



**ARCTIC**  
SECURITIES

# BIOTECH WEBINAR

**Business Update**

22<sup>nd</sup> April 2021



**BerGenBio**

Richard S. Godfrey CEO  
Oslo Børs: BGBIO

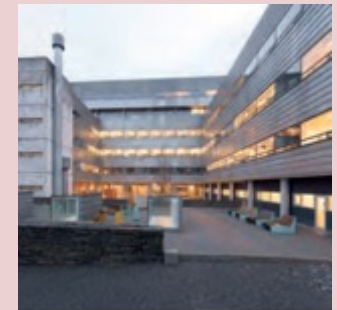
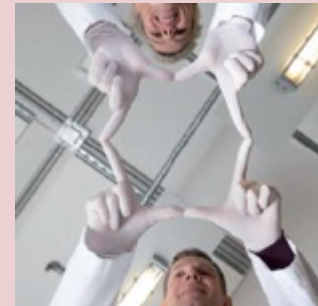
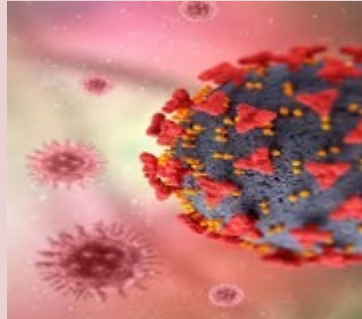
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# BerGenBio – Investment highlights



## PhII COVID-19

Top line data:

- ✓ Safety
- ✓ Fewer deaths
- ✓ Time to clinical improvement
- ✓ Patient sub-populations

update in May

## 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

## Near term clinical milestones

COVID-19 -  
AML & MDS  
Registration path

NSCLC

## Pioneering biology

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

## Well resourced organisation

Experienced Oxford based R&D team

Industry & academic partnership and collaborations

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

# Value Driving Milestone

2020



Bemcentinib in  
COVID-19  
Ph II

2L NSCLC data

Relapse AML  
and MDS data

Tilvestamab  
Phase Ia/Ib

Two rPh II  
- UK  
- India & South  
Africa

Interim data  
- 2.5 x mPFS in  
cAXL patients

Interim data  
confirms a new  
significant  
patient  
population

Phase Ia  
complete.  
Phase Ib PK-PD  
translational  
study initiated

2021



Data COVID-19  
Phase II

COVID-19  
Development

AML mOS data  
& regulatory  
alignment

Tilvestamab  
Ph II

Top line data

- Clinical data at  
Day 29  
- Determine  
development &  
regulatory options

- Survival data  
- Regulatory  
alignment

- Prepare to  
Initiate Ph II



# Introduction to AXL inhibitors



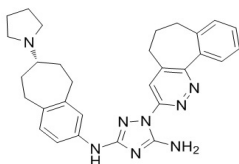
BerGenBio

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

## Bemcentinib\*



- Oral, once a day
- Size 0 capsule
- Stable simple drug product
- Favorable Safety and tolerability confirmed >400 patients
- Combines well with other drugs
- Phase III ready



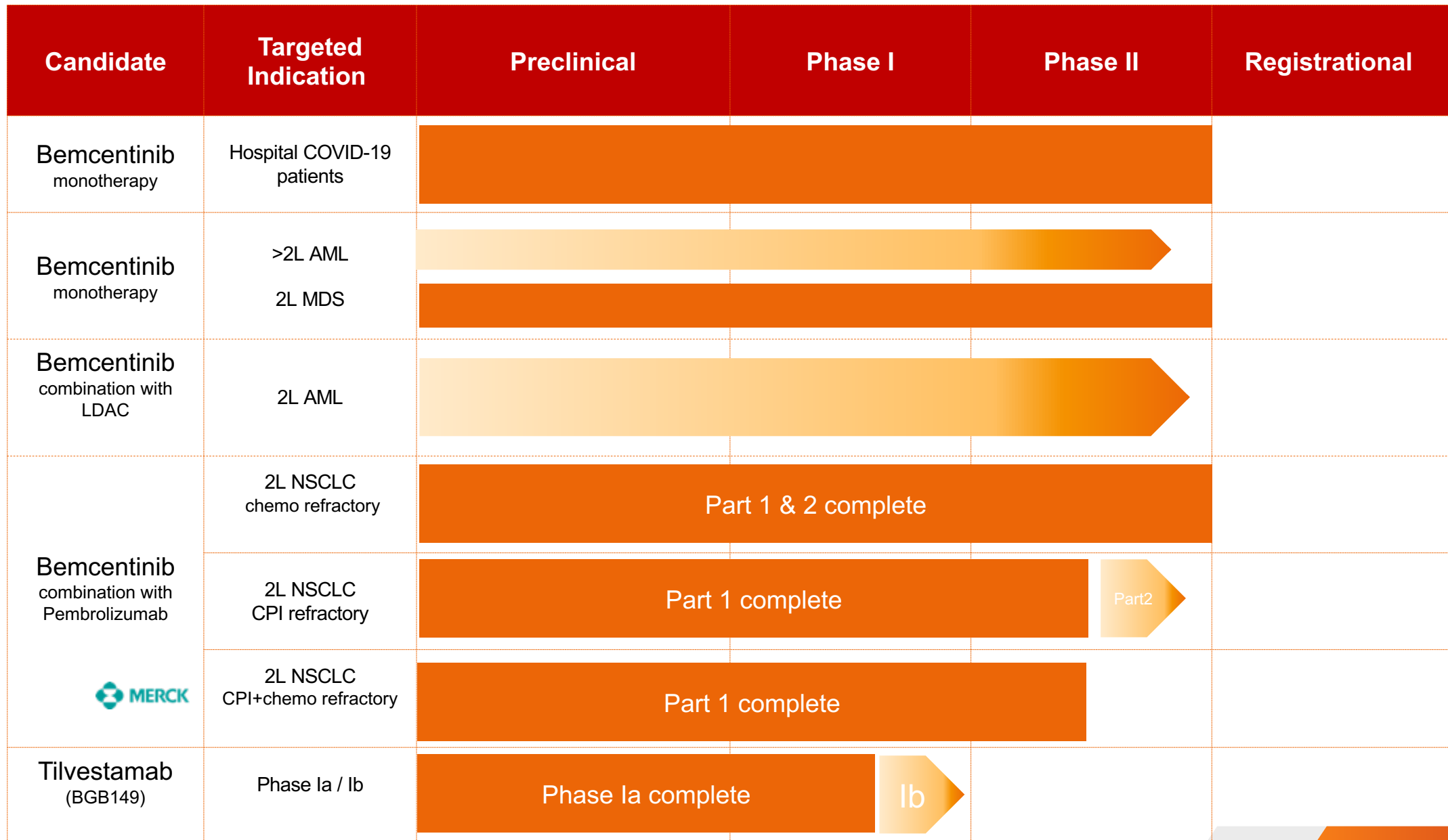
- Nano-molar potency
- 50-100 selective for Axl

## Tilvestamab\*\*





- Fully humanized mAb,
  - functionally blocking
- Biweekly infusion
- Robust manufacture and stable formulation
- High affinity, displaces GAS6
- Phase Ia complete
  - No DLTs, dose proportionate PK-PD
- Phase Ib/IIa ongoing
  - Serial biopsies to confirm PK-PD

# Pipeline of sponsored clinical trials



# 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
	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

Ongoing Trial

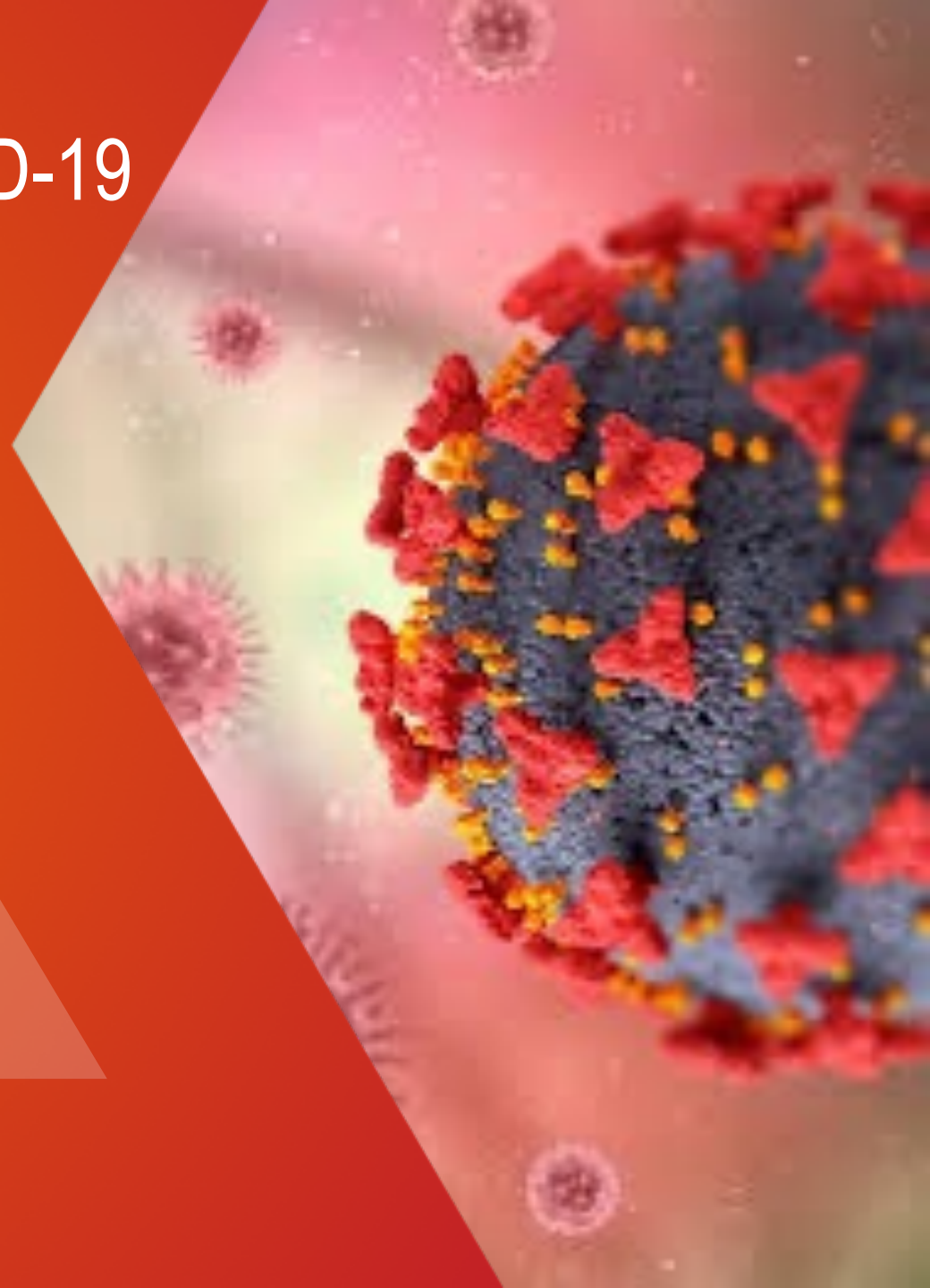
Completed Trial



# Bemcentinib clinical development in COVID-19

Two randomised phase II studies in 175 hospitalised COVID-19 patients  
(UK, India & South Africa)

- *ACCORD-2 trial - 60 patients (28 bemcentinib)*
- *BGBC020 trial – 115 patients (58 bemcentinib)*

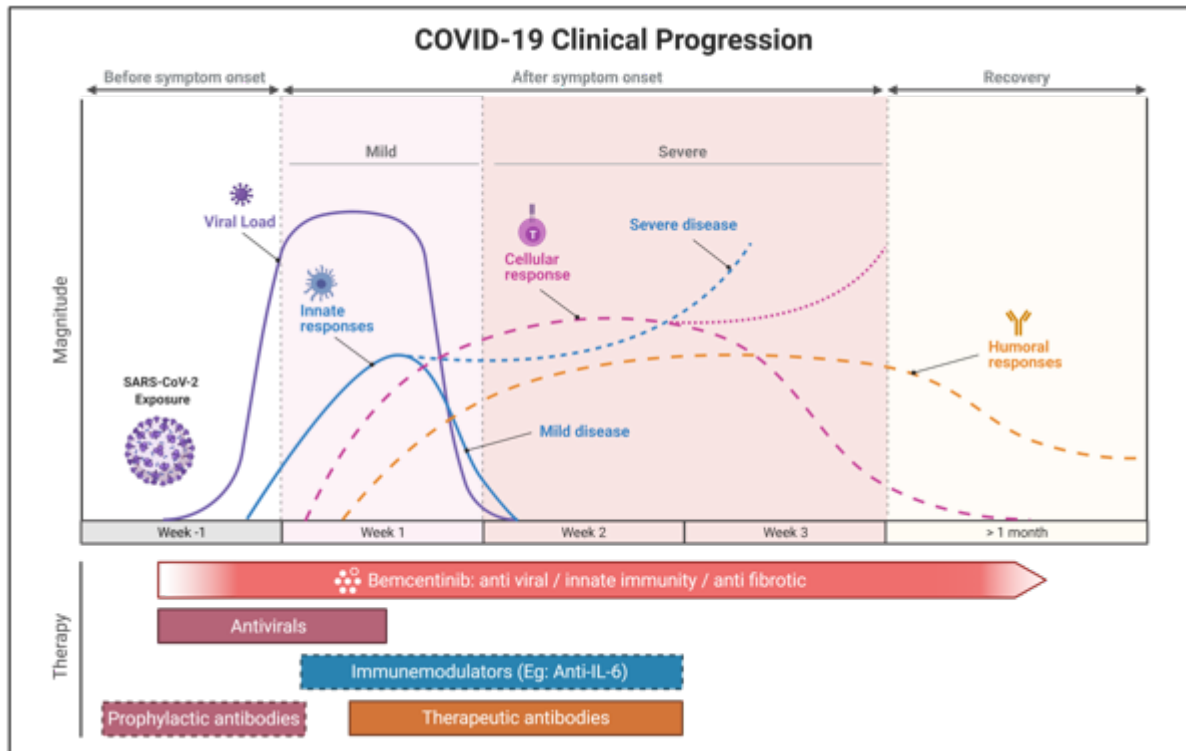


# Bemcentinib is a potential promising COVID-19 therapy that could warrant accelerated approval

- Currently **no approved comprehensive COVID-19 therapy**
  - Survival benefit, early hospital discharge & antiviral effect
- **AXL pathway is a novel mechanism** utilised by several enveloped **viruses to enter host cells** and **dampen viral immune response**<sup>1,2</sup>
- **Bemcentinib** is once-a day pill, **potent and highly selective inhibitor of AXL tyrosine kinase**
  - Preclinical data confirms **bemcentinib inhibits SARS-CoV-2 host cell entry** and **enhances anti-viral Type I interferon response**<sup>1,3</sup>
  - **MoA independent of spike protein** (or mutations) and therefore should remain effective against current and future variants
- Bemcentinib investigated in **two PhI clinical studies** in hospitalised COVID-19 patients (UK, South Africa & India)
  - **Generally well-tolerated** in COVID-19 (86 patients) => consistent with >350 patients studied in oncology programme (mild and reversible adverse events)

# Bemcentinib broad positioning for potential treatment of COVID-19

## Stages of the disease

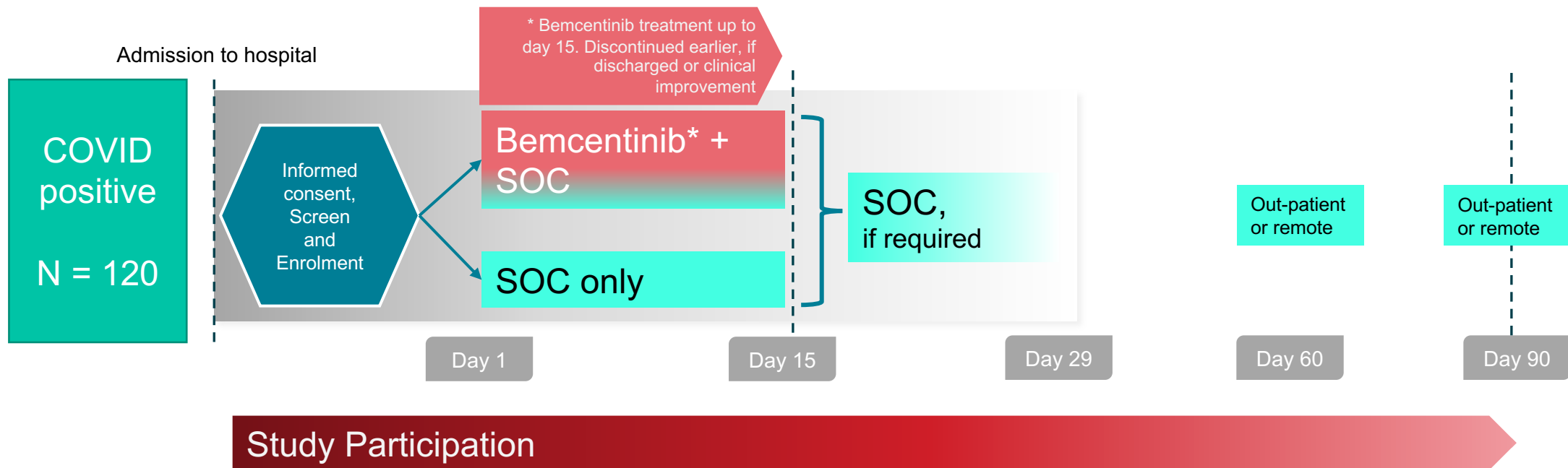


## WHO Ordinal Patient classification



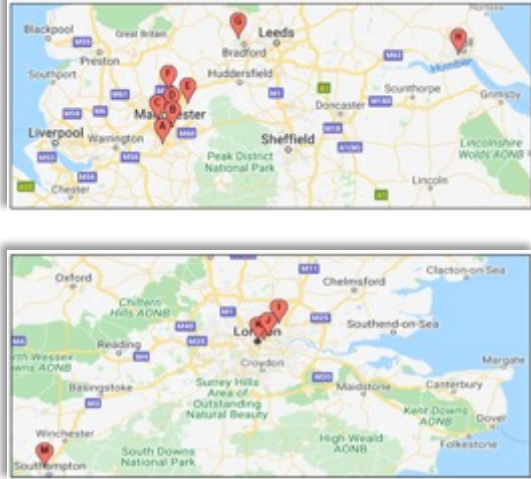
	Setting	Severity	Supportive intervention	BGBC020 ACCORD2	Dexamethasone	IL-6 receptor antagonists	Remdesivir
0	Uninfected	no clinical or virological evidence of infection					
1	Ambulatory	no limitation of activities					
2		limitation of activities					
3	Hospitalised	mild	no oxygen therapy	bemcentinib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

# Clinical Study design

## BGBC020 and ACCORD2 share identical design



# Bemcentinib studied in hospitalised COVID-19 patients across three district geographies, with differing demographics and ethnicities

Patient Accrual	BGBC020: India	BGBC020 South Africa	ACCORD2 UK	Total
				
Bemcentinib	30	28	28	86
SoC	30	27	32	89
				175



# Bemcentinib randomised Studies in COVID-19

BGBC019 – ACCORD -120 pts & BGBC020 – 120 pts

## 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

# Clinical Data Update

- ✓ Day 29 follow up of last patient enrolled in both BGBC020 and ACCORD2\_002
- ✓ Data receipt is on going and evaluation of efficacy is underway
- ✓ Exploring subsets of patients with baseline markers indicative of increased disease severity, with potential for greater benefit
- ✓ Numerically lower number of deaths in bemcentinib treated patients

## Patient Disposition

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81% grade 4 – require oxygen but not ventilatory assistance

75% patients received steroids

50% patients received remdesivir

No safety signals of concern

### Survival

#### ACCORD2\_002

1 death in 28 bemcentinib treated patients

5 deaths in 32 SOC treated patients

#### BGBC020

2 deaths in 58 bemcentinib treated patients

3 deaths in 57 SOC treated patients

## End Points

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**Primary:** time to clinical improvement of at least two points (from randomisation) on the 9-point WHO ordinal scale, or live discharge from the hospital, whichever comes first.

- numerically in bemcentinib's favour (p>0.05- statistical significance)

(small study, in a diverse population and demographic )

### Key Secondary:

- Avoidance of worsening of the WHO scale throughout hospitalisation,
- Duration for which patients required oxygen,
- Changes over time in levels of virus detected in different body fluids.

# Summary

## Bemcentinib potential treatment for COVID-19

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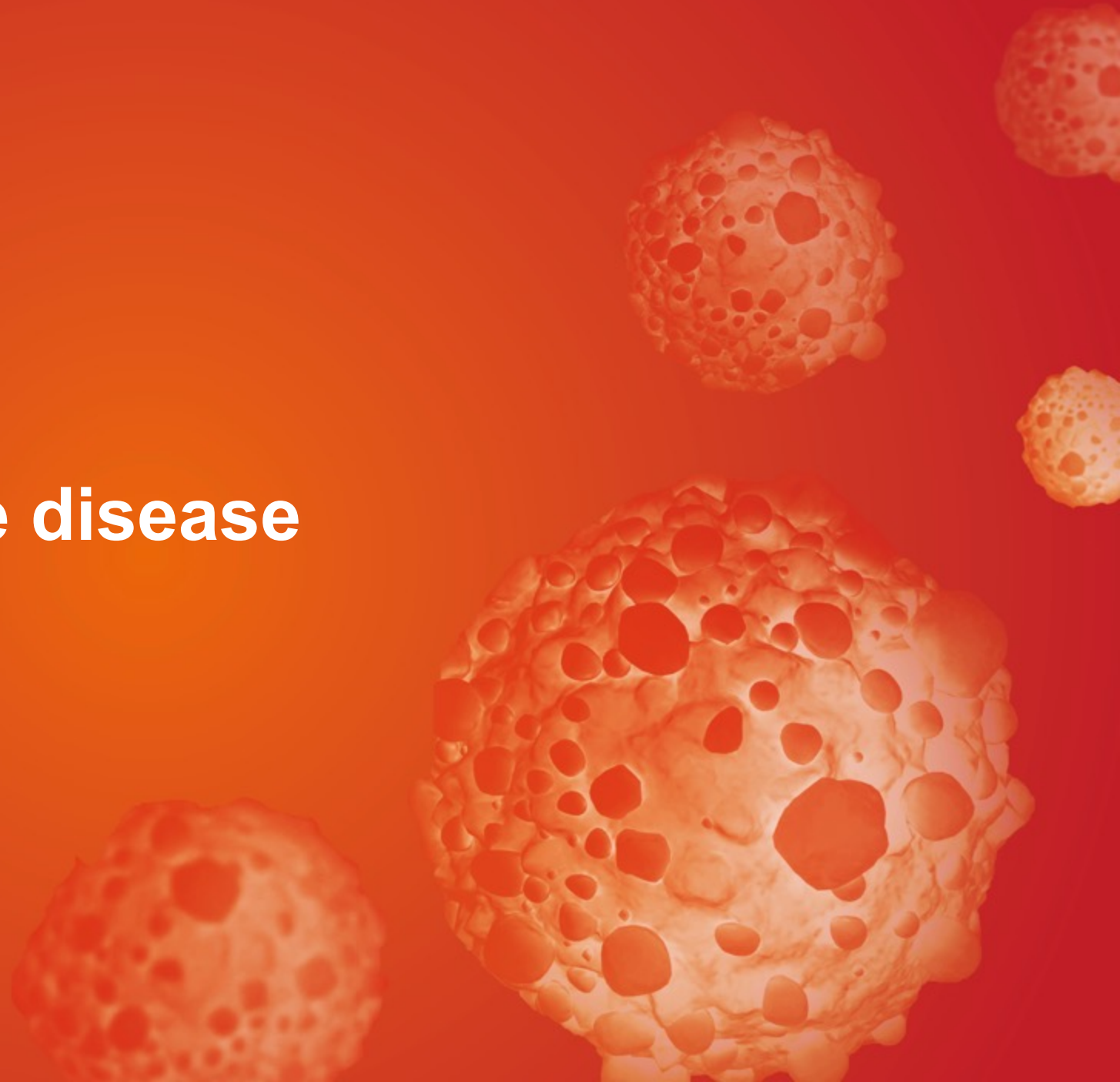


## Bemcentinib advantage

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- For a very broad spectrum of COVID-19 patients, throughout the disease cycle
- Convenient, once-a-day oral pill, which combines with other treatments including steroids and/or remdesivir, and others
- Favorable safety profile, no safety signals of concern reported
- The novel mechanism of action is independent of the SARS-CoV2 spike protein and thus would be expected to retain its effect with the emergence of new, potentially vaccine-resistant, strains of the virus.
- Potential for broad application across multiple indications
- Able to combine with other drugs to establish best treatment regimens

# **AXL biology: Mediating aggressive disease**



# AXL mediates aggressive disease

Very low expression under healthy physiological conditions

**AXL signaling is upregulated by hostile cellular microenvironment and viral infection**

## Cancer

- Immune evasive
- Drug resistant
- Metastatic

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

## Viral infection

- SARS-CoV-2
- Ebola
- Zika

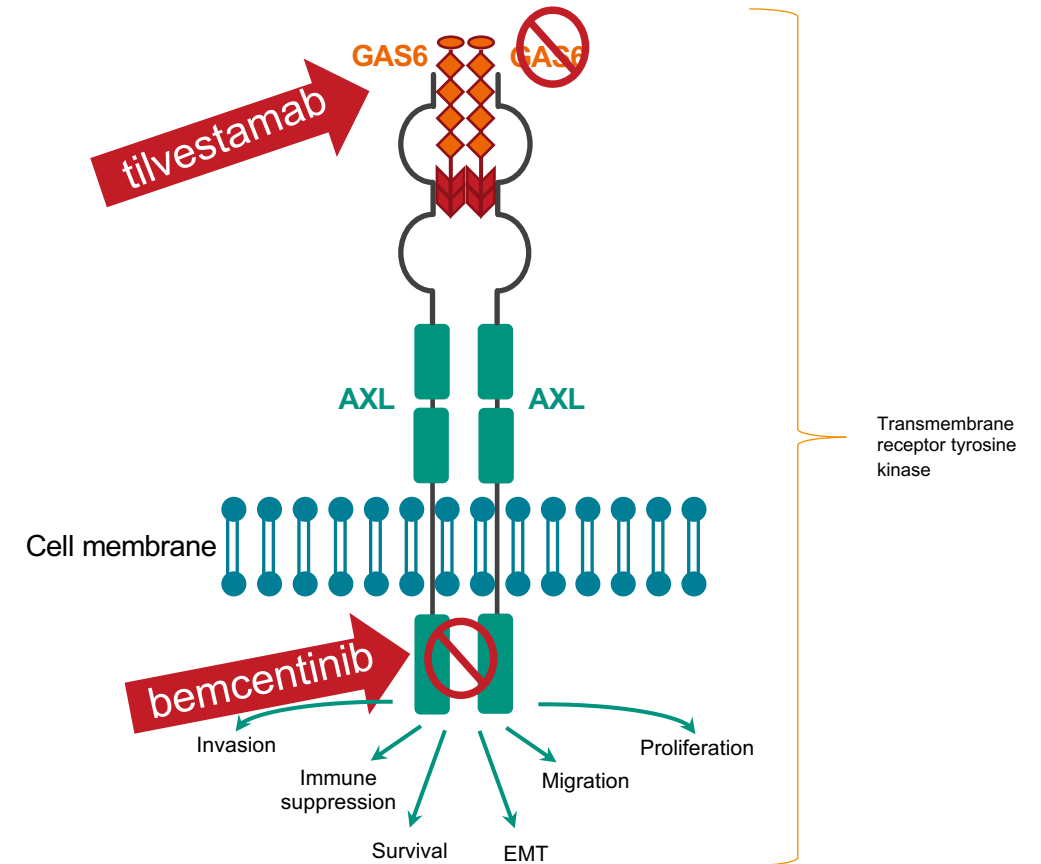
AXL mediates viral entry to cells and dampening of viral immune response

## Fibrosis

- Renal
- NASH
- IPF
- MF
- COPD

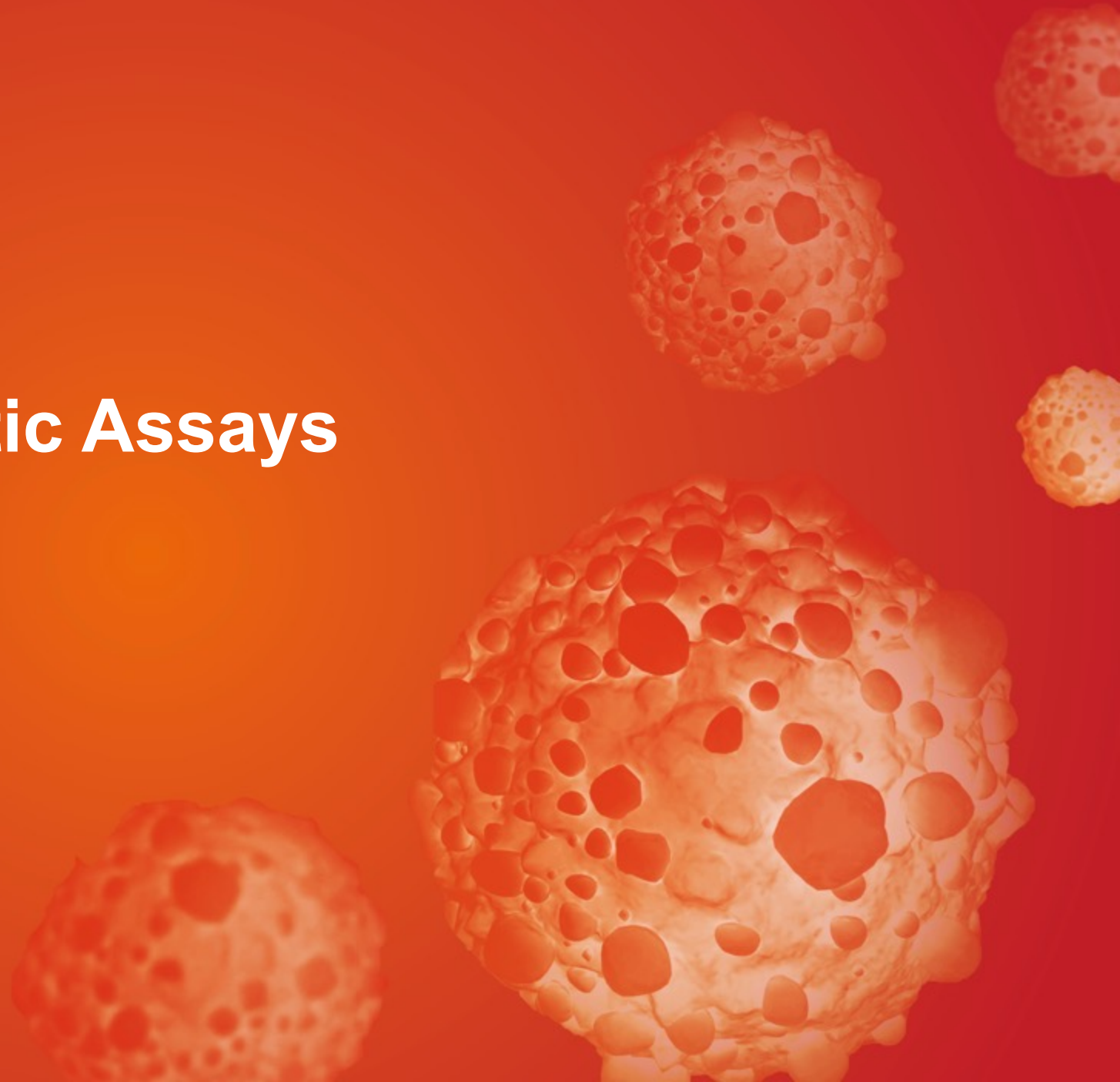
Axl regulates cellular plasticity implicated in fibrotic pathologies e.g. EMT, EndMT, Macrophage polarity

## Bemcentinib & Tilvestamab selective AXL inhibitors





# Companion Diagnostic Assays



# Two Companion Diagnostic Assays\* for patient selection

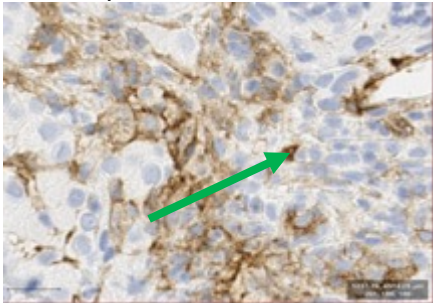
## Composite AXL score (cAXL) – solid tumours

simultaneously computes the presence of AXL on membranes of tumor & immune cells

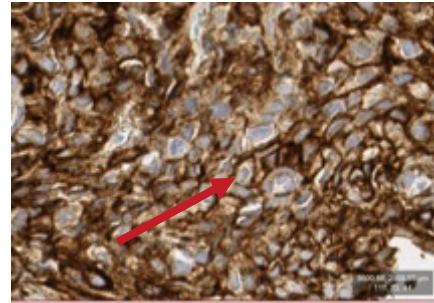


- Immunohistochemistry (IHC) method
- IHC most widely used CDx in cancer
- Requires a tissue biopsy
- Method stains for Axl protein
- Slides are read by trained pathologists
- cAXL score by a proprietary Dx algorithm

Example of tumour with a high number of AXL positive immune cells: cAXL<sup>+ve</sup>



Example of high AXL expression on tumour cells: cAXL<sup>+ve</sup>



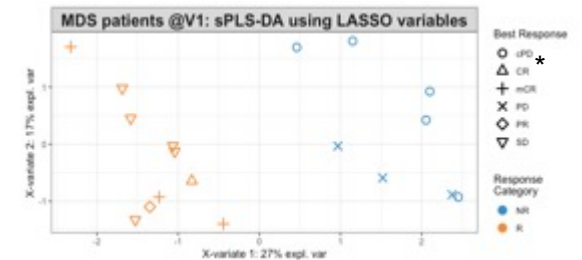
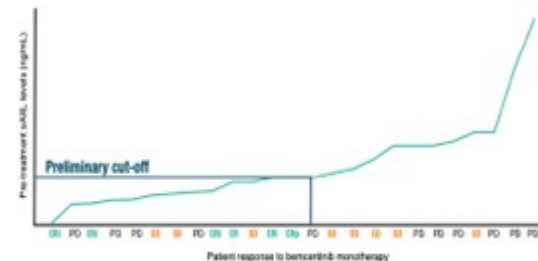
## Soluble AXL score (sAXL) - Blood tumours (+ possibly Fibrosis & COVID-19)

Measures the concentration of soluble AXL in plasma



- Requires blood sample
- Automated assay method
- Inverse correlation with AML response rate
- Improved sensitivity and selectivity with a signature of blood based immune markers
- Reported for monotherapy in MDS

Identification of a preliminary cut-off for sAXL levels at screen predictive of response



# 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 Patient Benefit Reported
  - Data update anticipated at EHA conference (June)



# 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

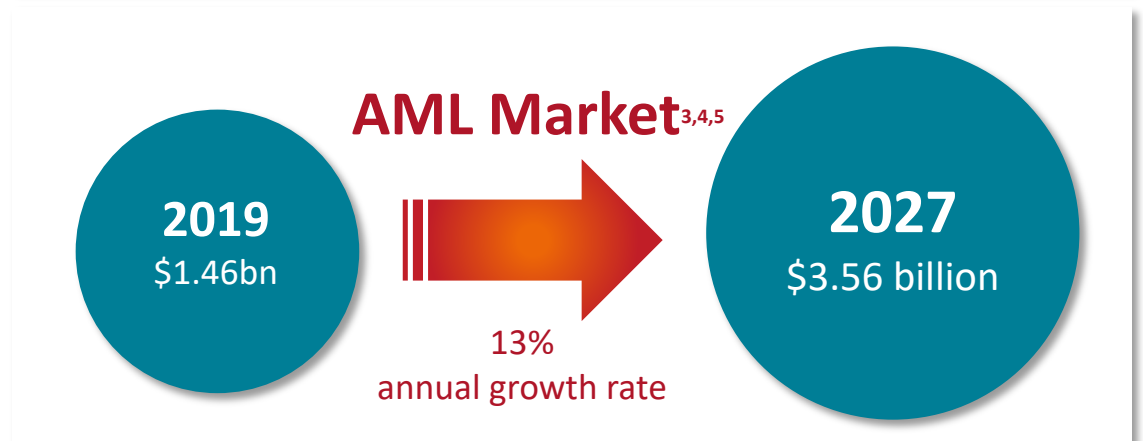
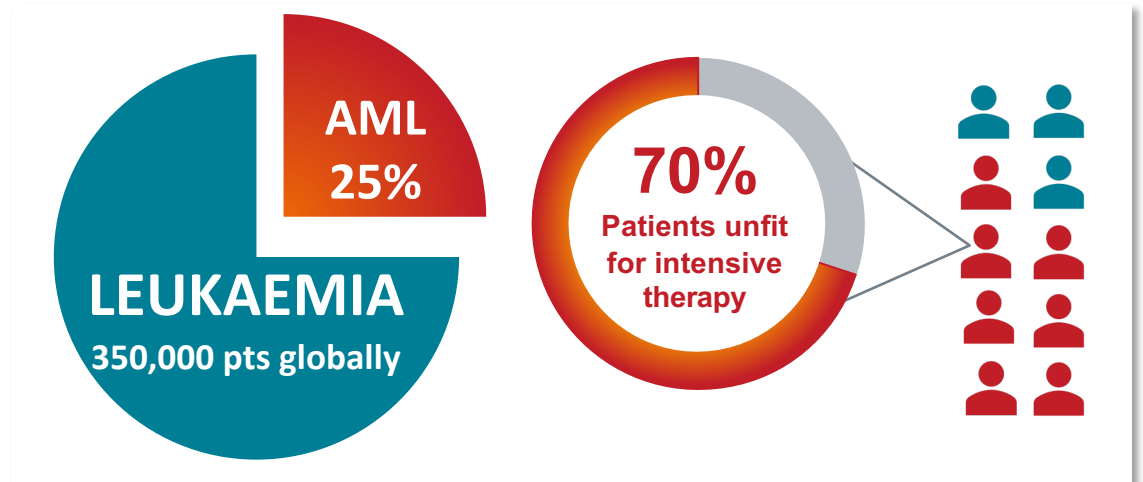
Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years<sup>6</sup>

### Standard of Care:

1L: 66% CR/CRi, mOS 14.7mo.<sup>8</sup>

Relapse: mOS 4.5mo.

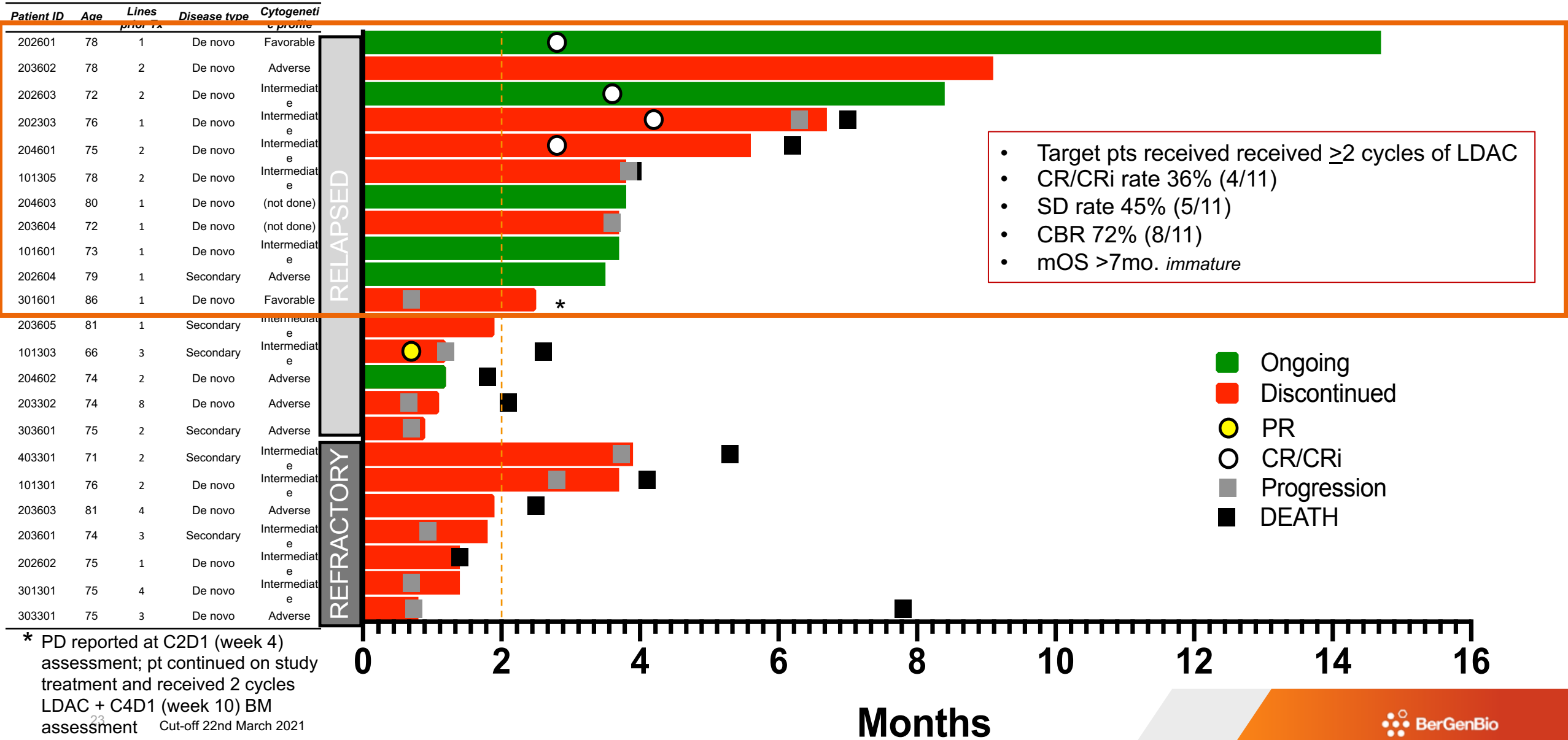
5-year survival rates of 3-8% in patients over 60 years old<sup>7</sup>



(1) Cancer.gov; (2) SEER; (3) [https://www.who.int/selection\\_medicines/committees/expert/20/applications/AML\\_APL.pdf?ua=1ble](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

# Time on treatment in relapsed/refractory AML patients (bemcentinib + LDAC)

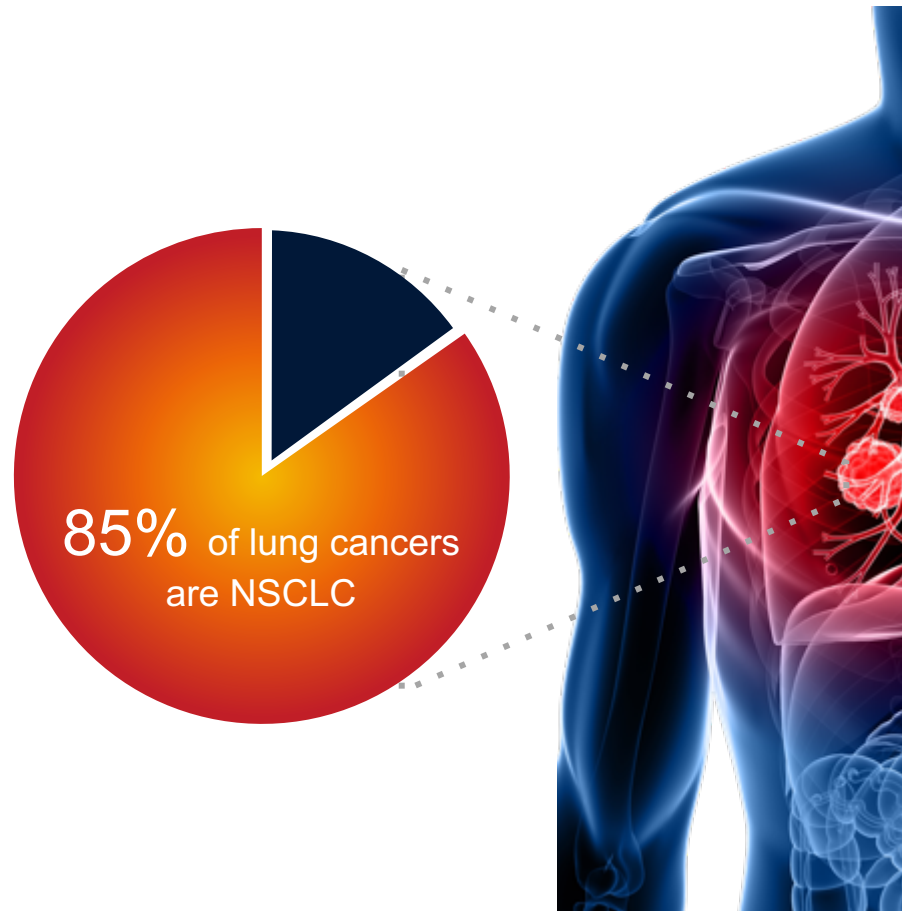
n=17 relapsed, n=7 refractory (16 evaluable) Ongoing study





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

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



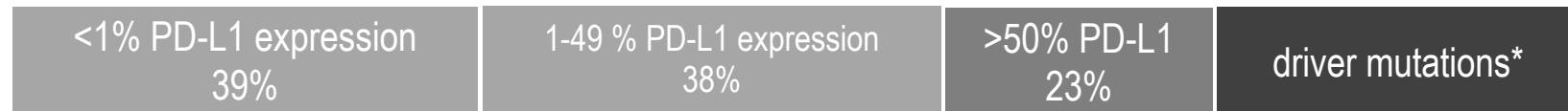
## The largest cancer killer, most patients depend on drug therapy

- 2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases<sup>1</sup>
- 1.76 million lung cancer deaths/yr worldwide<sup>1</sup>
- NSCLC market opportunity \$39bn
- In the U.S, 5-year survival rate is approximately 18.6%, and 4.7% in patients with distant metastases<sup>2</sup>

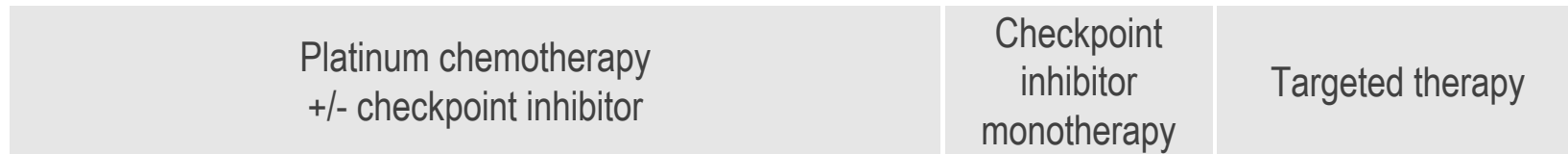
**Non-small cell lung cancer is the most common type of lung cancer, making up 80-85% of lung cancers**

# Non-Small Cell Lung Cancer (NSCLC)

Rapidly evolving SoC creates opportunities for novel effective, chemo free regimens



**1st Line**  
~375,000 pts



Deepening 1L responses, particularly PD-L1 negative/low

**2nd & 3rd Line**  
~220,000 pts



**Opportunities**  
Effective and well tolerated 2L therapies

# Summary Update: 2L ad. NSCLC Study with bemcentinib + pembrolizumab

**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

➤ Encouraging Survival in cAXL<sup>+</sup>

**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

➤ Encouraging mPFS in cAXL<sup>+</sup>

**Recruitment ONGOING**  
Stage 2

N=29 patients

**Cohort C**

- Previously treated 1<sup>st</sup> line with a combination of checkpoint inhibitor + platinum-containing chemotherapy
- Must have had disease control on 1<sup>st</sup> line therapy
- Has PD at screening

**Interim Analysis**  
Stage 1 N=13 patients

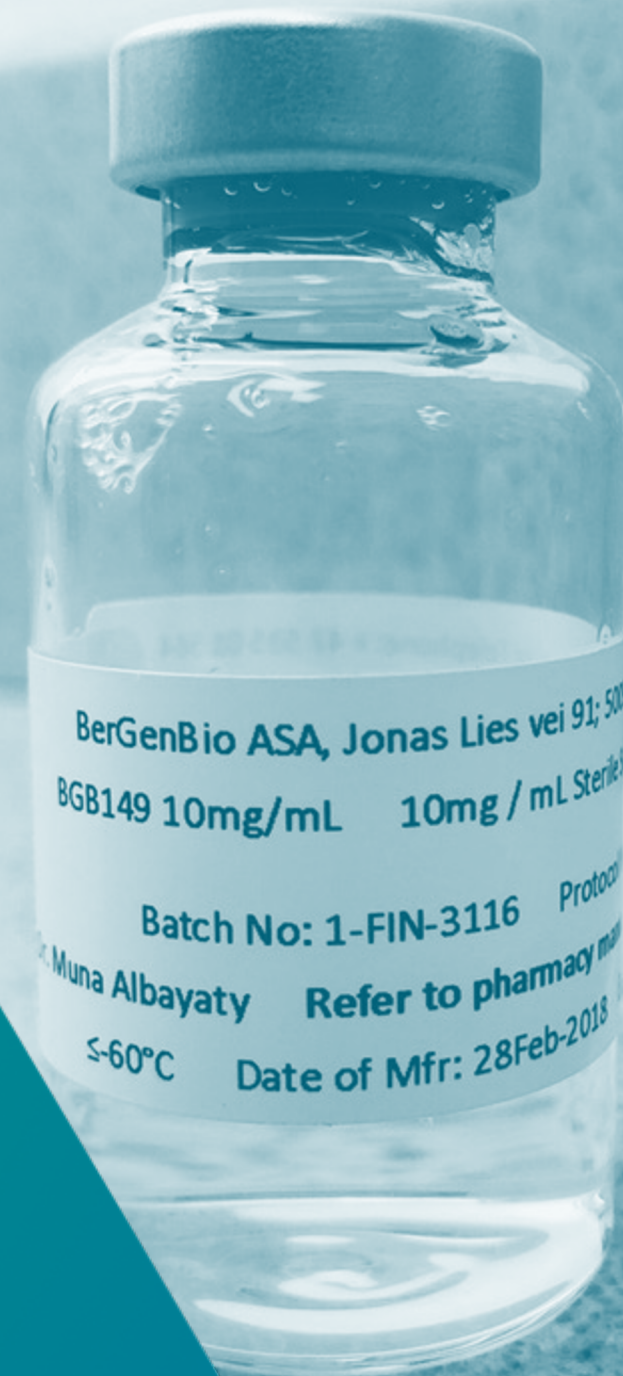
➤ ORR and biomarker data pending

**Hold**  
Stage 2

N=29 patients



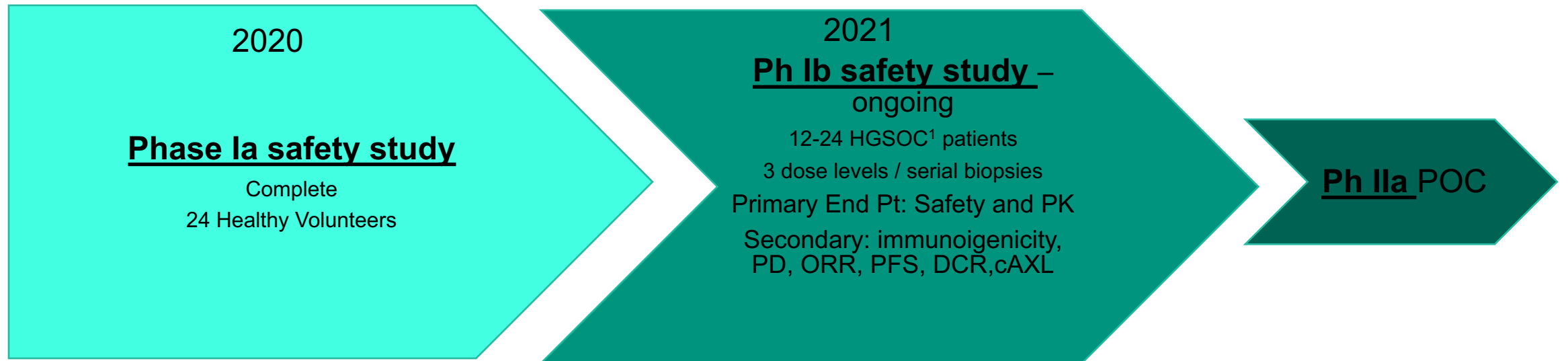
# Tilvestamab (BGB149) anti-AXL monoclonal antibody



BerGenBio ASA, Jonas Lies vei 91, 500  
BGB149 10mg/mL 10mg / mL Sterile  
Batch No: 1-FIN-3116 Protocol  
Muna Albayaty Refer to pharmacy  
≤-60°C Date of Mfr: 28Feb-2018



# Tilvestamab development plan



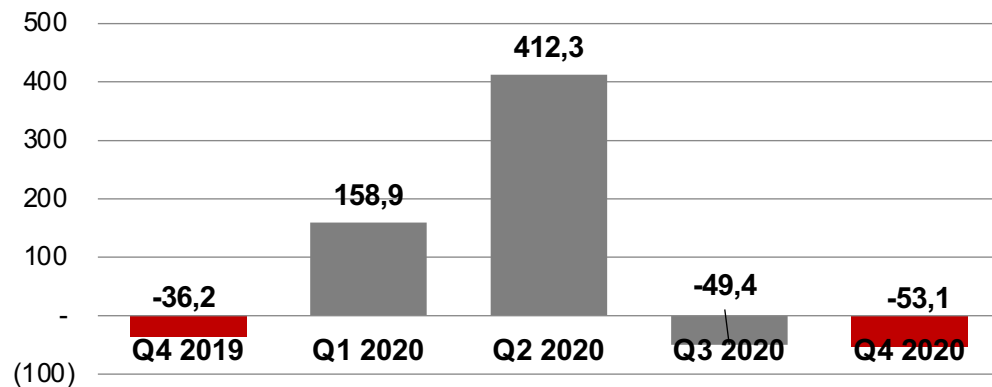
**Safety** – no dose limiting toxicity seen up to 3mg/kg dose  
**Pharmacokinetics** - exposure predictable with dose proportional C<sub>max</sub> increase  
Confirmatory evidence of *in vivo* target engagement with sAXL -- stabilisation in circulation

Well positioned for continued success....

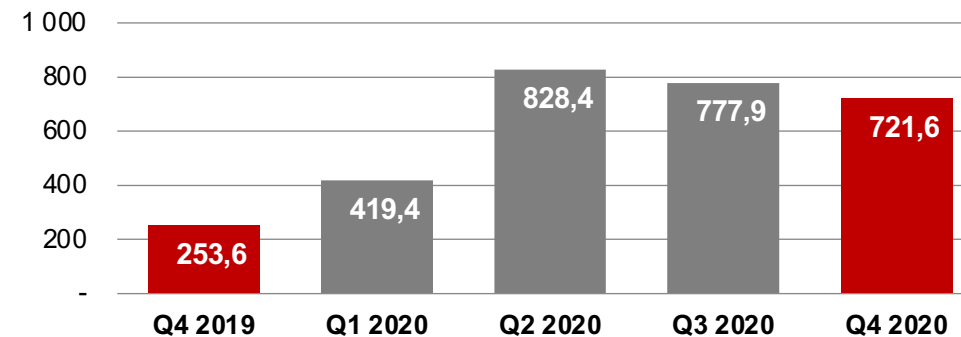


# Cash flow and cash position

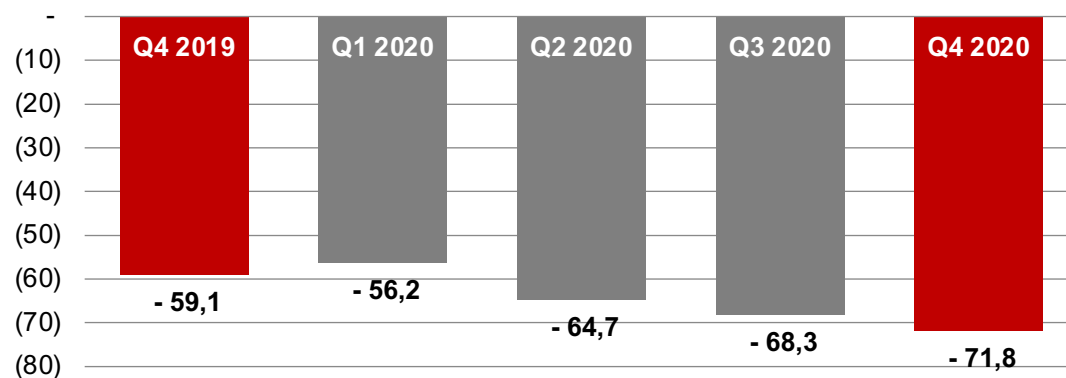
## Cash flow (million NOK)



## Cash position (million NOK)

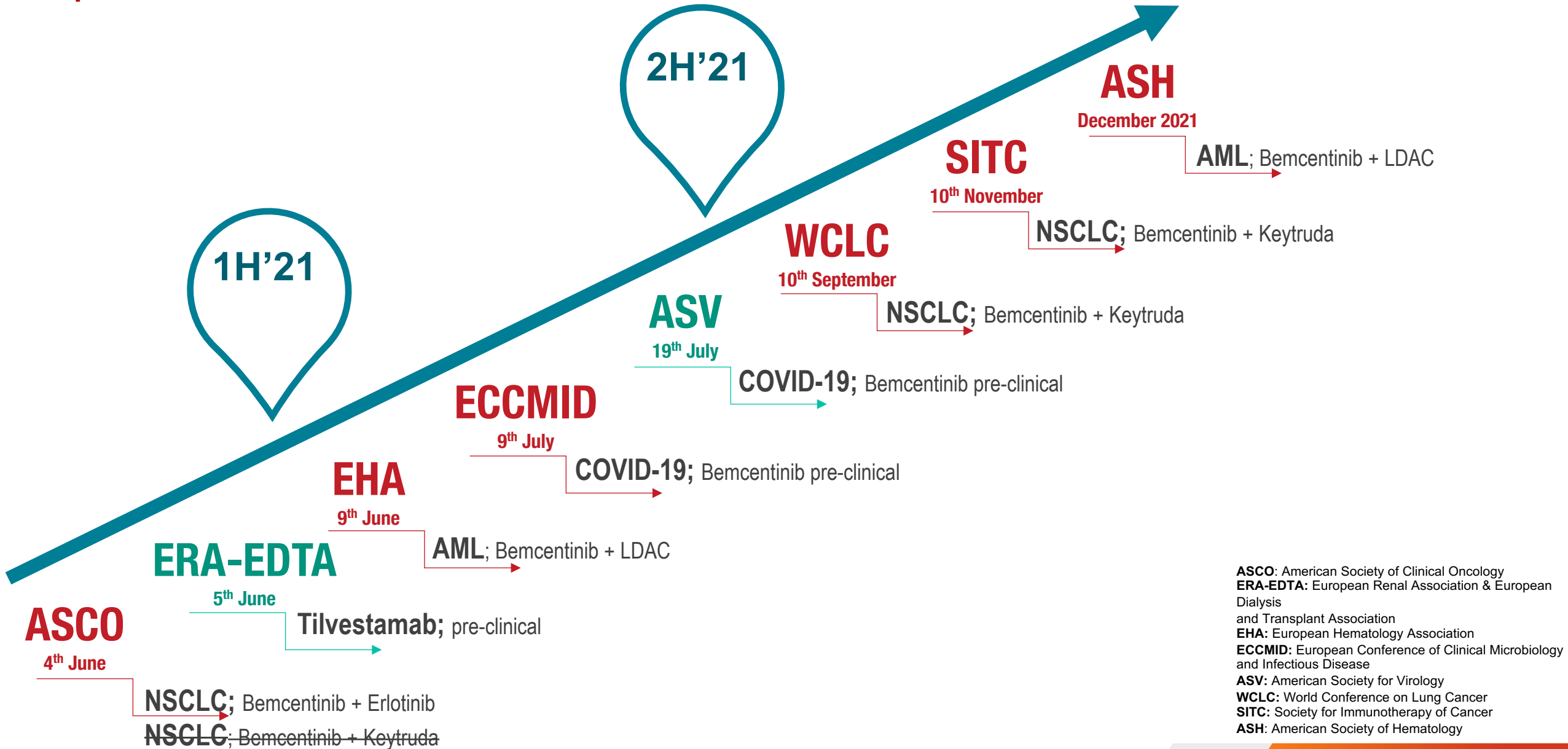


## Operating profit (-loss) million NOK



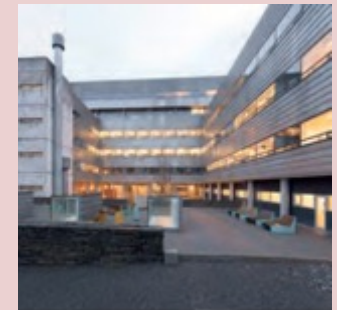
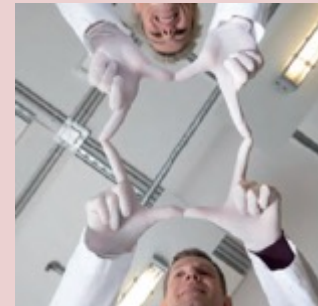
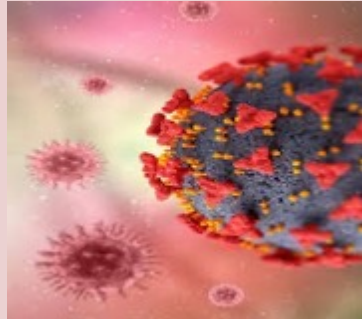
- Cash position Q4 2020 NOK 721.6 million (USD 84.6m).
- Quarterly average cash burn (Q419 – Q420) NOK 54.0m (USD 5,8m)

# 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

# BerGenBio – Investment highlights



## PhII COVID-19

Top line data:

- ✓ Safety
- ✓ Fewer deaths
- ✓ Time to clinical improvement
- ✓ Patient sub-populations

update in May

## 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

## Near term clinical milestones

COVID-19 -  
AML & MDS  
Registration path

NSCLC

## Pioneering biology

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

## Well resourced organisation

Experienced Oxford based R&D team

Industry & academic partnership and collaborations

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



# Thank you - Questions?



Richard S. Godfrey CEO  
Oslo Børs: BGBIO