Carnegie Virtual Healthcare Seminar 2021

Company Presentation

12th March 2021

BerGenBio

Richard S. Godfrey CEO
Oslo Børs: BGBIO

BerGenBio – Investment highlights

Pioneering biology

World leaders in understanding AXL biology, as a mediator of aggressive cancer, fibrosis and viral infections

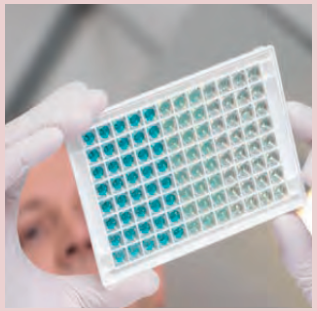
TWO first in class selective AXL inhibitors

Bemcentinib - oral once-a-day capsule

Tilvestamab – humanised functionally blocking mAb

Diversified Clinical Pipeline

AML
MDS
NSCLC
Multiple ISTs
Covid-19



Biomarkers and CDX

Proprietary biomarkers and CLIA lab validated clinical trial use ready

Companion Diagnostic assays

Near term clinical milestones

COVID-19
AML – mOS
MDS – mOS
NSCLC

Well resourced organisation

Experienced Oxford based R&D team

Industry Development partnership and collaborations

AML – Acute Myeloid Leukaemia
MDS – Myelodysplastic Syndrome
NSCLC – Non-Small Cell Lung Cancer
IST – Investigator Sponsored Trial

Leadership Team

Richard Godfrey, MPharmS, MBA

Chief Executive Officer

Rune Skeie

Chief Financial Officer

Professor Hani Gabra, MD, PhD, FRCPE, FRCP

Chief Medical Officer

Alison Messon, PhD

Director of Clinical Operations

Nigel McCracken, MSc, PhD,

Chief Scientific Officer

James Barnes, PhD

Director of Operations

Recent Value Driving Achievements

Relapse AML and MDS

Defining a new, emerging and substantial relapse patient population, with no approved treatment option

Encouraging interim POC survival data from Phase 2 studies

- AML
  - Bem + LDAC
- HR-MDS
  - Bem mono
  - Biomarker correlation

Check point combination in 2L NSCLC

Survival benefit reported in chemo & CPI refractory patients

cAXL proprietary biomarker and CDx development

Translational research support clinical data

Explore Bemcentinib in COVID-19

Started an international clinical development program for treatment of COVID-19

- 2 randomized phase 2 studies underway in UK, South Africa& India

Supportive mechanistic and preclinical research

Advance Tilvestamab clinical development

Completed Phase 1a safety study

- Do DLTs
- Dose proportional PK

Initiated Phase Ib

- PK-PD safety study
- Serial biopsies
- Refractory OC

Introduction to bemcentinib

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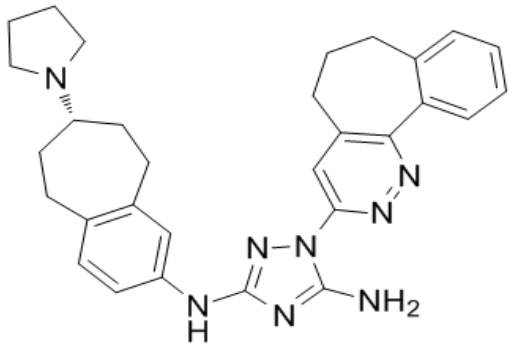
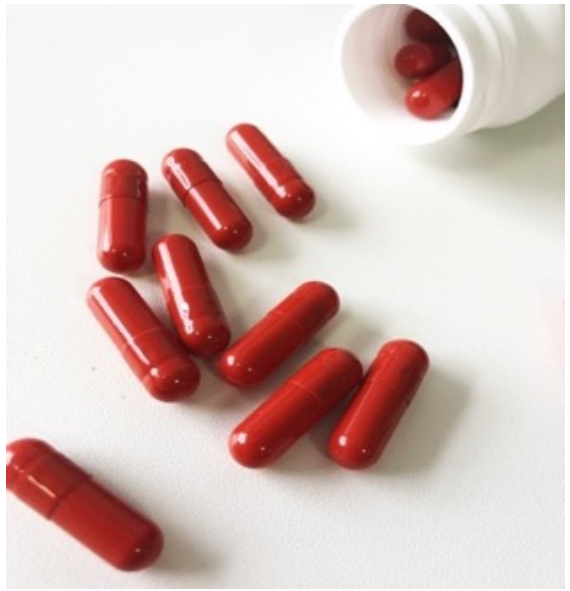
Bemcentinib, a first-in-class, potent, oral, highly selective AXL inhibitor



- ✓ 14 Nanomolar in vitro potency
- ✓ Uniquely selective for AXL, 50 to 100-fold over other TAM kinases (Tyro3 and Mer)



- ✓ Size-0 100mg HPMC capsules
- ✓ 30 Months shelf-life confirmed

- ✓ Clinical development stage; Phase 2 in oncology indications (haem, solid tumour) and COVID-19
- ✓ Safety and tolerability profile supports use in combination with other drugs
- ✓ MOA is synergistic with other therapies, enhancing response
- ✓ Favourable safety and tolerability profile in over 400 patients studied
- ✓ Once daily oral dosing

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 MERCK	2L NSCLC chemo refractory				
	2L NSCLC CPI refractory				
	2L NSCLC CPI+chemo refractory				
Bemcentinib monotherapy	Hospital COVID-19 patients				
Tilvestamab (BGB149)	Phase I				

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Pipeline of Investigator Sponsored Trials (ISTs)

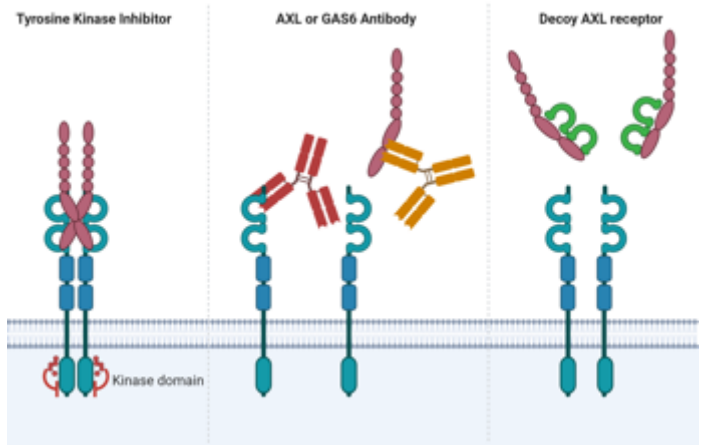
Candidate	Targeted Indication	Phase I	Phase II	Registrational	Sponsor
Bemcentinib	COVID-19	Monotherapy			Uni. Hospital Southampton/UKRI funded
	2L AML	Monotherapy			European MDS Cooperative Group
	2L MDS	Monotherapy			European MDS Cooperative Group
	Recurrent Glioblastoma	Monotherapy			Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
	Relapse Mesothelioma	+ pembrolizumab			University of Leicester MERCK
	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

Competitor Landscape

Modes of AXL inhibition



Benefits of selective AXL inhibitors	
No On-target toxicity	No Off-target toxicity
Combination with other drugs	Patient selection based on AXL expression (CDx)

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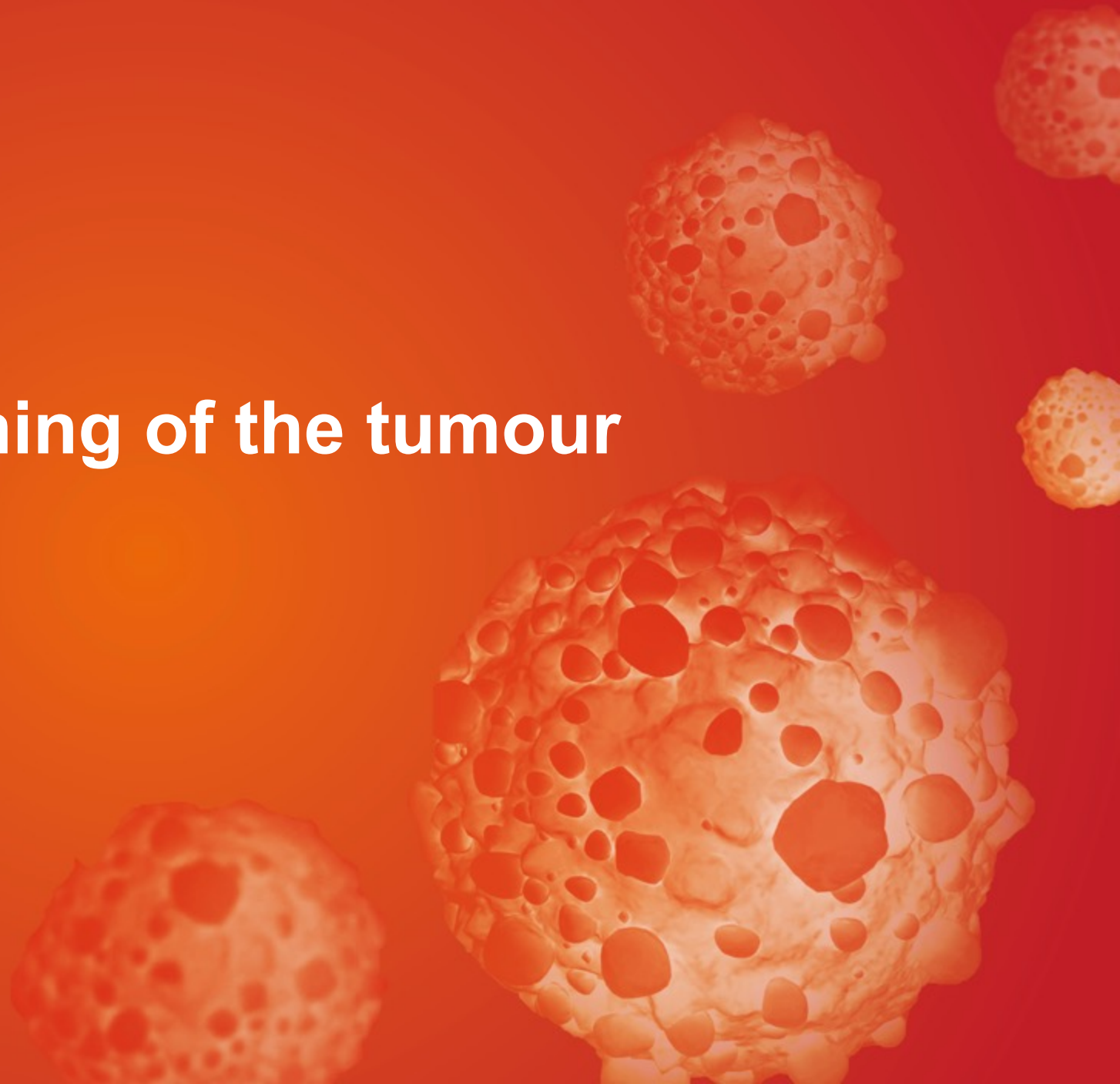
AXL and reprogramming of the tumour microenvironment



AXL is up regulated in hostile cellular micro environments

Very low expression under healthy physiological conditions

AXL signaling mediates aggressive disease

Cancer
- Immune evasive
- Drug resistant
- Metastatic

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

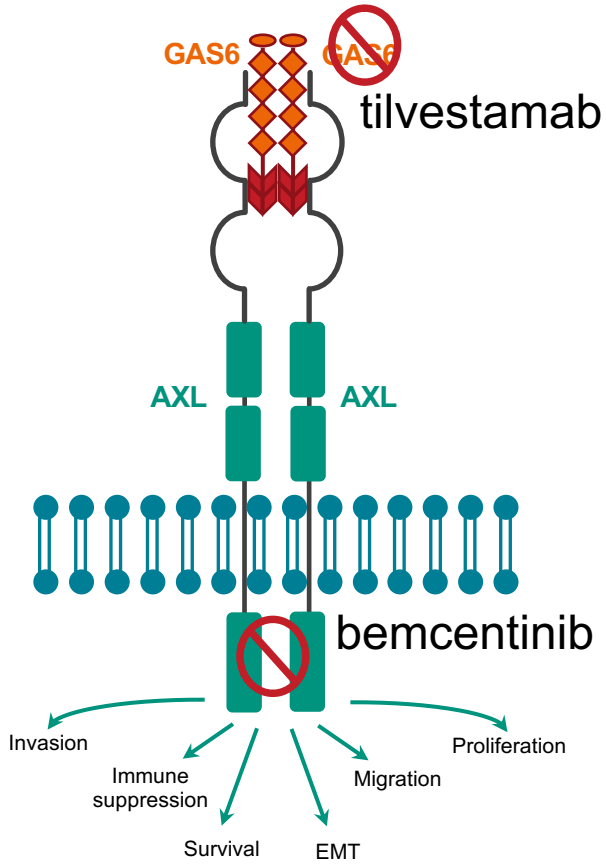
Fibrosis
- Renal
- NASH
- IPF
- MF
- COPD

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

Viral infection
- SARS-CoV-2
- Ebola
- Zika

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

Bemcentinib & Tilvestamab selective AXL inhibitors



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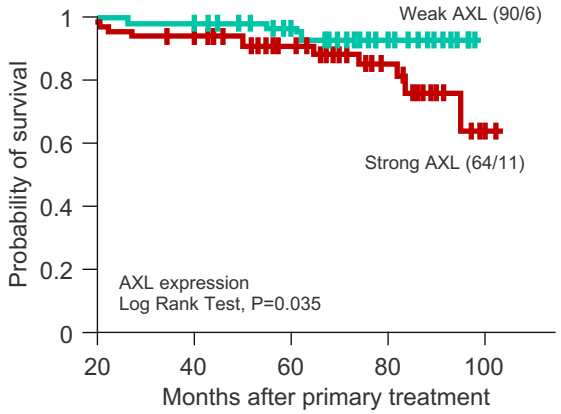
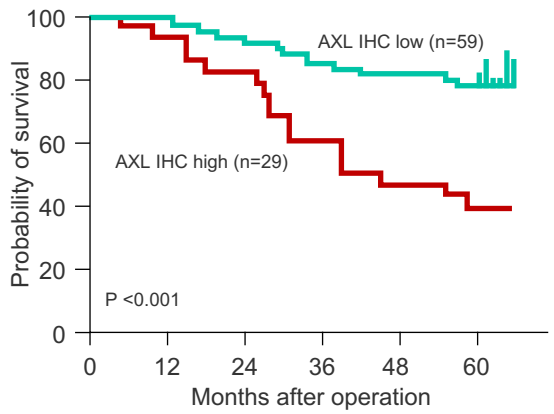
AXL is an independent negative prognostic factor in many cancers

Strong AXL expression correlates with poor survival rate

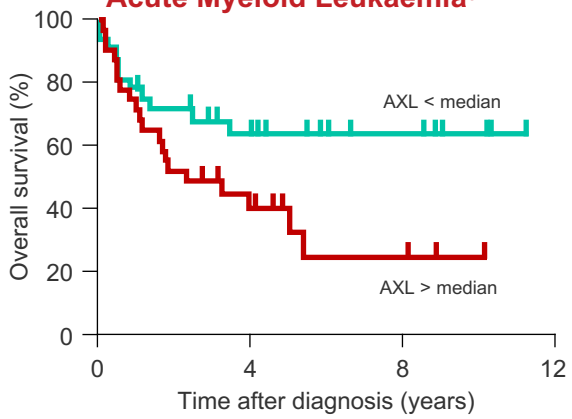
Breast carcinoma[1]



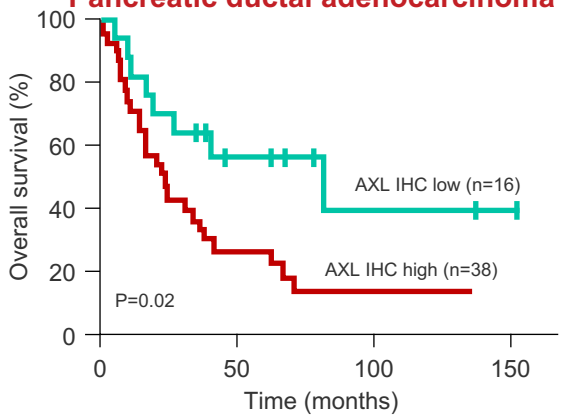
Lung adenocarcinoma (NSCLC)[2]



Acute Myeloid Leukaemia[3]



Pancreatic ductal adenocarcinoma[4]



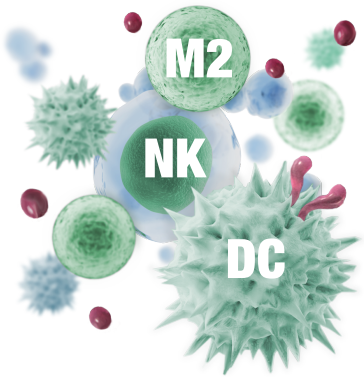
Broad evidence of AXL linked with poor prognosis[5]

Astrocytic brain tumours	Melanoma
Breast cancer	Mesothelioma
Gallbladder cancer	NSCLC
GI	Pancreatic cancer
• Colon cancer	Sarcomas
• Oesophageal cancer	• Ewing Sarcoma
• Gastric cancer	• Kaposis sarcoma
Gynaecological	• Liposarcoma
• Ovarian cancer	• Osteosarcoma
• Uterine cancer	Skin SCC
HCC	Thyroid cancer
HNC	Urological
Haematological	• Bladder cancer
• AML	• Prostate cancer
• CLL	• RCC
• CML	

1 Gjerdrum, 2010; 2 Ishikawa, 2012; 3 Ben-Battala, 2013; 4 Song, 2010, 5 supported by > 100 publications

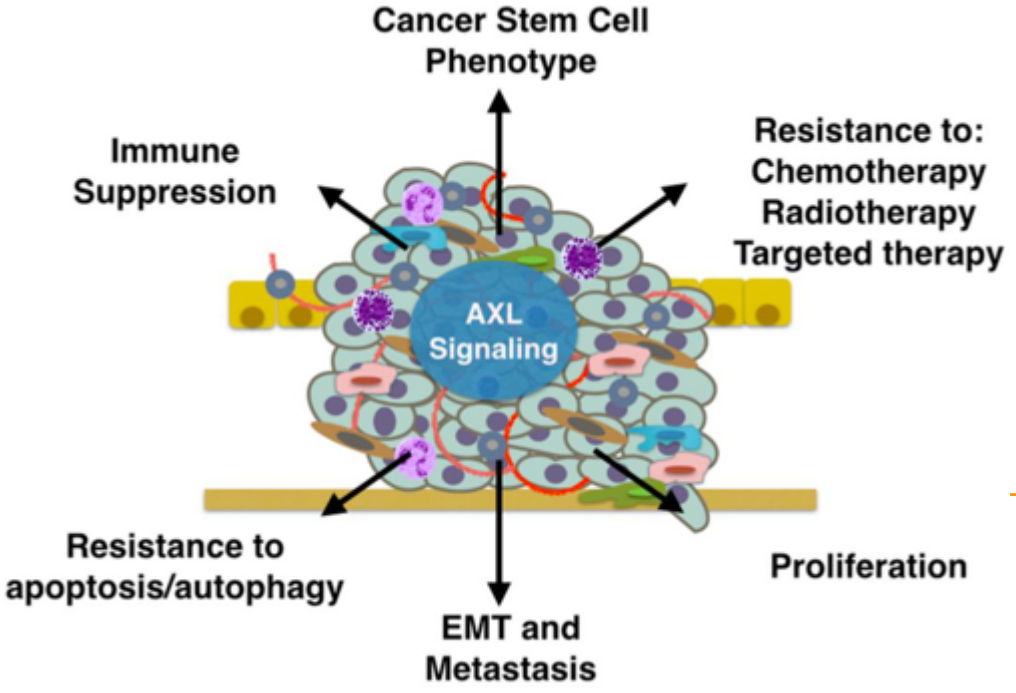
AXL is a key survival mechanism ‘hijacked’ by aggressive cancers and drives drug resistance, immune-suppression & metastasis

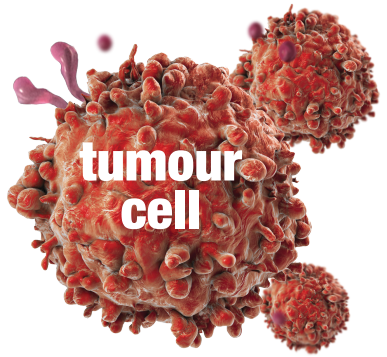
very low expression under healthy physiological conditions → overexpressed in response to hypoxia, inflammation, cellular stress & drug treatment → overexpression correlates with worse prognosis in most cancers



AXL increases on immune cells and suppresses the innate immune response

- M1 to M2 macrophage polarisation
- Decreased antigen presentation by DCs
- Prevent CD8+ T cell mediated cell death
- Activates Treg cells





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

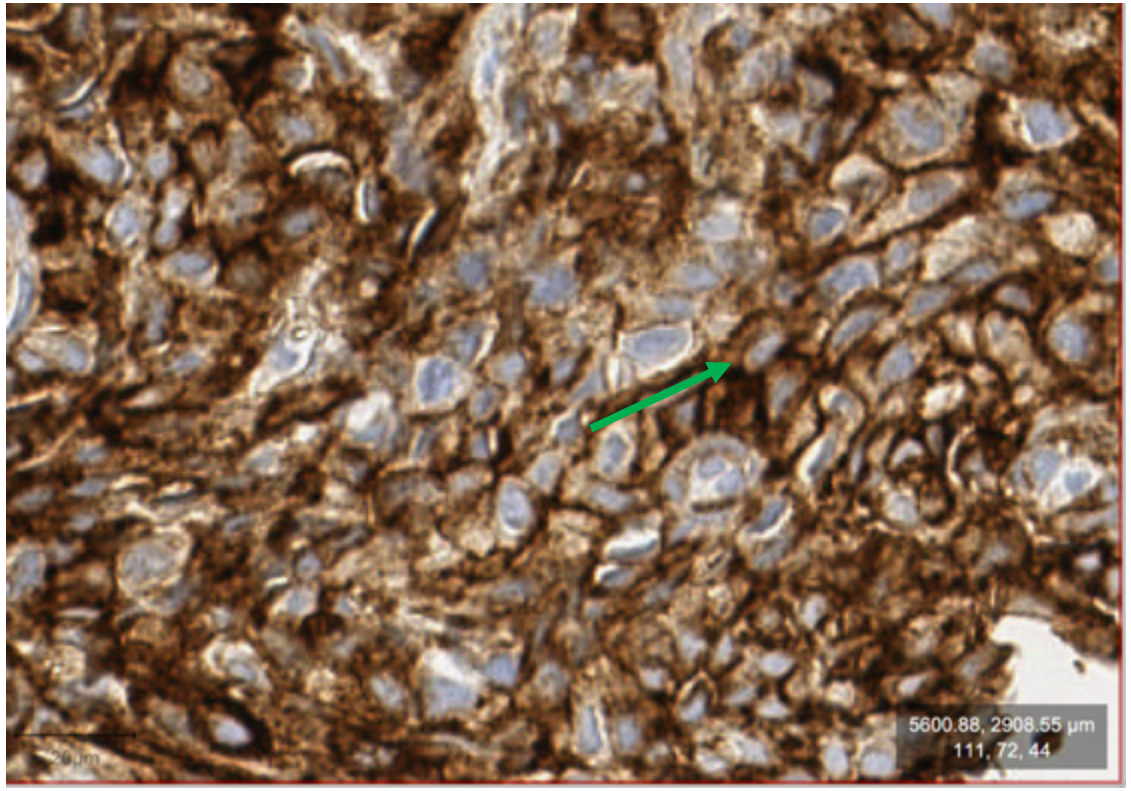
- AXL is a unique type I interferon (IFN) response checkpoint
- Acquired drug resistance
- Immune cell death resistant
- Metastasis

DC- dendritic cells Treg – Regulatory T Cell

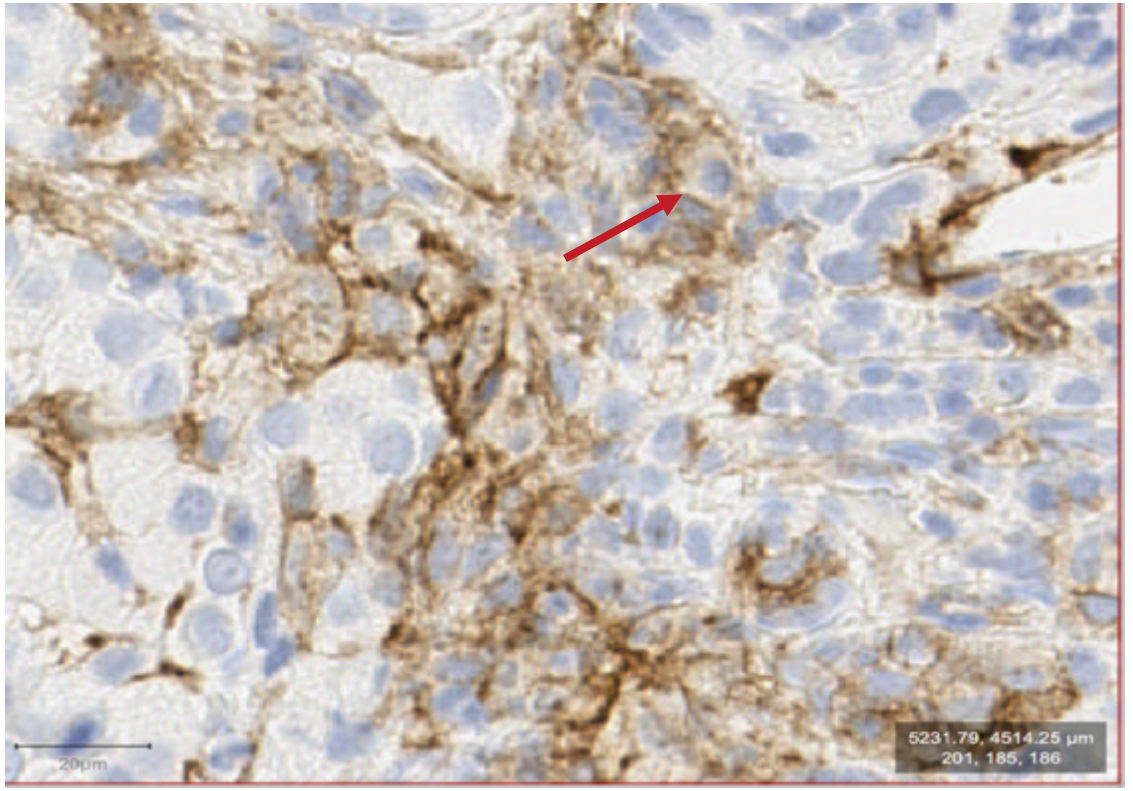
Companion Diagnostic Assay
Composite AXL score (cAXL) – CLIA Validated Clinical Use Assay

simultaneously computes the presence of AXL on membranes of tumor & 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

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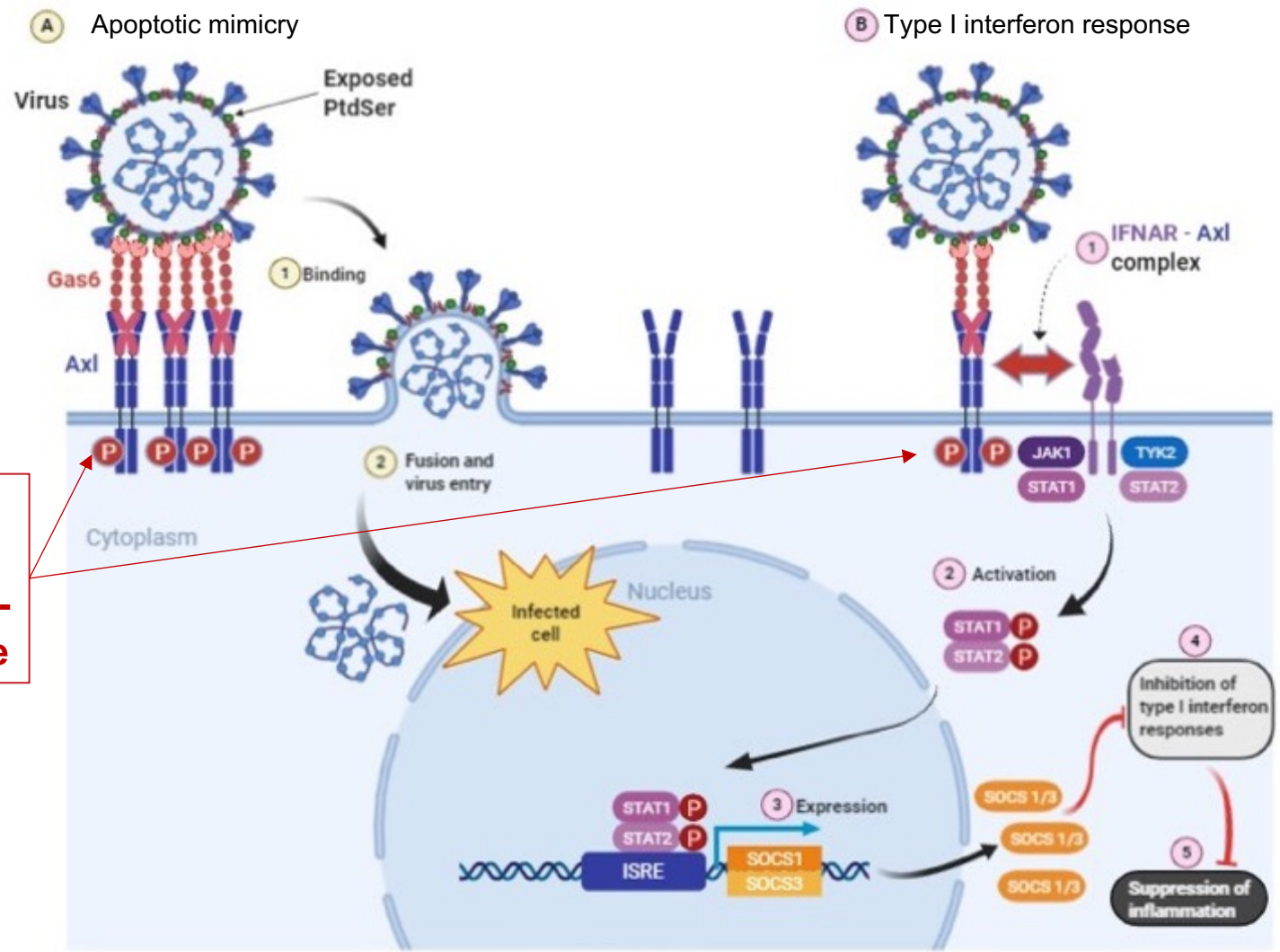
AXL is targeted by enveloped viruses to enter cells and dampen the viral immune response

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



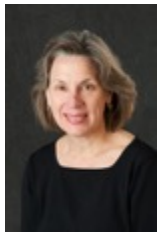
Viral-mediated AXL receptor activation dampens type I interferon responses, a key anti-viral defence mechanism for all cells

bemcentinib blocks AXL-dependent viral entry and enhances anti-viral interferon response

Bemcentinib potently inhibits SARS-CoV-2 infection of cells.[1]

[1] Maury IOWA unpublished / Meertens L *et al. Cell Host & Microbe* 2012, *12*:544 / Chen J *et al. Nat Microbiol* 2018 *3*:302

BerGenBio R&D Day with prominent independent expert KOL's

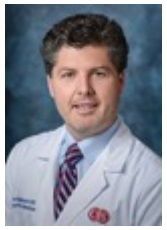


Professor Wendy Maury, PhD

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 failitating virus entry via an endosmal pathway
- Bemcentinib control of virus infection likely involves both reduced viral entry and enhanced interferon responses



Cory M.Hogaboam, PhD

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

The Role of AXL in Fribrosis

- Gas6, AXL and pAXL are increased in severe IPF
- Tergeting 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 + prembrolizumab 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

All presentations and Q&A sessions available on our website: www.bergenbio.com

Bemcentinib development Acute Myeloid Leukaemia

- FDA granted Orphan status in AML
- FDA granted Fast Track Designation in AML

- Defining a new patient population: **relapsed AML and MDS**
  - Patients having failed HMA +/- BCL2, FLT3 or IDH inhibitors
- Encouraging 1L data / opportunities

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Acute Myeloid Leukaemia (AML)

Most common type of acute leukaemia in adults[1]

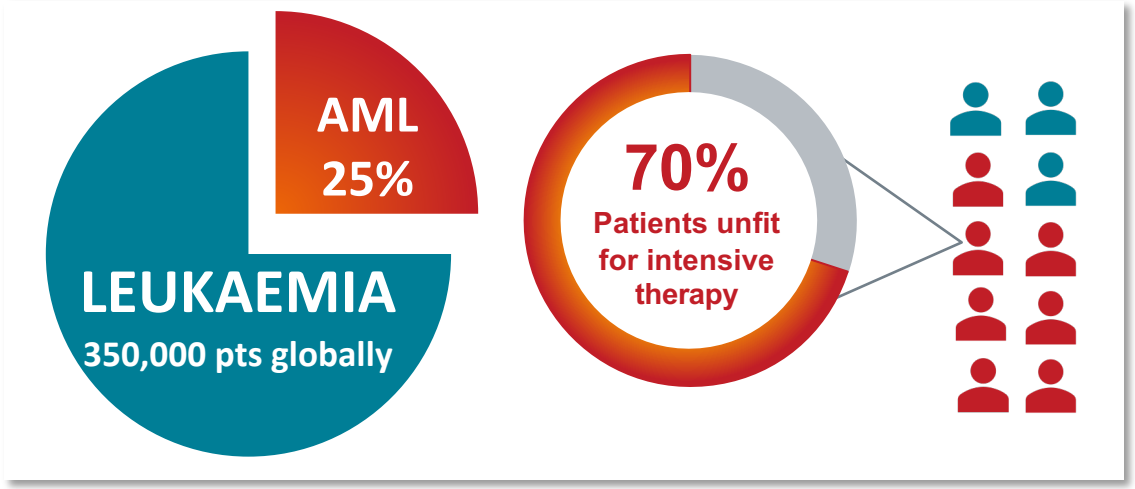
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

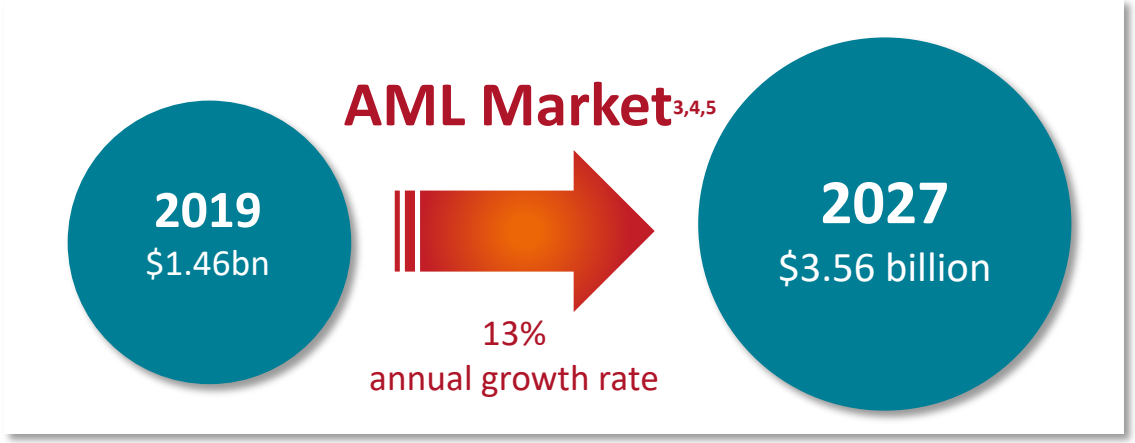
~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018[2]

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 [6]

5-year survival rates of 3-8% in patients over 60 years old [7]

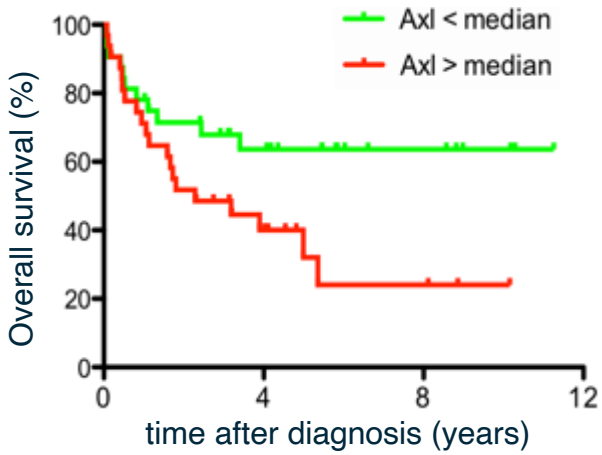




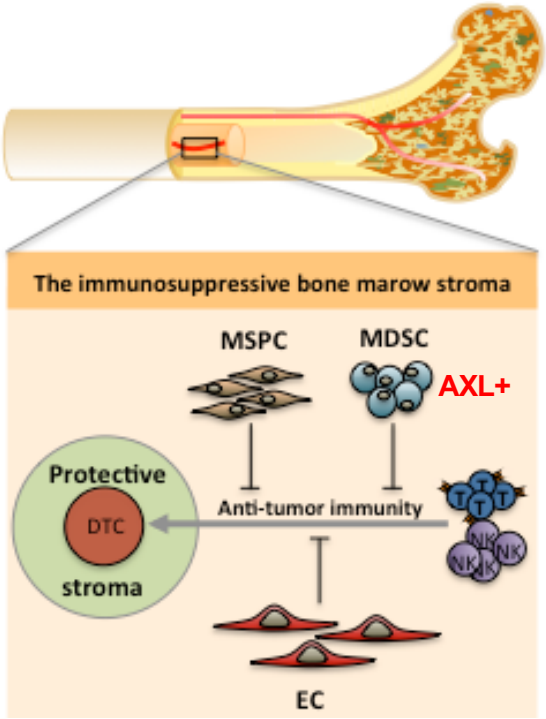
(1) Cancer.gov; (2) SEER; (3) https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble
(4) https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics (5) https://www.businesswire.com/news/home/20190319005442/en/ (6) http://asheducationbook.hematologylibrary.org/content/2010/1/62.long, (7) https://www.ncbi.nlm.nih.gov/books/NBK65996/ (8) VIALE A & C

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

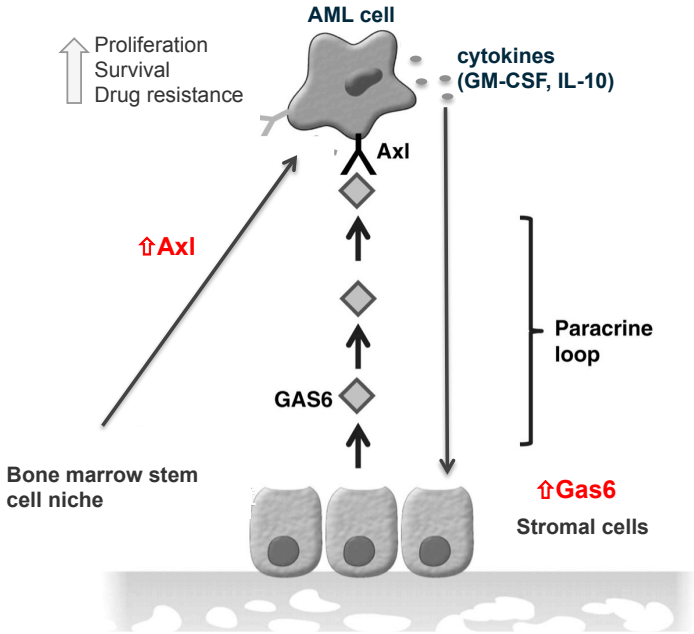
AXL is associated with therapy resistance and poor overall survival in AML patients.



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

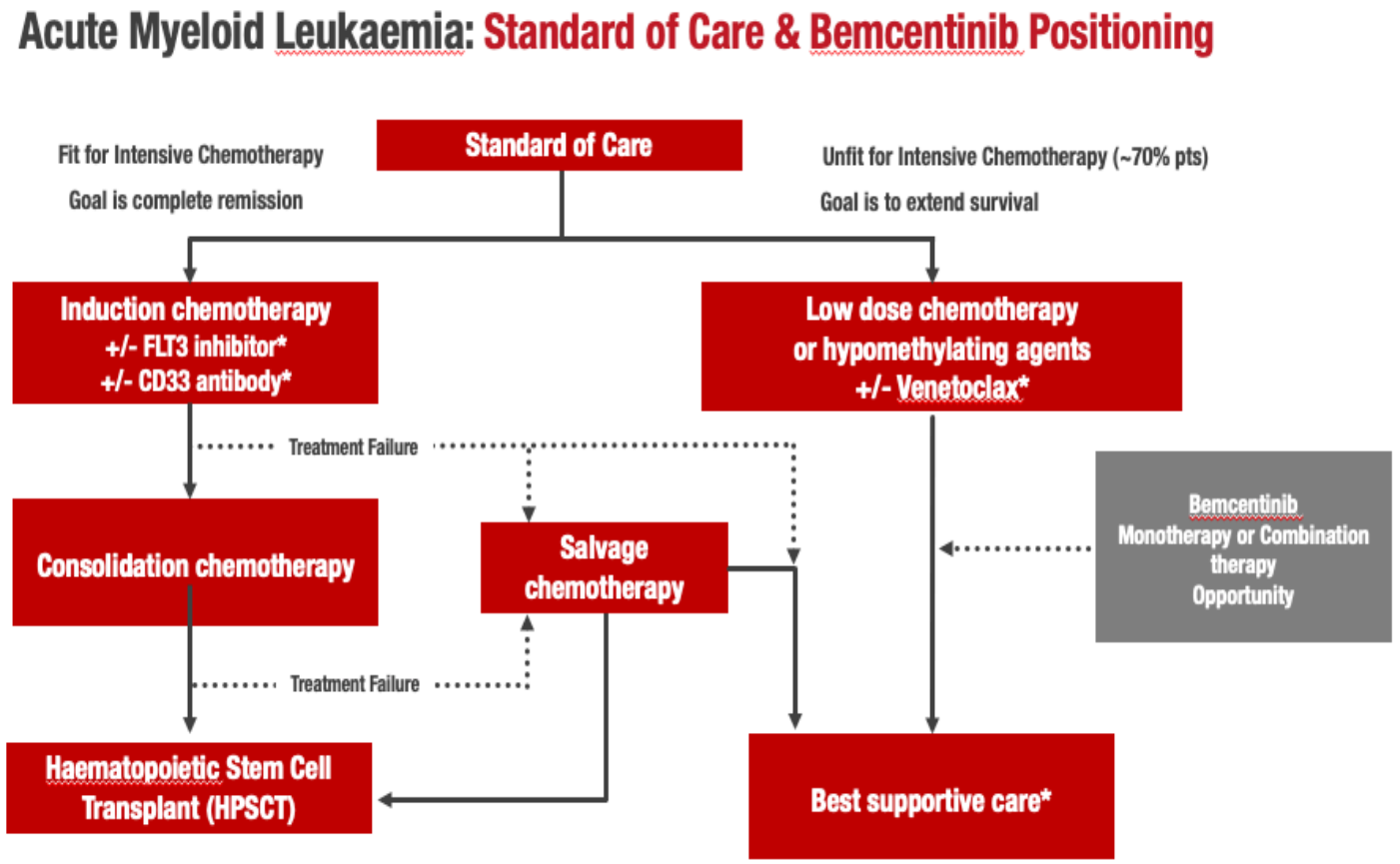


A paracrine axis between AML cells and the BM stroma establishes an immune and therapy- protective tumor cell niche

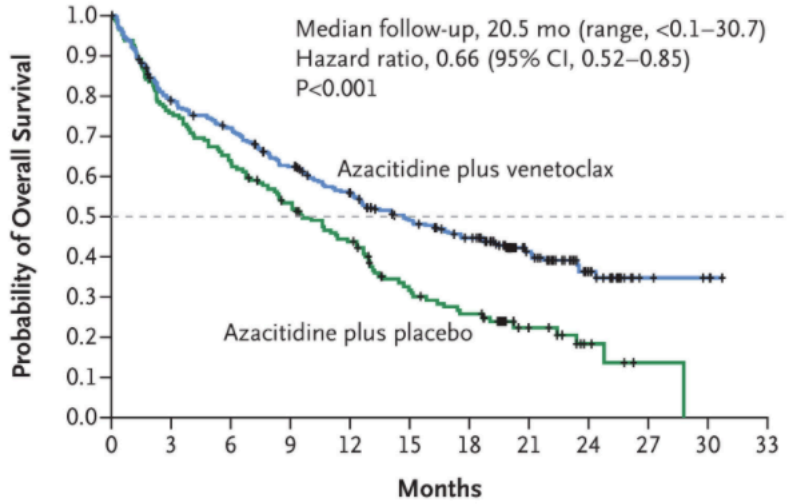


Source: Loges, 2015; Ben-Battala, 2011

Relapse AML – the need for new treatment options



- 1L treatment has evolved to include venetoclax in combination with HMA or low-dose cytarabine
- CR 37% rate and mOS of 14.7mo[1]
- Relapse patients mOS 4.7mo[2].



1. VIALE-A NCT02993523
2. 2 Leukemia Research Volume 90, March 2020, 106314

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Phase Ib/II study of bemcentinib administered as single agent or in combination with LDAC or decitabine in patients with AML; or as a single agent in patients with MDS

Phase I/II study in elderly AML patients unfit for intensive chemo and transplant

Phase 1 n=36

Single agent bemcentinib dose-finding in relapsed AML/MDS

Established safety and recommended Phase 2 dose in this population, and biomarker correlation

Recommended Phase 2 dose of bemcentinib in AML or MDS is 400/200 mg as single agent OR in combination.

Phase 2 Expansion Cohorts

Cohort B1 n=14

Monotherapy AML

Cohort B2 n=16

Combination with LDAC in newly diagnosed or relapsed AML

Cohort B5 expansion

Combination with LDAC relapsed AML (ongoing)

Cohort B3 n=14

Combination with decitabine in ND or relapsed AML

Cohort B4 n=14

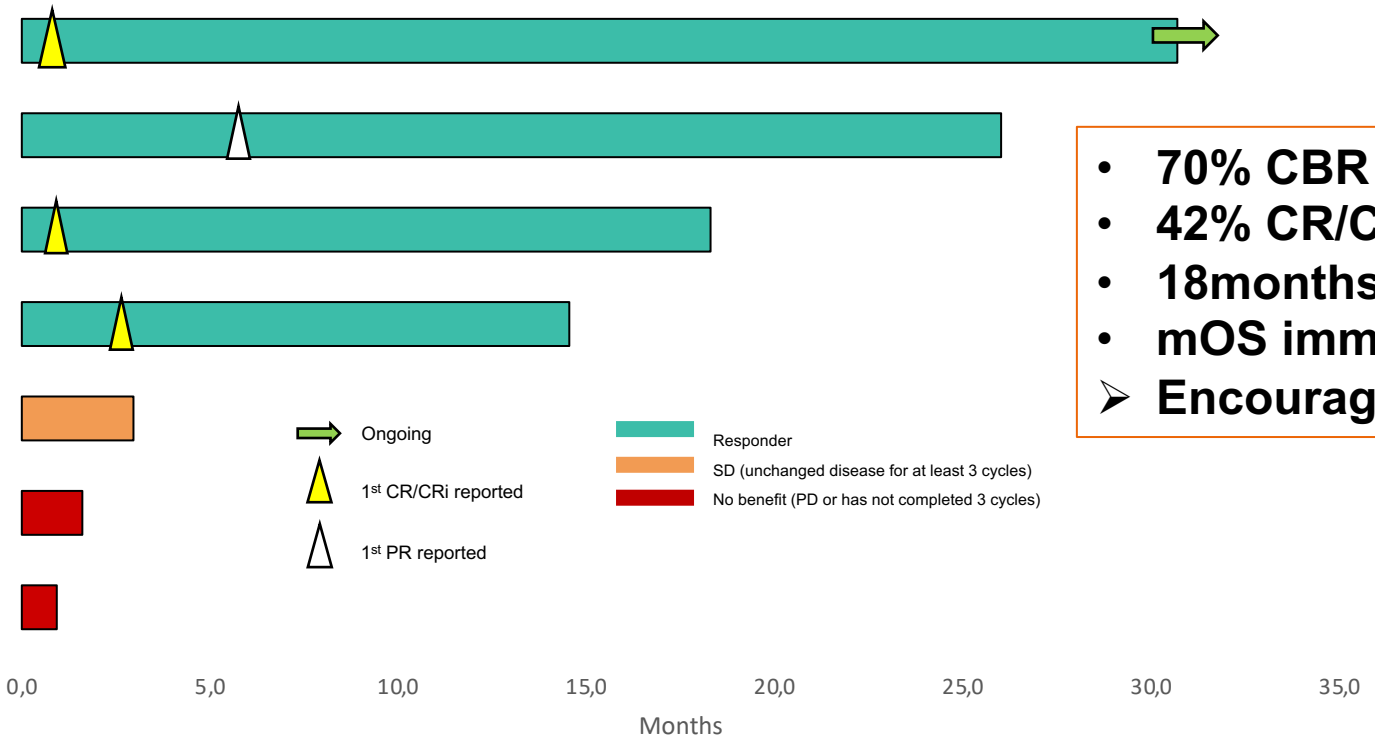
Monotherapy MDS

LDAC = Low Dose Cytarabine
AML = Acute Myeloid Leukaemia
MDS = Myelodysplastic syndromes

Strong durable responses observed in 1L AML patients
(bemcentinib + LDAC)

Part B2, n=7 06 Jan 2021

Pt ID	Age	Disease type	Cytogenetic risk
203301	83	S	A
101302	76	S	I
202301	79	P	I
202302	77	S	A
202304	75	S	I
402301	79	P	A
401301	78	P	F



- **70% CBR (5/7)**
- **42% CR/Cri**
- **18months mTime-on-Treatment**
- **mOS immature**

➢ **Encouraging cf. SoC!**

P – de novo/primary disease
S – secondary disease

A – adverse cytogenetic risk
I – intermediate cytogenetic risk
F – favorable cytogenetic risk

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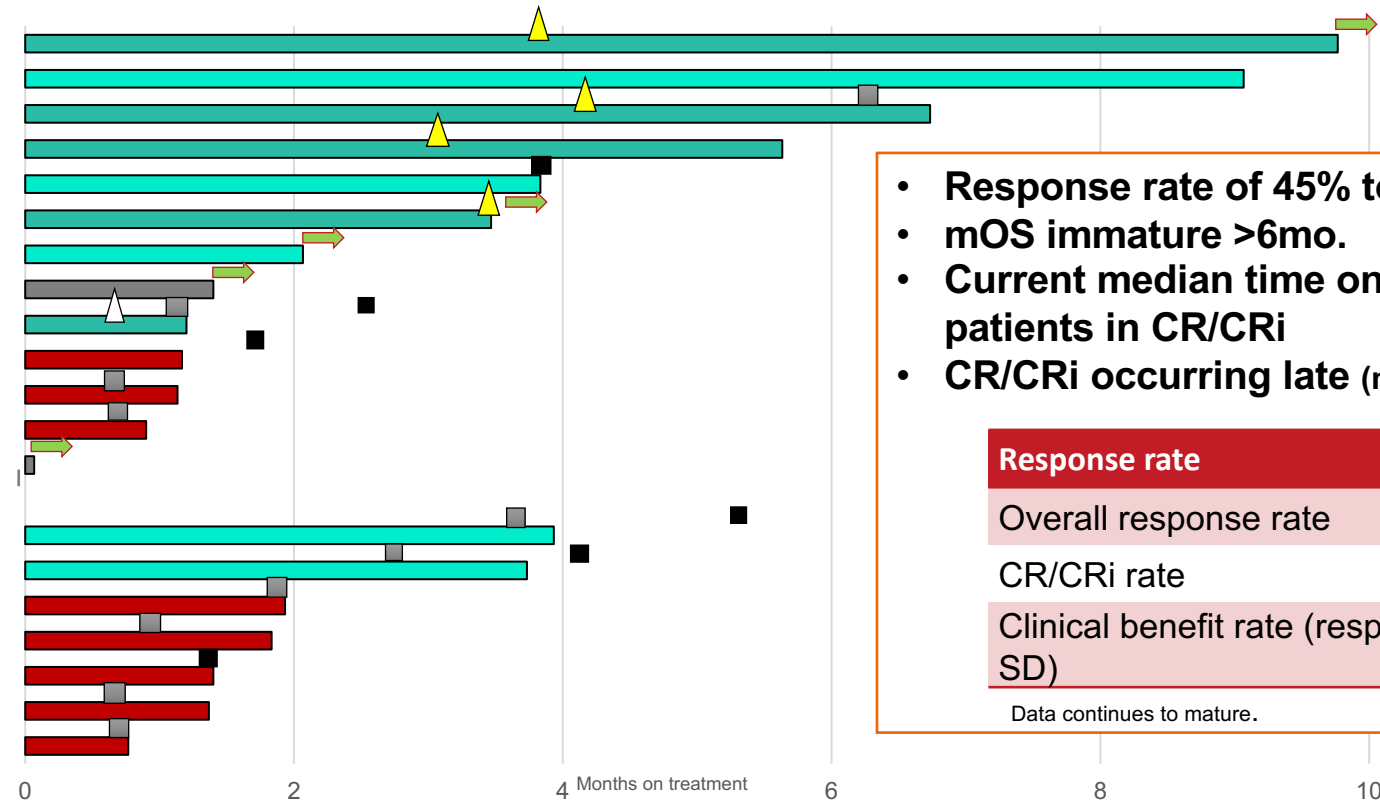
Encouraging Patient benefit observed in relapsed AML (bemcentinib +LDAC)

(Part B2+B5 - Recruitment is ongoing)

	Age	Disease Type	Cytogenetic profile
Relapsed disease	78	P	F
	78	P	A
	76	P	I
	75	P	I
	78	P	I
	72	P	I
	72	P	Not done
	86	P	F
	66	S	I
	74	P	A
	74	P	A
	75	S	A
	73	P	I
	74	P	I
Refractory disease	71	S	I
	76	P	I
	81	P	A
	74	S	I
	75	P	I
	75	P	I
	75	P	A

P – de novo / primary disease
S – secondary disease

F – favorable risk
I – intermediate risk
A – poor / adverse risk



- **Response rate of 45% to date**
- **mOS immature >6mo.**
- **Current median time on treatment of 6.2 months in patients in CR/CRi**
- **CR/CRi occurring late (median time to remission: 3.8 months)**

Response rate	Relapsed disease
Overall response rate	5/11 (45%)
CR/CRi rate	4/11 (36%)
Clinical benefit rate (responses + SD)	8/11 (73%)

Data continues to mature.

Cut-off date: 29 Oct 2020

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

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Phase II study of bemcentinib monotherapy in relapsed HR-MDS

Myelodysplastic Syndromes (MDS)

a heterogeneous group of closely-related clonal hematopoietic disorders

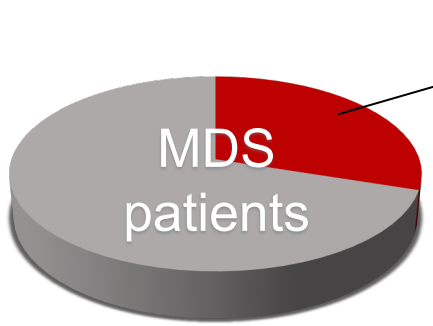
All are characterized by one or more peripheral blood cytopenias.

The incidence of MDS is estimated to be 4 in 100,000.[1]

The incidence in those aged ≥80 years is 50-75 in 100,000, sometimes estimated to be higher.[1,2,5]

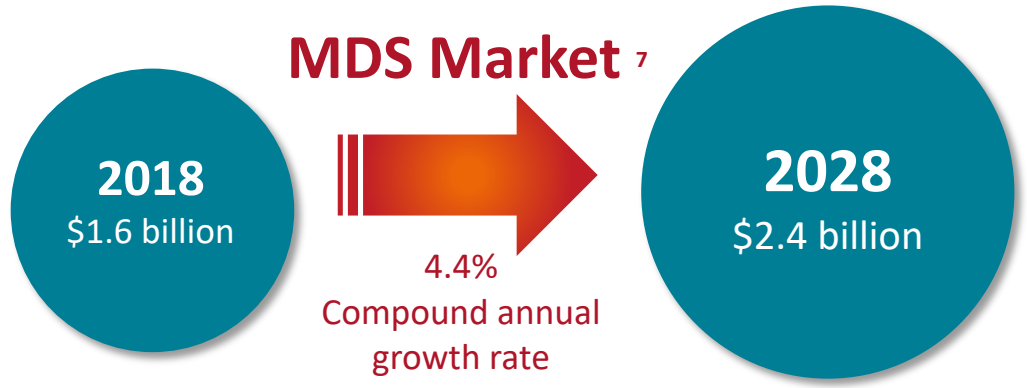
Average age of diagnosis is 60 years[3], and only 10% of patients are less than 50 years old.[2,4]

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



30% of MDS patients develop AML[6]

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

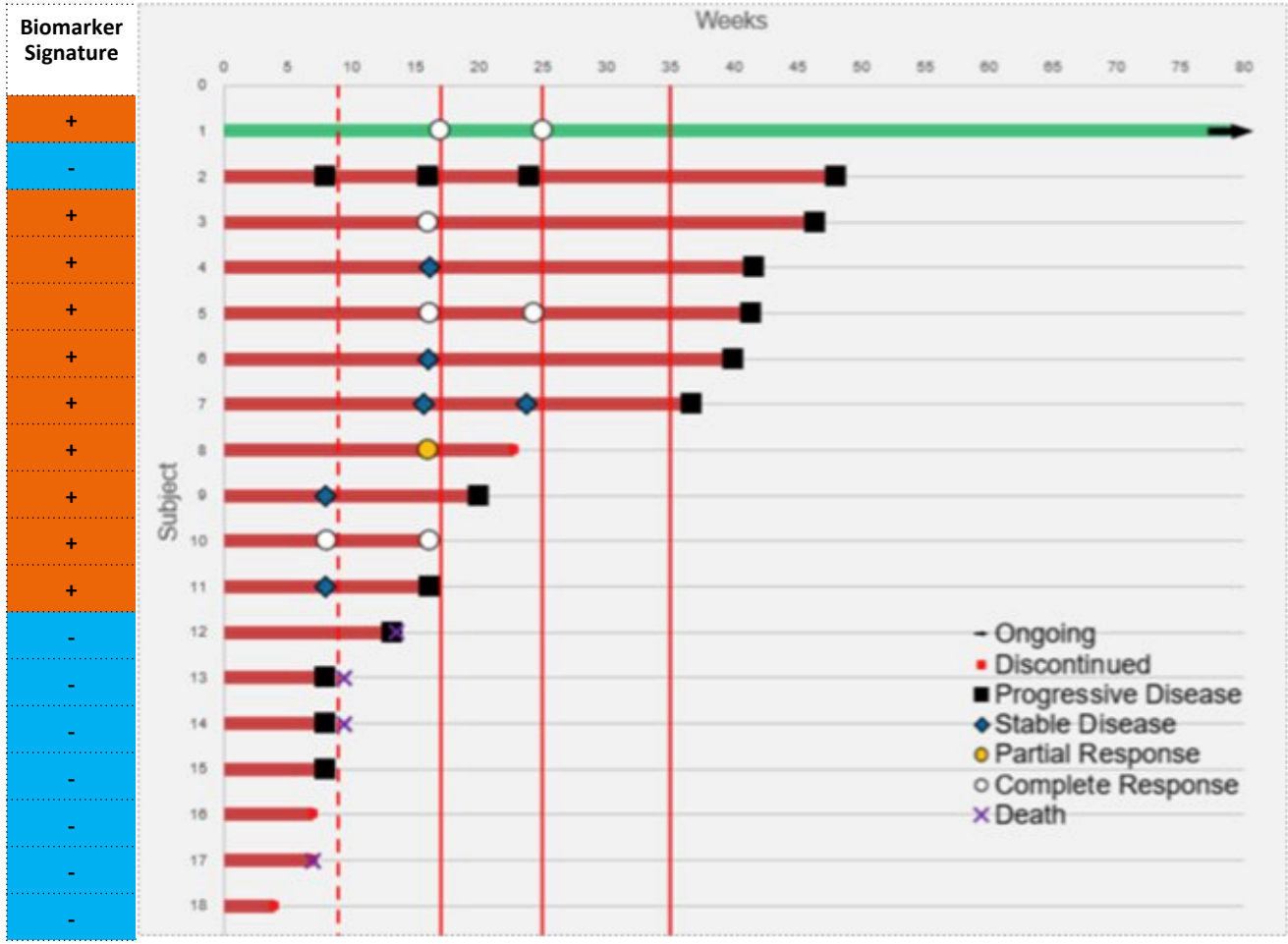


(1) SEER; (2) Neukirchen et al., 2011 (3) Greenberg et al., 2012, (4) Lubeck et al., 2016, (5) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3143554/, (6) WPSS, (7) GlobalData, June 2020.

Encouraging ORR and mOS from bemcentinib monotherapy in relapsed HR-MDS

A small set of soluble plasma biomarkers (Incl. sAXL & Immune mediators) predictive of response to bemcentinib monotherapy in HR-MDS patients

Best Response	Number (%) n=18
ORR (CR, CRi, PR, SD)	10 (56%)
CR/Cri	4 (22%) CR:1 (4%); CRi:3 (14%)
PR	1 (6%)
SD/HI	5 (28%)



Companion Diagnostic

BerGenBio has developed a CLIA Lab validated Diagnostic assay ready for clinical trial use.

*data cut-off June 2020

Bemcentinib clinical development in Non Small Cell Lung Cancer (NSCLC)

1) 2L combination with pembrolizumab
2) 1L & 2L combination with erlotinib in EGFRm patients

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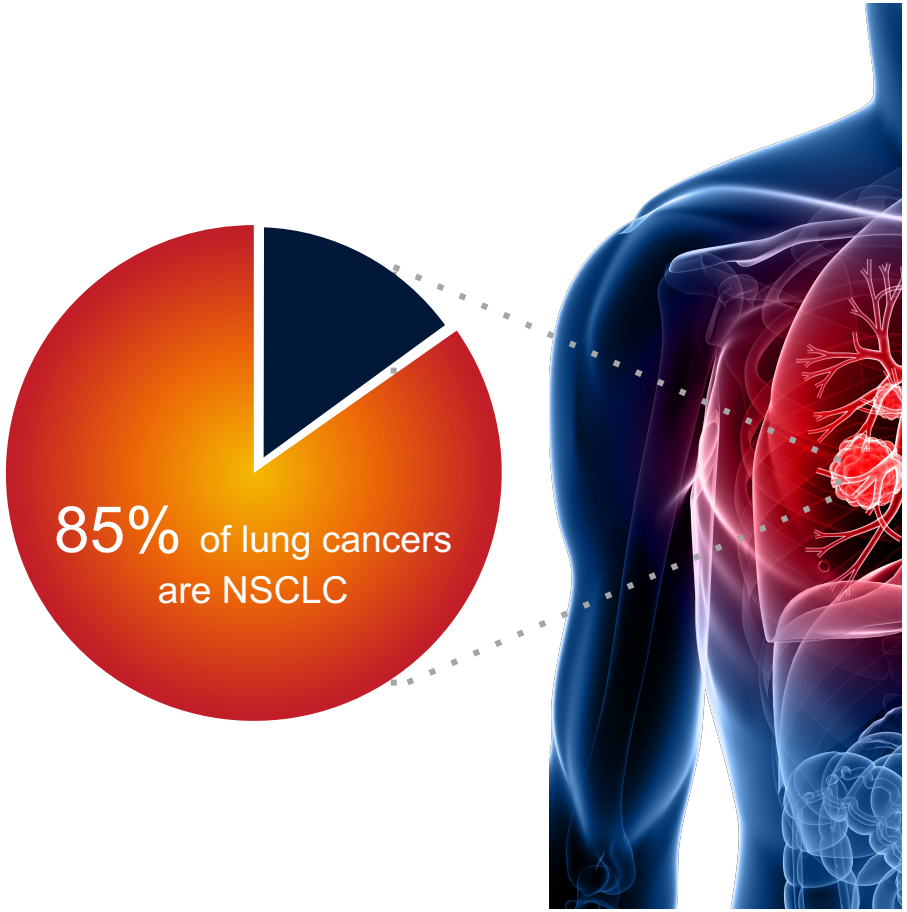
NSCLC causes more cancer related deaths than breast, colon, pancreas and prostate combined



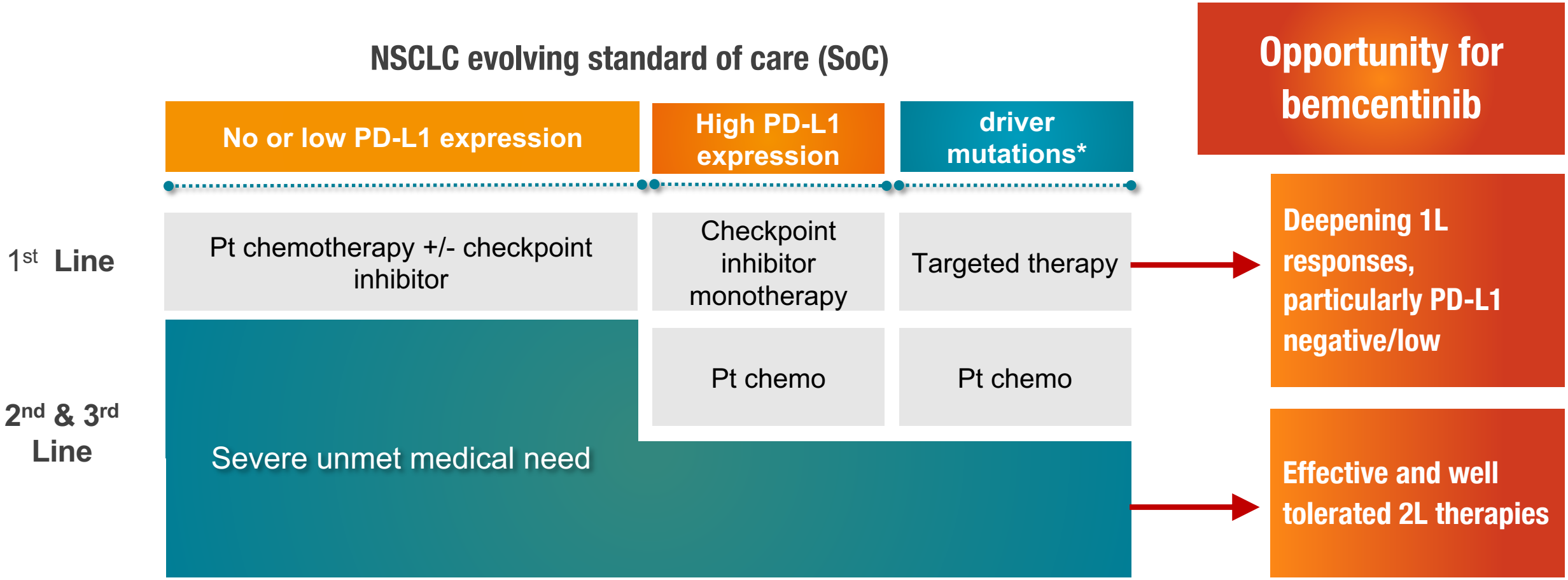
The largest cancer killer, most patients depend on drug therapy

- 2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases[1]
- 1.76 million lung cancer deaths/yr worldwide[1]
- In the U.S, 5-year survival rate is approximately 18.6%, and **4.7%** in patients with distant metastases[2]

Non-small cell lung cancer is the most common type of lung cancer, making up 80-85% of lung cancers

(1) Globocan 2018 (2) SEER

Large unmet need in Refractory NSCLC



* Mutations / rearrangements with available targeted therapies such as EGFR and ALK

2L ad. NSCLC Study with bemcentinib + pembrolizumab

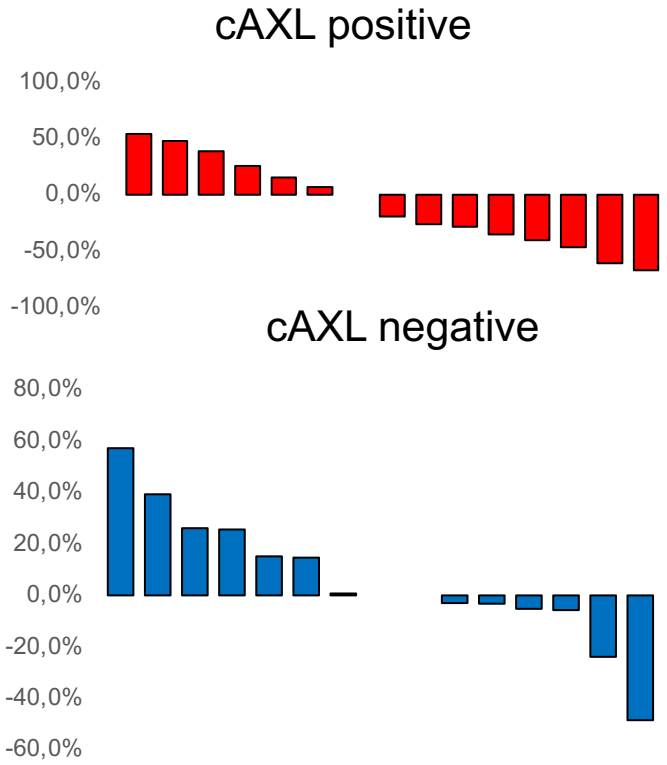
Open-label multi-center single arm phase II study

Cohort A • Previously treated with a platinum containing chemotherapy • CPI-naïve • Has PD at screening	**Interim Analysis** **Stage 1** **N=22 patients**	**Final Analysis COMPLETE** **Stage 2** **N=48 patients**
Cohort B • Previously treated with a mono therapy PD-L1 or PD-1 inhibitor • Must have had disease control on most recent treatment • Has PD at screening	**Interim Analysis** **Stage 1** **N=16 patients**	**Final Analysis ONGOING** **Stage 2** **N=29 patients**
Cohort C • Previously treated 1st line with a combination of checkpoint inhibitor + platinum-containing chemotherapy • Must have had disease control on 1st line therapy • Has PD at screening	**Interim Analysis** **Stage 1** **N=13 patients**	**Final Analysis** **Stage 2** **N=29 patients**

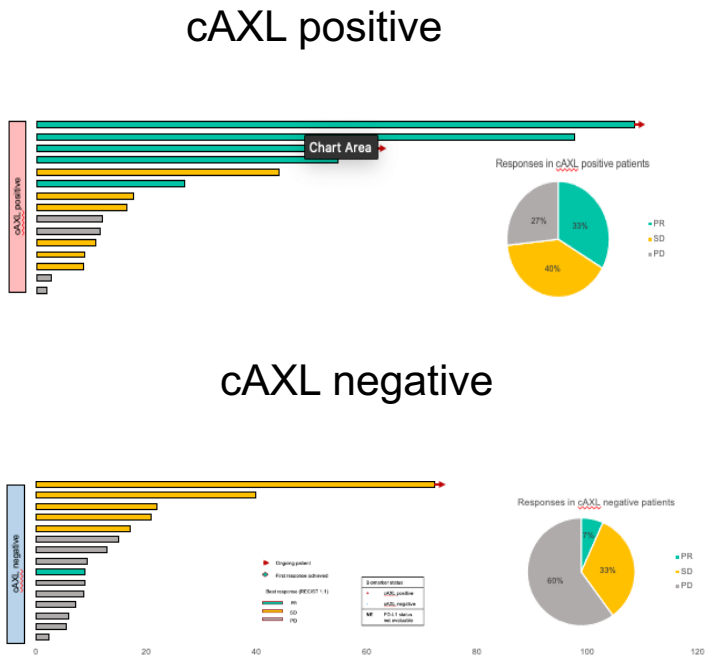
Cohort A

cAXL predicts response and survival benefit with Bemcentinib + Pembrolizumab in 2L NSCLC CPI naïve patients

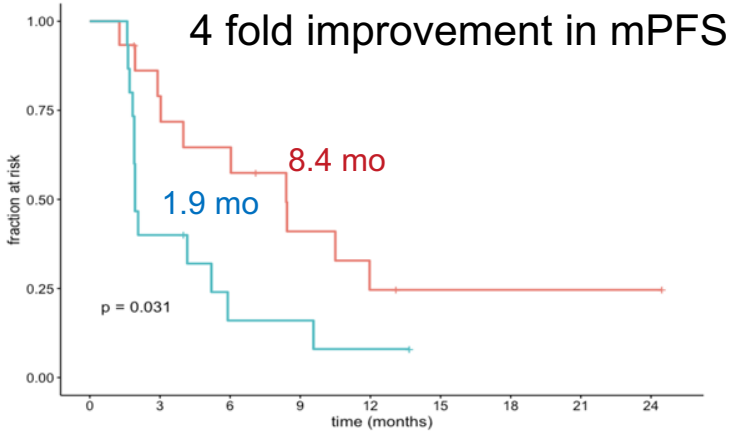
Change in tumor size



Duration of response



Survival benefit



Cohort	mOS	12-mo OS
Cohort A – cAXL +ve pts**	**17.3 mo***	**79%**
Cohort A – cAXL -ve pts**	12.4 mo*	60%
BGB Cohort A – all pts**	12.6 mo*	64%* (up to 67%)
CheckMate-057 (Opdivo)	12.2 mo	51%
KEYNOTE-010 (Keytruda)	10.4 mo	43.2%

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Cohort B: Patient Disposition and Demographics

Patient disposition	N
Screened	21
Enrolled	16
Evaluable*	15
Ongoing	3

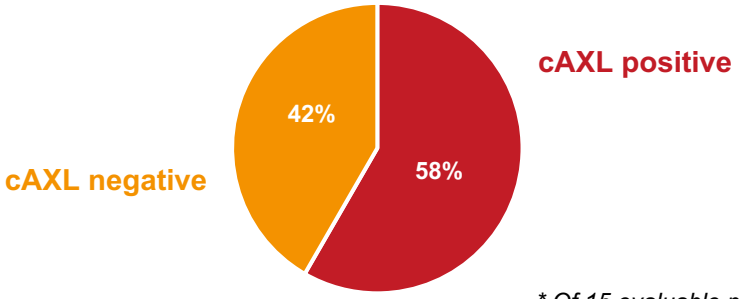
* with at least 1 post-baseline scan assessment

Disease mutations	N (%)
None	13 (81)
KRAS	2 (13)
BRAF	1 (6)

Patient demographics		N (%)
Age	Median	64,5
	Range	40-76
ECOG at screen	0	6 (38)
	1	10 (63)
Sex	Female	3 (19)
	Male	13 (81)
Smoking status	Smoker	6 (38)
	Ex-smoker	8 (50)
	Never smoked	0 (0)
	Unknown	1 (6)

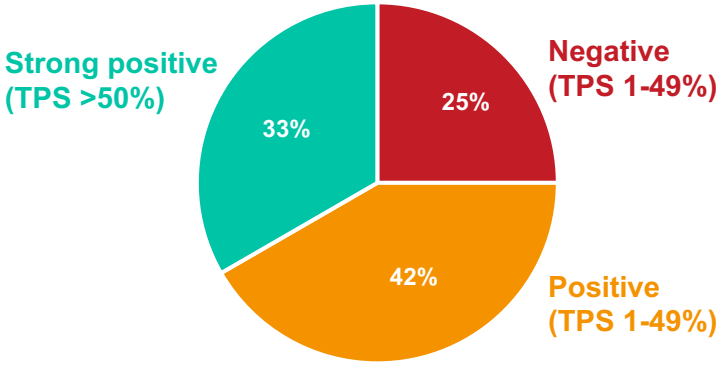
Biomarkers

cAXL status
n = 12*



** Of 15 evaluable patients, 3 not evaluable for AXL*

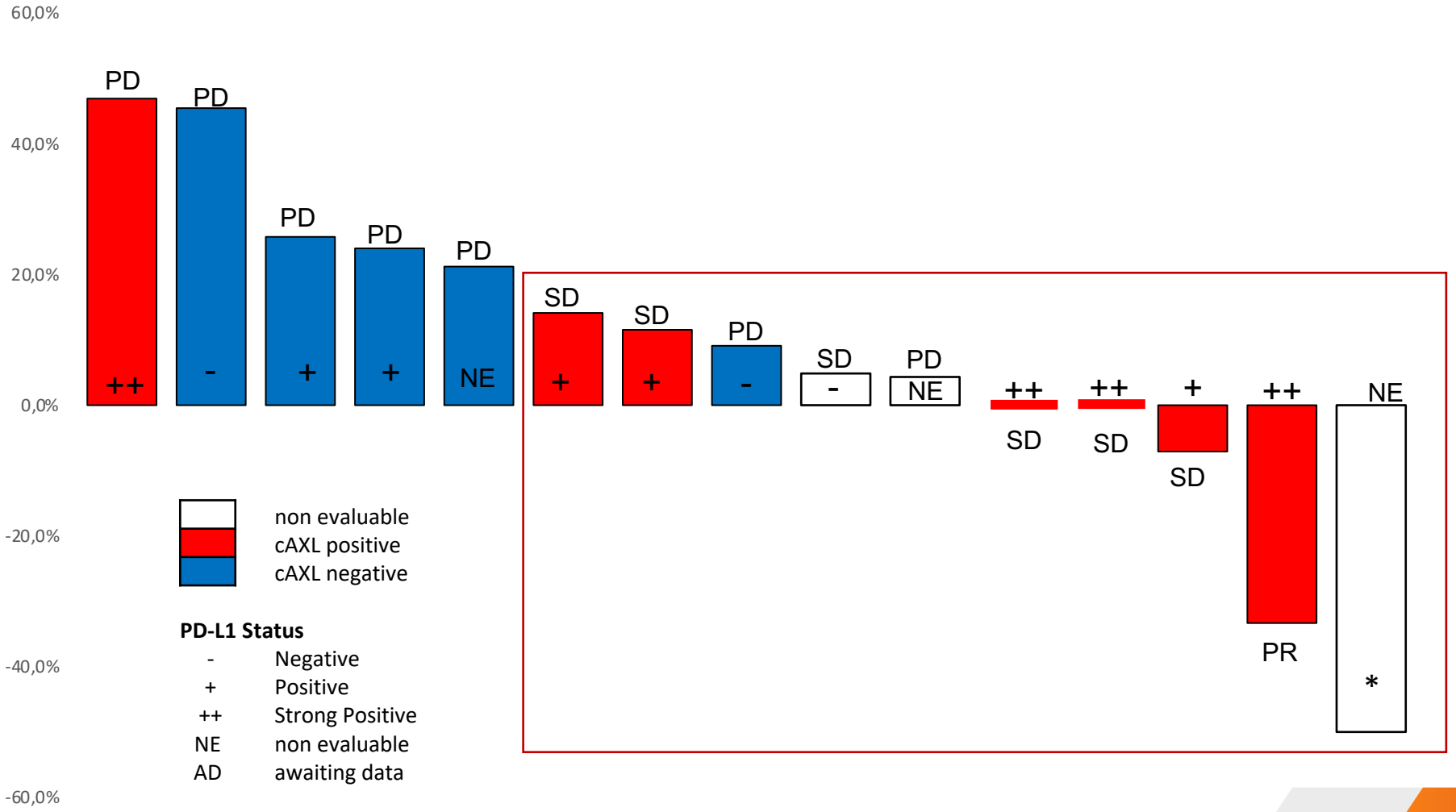
PD-L1 status
n = 12**



*** Of 15 evaluable patients, 3 not evaluable for PD-L1*

Cohort B1

Best % change in sum of target lesions from baseline



Data cut-off: 17-April-2020

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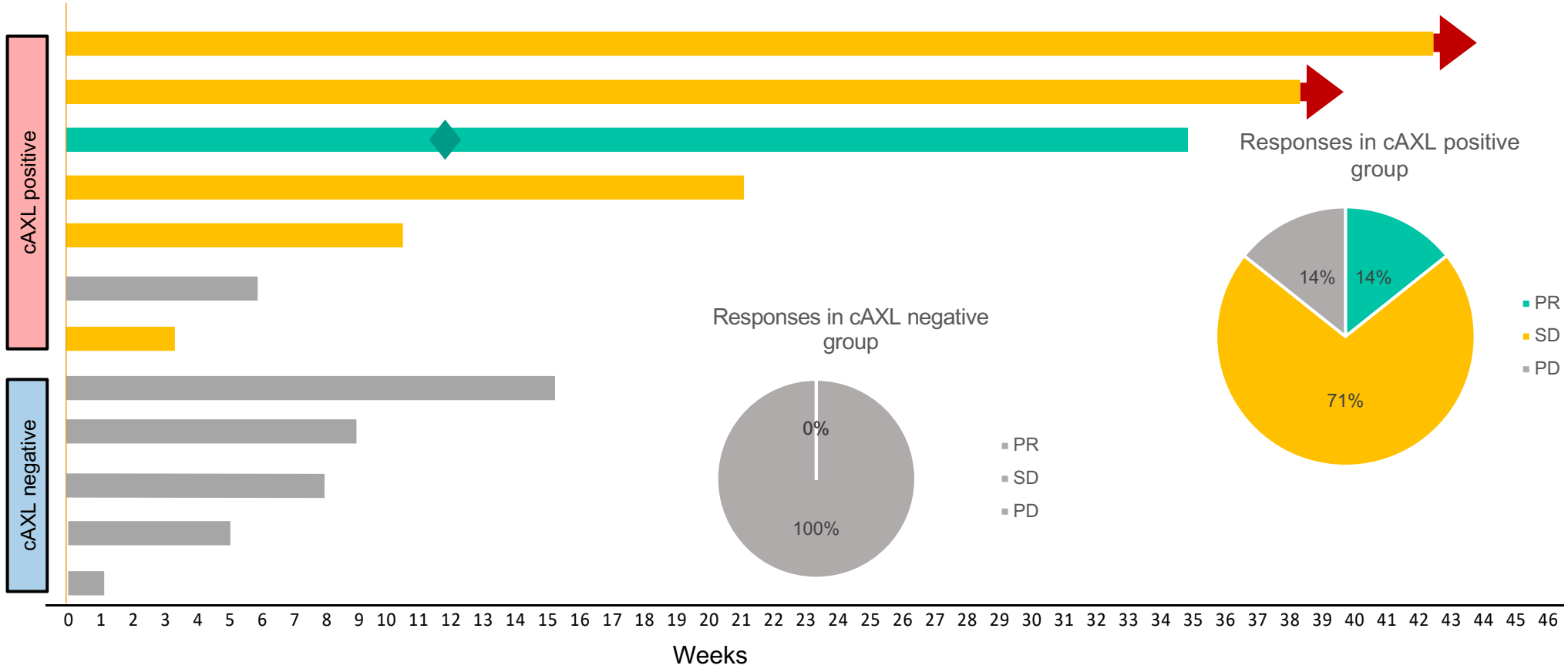
Time on treatment in patients evaluable for cAXL

Cohort B1

Pre Tx	PD-L1	cAXL
1L P	20	+
2L A/O	65	+
1L A	95	+
2L P	15	+
2L N	100	+
2L P	95	+
1L I/N	2	+
2L P	35	-
2L N	30	-
2L A	0	-
2L C	NE	-
2L P/O	0	-



\+ cAXL positive

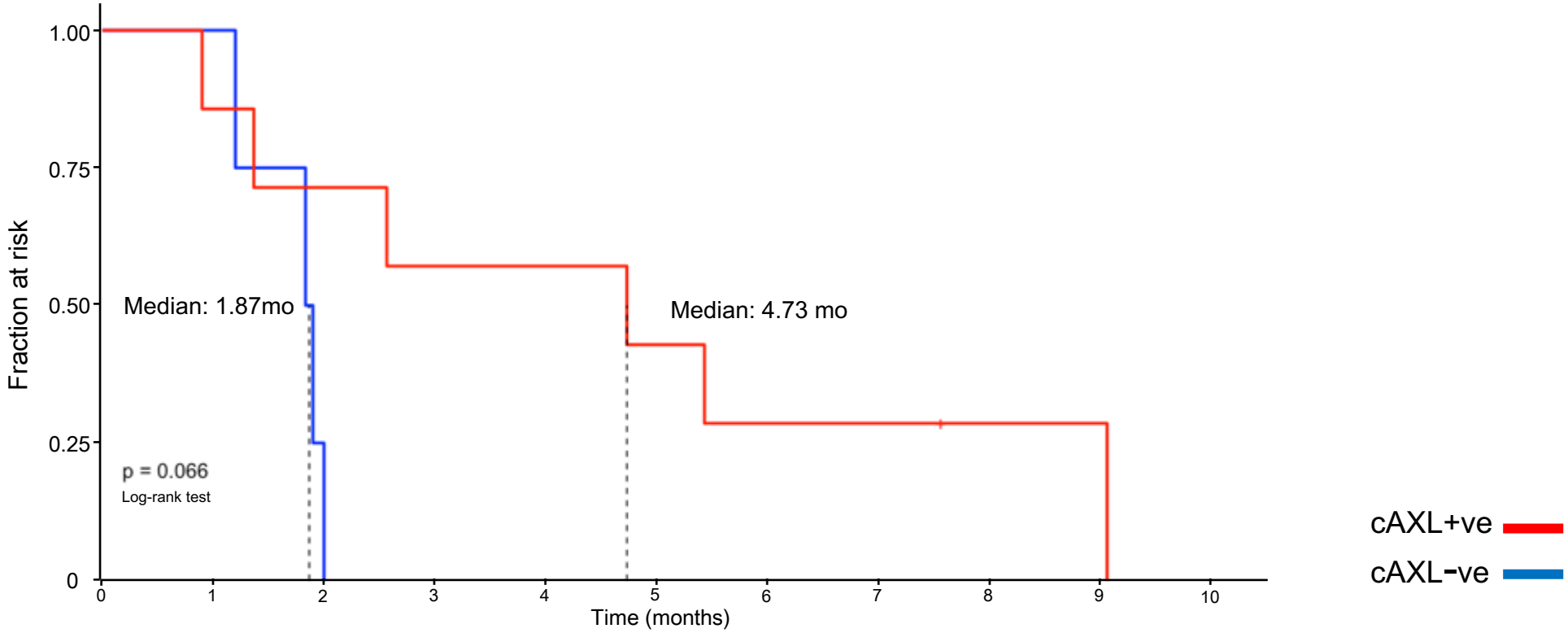
\- cAXL negative

Previous immunotherapy (1 or 2L)
P: pembrolizumab; **A**: atezolizumab; **N**: nivolumab; **C**: cetrelimab; **I**: ipilumimab; **O**: other

Data cut-off: 17-April-2020

Cohort B1

mPFS improvement in cAXL +ve patients



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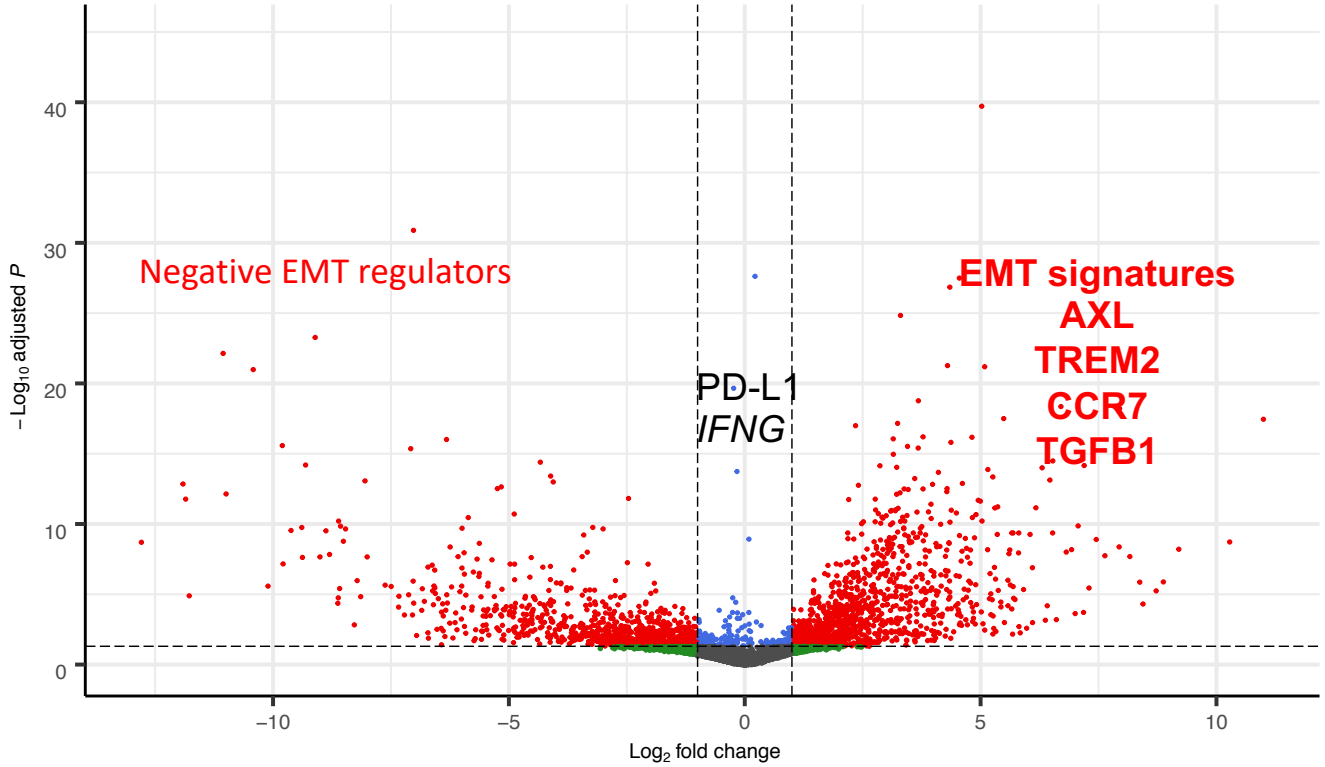
Cohort B1

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 tumour cell EMT[1]
- PD-L1 and IFNg expression do not predict response
- Presence of TREM2+ TAMs[#,2]
- Presence of CCR7+ mregDC1[##,3]

[#] tumor-associated macrophages
[##]regulatory dendritic cells

[1]Liberzon, Cell Systems 2015;[2]Katzenelenbogen *Cell* 2020, Molgora *Cell* 2020; [3]Maier *Nature* 2020

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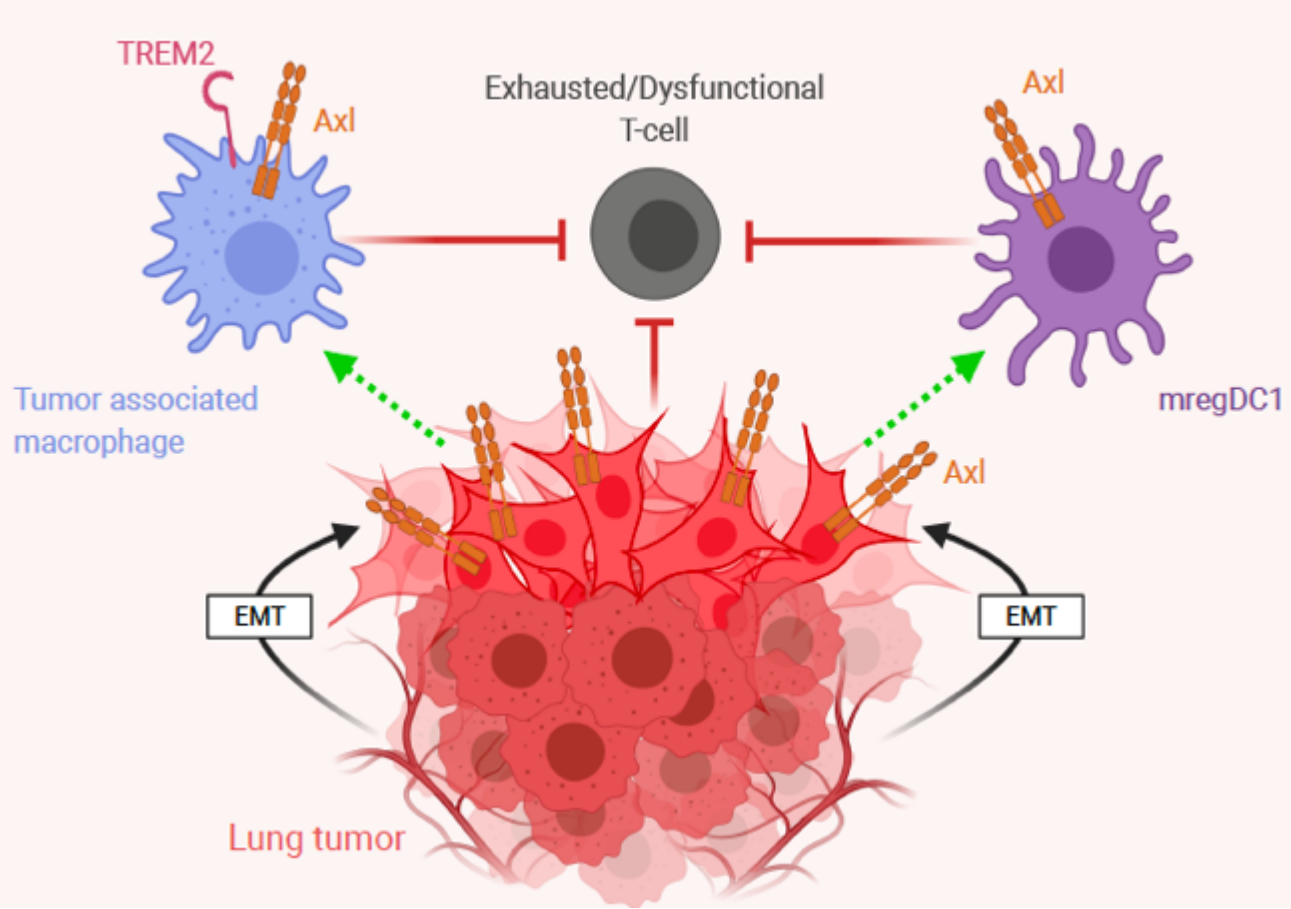
Proposed mechanism

AXL+ suppressive myeloid cells drive T cell dysfunction



- AXL promotes tumour-cell EMT and recently-described regulatory myeloid cells:
  - AXL⁺ TREM2⁺ Tumour Associated Macrophage[1,2]
  - AXL⁺ CCR7⁺ mregDC1[3]
- AXL expression in these cells promotes T cell dysfunction/exhaustion[2]
- Bemcentinib may reverse acquired resistance to checkpoint inhibition by targeting AXL+ TREM2 macrophages and regulatory DCs
- Bemcentinib inhibition of AXL reverses this state of immune suppression in the microenvironment, and promotes checkpoint inhibitor re-engagement

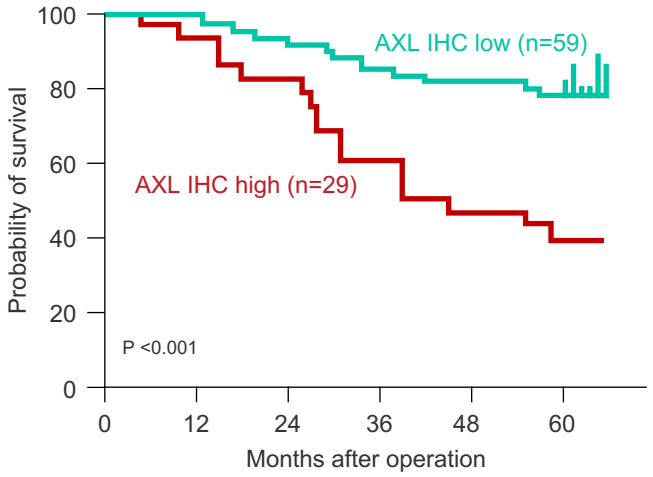
1. Katzenelenbogen *Cell* 2020; 2. Molgora *Cell* 2020; 3. Maier. et al. *Nature* 2020

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

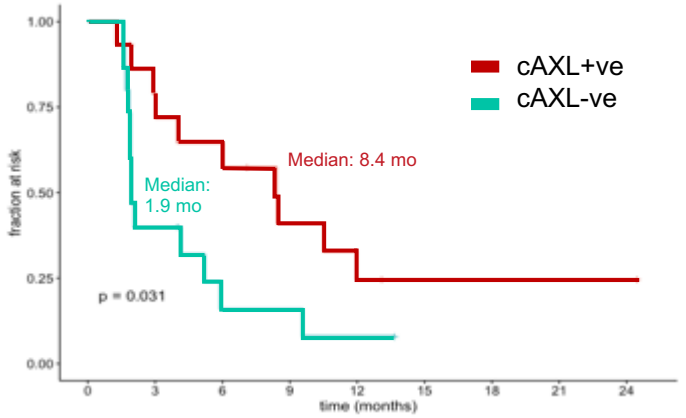
AXL expression defines a poor prognosis subgroup of NSCLC

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

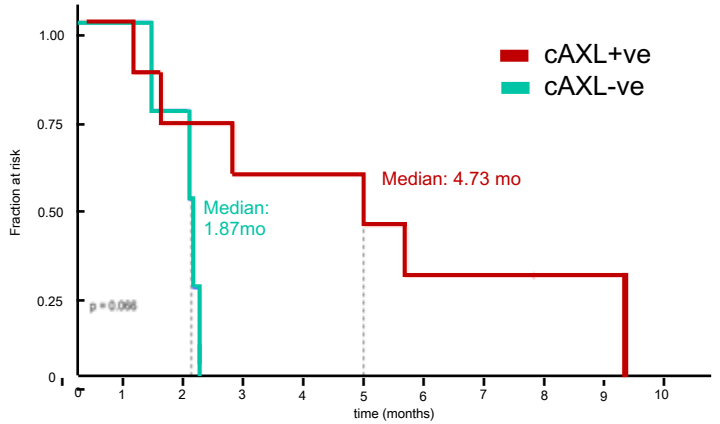
In NSCLC, the AXL expression encodes poor-prognosis[1]: defines expectations of the control arm



Cohort A PFS : CPI-naïve



Cohort B1 PFS: CPI-refractory



BIOLOGY = RATIONALE = OUTCOME

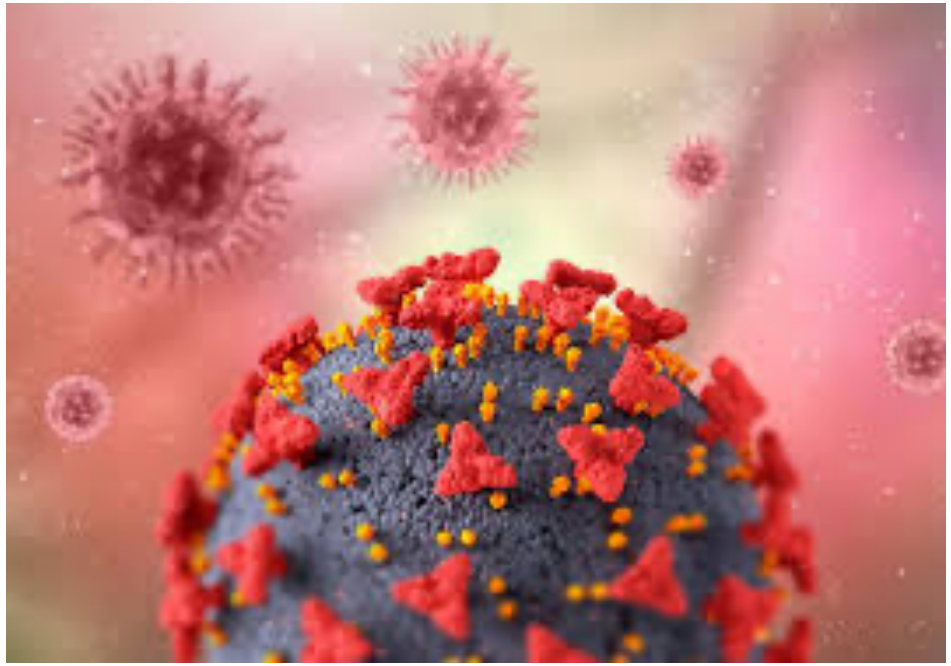
[1]Ishikawa, 2012

Bemcentinib clinical development in COVID-19

To evaluate the efficacy and safety in hospitalized COVID-19 patients

- *ACCORD-2* trial
- *BGBC020 trial in set up*

Bemcentinib evaluation in COVID-19



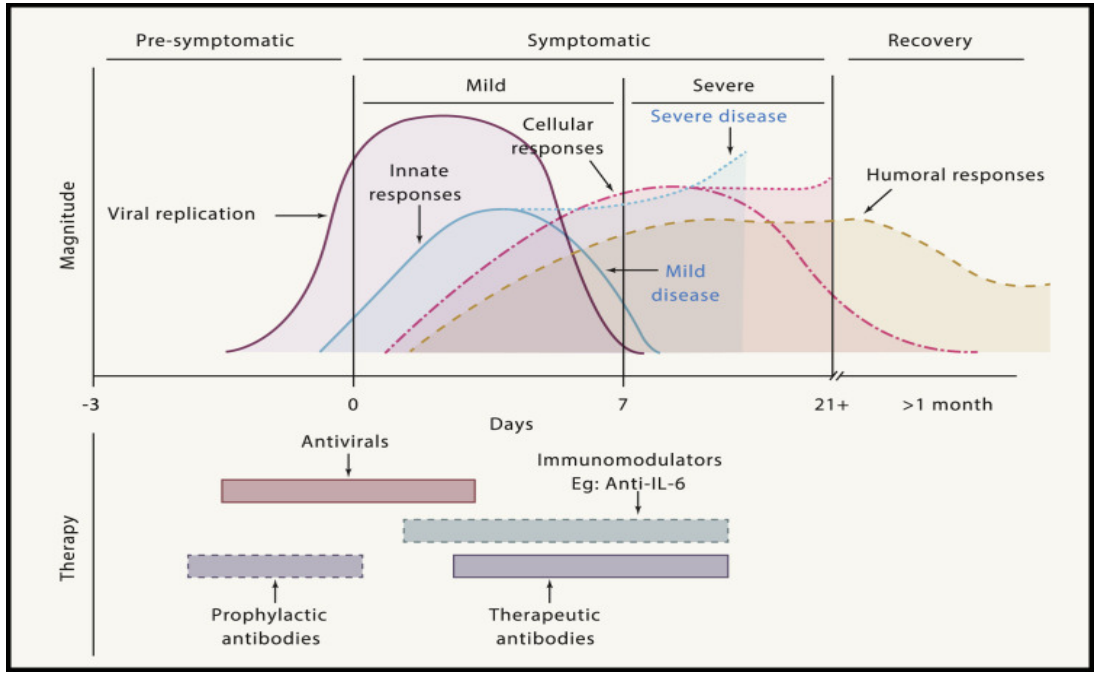
- Therapeutic potential of bemcentinib is supported by sound scientific rationale and external research and review[1]
- Orally available, potent and highly selective inhibitor of AXL tyrosine kinase
  - Preclinical data confirms bemcentinib inhibits SARS-CoV-2 host cell entry and promotes anti-viral Type I interferon response[1,3]
  - MoA independent of spike protein (or mutations) and therefore should remain effective against current and future variants
- Currently being investigated in PhII clinical studies in hospitalised COVID-19 patients (3 ethnically diverse countries UK, South Africa & India
- Safety and tolerability profile in COVID-19 patients consistent with >350 patients studied in oncology programme
  - Mild and reversible adverse events
  - IDMC have twice recommended continuation of BGBC020 without amendment to protocol

[3] Maury IOWA unpublished [3] Meertens L *et al. Cell Host & Microbe* 2012, *12*:544 / [1]Chen J *et al. Nat Microbiol* 2018 *3*:302

COVID-19 Clinical Progression

Stages of the disease

Bemcentinib: anti viral / innate immunity / anti fibrotic



Patient classification

	Setting	Severity	Supportive intervention	BGBC020 ACCORD2	Dexamethasone	IL-6 receptor antagonists	Remdesivir
0	Uninfected	no clinical or virological evidence of infection					
1	Ambulatory	no limitation of activities					
2		limitation of activities					
3	Hospitalised	mild	no oxygen therapy	bemcentinib			
4			oxygen by mask or nasal prongs				
5		severe	non-invasive ventilation or high-flow oxygen				
6			intubation and mechanical ventilation				
7			ventilation and additional organ support –				
8		Death					

Immunity 2020 Jun 16;52(6):905-909. doi: 10.1016/j.immuni.2020.05.004.

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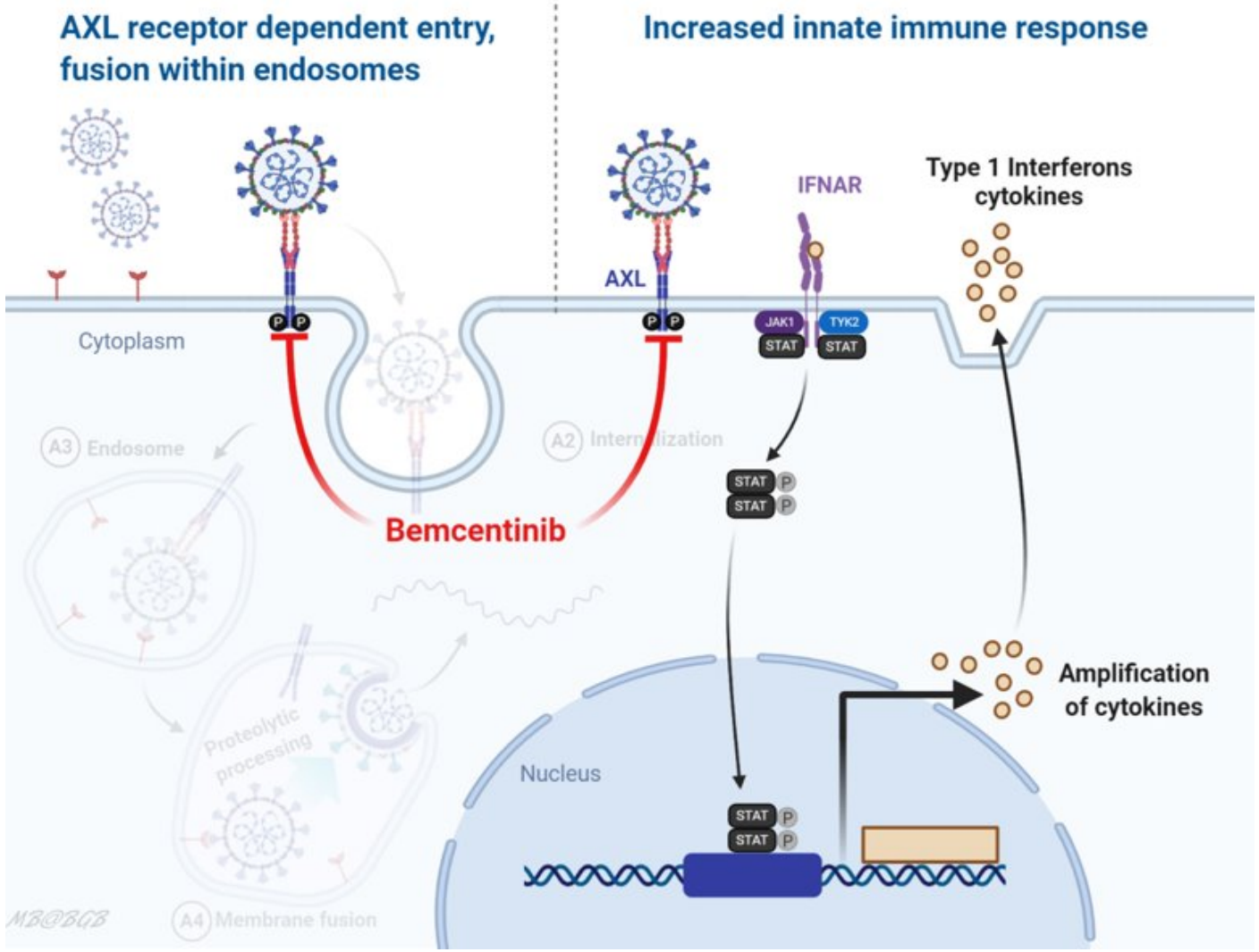
Potential of Bemcentinib on SARS-CoV-2 infection of host cells

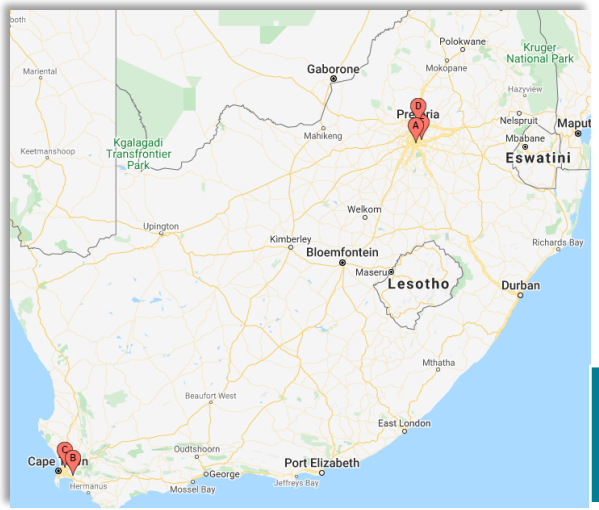


- Utilization of AXL contributes to ACE2-dependent entry
- AXL enhances virus infection by facilitating virus entry via an endosomal pathway
- Bemcentinib control of virus infection likely involves both reduced viral entry and enhanced interferon responses

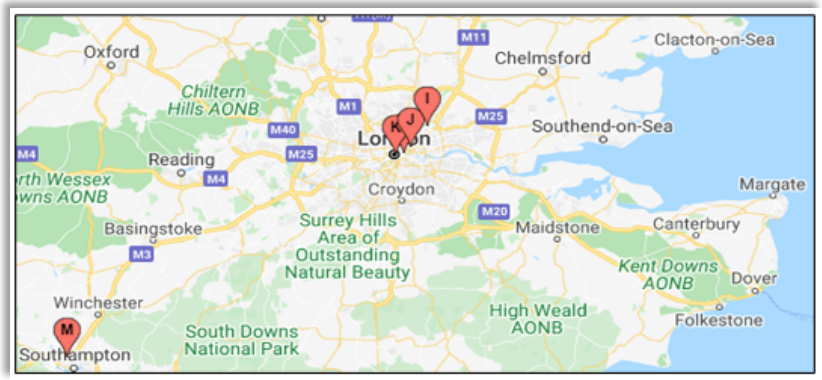
Professor Wendy Maury, BerGenBio R&D Day 6 Nov 2020

Slide for Presentation

Bemcentinib studied in COVID19 across 3 countries



Patient Accrual	India	South Africa	UK	Total
Bemcentinib	30	27	TBA	57
SoC	30	27	TBA	57
				114



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Bemcentinib randomised Studies in COVID-19

BGBC019 – ACCORD & BGBC020

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

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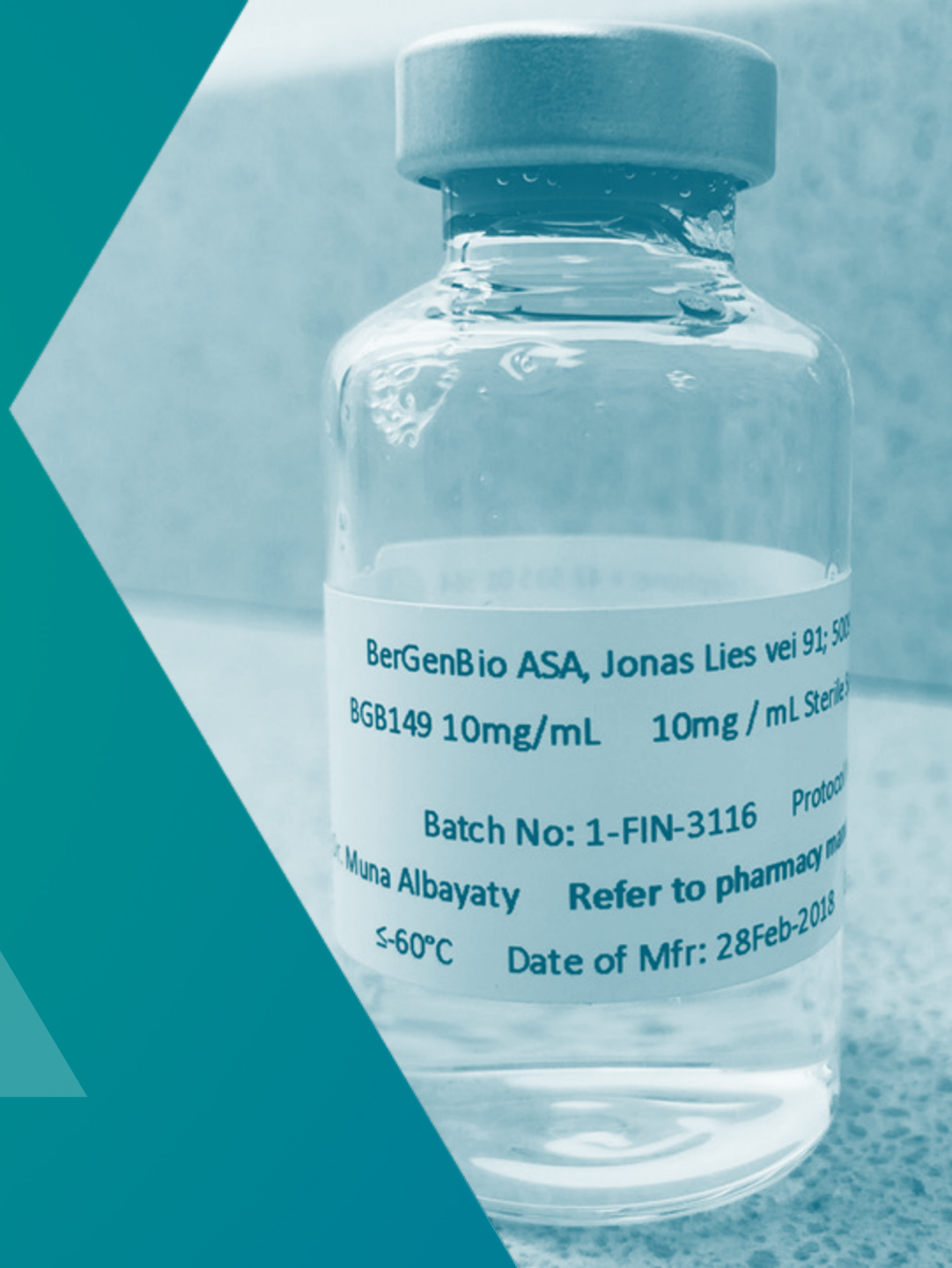
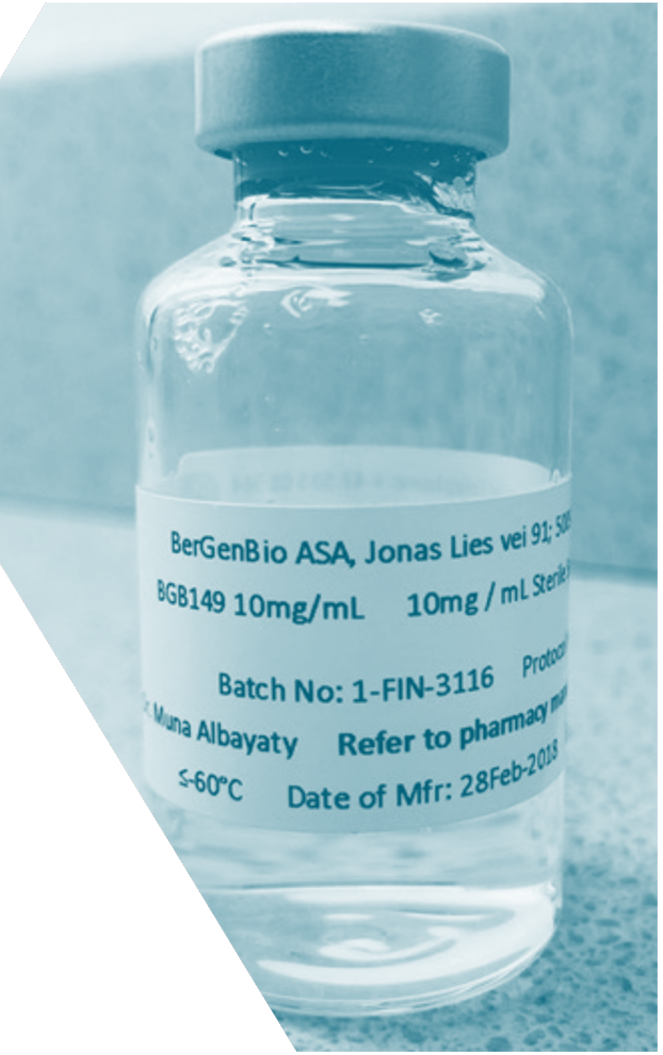
Tilvestamab (BGB149)
anti-AXL monoclonal antibody



Ref. BGB149-101 / NCT03795142

TILVESTAMAB: Anti-AXL monoclonal antibody

Phase I/II clinical trial ongoing



Functional blocking fully-humanised IgG1 monoclonal antibody

Binds human AXL, blocks AXL signalling

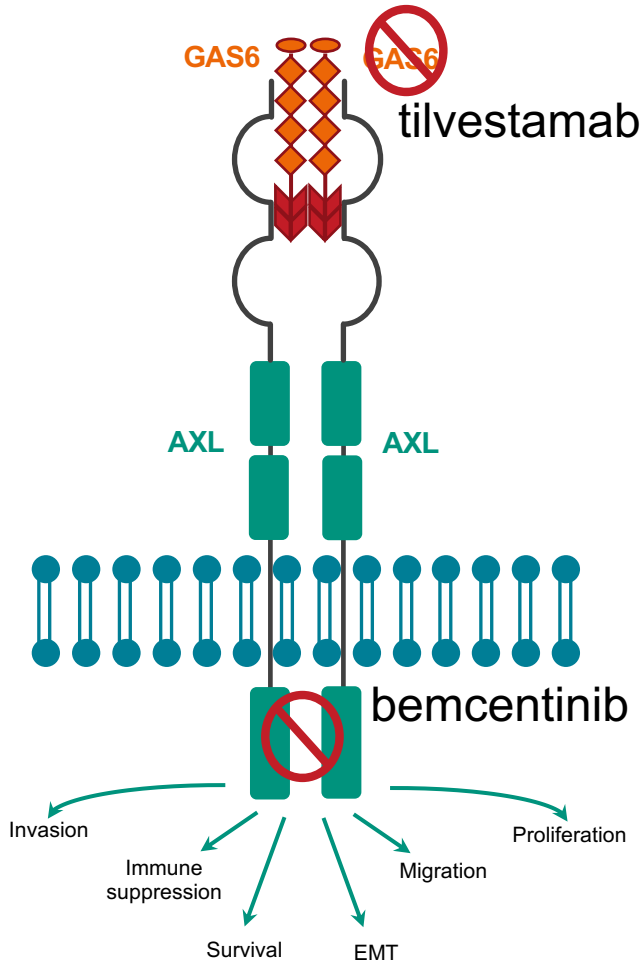
High affinity (KD: 500pM), displaces GAS6
Anti-tumour efficacy demonstrated *in vivo*

Robust manufacturing process 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 Ib patient study recruiting
MAD PK/PD



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Well positioned for continued success

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Why BerGenBio – key take-aways ……

AXL
- Leveraging leadership in AXL biology
- Oncology, Virology, Fibrosis

Pipeline
- Bemcentinib – selective oral AXL inhibitor, in more than 15 active sponsored or IST phase II trials
- Tilvestamab – mAb in Ph Ib
- Biomarkers and CDx assays

Patient
- Relapse AML – emerging significant patient population with no approved treatment. Encouraging efficacy and survival benefit
- Relapse HR-MDS potential survival benefit
- 2L NSCLC – translational data supports rationale for chemo-free 2L position.

Registration
- Route to first approval is becoming apparent
- FDA approved Fast Track and orphan designation in AML

News Flow
- COVID-19 top line clinical data end of Q1'21
- AML survival data update
- NSCLC clinical & translational data

Resources
- International experienced team
- 2020 YE cash NOK 722m ($85m)

2021 Anticipated Value Driving Catalysts

Relapse AML and MDS

Report update survival data
- Relapse AML
- Relapse HR-MDS

Seek regulatory advice on potential registration path

Bemcentinib in COVID-19

Top line clinical data from trial in South Africa and India at end of Q1’21

ACCORD data anticipated Q2’21

Seek regulatory guidance to accelerate approval if supported by data

Advance solid tumour pipeline

NSCLC (2L Keytruda combo)
- Report Survival benefit chemo & CPI refractory patients

IST data in multiple indications

Advance Tilvestamab clinical development

Completed Phase 1b safety study
- Pk/PD
- RP2D

Initiated Phase 2a study

Thank you

BerGenBio

Richard S. Godfrey CEO
Oslo Børs: BGBIO