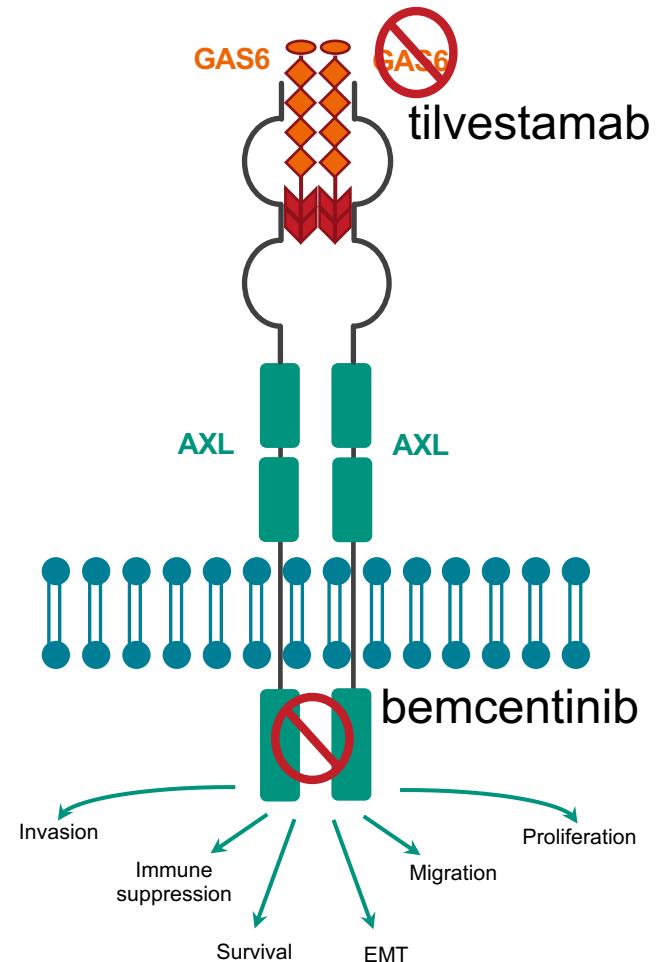
Phase Ia healthy volunteer SAD study complete

**Safety** – no dose limiting toxicity seen up to 3mg/kg dose

**Pharmacokinetics** - exposure predictable with dose proportional Cmax increase

Confirmatory evidence of *in vivo* target engagement with sAXL -- stabilisation in circulation

Phase I SAD trial complete  
Phase Ib/IIa MAD in set up phase



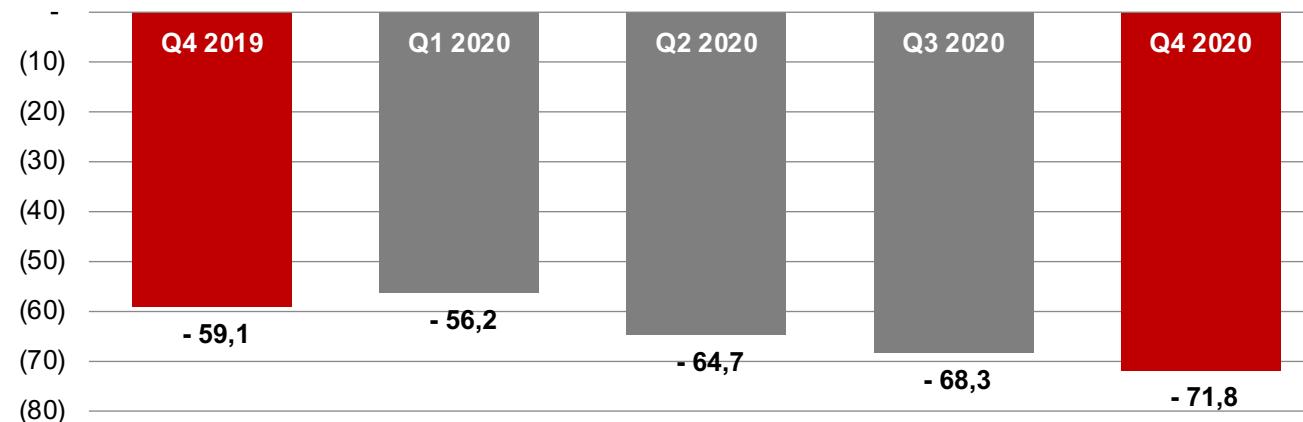
# Finance Report

## CFO Rune Skeie

# Key financial figures

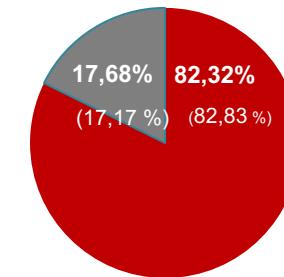
(NOK million)	Q4 2020	Q4 2019	FY 2020	FY 2019
Operating revenues	0,6	0,2	0,6	8,9
Operating expenses	72,4	59,3	261,7	213,3
Operating profit (-loss)	-71,8	-59,1	-261,1	-204,4
Profit (-loss) after tax	-73,9	-57,6	-257,0	-199,3
Basic and diluted earnings (loss) per share (NOK)	-0,85	-0,94	-3,43	-3,43
Net cash flow in the period	-53,1	-36,2	468,8	-107,2
Cash position end of period	721,6	253,6	721,6	253,6

## Operating profit (-loss) million NOK



- Operating expenses and loss in the quarter attributed to start up of new clinical studies and organisational growth in preparation for late stage development.

## Operating expenses Q4 2020 (FY 2020)

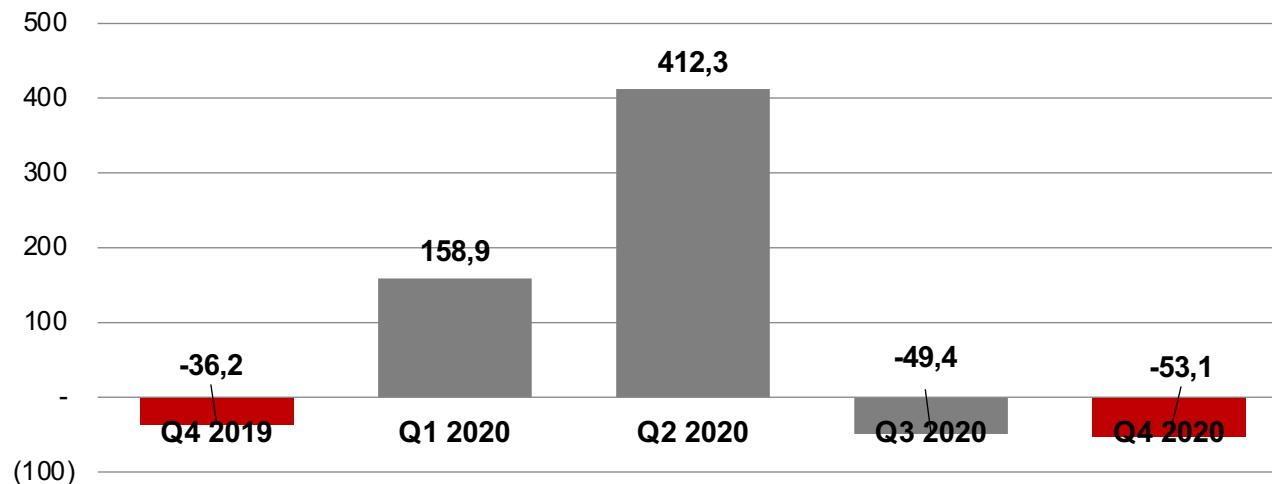


■ R&D ■ Administration

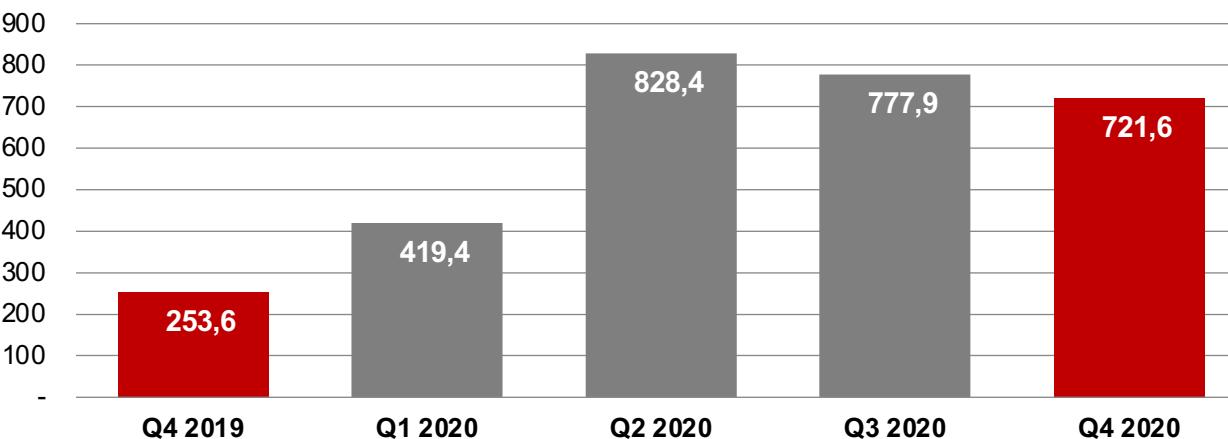
- Well managed overhead costs
- Over 80 % of operating expenses is attributable to Research & Development activities

# Cash flow and cash position

**Cash flow (million NOK)**



**Cash position (million NOK)**



- Cash burn operating activities Q4 2020 NOK 56.4m.
- Quarterly average cash burn (Q419 – Q420) NOK 54.0m (USD 5,8m).
- Cash position Q4 2020 NOK 721.6 million (USD 84.6m).

# Financial Calendar 2021

25th February 2021

Annual Report 2020

19th March 2021

Annual General Meeting

19th May 2021

Quarterly Report - Q1 2021

17th August 2021

Half-year report 2021

16th November 2021

Quarterly Report – Q3 2021

# Analyst coverage



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# 2020 Highlights & Outlook

# 2020 Highlights

- Efficacy endpoint met for first stage of phase II cohort B, combination trial, in CPI refractory NSCLC
- Bemcentinib selected for UK ACCORD phase II trial in hospitalised COVID19 patients
- BerGenBio completed fundraising of total NOK 740m (USD 74.5m) in 2020
- Encouraging interim translational data reported from Phase II cohort B, combination trial in CPI refractory NSCLC
- First patient dosed with bemcentinib in recurrent glioblastoma Phase I/II investigator-sponsored study
- First patient enrolled in South Africa and India in company sponsored randomised phase II trial assessing bemcentinib as a potential treatment for hospitalised COVID-19 patients.
- Efficacy endpoint met in BERGAMO phase II trial of bemcentinib in patients with relapsed HR-MDS or AML
- Encouraging interim clinical data from ongoing phase II study of bemcentinib/LDAC in relapse AML patients

# 2021 Outlook – well positioned for continued success

## Promising pipeline

- Two first-in-class AXL inhibitors in broad clinical development program
- Encouraging clinical POC, safety and translational data, in multiple cancer indications

## Robust science supporting COVID-19 trials

- South Africa and India COVID-19 studies recruiting, with iDMC confirming safety

## Upcoming data

- Relapse AML and relapse HR-MDS: mOS data - when data is mature
- NSCLC: top line clinical data from checkpoint inhibitor refractory NSCLC combination trial
- COVID-19: top line clinical data anticipated in Q1 2021

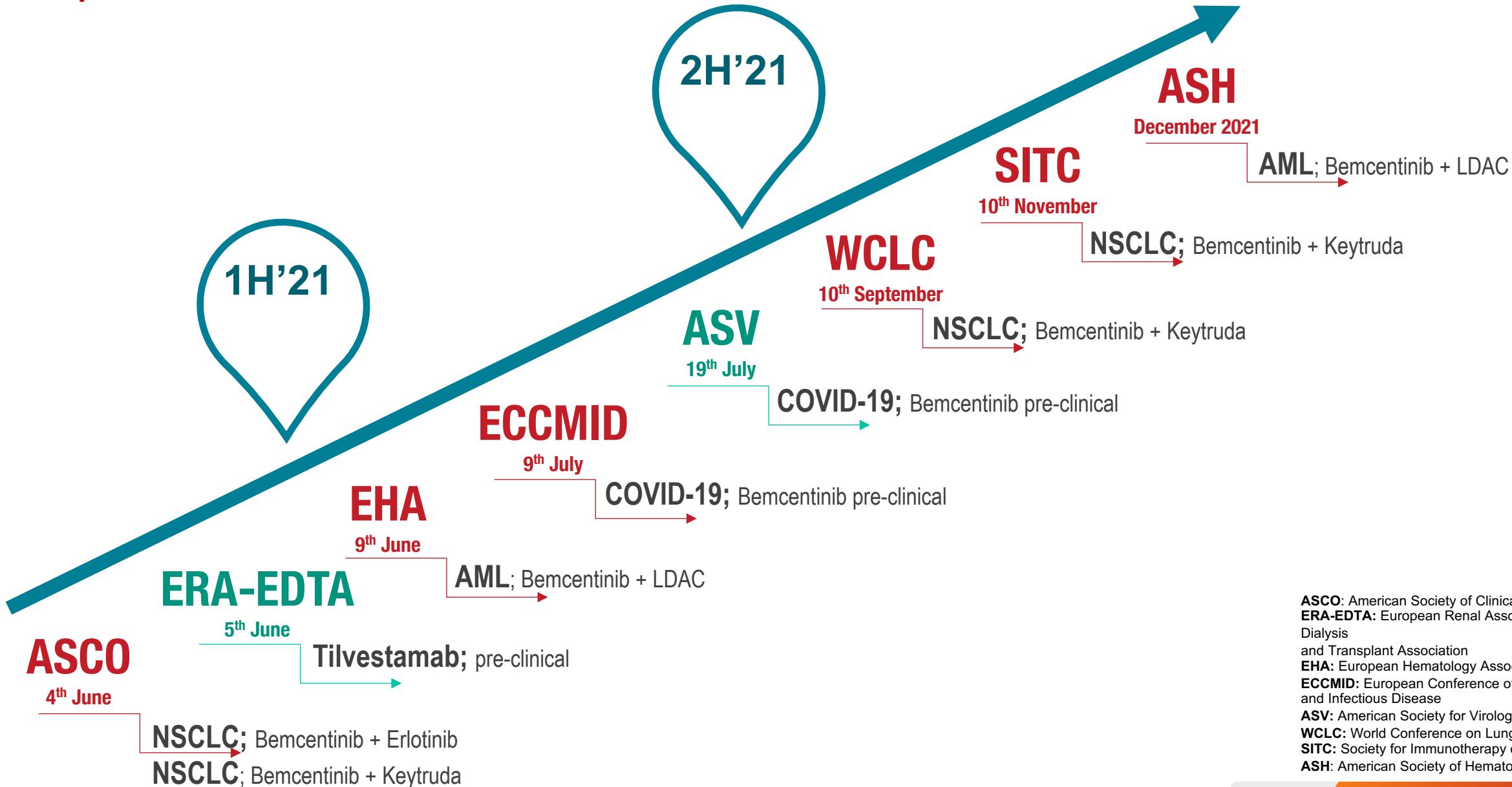
## • Strategic

- AML/MDS indications are under consideration for late stage registration directing studies
- Tilvestamab will progress to PhIb/Ila trials

## • Strong cash position

- Well funded, Q4 cash position NOK 722 million

# Expected news flow at conferences in 2021



ASCO: American Society of Clinical Oncology  
ERA-EDTA: European Renal Association & European Dialysis and Transplant Association  
EHA: European Hematology Association  
ECCMID: European Conference of Clinical Microbiology and Infectious Disease  
ASV: American Society for Virology  
WCLC: World Conference on Lung Cancer  
SITC: Society for Immunotherapy of Cancer  
ASH: American Society of Hematology