



BerGenBio

Q3 2020 REPORT, HIGHLIGHTS AND FINANCIALS

17th Nov 2020

Richard Godfrey, CEO

Rune Skeie, CFO

Hani Gabra, CMO

James Lorens, CSO

BerGenBio ASA

Jonas Lies vei 91, Bergen, 5009, Norway

www.bergenbio.com

IR contact: IR @bergenbio.com

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2. AXL Biology

3. Bemcentinib – the unique BGBIO story

- COVID
- Acute Myeloid Leukemia / Myeloid Dysplastic Syndrome (AML & MDS)
- Non-Small Cell Lung Cancer NSCLC
- Mesothelioma (MiST3)

4. Tilvestamab

5. Finance

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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

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

Cash Q3'20 NOK 778m,

Q3 and recent highlights

Jul
2020

First patient dosed in investigator sponsored Phase II study assessing bemcentinib in recurrent glioblastoma (GBM)

Aug
2020

MET primary endpoint of Overall Response Rate in BERGAMO Phase II Trial in 2L patients with High Risk Myelodysplastic Syndromes (HR-MDS) or Acute Myeloid Leukemia (AML)

Sep
2020

Presented at SACHs Annual Biotech in Europe Forum

Oct
2020

First patient dosed in MiST3 trial assessing bemcentinib in relapsed malignant pleural mesothelioma patients, which forms part of the world's first molecularly stratified umbrella study in mesothelioma

Oct
2020

First patient enrolled in BerGenBio's Phase II clinical trial in South Africa and India (BGBC020), assessing the safety and efficacy of bemcentinib for the treatment of hospitalised COVID-19 patients

Presented pre-clinical data on humanized anti-AXL antibody Tilvestamab (BGB149) at 32nd ENA Symposium

Nov
2020

Selected for oral presentation at SITC 35th Annual Meeting; presented clinical translational research updates from Phase II bemcentinib and pembrolizumab combination study (BGBC008) in NSCLC

Hosted a virtual R&D Day with prominent expert independent KOLs 6th November 2020

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 facilitating virus entry via an endosomal 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 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

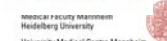


Professor Sonja Loges, MD, PhD


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






BerGenBio pipeline of sponsored clinical trials and near-term news flow

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

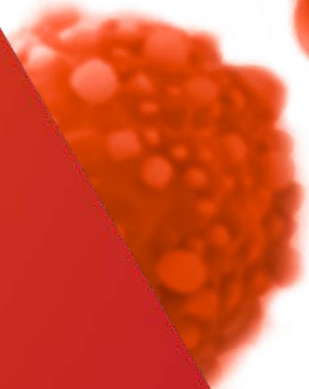
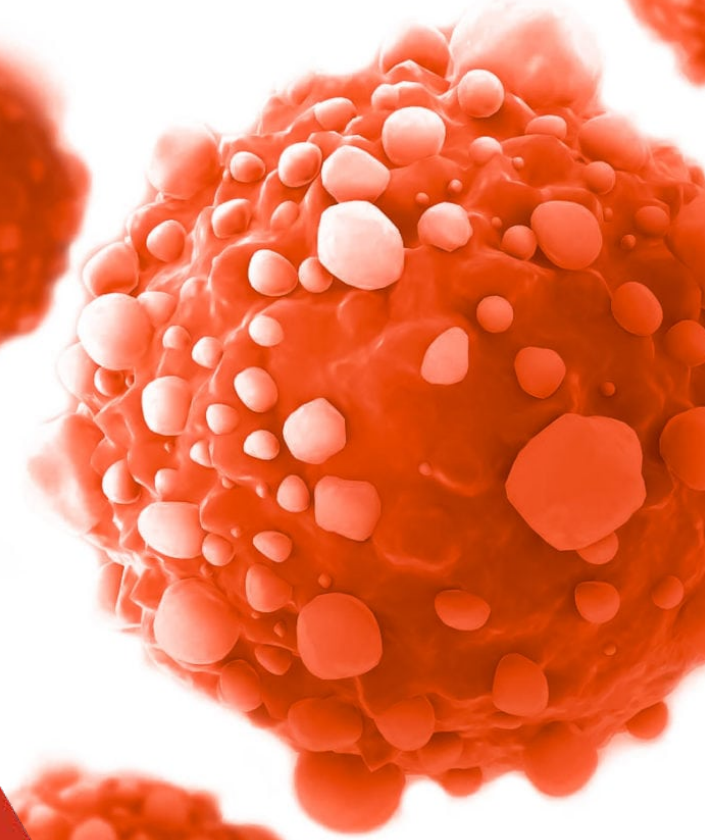
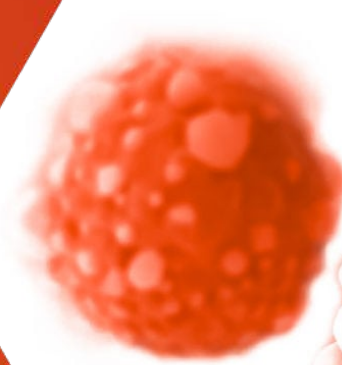
Ongoing Trial
 Completed Trial

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 NSMDS	Monotherapy			European MDS Cooperative Group
	Recurrent Glioblastoma	Monotherapy			Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
	Relapse 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

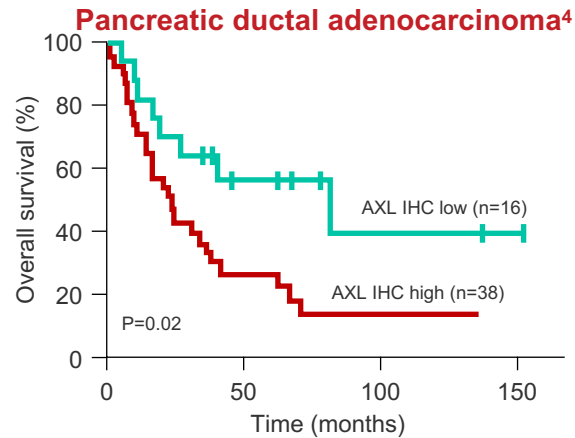
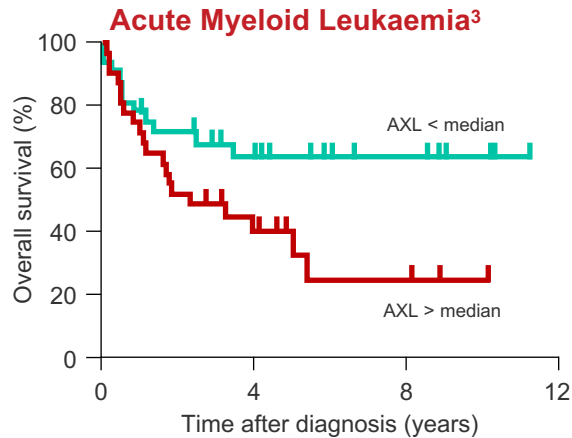
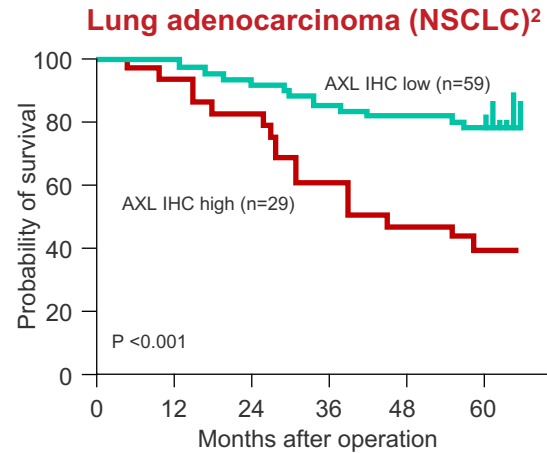
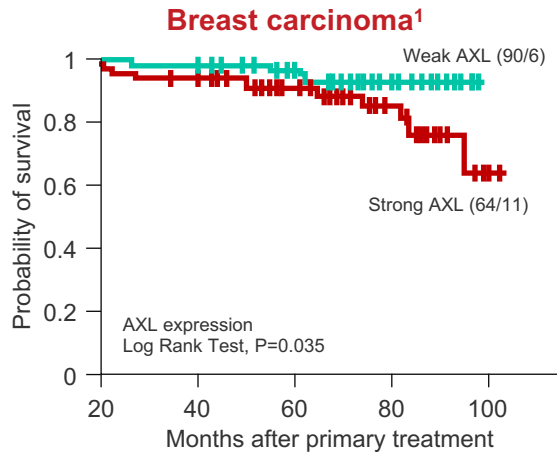


AXL Biology



AXL is independent negative prognostic factor in a broad variety of cancers

Strong AXL expression correlates with poor survival rate



Broad evidence of AXL linked with poor prognosis⁵

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 sarcoma

- Liposarcoma

- Osteosarcoma

Skin SCC

Thyroid cancer

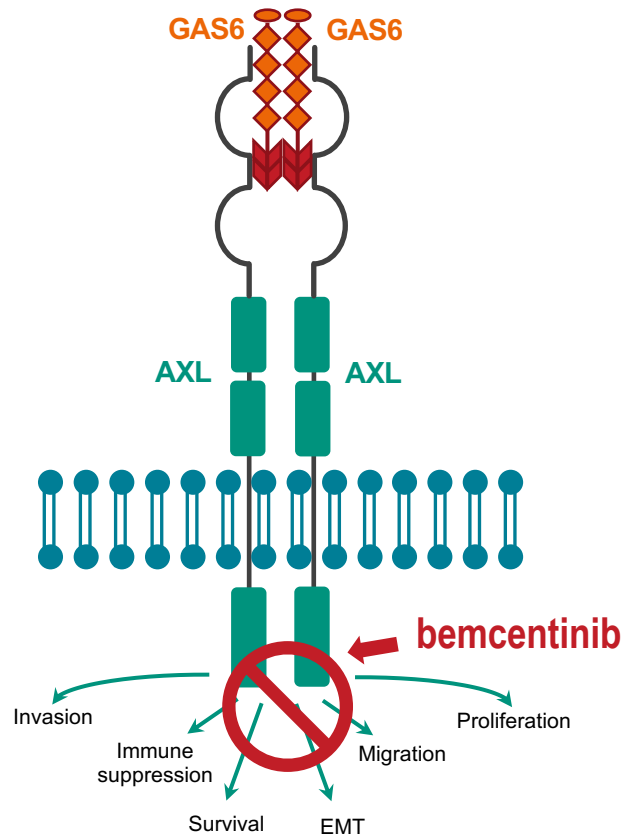
Urological

- Bladder cancer

- Prostate cancer

- RCC

AXL Biology



- AXL mediates multiple survival mechanisms used by cancers:
 - Chemo drug resistance, immune evasion, metastasis
- AXL mediates viral entry to host cells and reduces anti-viral immunity

- AXL is a member of the Tyro3, AXL, Mer (TAM) family of receptor tyrosine kinases, activated by Growth Arrest Specific Factor (Gas6) - involved in phagocytosis of apoptotic cells
- AXL a receptor tyrosine kinase that is important for regulating innate immune cells.¹
- AXL levels are elevated by cellular stress and is strongly associated with inflammatory diseases including cancer and fibrosis.²
- It functions as a homeostatic regulator in adult tissues and organ systems that are subject to continuous challenge and renewal throughout life – immune, nervous, vascular and reproductive
- AXL drives cancer progression, immune evasion, and resistance to targeted therapies.³
- AXL is a key suppressor of the type I interferon response and is targeted by viruses to block the anti-viral immunity.⁴
- AXL is used by several different enveloped viruses (e.g. Ebola, Zika) to enter cells.⁵

Very low expression under healthy physiological conditions

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

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

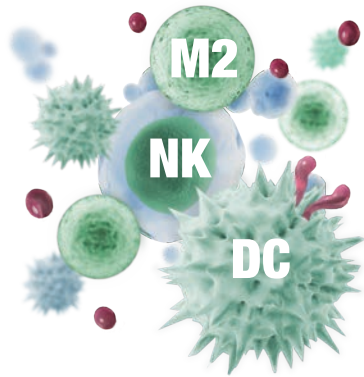
¹Lemke Cold Spring Harb Perspect Biol 2013; ²Zagórska Nat Immunol 2014, Ludwig Cancer Res 2018, Espindola, Am J Respir Crit Care Med. 2018;³Gay, Br J Cancer 2013; ⁴Chen Nat Microbiol 2018; ⁵Moller-Tank Virology 2014;

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

very low expression under healthy physiological conditions

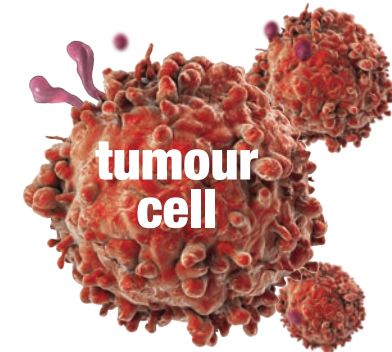
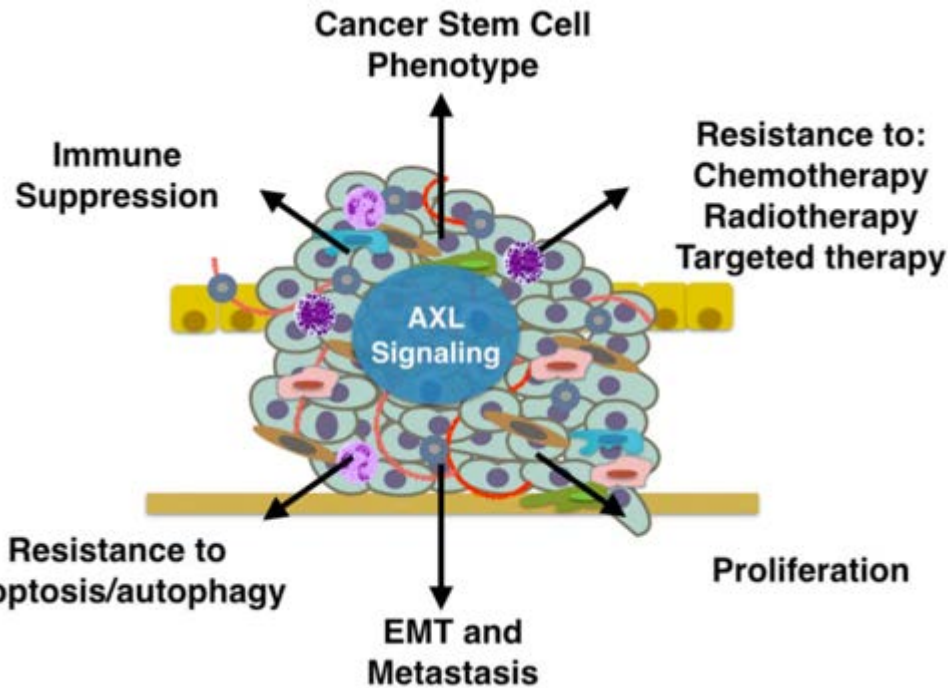
overexpressed in response to hypoxia, inflammation, cellular stress & drug treatment

overexpression correlates with worse prognosis in most cancers



AXL increases on immune cells and suppresses the innate immune response

- M1 to M2 macrophage polarisation¹
- Decreased antigen presentation by DCs²
- Prevent CD8+ T cell mediated cell death³
- Activates Treg cells



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

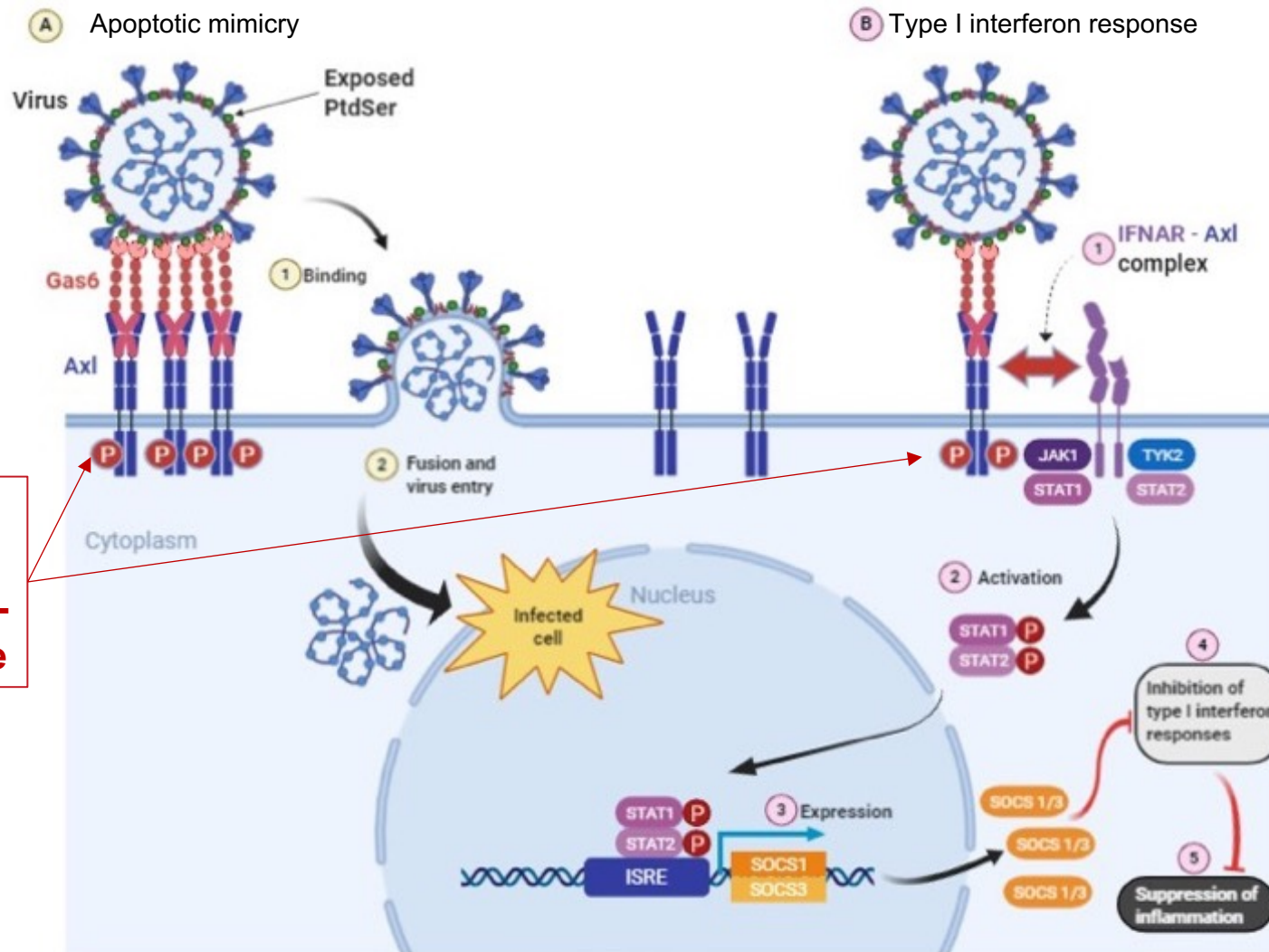
- AXL is a unique type I interferon (IFN) response checkpoint
- Acquired drug resistance
- Immune cell death resistant
- Metastasis

DC- dendritic cells Treg – Regulatory T Cell

¹² 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

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”.



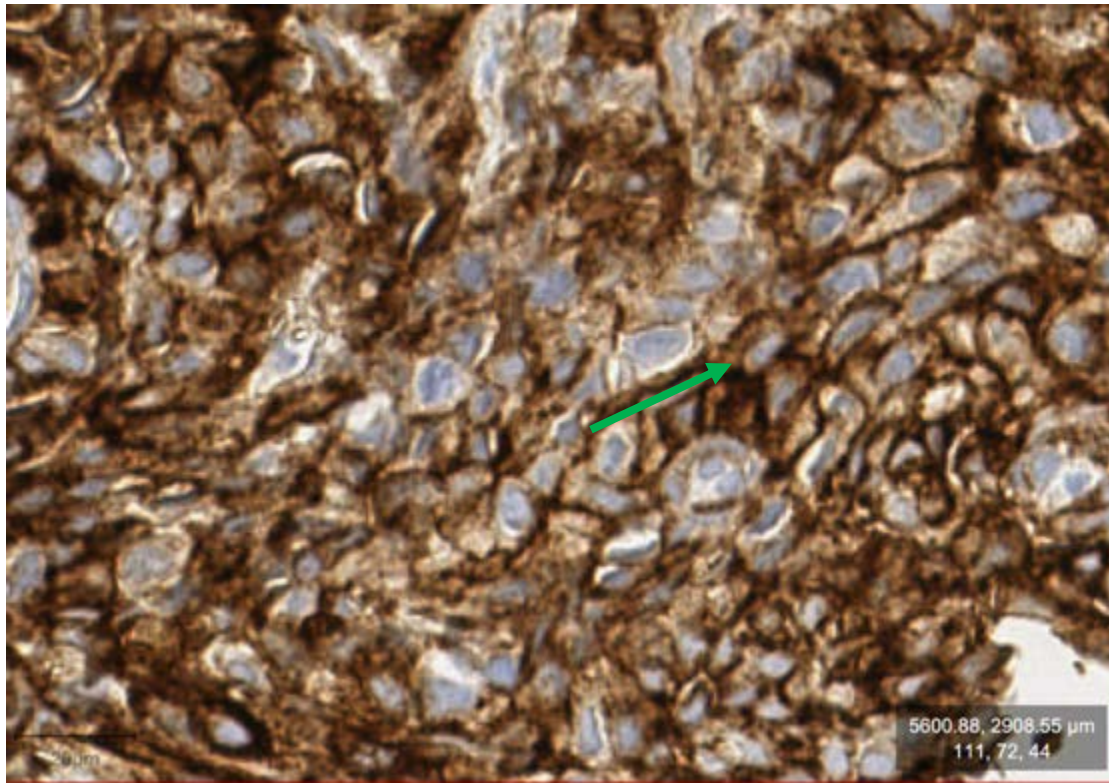
Viral-mediated AXL receptor activation dampens type I interferon responses, a key anti-viral defence mechanism for all cells

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

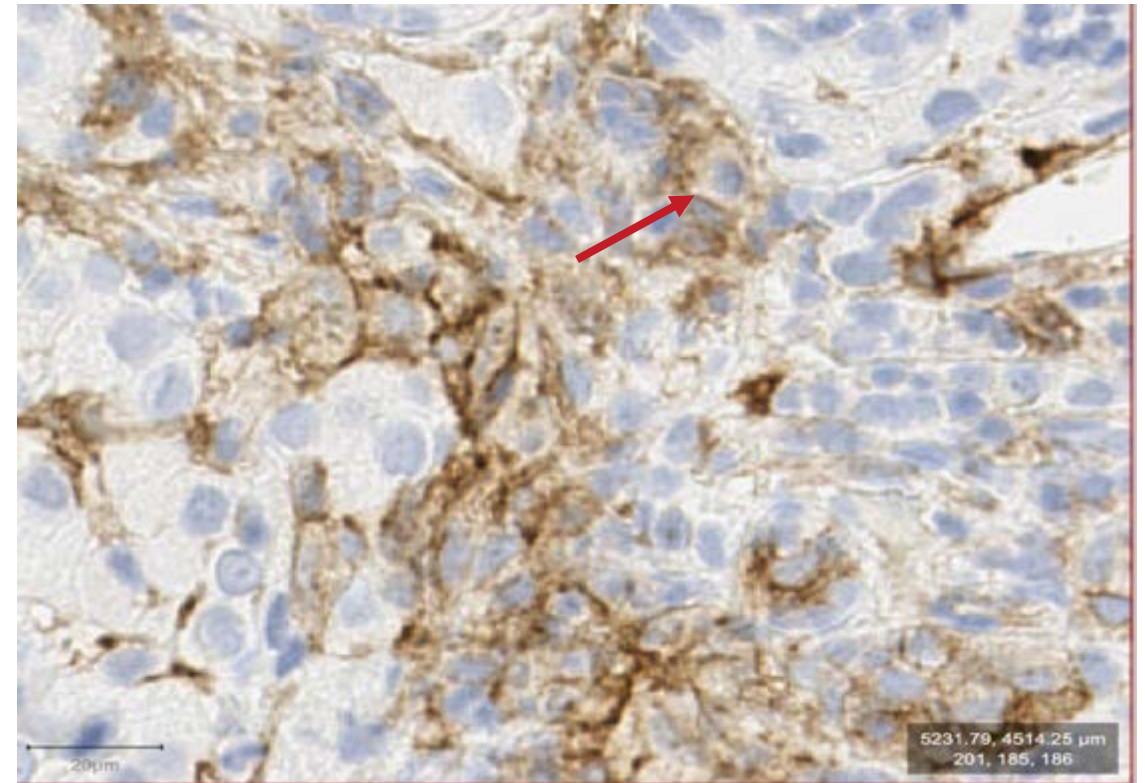
Bemcentinib potently inhibits SARS-CoV-2 infection of cells.¹

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

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



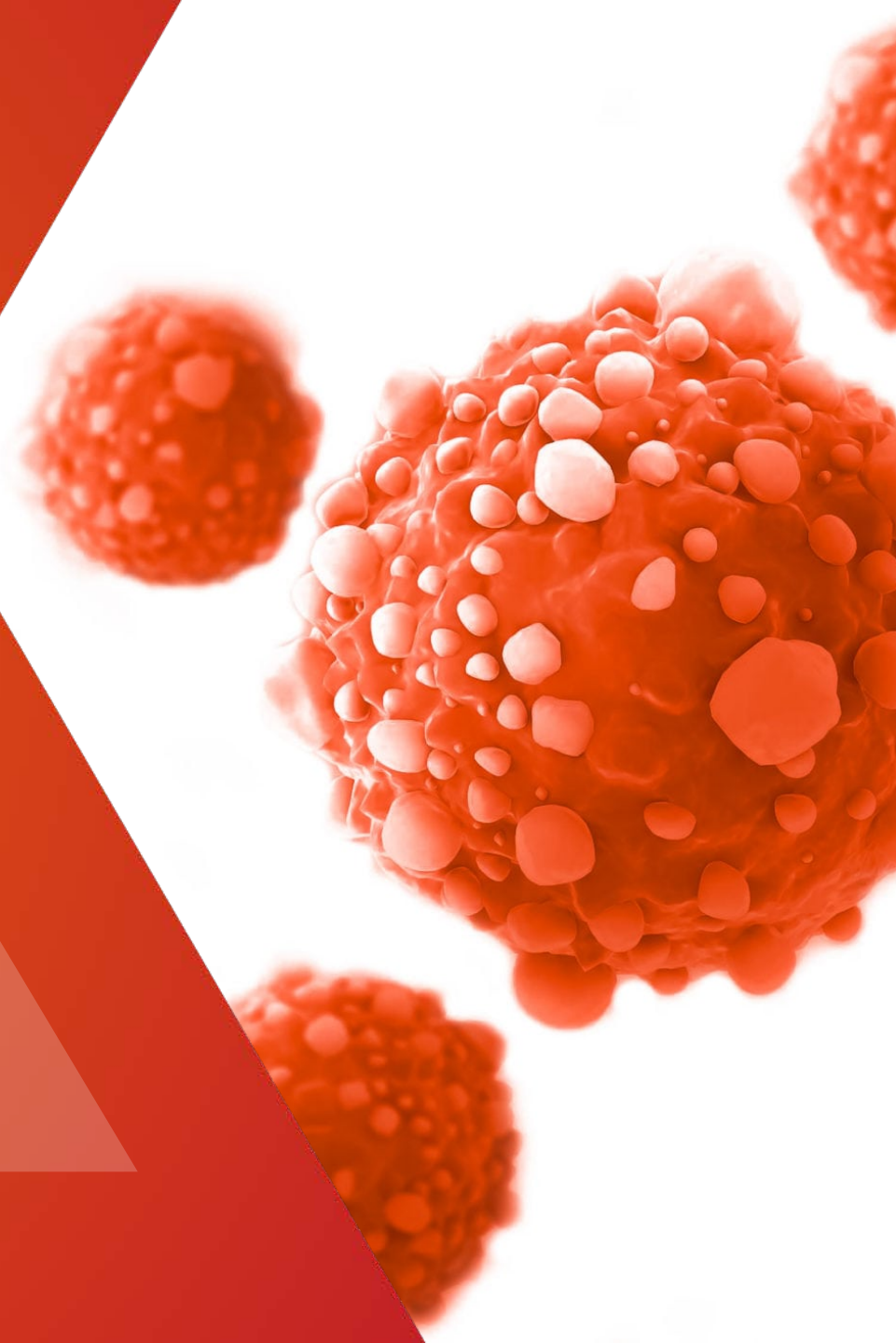
Example of tumour with a high number of AXL positive immune cells: cAXL status of this patient is positive



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

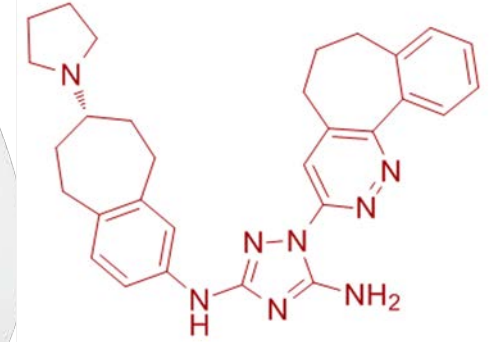
Bemcentinib

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



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

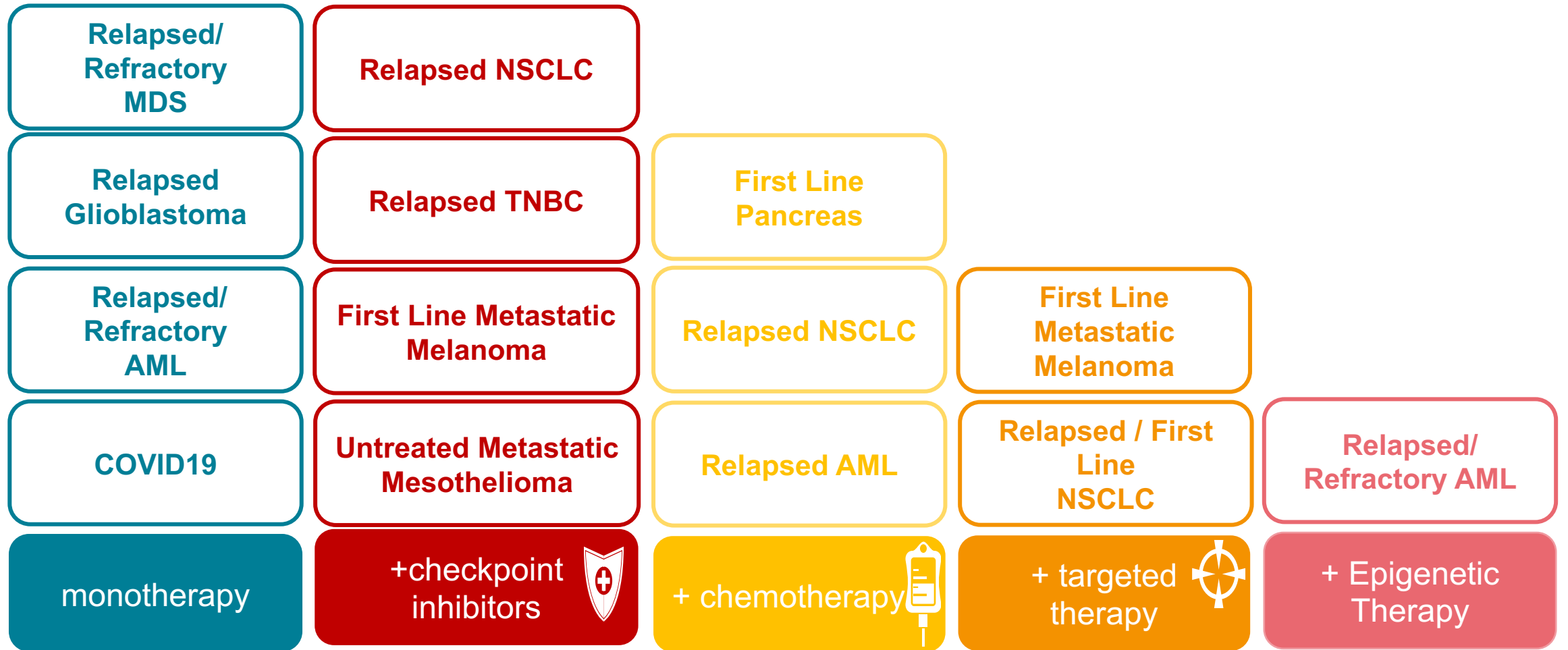
- ✓ Nanomolar in vitro potency ($IC_{50} = 14 \text{ nM}$)
- ✓ Uniquely selected for AXL
 - ✓ 50-100-fold selective cf. TAM kinases
- ✓ Manufacturing at increased scale for late-stage regulatory filing
- ✓ Size 0 100mg HPMC capsules
- ✓ 3 years stability confirmed
- ✓ Once daily oral dosing



- ✓ MOA is synergistic with other therapies, enhancing response
- ✓ Extensive Phase I & II experience
 - ✓ >300 patients
- ✓ Safety and tolerability profile supports use in combination with other drugs

Bemcentinib Phase II clinical trials

AXL inhibition as cornerstone for aggressive disease



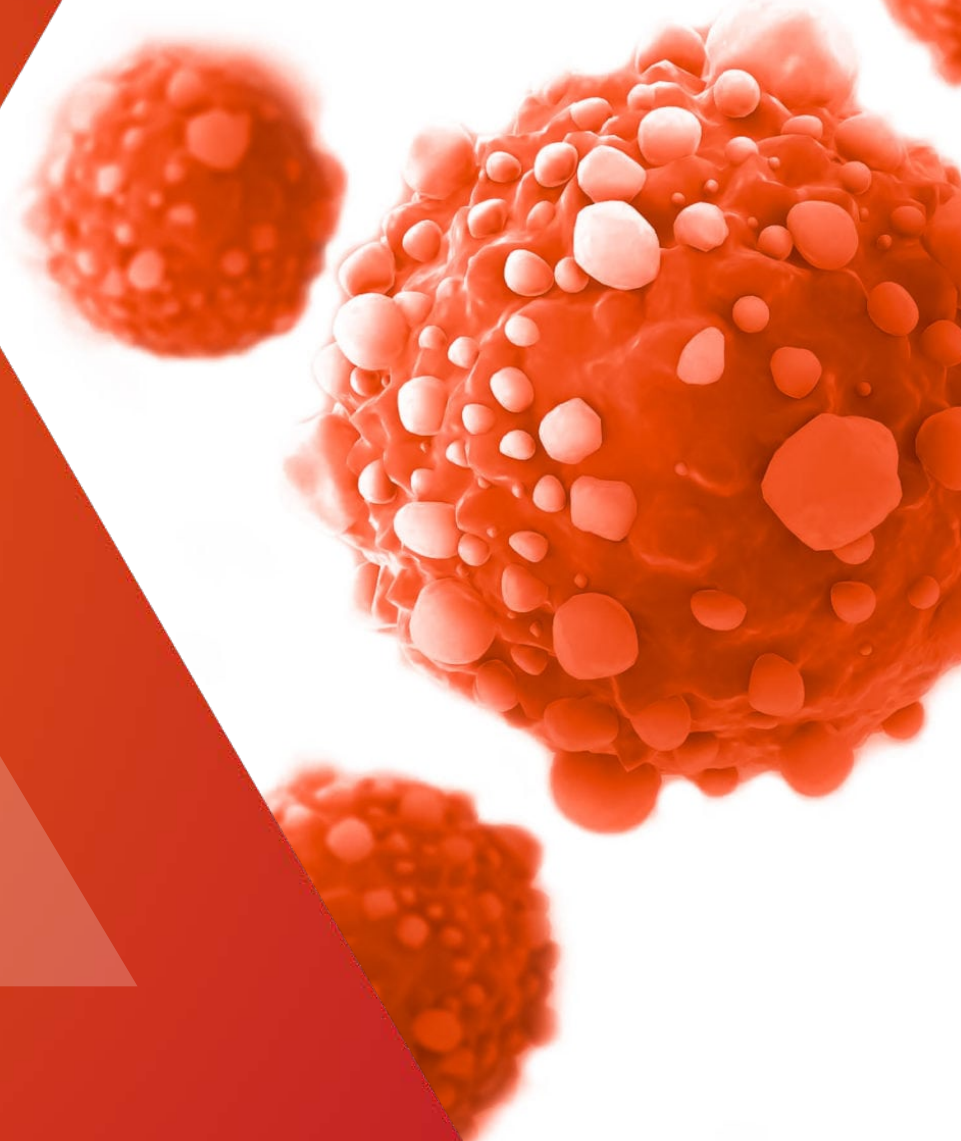
Bemcentinib foundation therapy

COVID-19

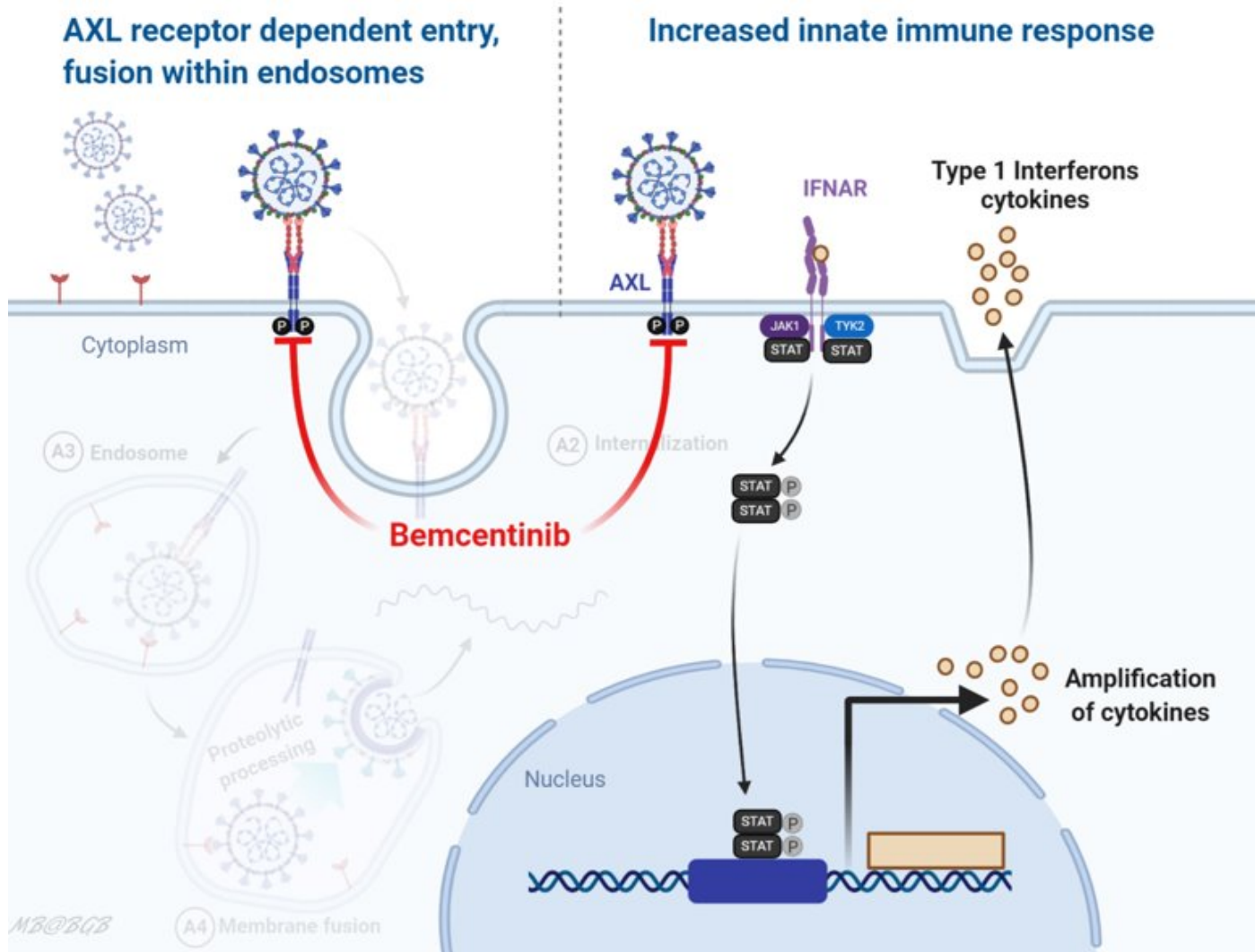
Bemcentinib clinical development in COVID-19

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

Bemcentinib Study in COVID-19

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



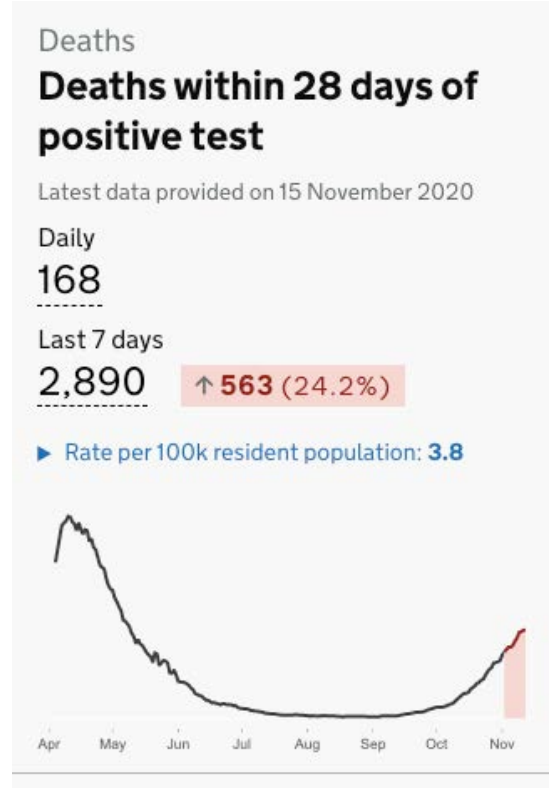
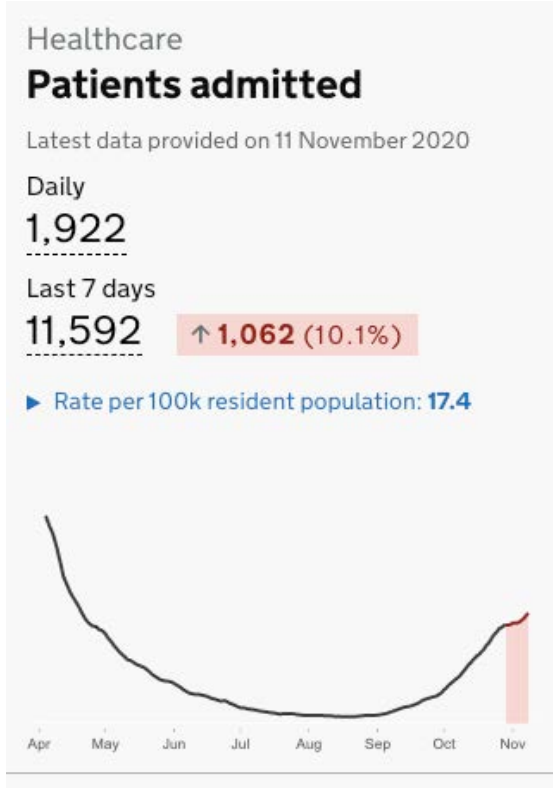
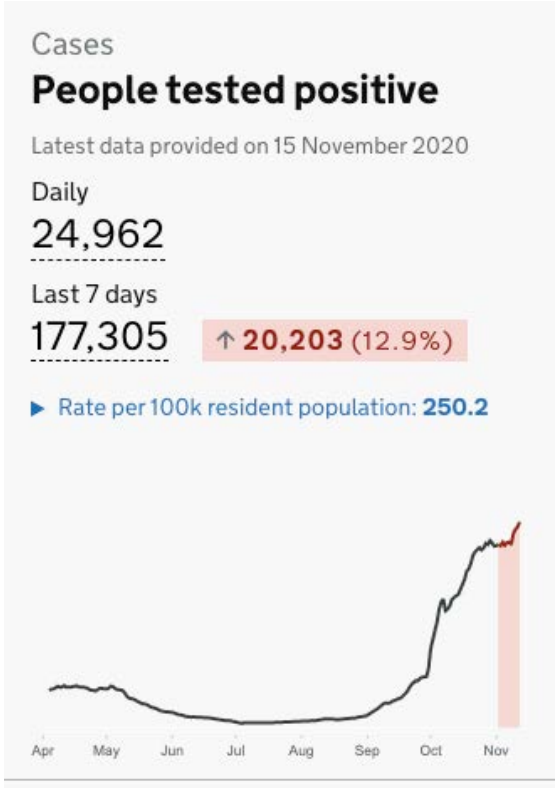
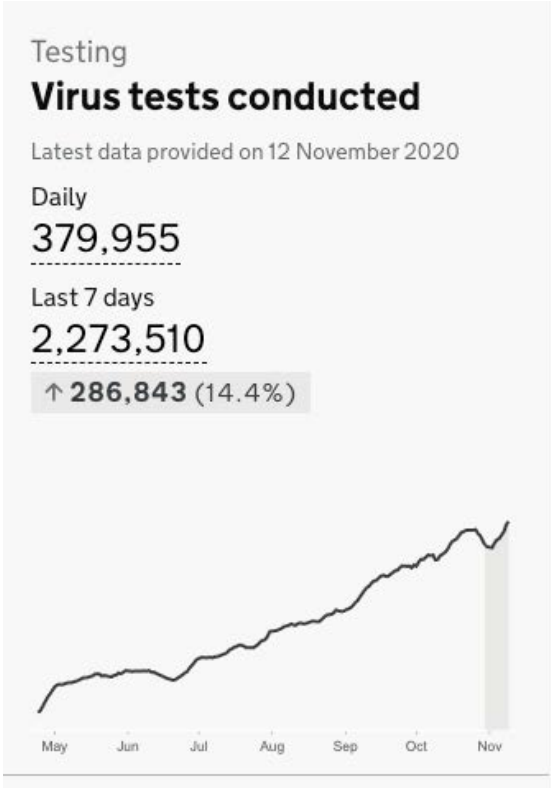
Exploratory objectives

- 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

ACCORD II UK COVID-19



The latest R number is estimated at **1 to 1.2** with a daily infection growth rate range of **+1% to +3%** as of 13 November 2020



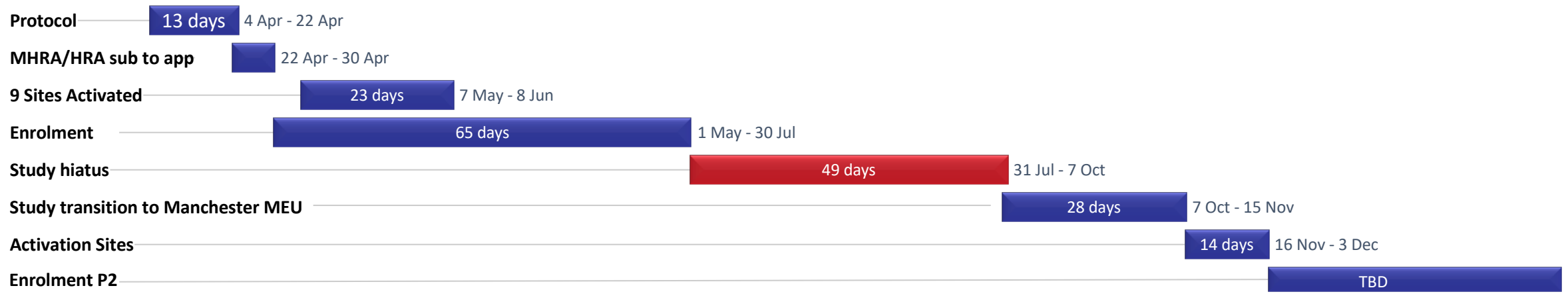
ACCORD II



- Multicentre, seamless, Phase II adaptive randomisation platform trial
- Assessing the safety and efficacy of three candidate agents in hospitalised COVID-19 patients
- Up to 25 sites across the UK to recruit patients into the trial
- 60 patients will receive bemcentinib and 60 patients in a control group will receive standard of care treatment.
- Patient recruitment to recommence very soon



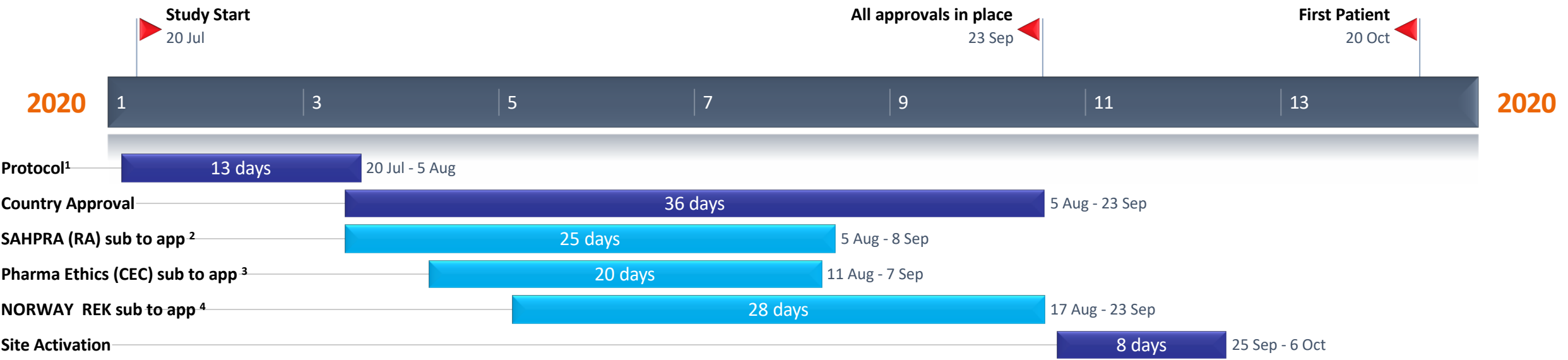
ACCORD Timeline through to restart



Study Timelines

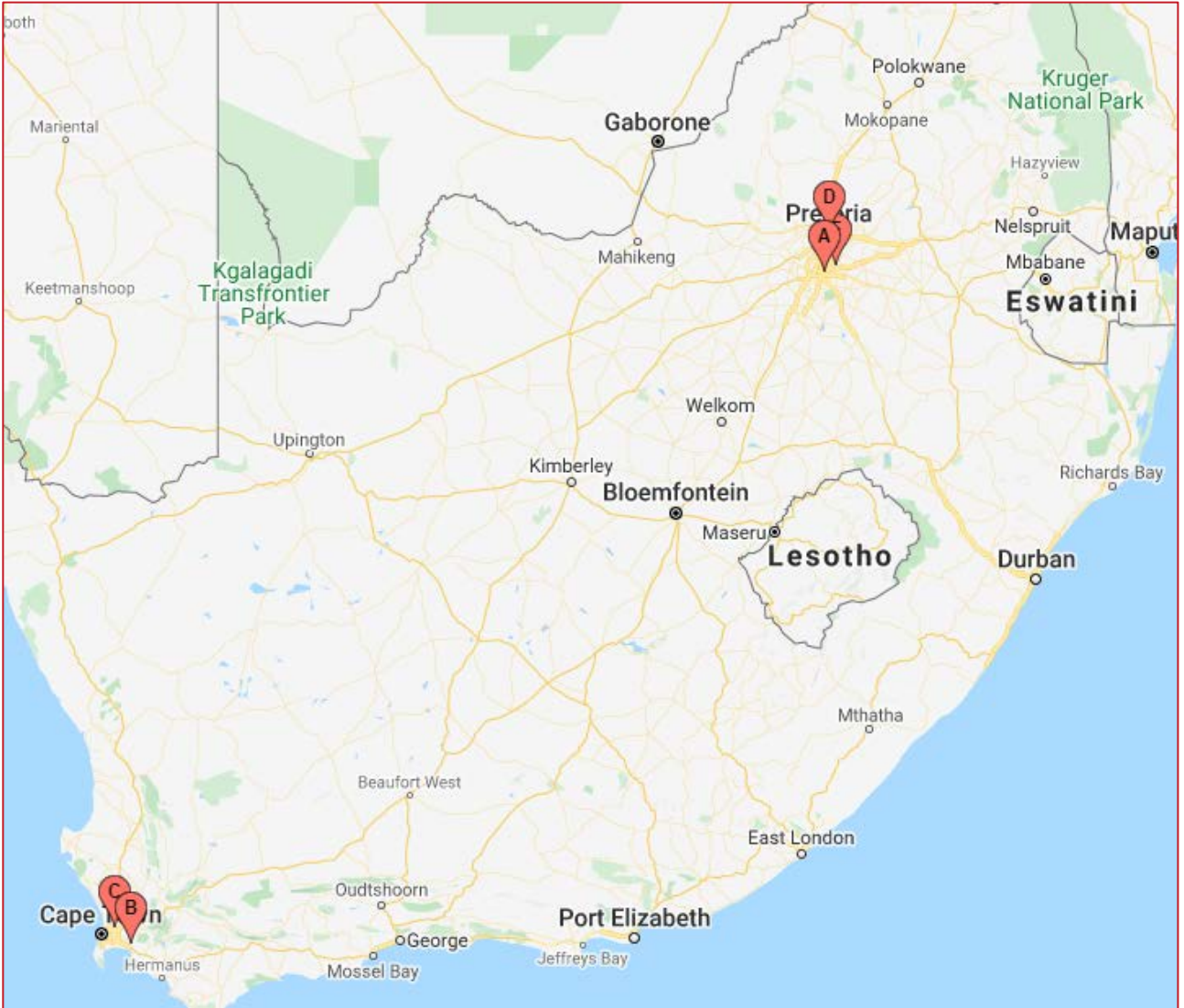
Start up through to end of enrolment

BGBC020: Study start-up in South Africa (- 13 weeks)



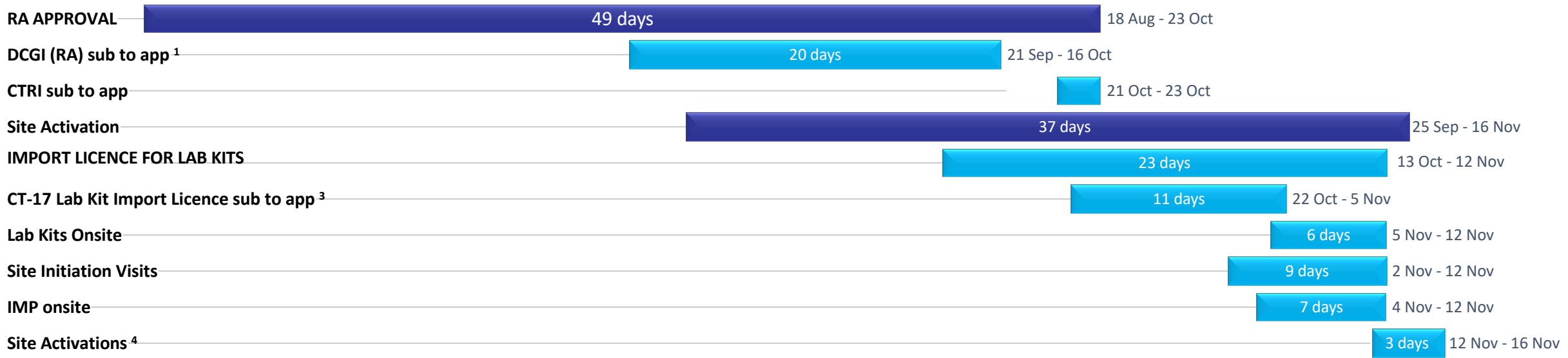
- Expediated complex multi-agency process to establish clinical trial
- Regulatory, ethics, CRO liaison achieved in less than 13 weeks
- Unprecedented timeframe to set up a trial of this kind in developing nations

BGBC020: Five sites recruiting across South Africa



Cities
Worcester
Cape Town
Bellville, Cape Town
Pretoria
Benoni

BGBC020: Study start-up in India (-13 weeks)



BGBC020: Seven sites recruiting across India



Institution

Kasturba Medical College

Sahyadri Specialty Hospital

JSS Hospital

Krishna Institute of Medical Sciences (KIMS)

Maulana Azad Medical College

Unity Hospital

Chopda Medicare & Research Center Pvt, Ltd; Magnum Heart Institute

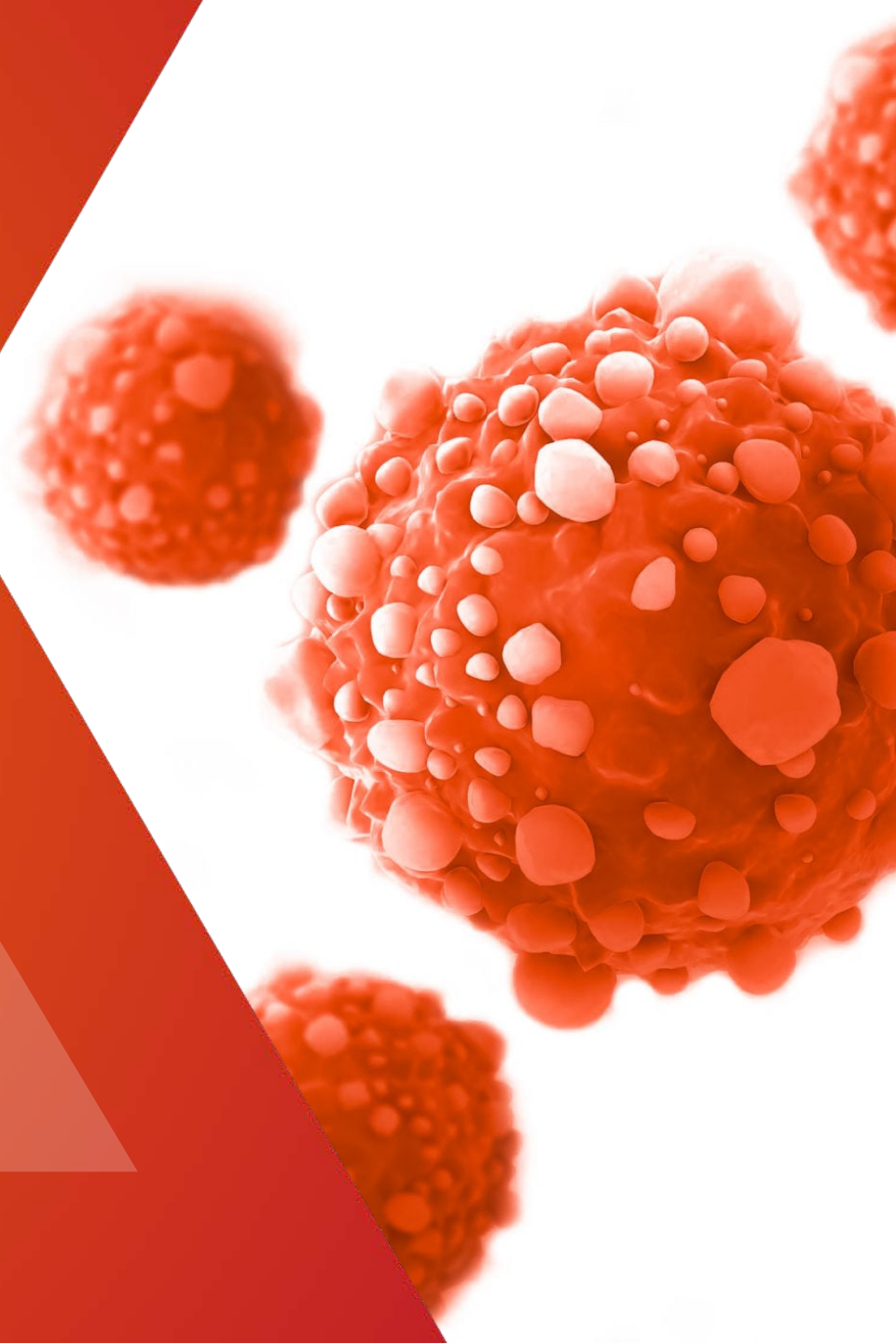
Bemcentinib in Acute Myeloid Leukaemia (AML) and Myelodysplastic syndromes (MDS)

BGBC003 - NCT02488408

- Company sponsored clinical trial in elderly r/r AML and MDS patients
- Monotherapy and chemo-combination therapy

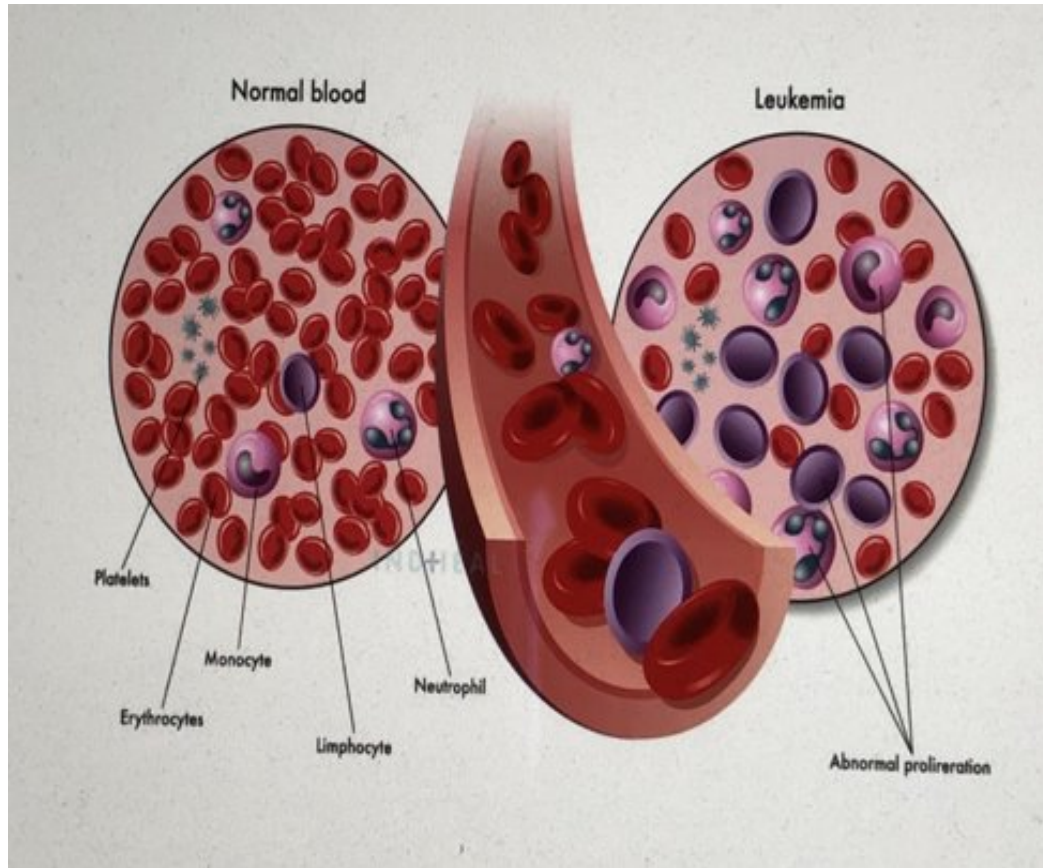
BGBIL009 – BERGAMO ILS study

- Monotherapy in elderly r/r AML and MDS patients



What is AML / HR MDS ?

- AML / HR MDS is a cancer that affects the blood and bone marrow
- Occurs in the elderly, frail population mainly in patients >60 years of age
- AML is the result of excessive production of immature myeloblast cells leading to anemia, thrombocytopenia and neutropenia



Symptoms include:

- Fever
- Bone pain
- Fatigue
- Shortness of breath
- Frequent infections
- Bruising
- Unusual bleeding (nosebleeds, bleeding from gums)

1L treatment AML

- Venetoclax + HMA³
 - CR 37%, mOS 14-7mos.
- Venetoclax + LDAC
 - CR 27% mDOR 11.1mos.
- 2L treatments^{1,2}
 - CR <15%, mOS approx. 6 mos.

Myelodysplastic Syndromes and Acute Myeloid Leukaemia

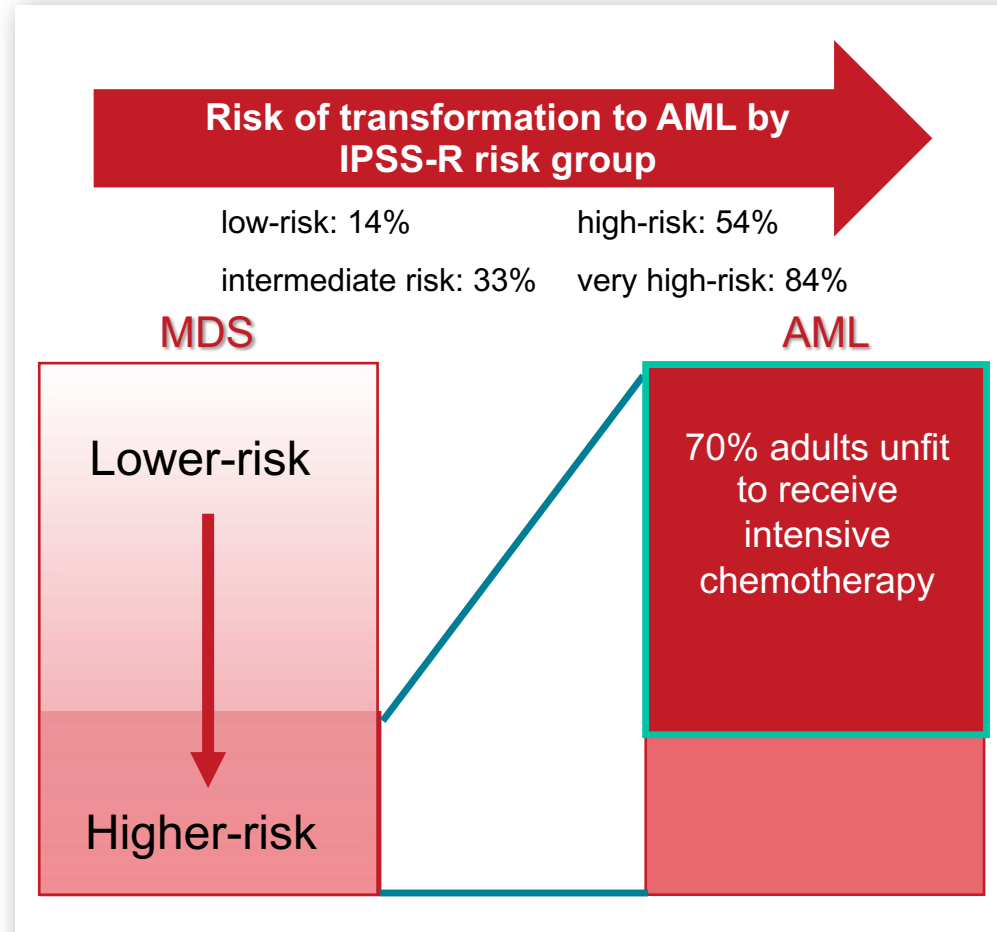
Approximately 30% of patients with MDS will develop AML, rates of transformation dependent on risk classification (IPSS-R)

Myelodysplastic syndromes

The incidence of MDS is estimated to be 4 in 100,000.²

The incidence in those aged ≥ 80 years is 50-75 in 100,000, sometimes estimated to be higher.^{2,4}

Average age of diagnosis is 60 years⁵, and only 10% of patients are less than 50 years old.^{4,6}



Acute myeloid leukemia

Globally, over 435,000 cases of leukemia were diagnosed in 2018.³


AML makes up 32% of leukemia cases in adults. Average age of diagnosis is 68 years.¹

It is estimated that in 2020, almost 20,000 cases will be diagnosed, and 11,000 deaths will be due to AML in the U.S.²

NCT03824080

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


 = Completed

Phase 1 n=36
**Single agent bemcentinib dose-finding
in relapsed AML/MDS** 




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

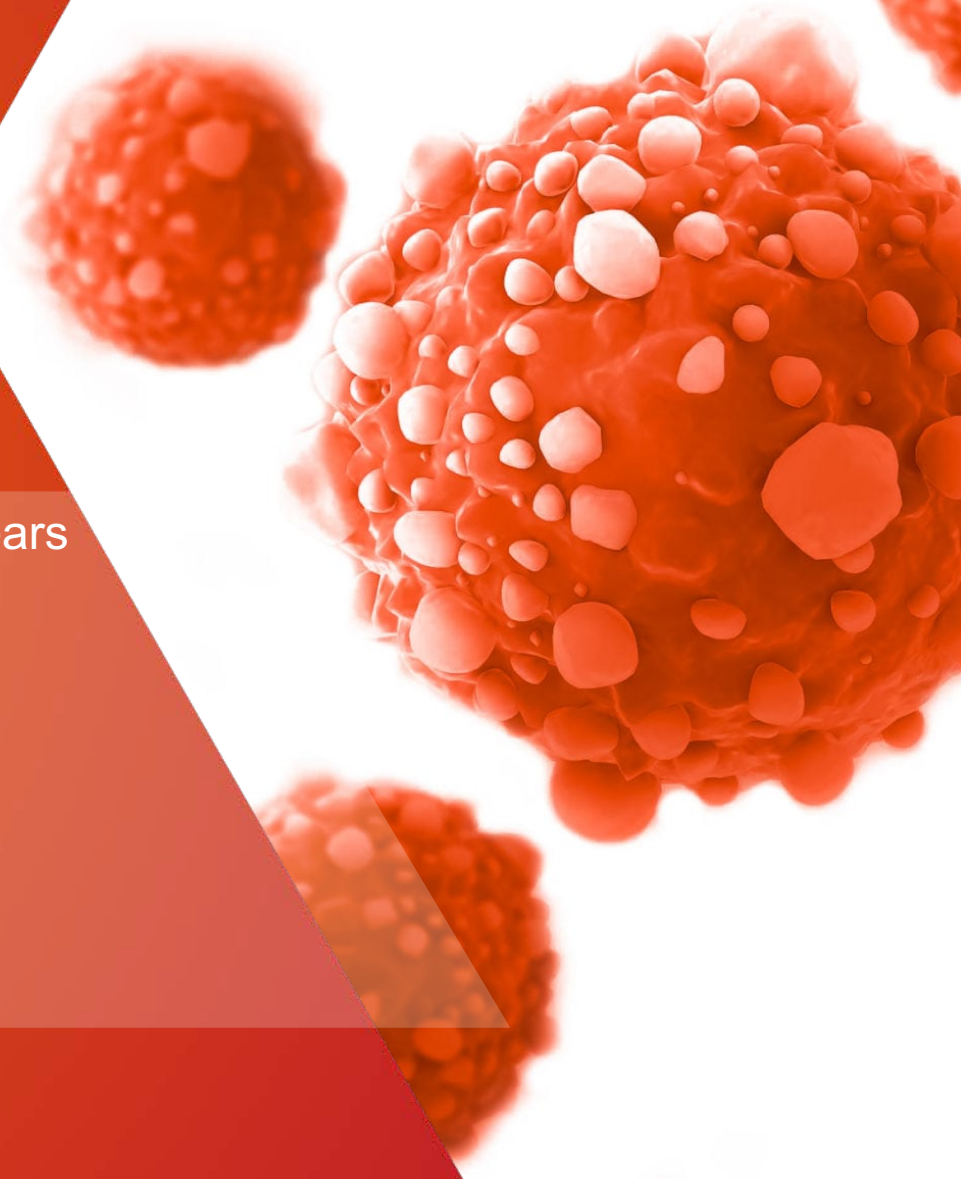
BGBIL009 / NCT03824080 (BERGAMO study)

- A phase II study evaluating the efficacy and safety of Bemcentinib in patients with MDS or AML failing standard of care therapy
- MET PRIMARY END POINT

- Investigator Sponsored Trial: EMSCO
- Chief Investigator : Uwe Platzbecker, MD, Leipzig University Hospital, Germany
- Open-label, multi-centre phase II trial of 45 patients with high risk MDS or AML who have failed or are refractory to hypomethylating agent treatment
 - Study Rationale: Poor prognosis / limited treatment options – mOS 5.6m after failing HMA for HR-MDS¹
 - Bemcentinib monotherapy standard dosing
- End Points:
 - Primary: Overall response rate assessed in week 17 (beginning of cycle 5)
 - Secondary: Toxicity, OS, PFS, TTF, DoR, BOR
 - Exploratory endpoint: Translational project evaluating the role of potential biomarkers, e.g. Axl/Gas6
- Full data to be disclosed at ASH medical congress 6th December 2020

Bemcentinib in 2L NSCLC

- Lung cancer outcomes have seen significant improvement in recent years
- 1L treatment for NSCLC is now directed by biomarkers
 - Molecular drivers (mutations) or PD-L1 status
 - Treatments includes targeted agents, chemo +/- CPI
 - Patient benefit to ORR >50% and mOS 1-2 yrs
- 2L treatment outcomes remain poor
 - SOC chemo ORR < 20% and mOS <12mo.



2L NSCLC study: 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

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)

Regimen

- **Pembrolizumab** 200mg fixed dose IV
- **Bemcentinib** oral 400mg loading dose X3/7, then 200mg OD
- **Q3/52**

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

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)

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

Cohorts C
Stage 1

N=13 patients
(each patient has the potential for at least 24 weeks follow-up)

Final Analysis

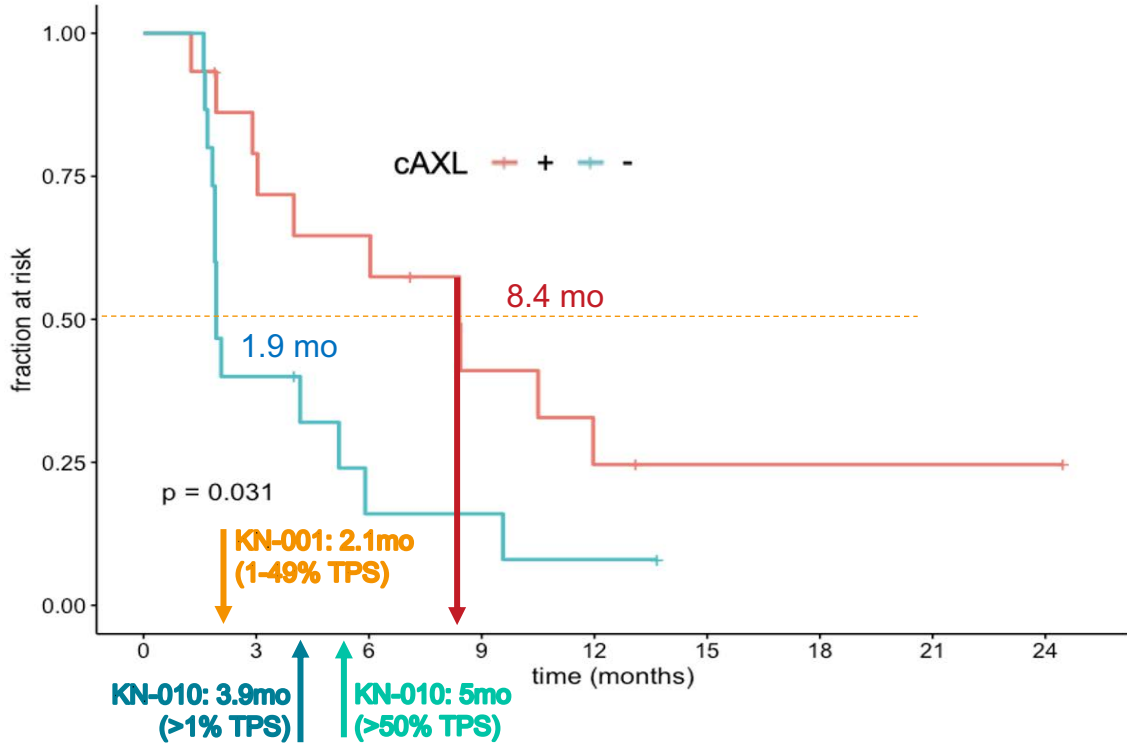
Cohorts C
Stage 2

N=29 patients
(each patient has the potential for at least 24 weeks follow-up)

Enhanced survival in cAXL +ve patients with addition of bemcentinib to pembrolizumab

AXL is an adverse prognostic biomarker

mPFS 8.4 months in cAXL+ patients



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%

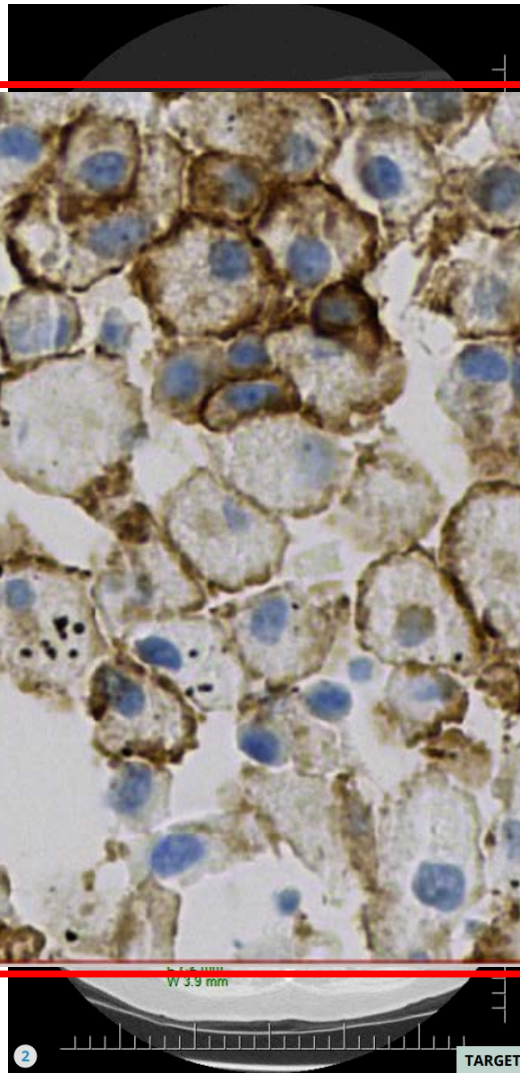
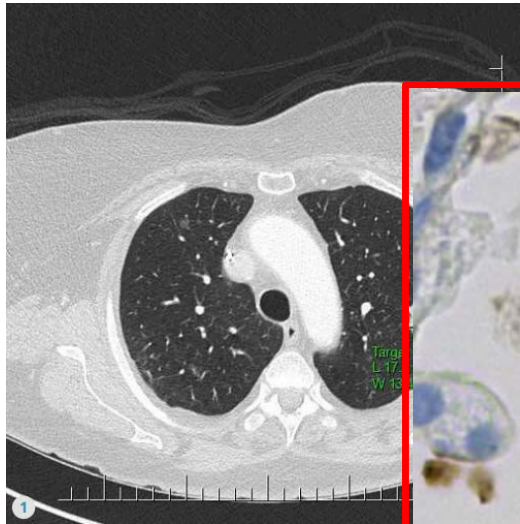
*OS data still maturing, current calculation (cut-off survival: 28-May-2020)
 **pts who have been on study treatment for at least 1 cycle (n=42)

- 4-fold improvement in PFS in cAXL +ve vs. cAXL -ve patients.
- 12 mo OS in cAXL positive patients 79% vs 60% in cAXL negative patients
- Clinical benefit reflected in mOS of cAXL +ve patients vs. cAXL -ve
- cAXL -ve patient survival data is comparable to historic controls

Patient 2

06 DEC 2017

23 SEP 2019



Baseline and disease characteristics

Demography	76-year-old female
Biomarker	PD-L1 Not evaluable cAXL +ve
Prior Rx	Carboplatin + pemetrexed (Best response = SD; PD after 6 th cycle)

Study Treatment (Bemcentinib + Pembrolizumab)

PR (target lesions shrunk from 32mm to 19mm)

17 months (study treatment commencement 12 Dec 2017, first PR assessment 23 Sep 19)

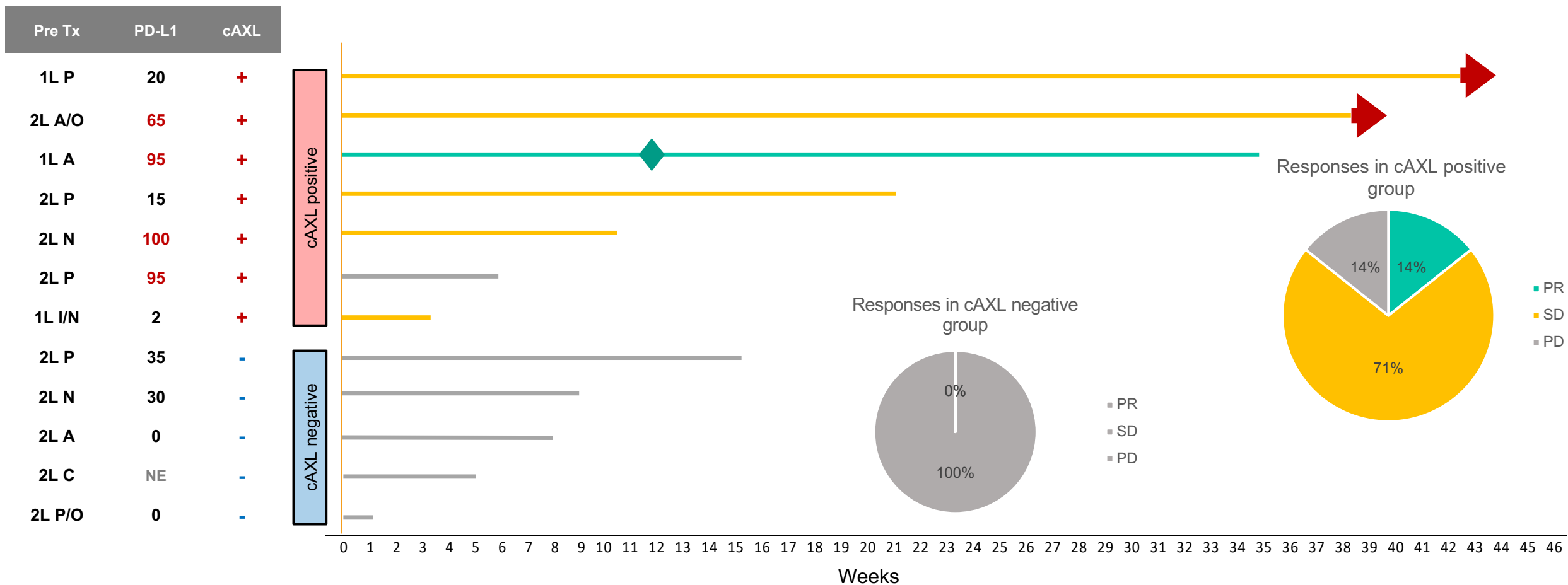
2 years of bemcentinib+pembrolizumab (Tx completion 16 Dec 19)

Combination treatment discontinued after 2 years as per protocol; patient is being followed up for survival



Positive AXL staining on **alveolar macrophages**. Some positive AXL staining on **tumour cells**.

Time on treatment in patients evaluable for cAXL

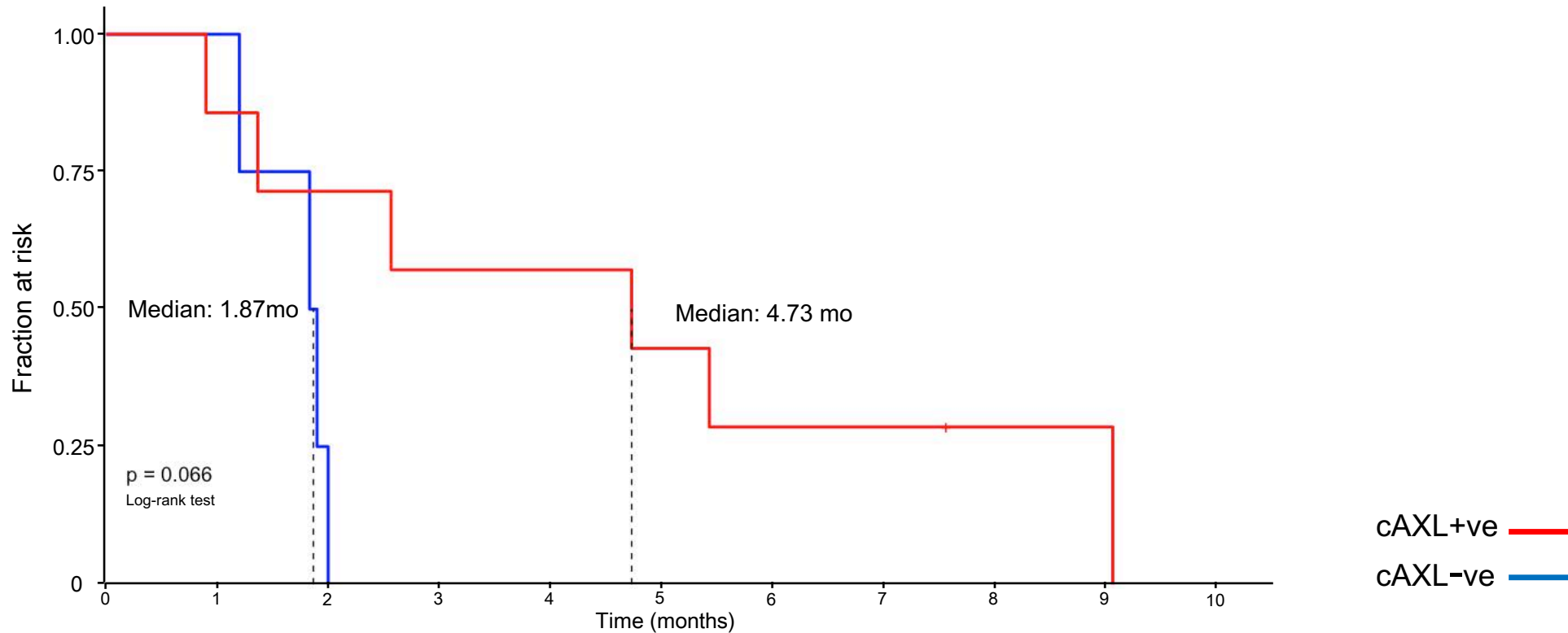


Data cut-off: 17-April-2020

+ cAXL positive
- cAXL negative

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

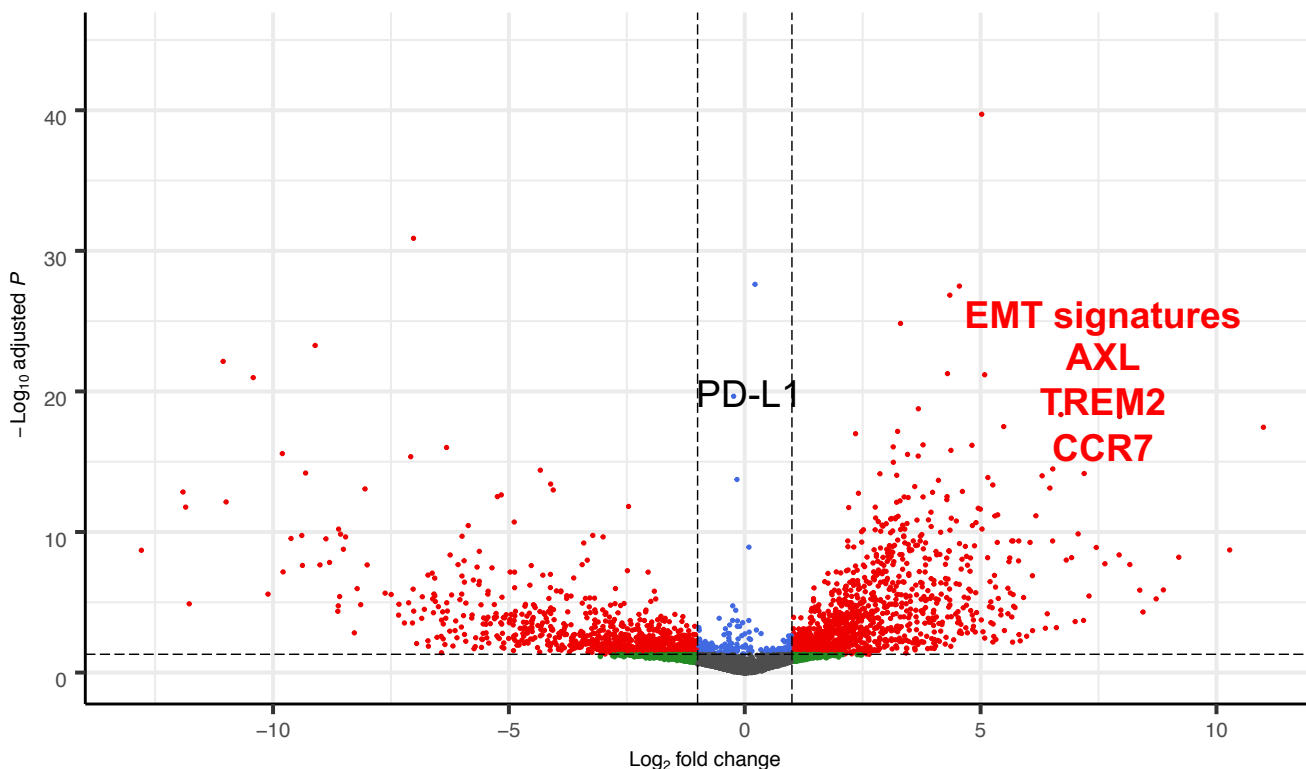
Progression Free Survival improvement in cAXL +ve patients





Clinical translational findings

Whole tumor 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:

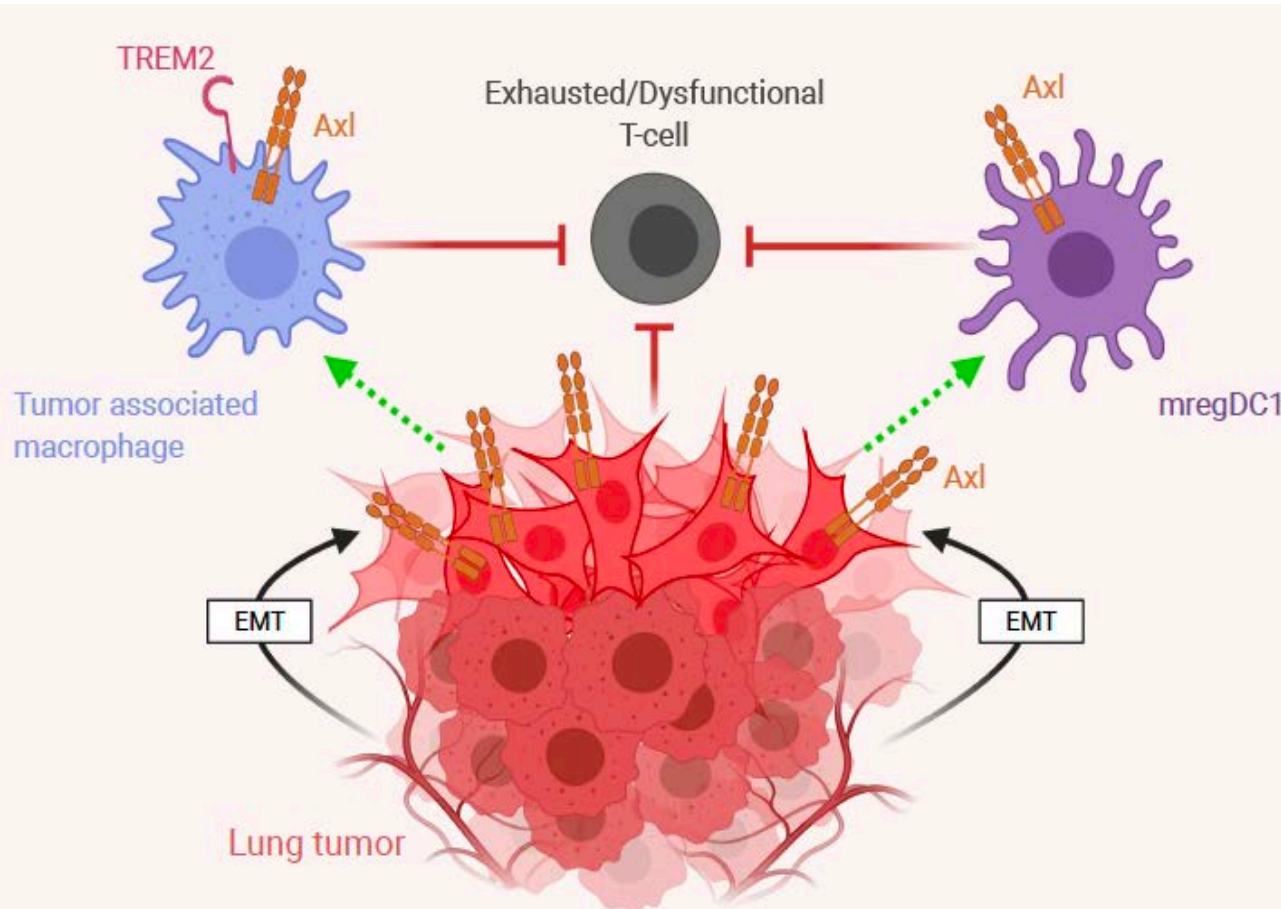
- Increased AXL expression
- Genes associated with tumor cell EMT¹
- Presence of TREM2+ TAMs^{#,2}
- Presence of CCR7+ mregDC1^{##,3}

tumor-associated macrophages
##regulatory dendritic cells



Proposed mechanism

AXL+ suppressive myeloid cells drive T cell dysfunction



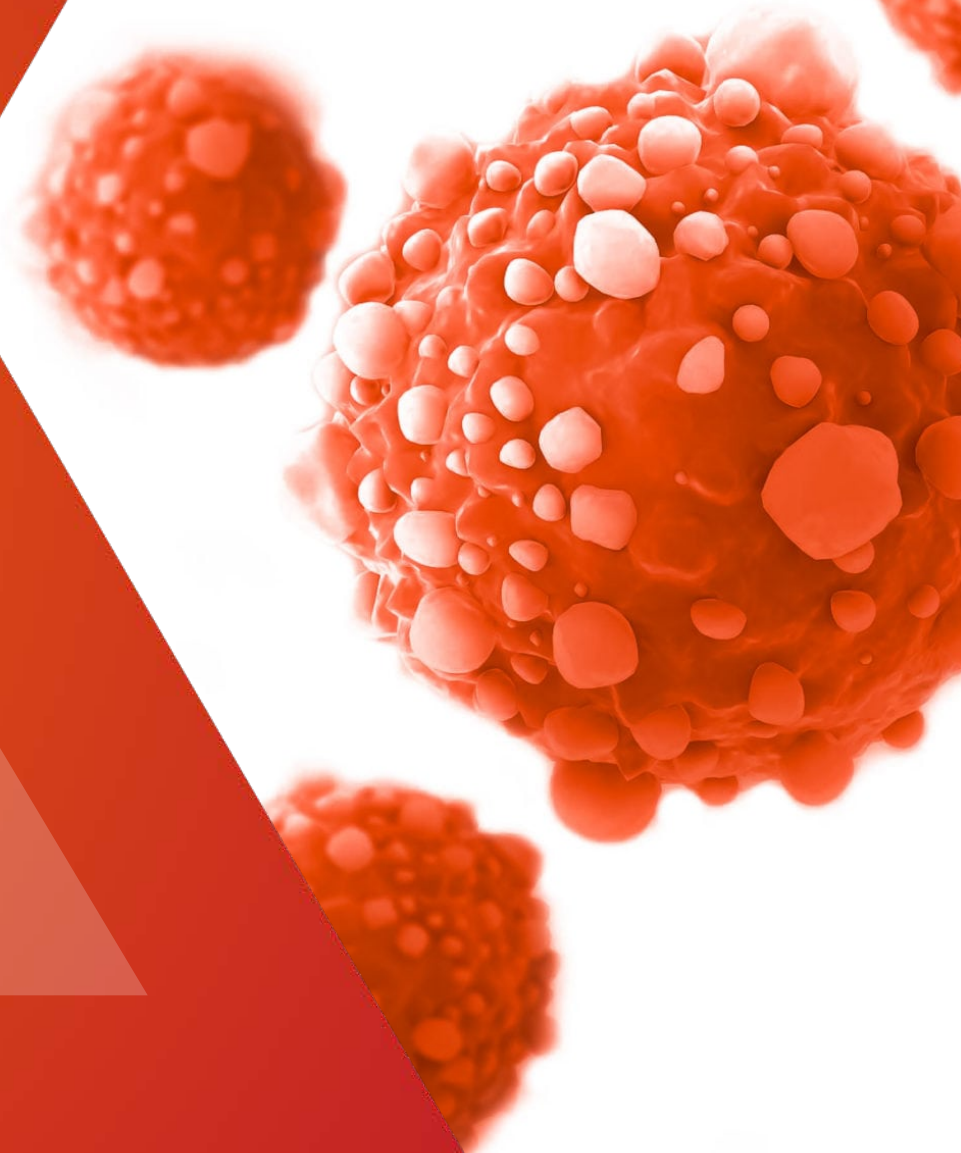
- AXL promotes tumor-cell EMT and recently-described regulatory myeloid cells:
 - AXL+ TREM2+ Tumor Associated Macrophage^{1,2}
 - AXL+ CCR7+ mregDC1³
- AXL expression in these cells promotes T cell dysfunction/exhaustion²
- Bemcentinib may reverse acquired resistance to checkpoint inhibition by targeting 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

Mesothelioma ILS

MiST: Mesothelioma Stratified Therapy
the world's first molecularly stratified umbrella study
in mesothelioma, designed to enable the acceleration of
novel, effective personalised therapy as a basis for improving
survival outcomes.

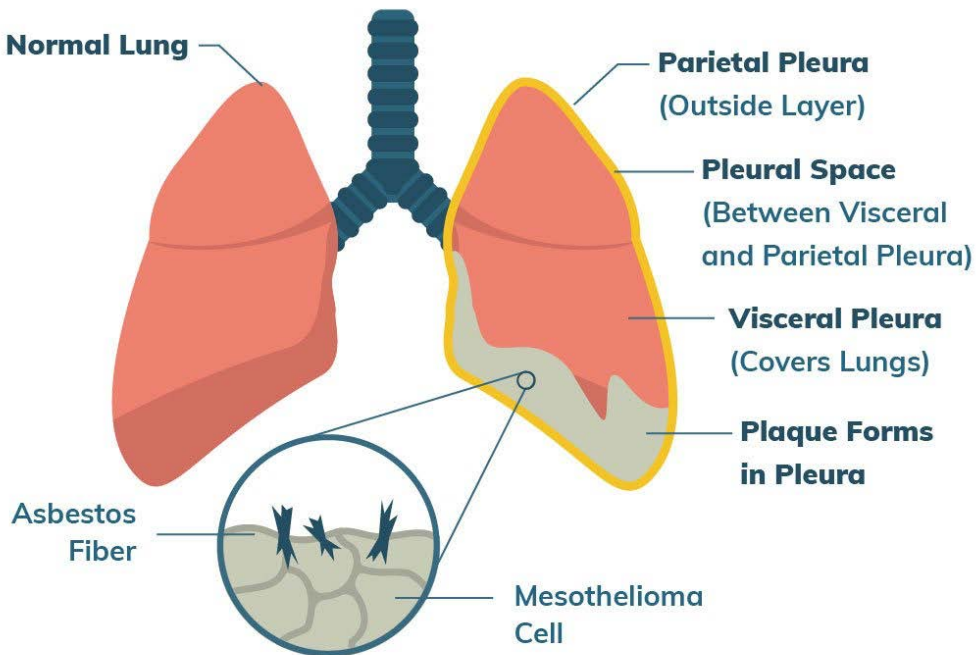
4 targeted drugs or combinations are being evaluated.

MiST3: Bemcentinib + pembrolizumab combination



Mesothelioma

Aetiology and incidence



- Associated predominantly with asbestos exposure
- AXL expression is high in mesothelioma tissue
- Incidence in the UK highest in the world (3.4/100,000); 2700 cases per year ↑
- WHO estimates asbestos-related disease accounts for 92,250 deaths per year globally, more than doubled from 1994-2008.
- Continued use of asbestos in the developing world could lead to a global epidemic of mesothelioma.
- **First line treatment not changed in over 16 years - platinum-pemetrexed** - median OS 12.1m compared to 9.3m in cisplatin only¹
- No effective standard-of-care in second line setting – median PFS 3.4m and median OS 7.8m in meta-analysis²

MIST3 – bemcentinib with pembrolizumab in patients with relapsed mesothelioma

Mesothelioma stratified therapy (MiST)

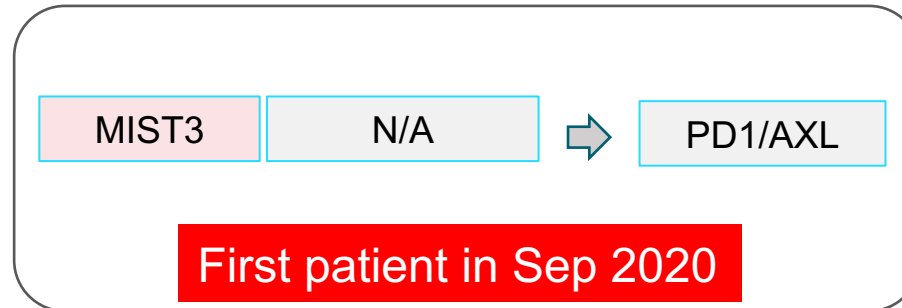


Mesothelioma
Research Programme
LEICESTER

Molecular pre-screening

Molecular
pre-screening

Treatment stratification



Genomic interrogation

Comprehensive
genomic
analysis

- Pleural mesothelioma
- Histologically confirmed
- ECOG 0-1
- 1-2 prior lines therapy
- **Consent for fresh biopsy**

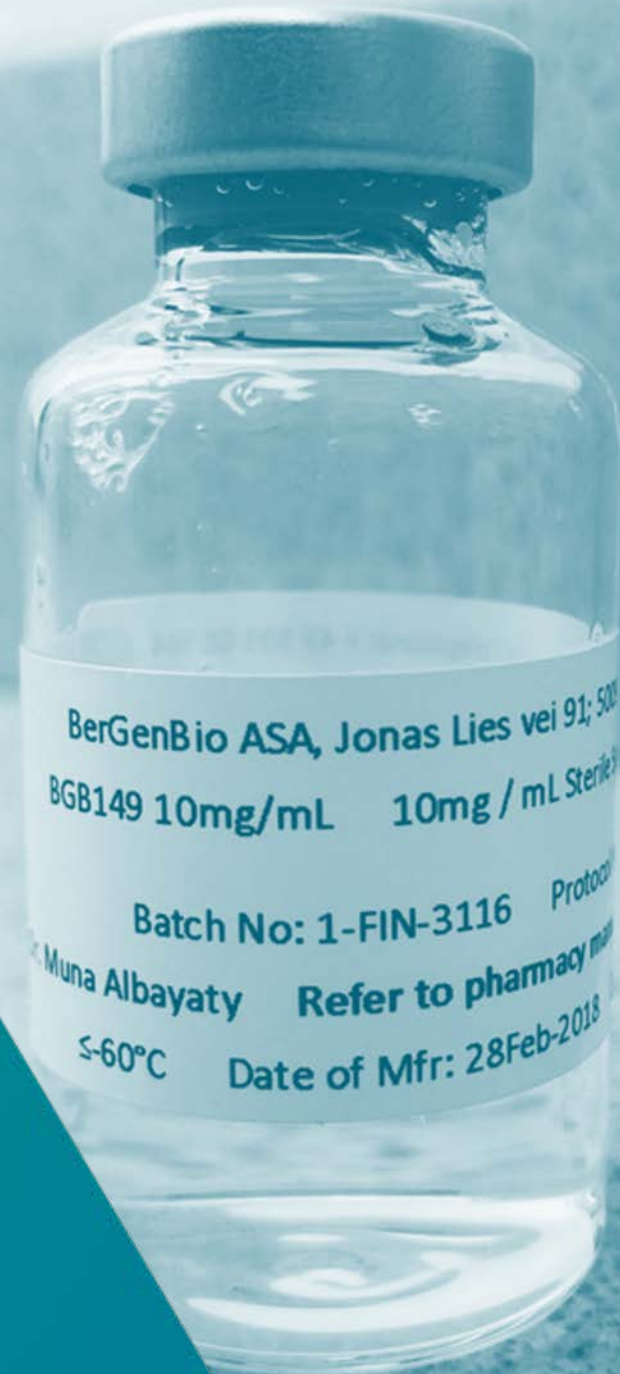
Pembrolizumab 200mg q3/52 +Bemcentinib 200mg OD

- Primary endpoint DCR 12 weeks
- Secondary endpoints DCR 24 weeks/ORR
- Max 2 years treatment
- **N=26**



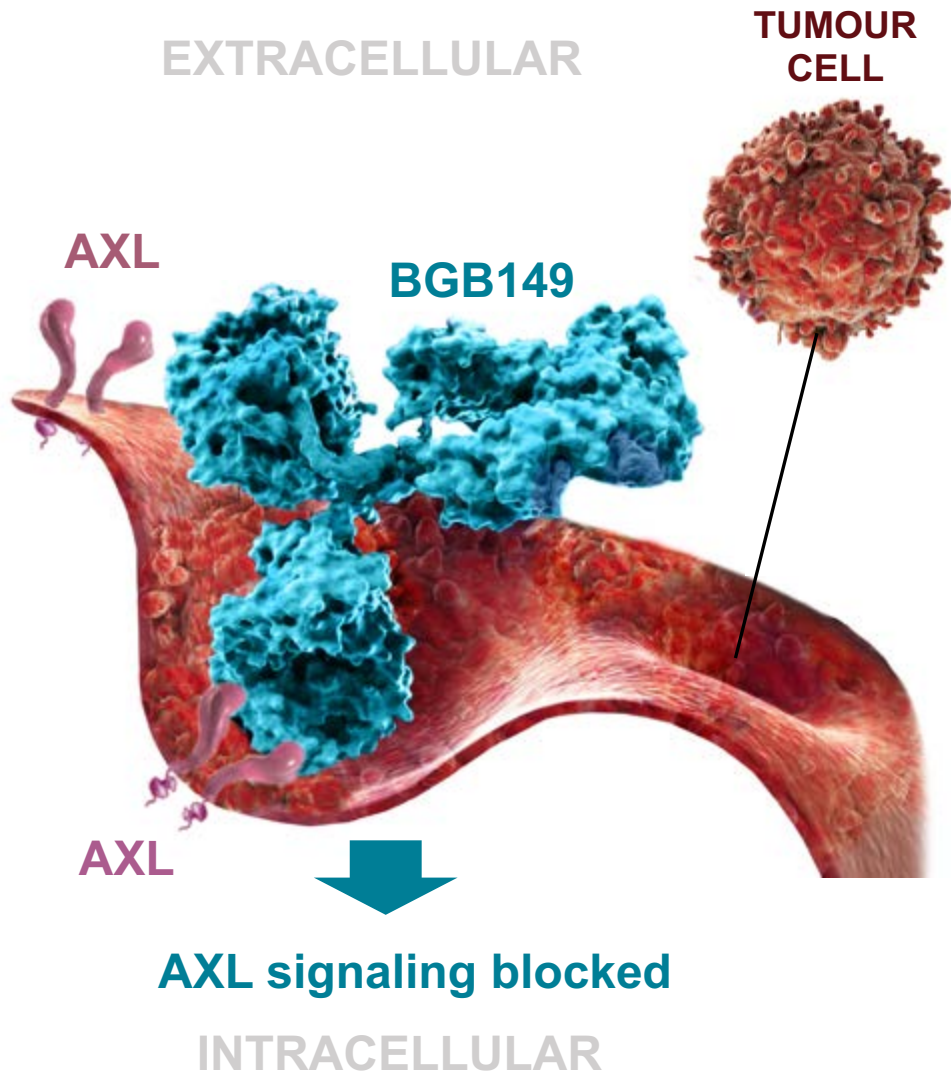
BerGenBio

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

High affinity (KD: 500pM), 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 C_{max} increase

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

Phase I MAD trial complete

Tilvestamab is currently being evaluated in a Phase I clinical study



BGB149-101; NCT03795142
First in human study
Healthy volunteer
6 per cohort, double-blind placebo-con-

Tilvestamab

0.1 mg/kg

0.3 mg/kg

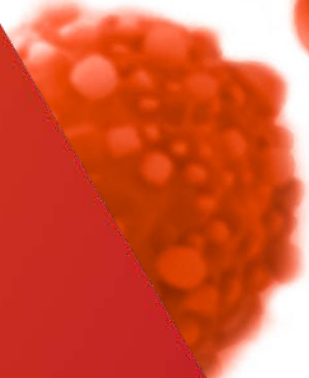
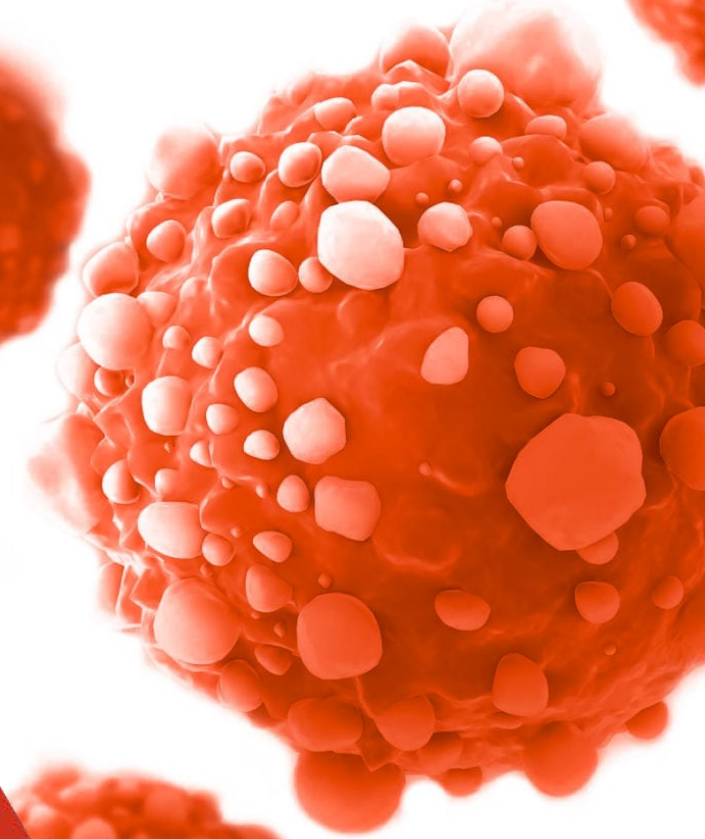
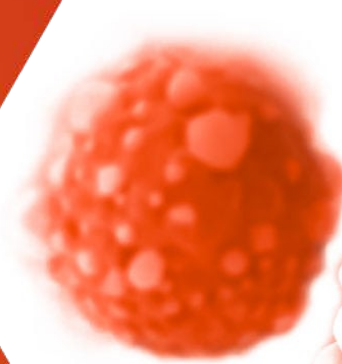
1.0 mg/kg

3.0 mg/kg

- Highly selective to human and non-human primate AXL
- No cross-reactivity with other TAM members: MerTK and Tyro3
- High Afinity (KD): 5-500 pM (by Biacore)
- Blocks binding of Gas6 to AXL
- In vivo anti-tumor efficacy demonstrated in animal models of disease: AML, NSCLC, pancreatic cancer and renal cancer carcinoma
- Low toxicity in monkeys
- Tilvestamab is currently being evaluated in a Phase I clinical study.
- Phase Ib / IIa in set up phase

Finance Report

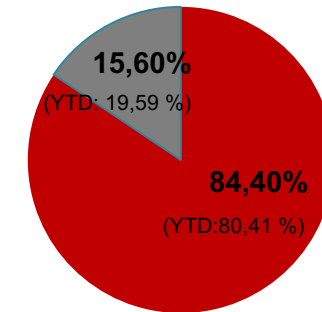
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Key financial figures

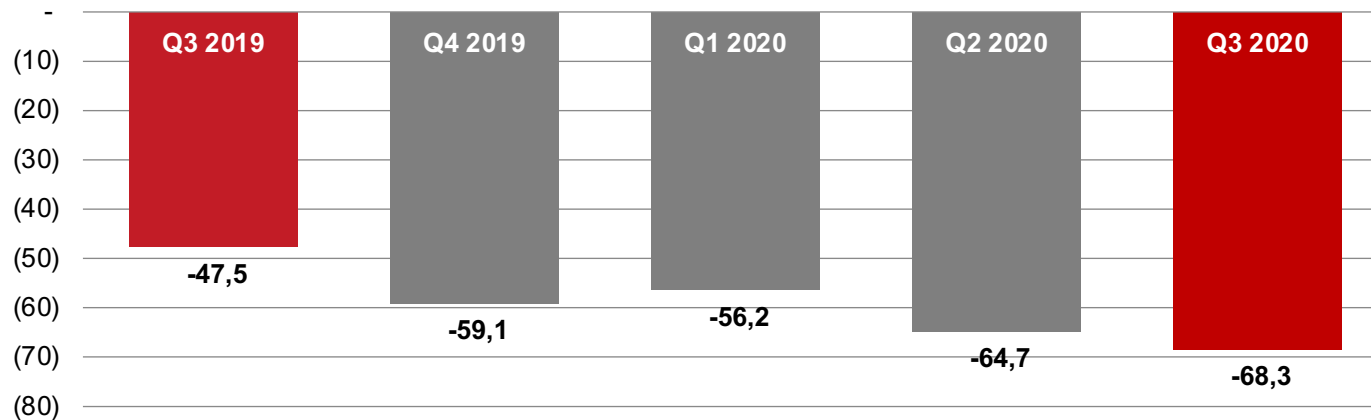
(NOK million)	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
Operating revenues	0,0	0,0	0,0	8,7	8,9
Operating expenses	68,3	47,5	189,3	154,0	213,3
Operating profit (-loss)	-68,3	-47,5	-189,3	-145,3	-204,4
Profit (-loss) after tax	-67,3	-44,6	-183,2	-141,7	-199,3
Basic and diluted earnings (loss) per share (NOK)	-0.77	-0.73	-2.51	-2.57	-3.43
Net cash flow in the period	-49,4	-35,8	518,5	-71,0	-107,2
Cash burn operating activities	-68,8	-40,1	-181,3	-148,7	-186,7
Cash position end of period	777,9	289,5	777,9	289,5	253,6

Operating expenses Q3 2020 (YTD)



■ R&D ■ Administration

Operating profit (-loss) million NOK

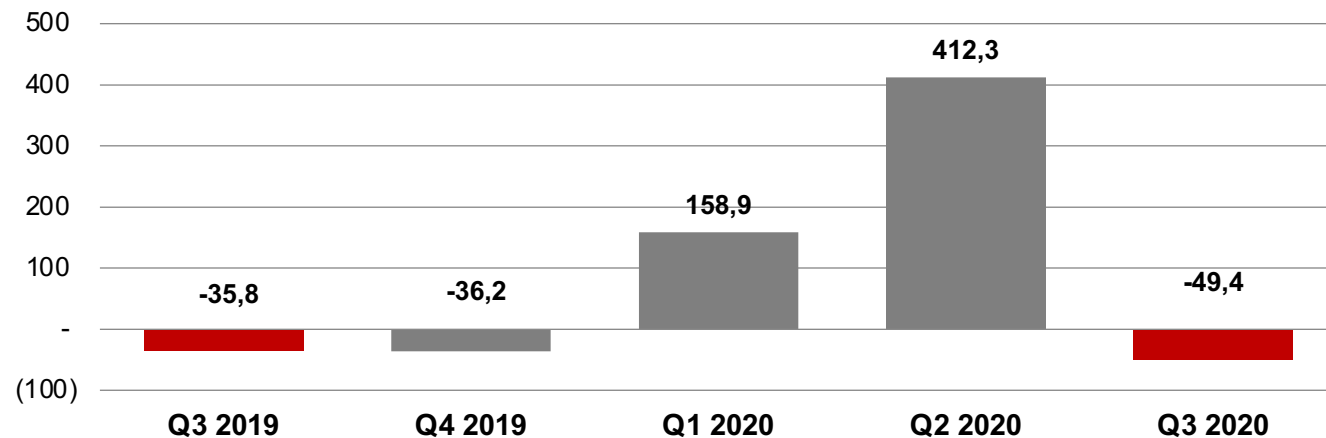


- Well managed overhead costs.
- 84,40 % of operating expenses Q3 2020 (YTD 80,41 %) is attributable to Research & Development activities.

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

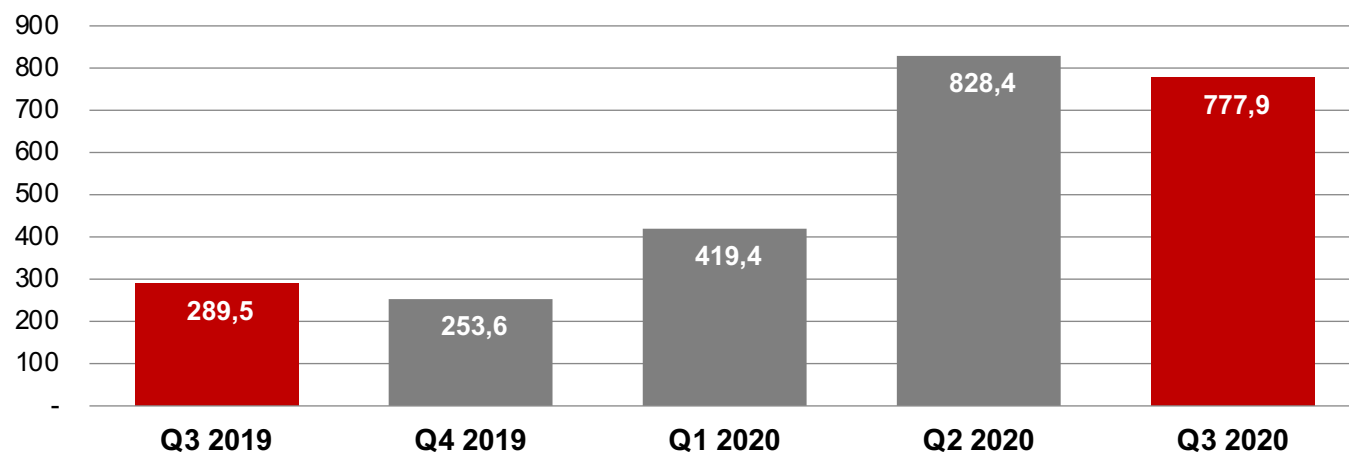
Cash flow and cash position

Cash flow (million NOK)



- Cash burn operating activities Q3 2020 NOK 68.8m.
- Quarterly average cash burn (Q319 – Q320) NOK 53.5m (USD 5,7 m)

Cash position (million NOK)



- Cash position Q3 2020 NOK 777.9 million (USD 82m).
- Subsequent repair offering completed July 2020 is included, raising an NOK 20m (USD 2.1m).

Analyst coverage



H.C. Wainwright & Co

Joseph Pantginis

Telephone: +1 646 975 6968

E-mail: jpantginis@hcwresearch.com



Jones Trading

Soumit Roy

Telephone: +1 646 454 2714

E-mail: sroy@jonestrading.com



Arctic Securities

Lars Mørland Knudsen

Telephone: +47 229 37 229

E-mail: la@arctic.com



Carnegie

Ulrik Trattner

Telephone: +46 8 5886 8589

ulrik.trattner@carnegie.se



DNB Markets

Patrik Ling

Telephone: +46 8 473 48 43

E-mail: patrik.ling@dnb.se

Sponsored research:



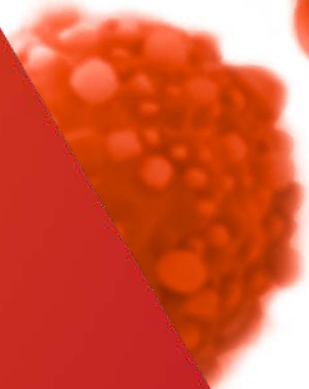
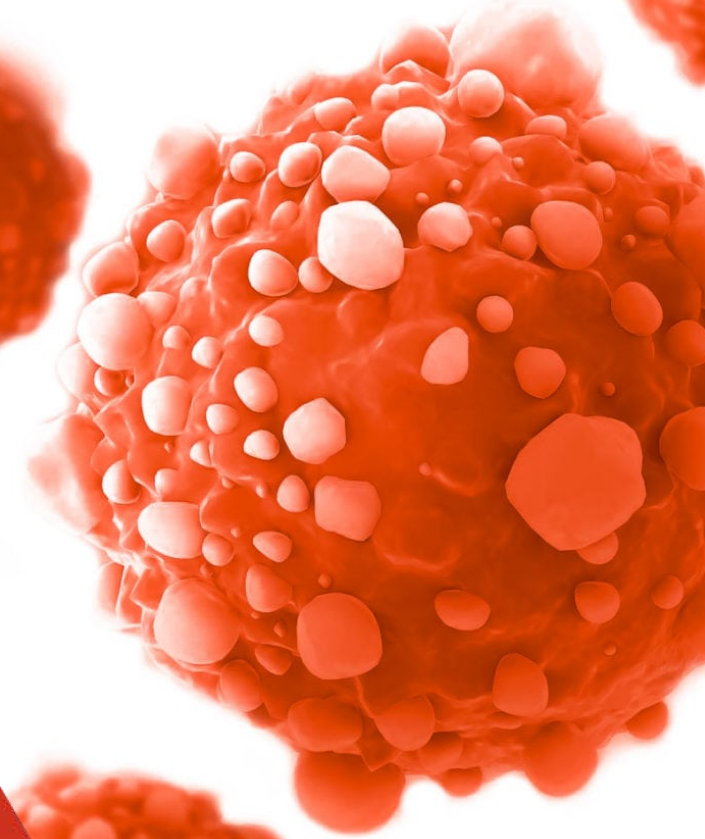
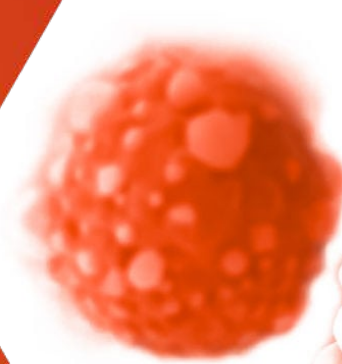
Edison Group

Dr. Susie Jana

Telephone: +44 20 3077 5700

sjana@edisongroup.com

Highlights of the Year & Outlook



Q3 Summary

- **Solid progress made across primary development objectives in lung cancer and leukaemia**
 - Update on clinical and translational research from Phase II bemcentinib and pembrolizumab combination study in NSCLC presented in Oral presentation at SITC Congress
 - Tilvestamab Anti-AXL monoclonal antibody completed Phase Ia clinical trial
- **Continued investigation of bemcentinib's potential as a treatment for infectious disease, especially COVID-19.**
 - COVID-19 trials expected to recruit quickly with rapid clinical readout
- **Promising data emerge from our broad program of investigator led studies**
 - Bemcentinib monotherapy met the primary endpoint of ORR in the BERGAMO Phase II Trial in MDS / AML
 - Commencement of US study in recurrent glioblastoma (GBM)
 - Commencement of UK study in relapse plural mesothelioma

62nd ASH Meeting, 5-8 Dec 2020: Clinical Data to be presented

AML : Study BGBC003 (Poster)

Title: The Combination of AXL Inhibitor Bemcentinib and Low Dose Cytarabine Is Well Tolerated and Efficacious in Elderly Relapsed AML Patients: Update from the Ongoing BGBC003 Phase II Trial (NCT02488408)

Presenter: Professor Sonja Loges

Director, Department of Personalised Oncology,
University Hospital Mannheim
Division of Personalised Medical Oncology, DKFZ
Heidelberg

MDS :Study BGBC009 (Poster)

Title: Efficacy and Safety of Bemcentinib in Patients With Myelodysplastic Syndromes or Acute Myeloid Leukemia Failing Hypomethylating Agents

Presenter: Professor Uwe Platzbecker

Department of Hematology, Cellular Therapy and Hemostaseology, Leipzig University Hospital, Leipzig, Germany

Outlook

Strong cash position

- Well funded, Q3 cash position NOK 778 million

Promising pipeline

- Two first-in-class drug candidates in multiple Ph II clinical trials
- Pioneering biology and a substantial amount of favourable clinical and translational data

Upcoming data

- Further clinical and translational data readouts anticipated in three aggressive cancer indications at major medical congresses (ASH December 2020, WCLC January 2021)

Strong science supporting COVID-19 treatment in 2 randomised phase II trials

- UK ACCORD II study
- BGBC020 South Africa and India