



7<sup>th</sup> ANNUAL IMMUNO-ONCOLOGY INNOVATION FORUM  
18<sup>th</sup> - 20<sup>th</sup> of May 2021

BerGenBio ASA

Business update presentation



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# Forward Looking Statements

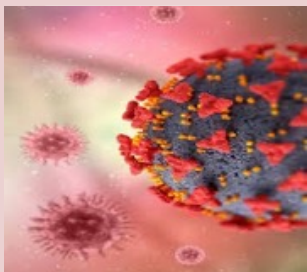
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# BerGenBio – Developing first in class AXL inhibitors for aggressive disease

## Investment highlights



### PhII COVID-19

Top line data:

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



### TWO first in class selective AXL inhibitors

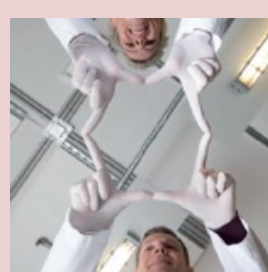
Bemcentinib - oral once-a-day capsule

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

# 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

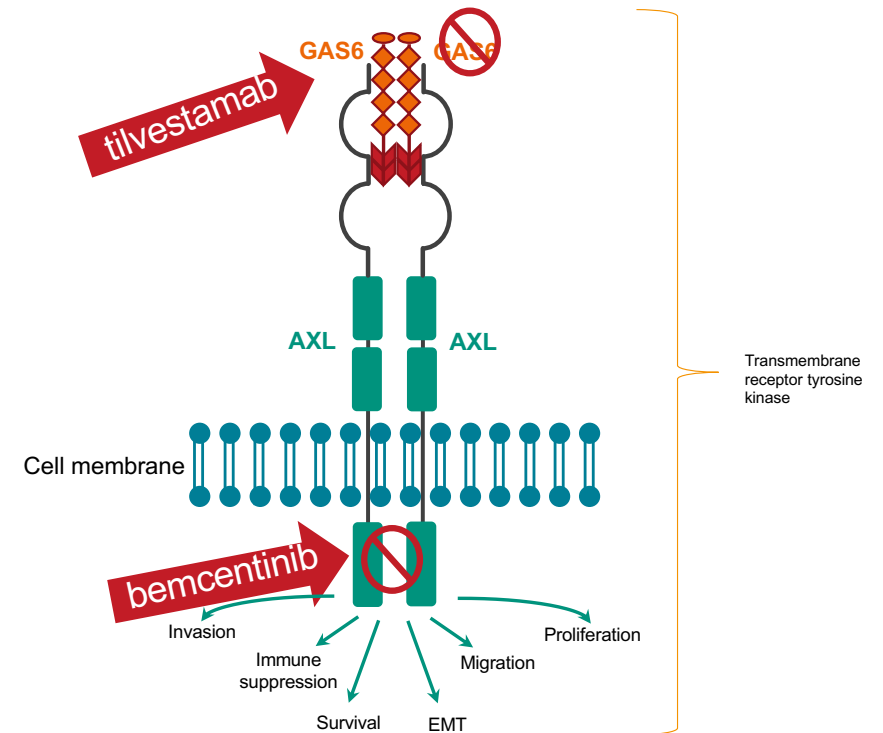
## Fibrosis

- Renal
- NASH
- IPF
- MF
- COPD

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

# First in class selective AXL inhibitors

**Bemcentinib & Tilvestamab block AXL signaling**

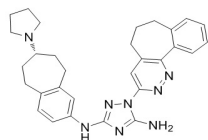


# Two first-in-class, potent, highly selective AXL inhibitors in clinical development

## Bemcentinib\*

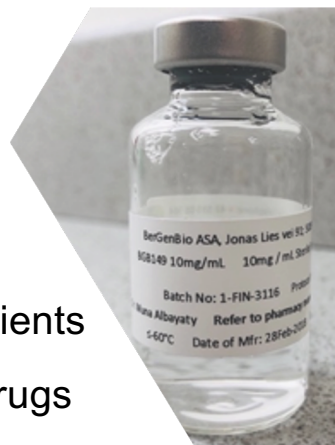


- Oral, once a day
- Size 0 capsule
- Stable simple drug product
- Favorable Safety and tolerability confirmed >400 patients
- Combines well with other drugs
- Phase III ready



- 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

Candidate	Targeted Indication	Preclinical	Phase I	Phase II	Registrational
Bemcentinib monotherapy	Hospital COVID-19 patients				Focus of todays Presentation
Bemcentinib monotherapy	>2L AML				
	2L MDS				
Bemcentinib combination with LDAC	2L AML				Focus of todays presentation
Bemcentinib combination with Pembrolizumab	2L NSCLC chemo refractory				
	2L NSCLC CPI refractory	Part 1 recruitment completed		Part2	
	2L NSCLC CPI+chemo refractory	Part 1 recruitment completed			
Tilvestamab (BGB149)	Phase Ia / Ib	Phase Ia complete		Ib	

# Value Driving Milestones

2020



Bemcentinib in  
COVID-19  
Ph II

Two rPh II  
- UK  
- India & South  
Africa



2L NSCLC data

Interim data  
- 2.5 x mPFS in  
cAXL patients



Relapse AML  
and MDS data

Preliminary data  
confirms a new  
significant patient  
population



Tilvestamab  
Phase Ia/Ib

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

2021



Data COVID-19  
Phase II

Top line data



COVID-19  
Development

Determine  
development &  
regulatory path



AML mOS data  
& regulatory  
alignment

- Survival data  
- Regulatory  
alignment



Tilvestamab  
Ph II

- Prepare to  
Initiate Ph II



# BEMCENTINIB CLINICAL DEVELOPMENT IN HOSPITALISED COVID-19 PATIENTS

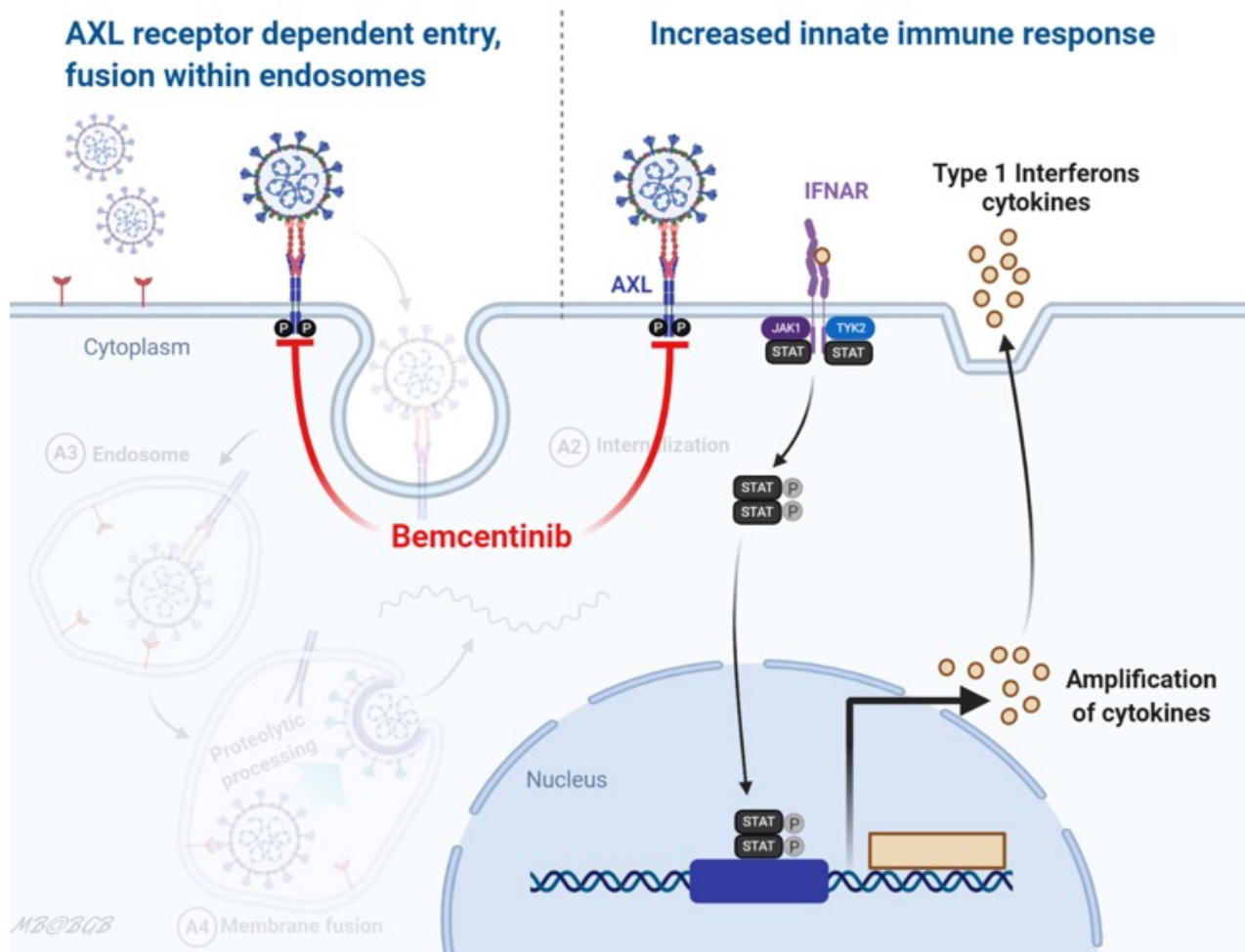
Top Line Data, May 2021:

The trial BGBC020 shows that Bemcentinib has the potential to increase the rate of ventilator free survival in more than 50% of hospitalised COVID-19 patients, addressing the greatest challenge faced by hospitals worldwide fighting the pandemic.



# Bemcentinib acts on two host pathways

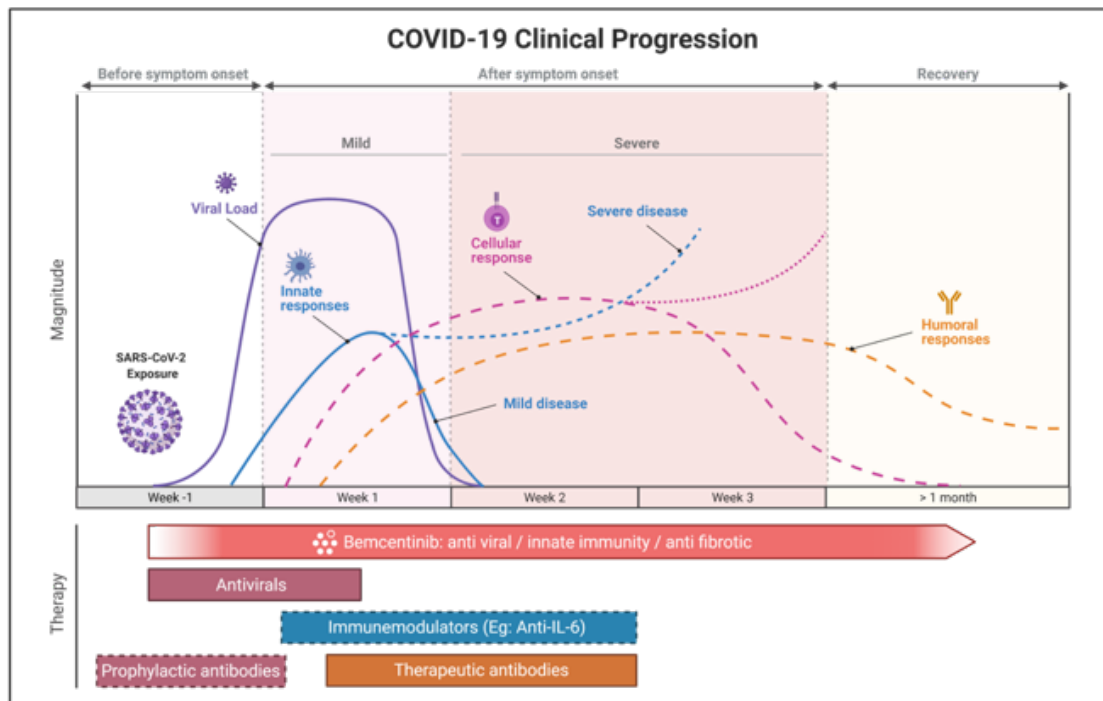
## Prevents viral infection and promotes innate immunity



### Bemcentinib:

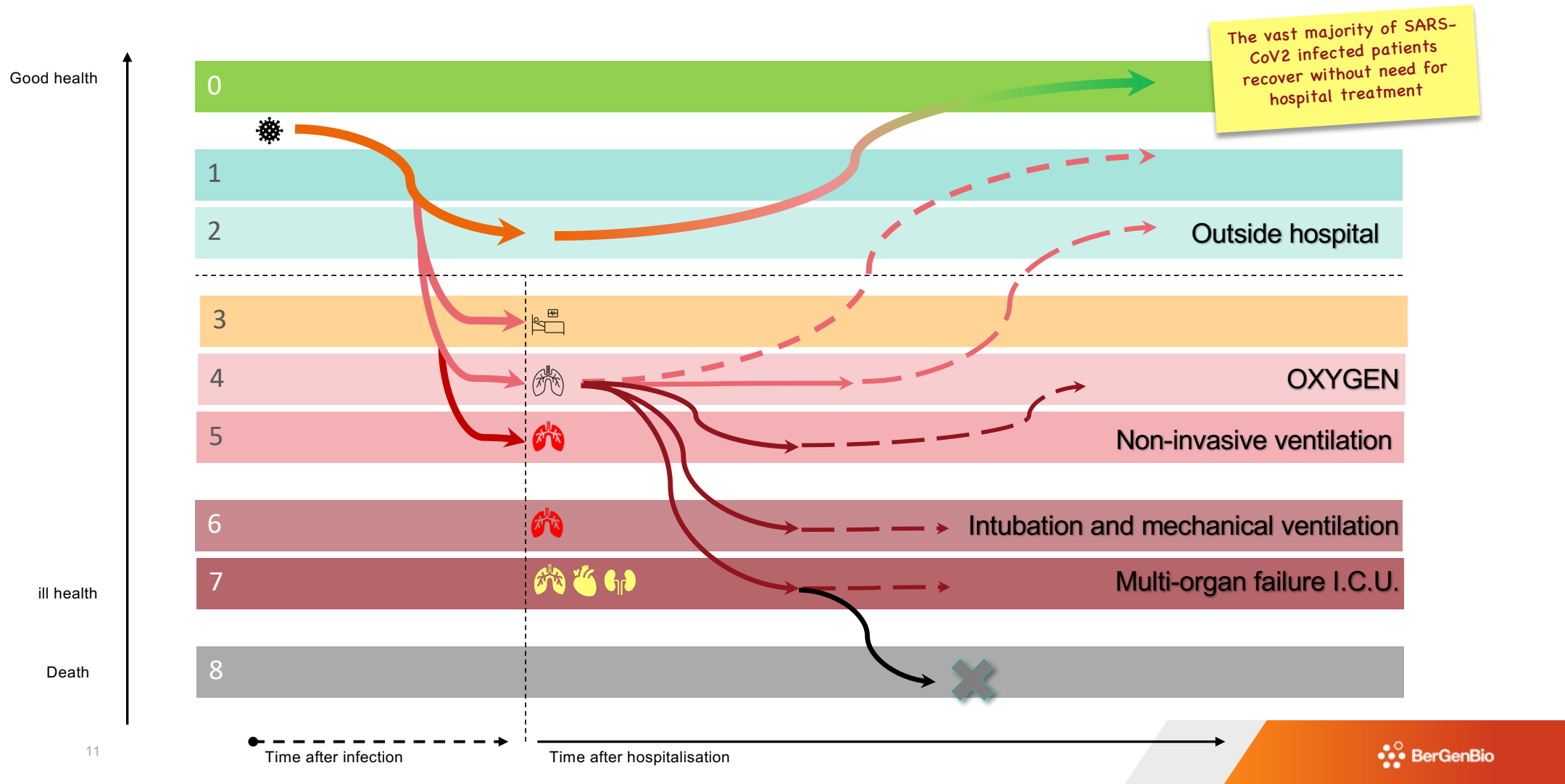
- blocks AXL-dependent viral entry
- enhances anti-viral interferon response
- Mode of action is independent of spike protein (or mutations)

# Summary of bemcentinib as a COVID-19 therapy



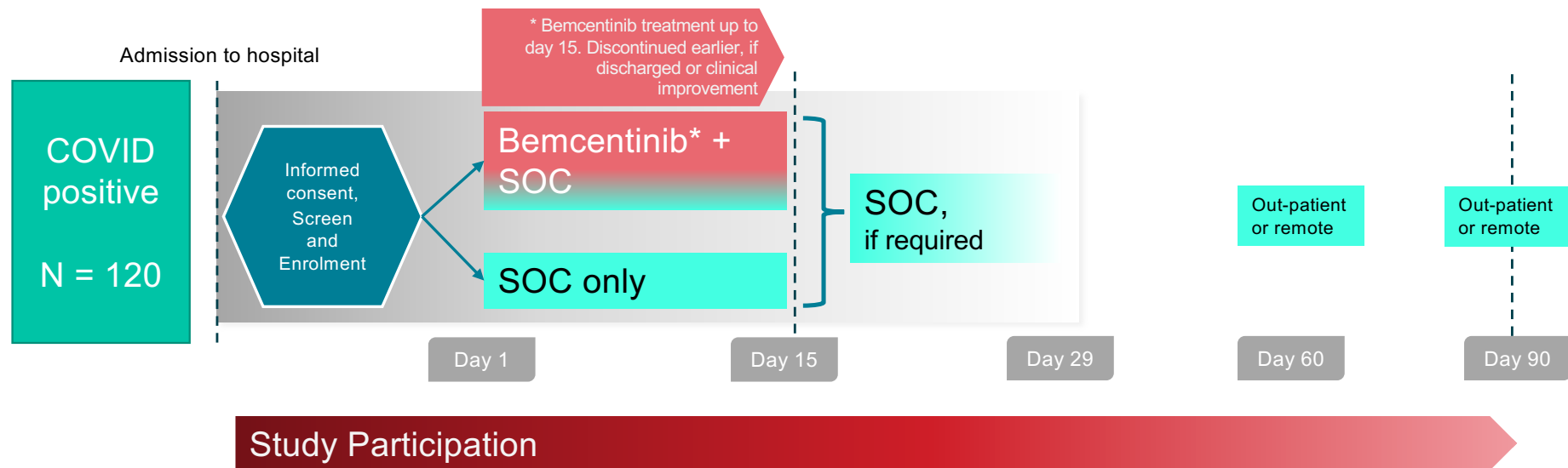
- **Bemcentinib acts on two host pathways**
  - Prevents viral infection
  - Promotes innate immunity
- **Bemcentinib inhibits viral entry by inhibiting AXL**
  - AXL is independent of viral spike protein and should remain effective against current and future variants
  - Ongoing work will confirm viral genome sequencing of clinical trial samples

# WHO 9-point scale – graded increase in pulmonary support

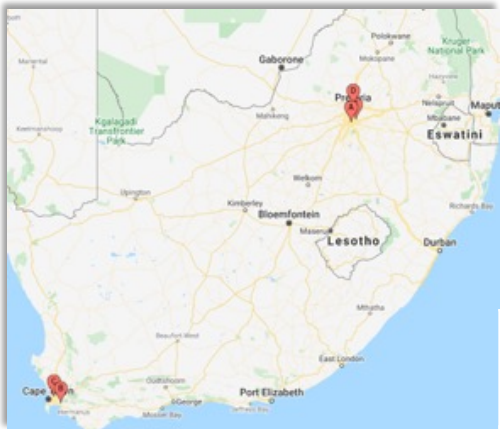


## Clinical Study design

### BGBC020 and ACCORD2 share identical design



# Bemcentinib studied in COVID-19 across 3 countries



Treatment arms	India	South Africa	UK	Total
Bemcentinib	30	28	30	88
SoC	30	27	32	89
				177



# Post-hoc exploratory analysis identified subset of patients (>50%) affected by more severe disease, benefit from bemcentinib

## PATIENT Subset: (Grade 4 & 5, CRP>30mg/L)

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### A. Grades 4 and 5 patients

Grade 3 patients (not on oxygen)

- Rarely admitted (not eligible in India)
- Did not usually progress to require oxygen
- Shorter stay in hospital (4-5 days)

### B. C-reactive protein

- bemcentinib benefit is greater in patients with higher baseline inflammation
- CRP is an acute phase blood based biomarker in routine clinical use
- 30 mg/L threshold identified

## VENTILATOR-FREE SURVIVAL (VFS)

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### GOALS of COVID19 therapy

1. Preventing death
2. Preventing progression to IUC and require ventilation
  1. Non-invasive
  2. Intubation and mechanical ventilation

**Ventilator Free Survival** is an endpoint derived from studies in Acute Respiratory Distress Syndrome

- Being alive at day 29

AND

- not deteriorating to require ventilation

Clinically meaningful endpoint for:

1. Individual Patient health – both acute, and long-term
2. Healthcare system; resource constraints

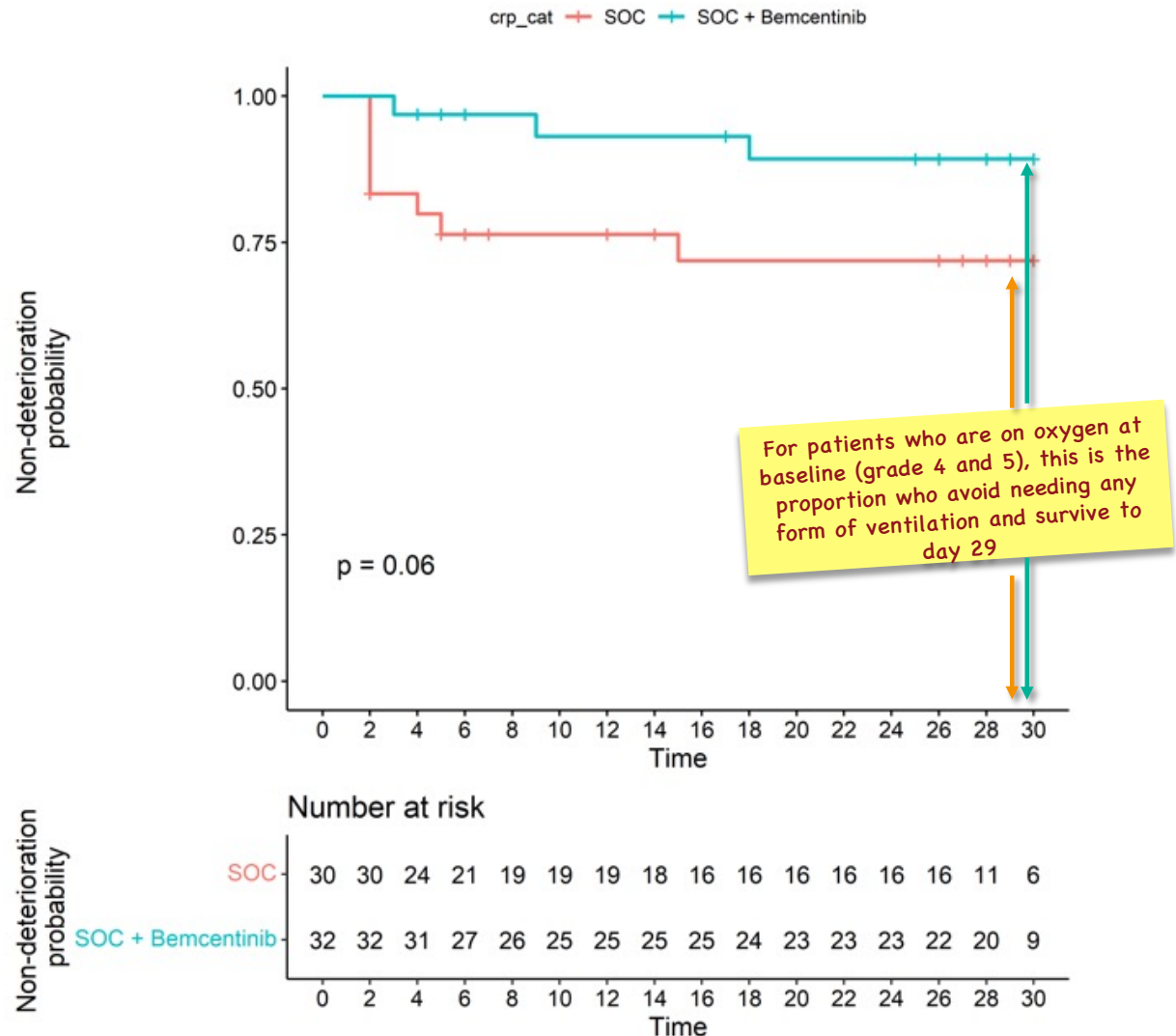


## Ventilator Free Survival

(Time to deterioration)

Grades 4, 5 with CRP>30mg/L

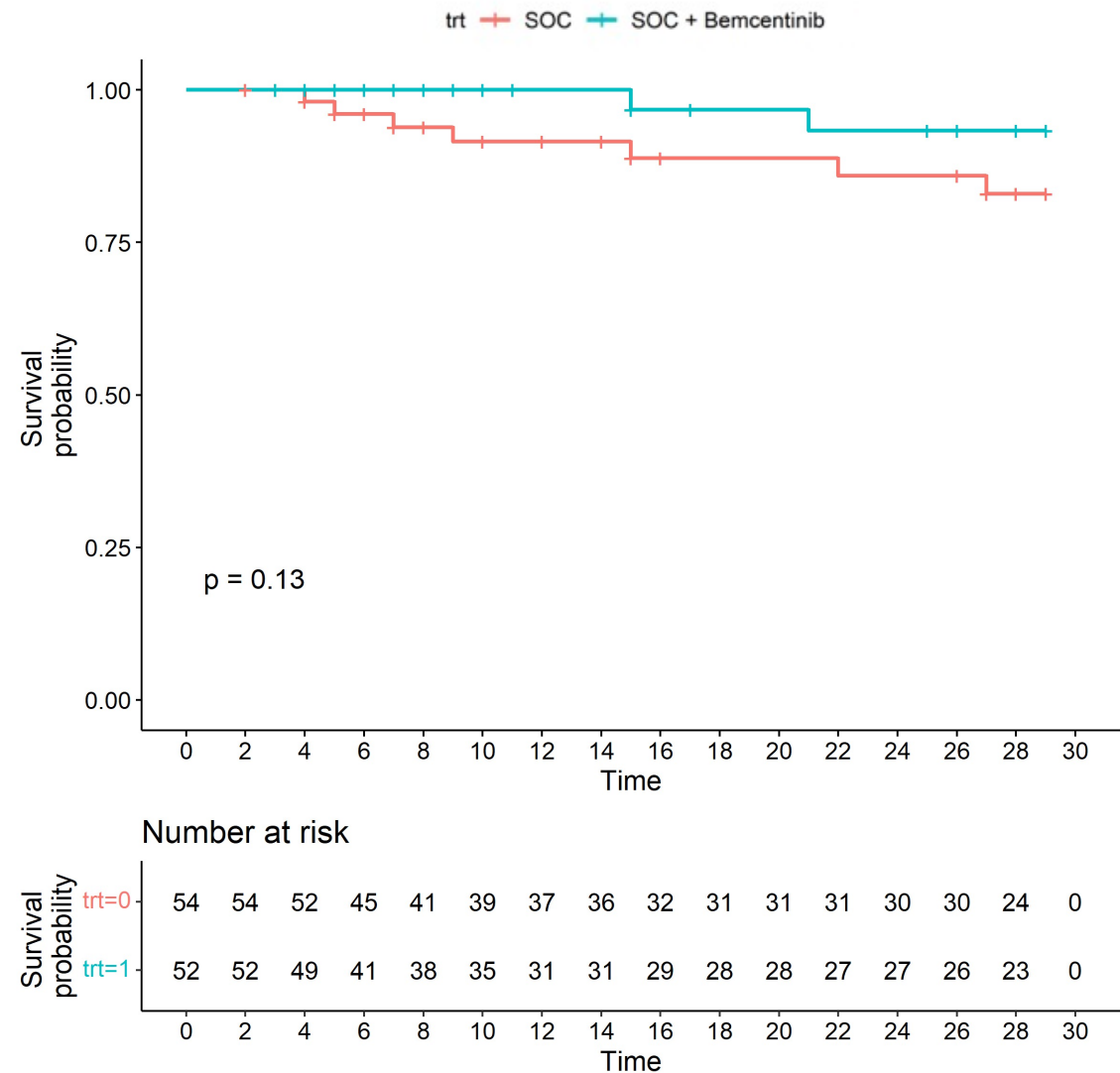
- Patients treated with bemcentinib appeared to be protected from an early deterioration, at day 2 or 3, compared to patients on SOC
- This effect was maintained through 29 days
- In sub-group of patients, ventilator free survival was higher (90%) with bemcentinib treatment compared to SOC only (72%)



## Survival at day 29

BGBC020 + ACCORD2  
Grades 4,5 with CRP $\geq$ 30mg/L

- bemcentinib treated arm 96.5% (83 of 86) versus 91.0% (81 of 89) in SoC treated arm.
- Mortality rates in ACCORD2 SOC treated patients were higher than those in BGBC020 at day 29; (5 of 32 patients (16%) in ACCORD2, versus 3 of 57 (5%) in BGBC020.



# Summary

## Bemcentinib potential treatment for COVID-19



## Bemcentinib advantage

- 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.
- Ventilator Free Survival observed to be 90% in bemcentinib treated patients vs 72% in SOC treated patients, in a sub-group of patients with increased disease severity
- Survival benefit was numerically greater in the bemcentinib treated patients (96.5%) vs SOC treated patients (91%)

Next steps include continued engagement with regulatory agencies, Governments and industry partners.

# Bemcentinib clinical development in:

## Acute Myeloid Leukaemia

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

## Defining a new patient population: relapsed AML

- ✓ Patients have 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

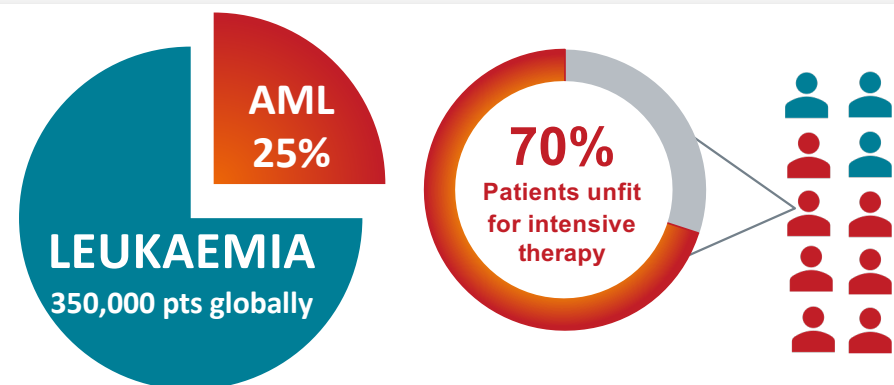
Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years<sup>6</sup>

## Standard of Care:

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

Relapse: mOS 4.7mo.<sup>9</sup>

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



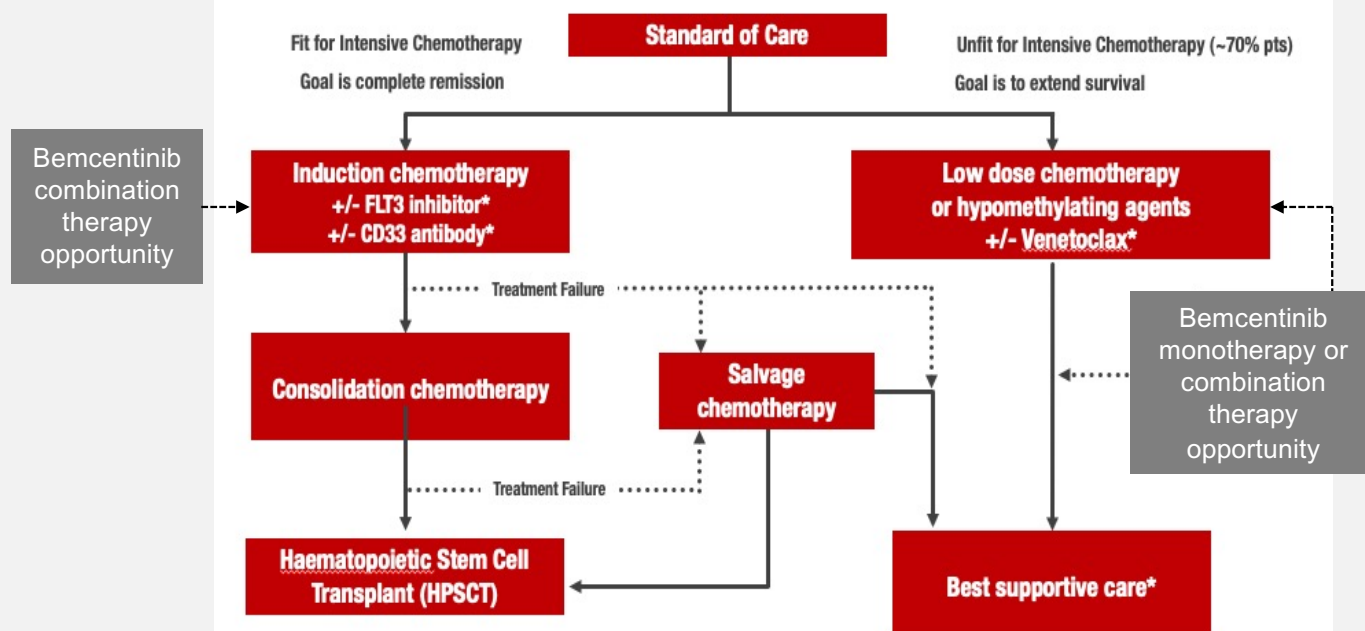
(1) Cancer.gov; (2) SEER; (3) [https://www.who.int/selection\\_medicines/committees/expert/20/applications/AML\\_APL.pdf?ua=1ble](https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble)

(4) <https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics> (5) <https://www.businesswire.com/news/home/20190319005442/en/> (6)

19 <http://asheducationbook.hematologylibrary.org/content/2010/1/62.long>, (7) <https://www.ncbi.nlm.nih.gov/books/NBK65996/> (8) VIALE A & C 9 [Leukemia Research Volume 90](#), March 2020, 106314

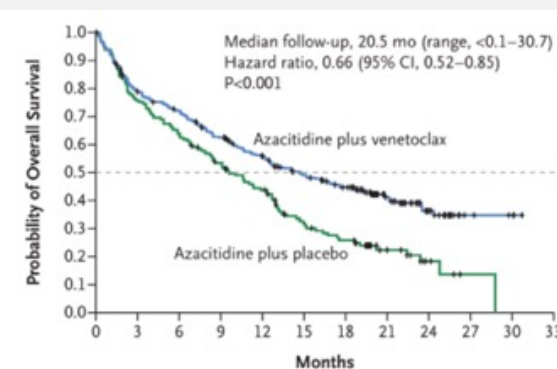
# Relapse AML – the need for new treatment options

## Acute Myeloid Leukaemia: Standard of Care & Bemcentinib Positioning



## First Line Treatment

- Evolved to include venetoclax in combination with HMA or low-dose cytarabine
- CR/CRi 65% rate and mOS of 14.7mo<sup>1</sup>
- Relapse patients mOS 4.7mo<sup>2</sup>



1. [VIALE-A NCT02993523](#)
2. [Leukemia Research Volume 90](#), March 2020, 106314



## 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

sAXL biomarker potentially predictive of CR/CRi at 43%

Translational research confirmed immuno-therapy mechanism of action



### Phase 2 Expansion Cohorts

**Cohort B1 n=14**  
Monotherapy AML

**Cohort B2 n=16**  
Combination with LDAC in AML

**Cohort B5 expansion**  
Combination with LDAC relapsed AML (ongoing)

**Cohort B3 n=14**  
Combination with decitabine in AML

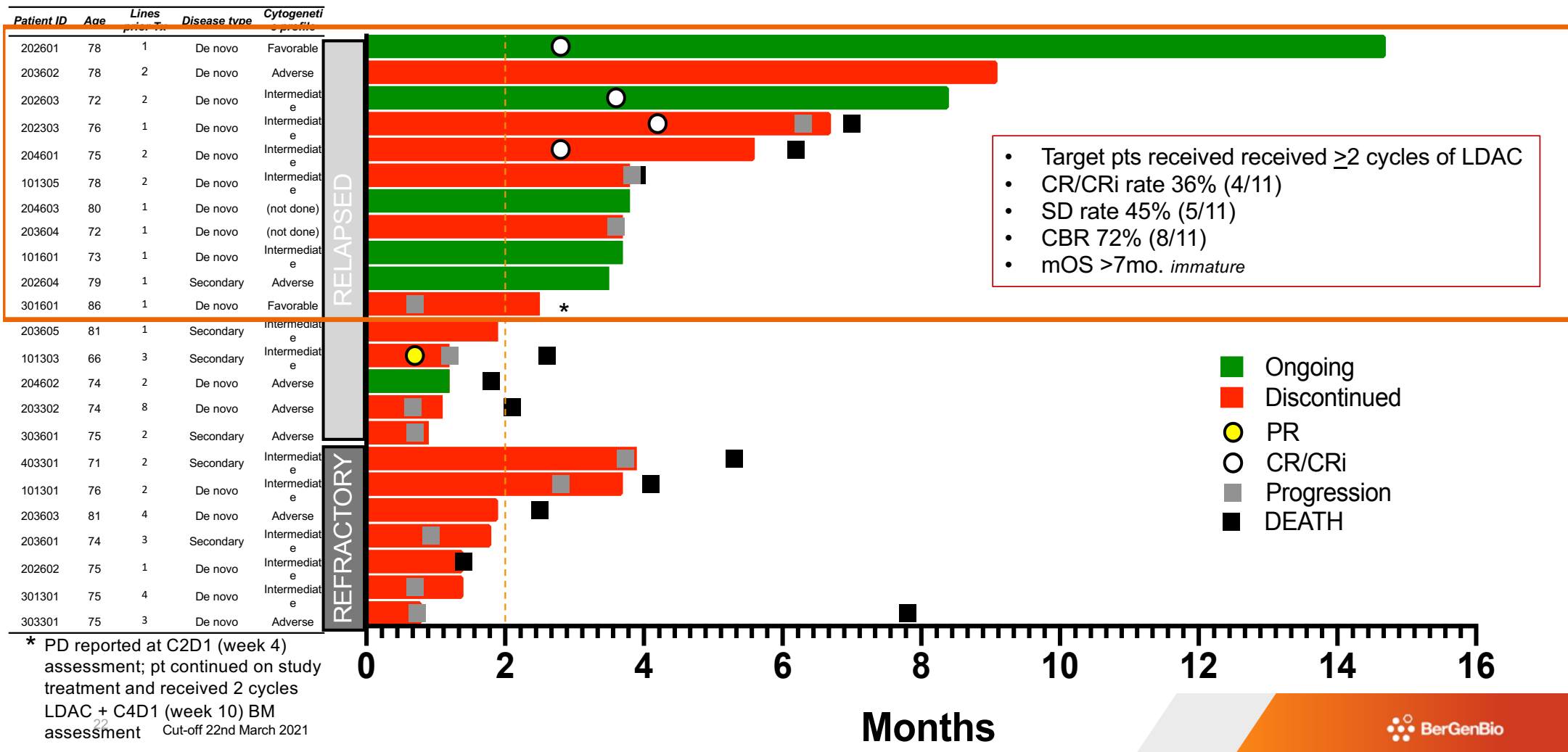
**Cohort B4 n=14**  
Monotherapy MDS

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

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

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

BGBC003 B2+B5

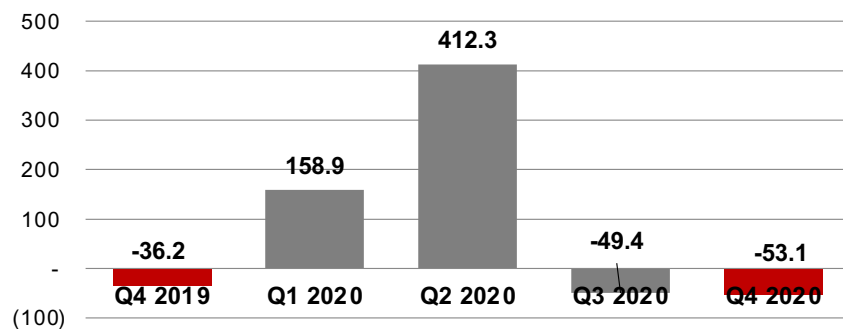


Well positioned for continued success....

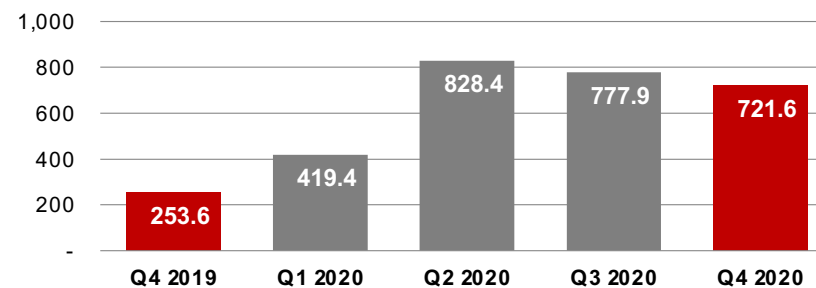


# Cash flow and cash position Q4'20

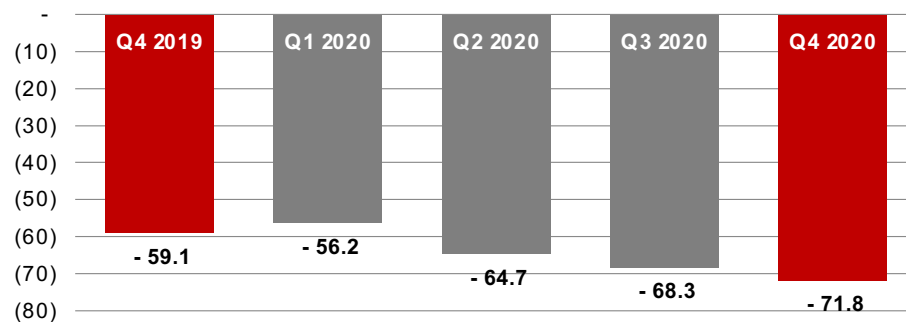
Cash flow (million NOK)



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

