



# H1/Q2 2021 REPORT, HIGHLIGHTS AND FINANCIALS

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# AGENDA

1. Q2 and Recent Highlights
2. AXL inhibitors
3. Bemcentinib clinical trial update:
  - COVID-19
  - Relapse Acute Myeloid Leukaemia (AML)
  - Refractory Non-Small Cell Lung Cancer (NSCLC)
4. Tilvestamab
5. Finance Report
6. 2021 Highlights & Outlook

# H1/Q2 2021 Summary and out look

COVID-19 impact	Operational adjustments are established, WFH remains in the UK. Sites/Patient recruitment remain slow
Organisation	Growth and development to support regulatory engagement and late stage trials
Bemcentinib COVID-19 AML NSCLC	<ul style="list-style-type: none"> <li>- Encouraging data from 2 rPhII trials suggest potential effective treatment option</li> <li>- <i>mOS</i> preliminary data are encouraging, regulatory alignment is ongoing</li> <li>- On going Ph II in CPI refractory patients, data pending</li> </ul>
Tilvestamab	- Ongoing Phase Ib
Regulatory	<ul style="list-style-type: none"> <li>- Active engagement with regulators seeking alignment for AML and COVID-19</li> <li>- FDA Fast Track designation awarded for 2L NSCLC</li> </ul>
Partners	Ongoing discussions with Governments and Industry Partners
Cash	NOK 574m
Outlook	<p>Clinical data in AML and COVID 19 is encouraging.</p> <p>Seeking Regulatory alignment for registration trials.</p> <p>Strong organization and well financed for current activities and immediate milestones.</p>



# Q2 and recent highlights

Apr  
2021

- Update from Phase II trials assessing bemcentinib in hospitalised COVID-19 patients. Latest data from BGBC020 and ACCORD2 show bemcentinib was well tolerated, and survival benefit for bem treated patients

May  
2021

- Pre-clinical and mechanistic data presented at Virtual Immunology 2021
- Top Line data from phase II trial assessing bemcentinib in hospitalised COVID-19 patients: post-hoc analysis identified 60% of patients with most severe disease report significant benefit from bemcentinib treatment

Jun  
2021

- Encouraging preliminary survival and response data from on-going phase II study an AML was presented at EHA
- End-of-trial data from a Phase I/II study of bemcentinib in combination with erlotinib in patients with advanced non -small cell lung cancer (NSCLC) at the American Society of Clinical Oncology (ASCO) Annual Meeting.

July  
2021

- Late Breaking Abstract at ECCMID 2021 presented COVID-19 trial data from BGBC020 and ACCORD2
  - Increased survival of 96.6% in bemcentinib arm vs. 91.2% in standard of care arm
  - Significantly reduced likelihood (69%) of progression to ventilation in higher severity patients
  - Significantly increased likelihood (88%) of shorter time to recovery or discharge in higher severity patients
  - Clinical evidence of anti-viral mechanism of action
  - Preclinical analysis highlights bemcentinib's potential against COVID-19 variants

# 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

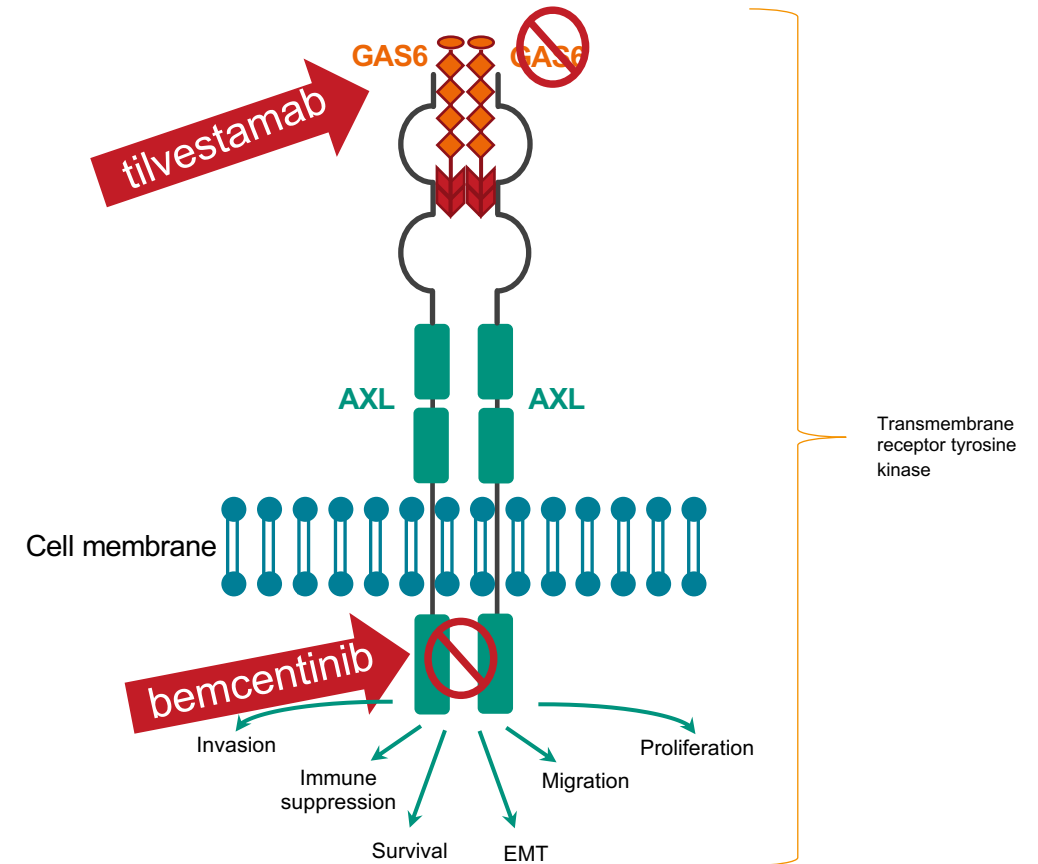
## Fibrosis

- 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**



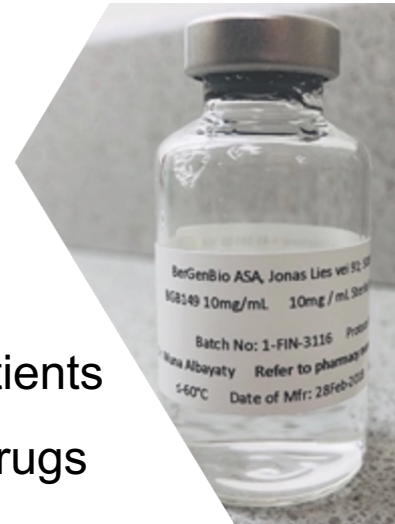
# Two first-in-class, potent, highly selective AXL inhibitors in clinical development

## Bemcentinib\*



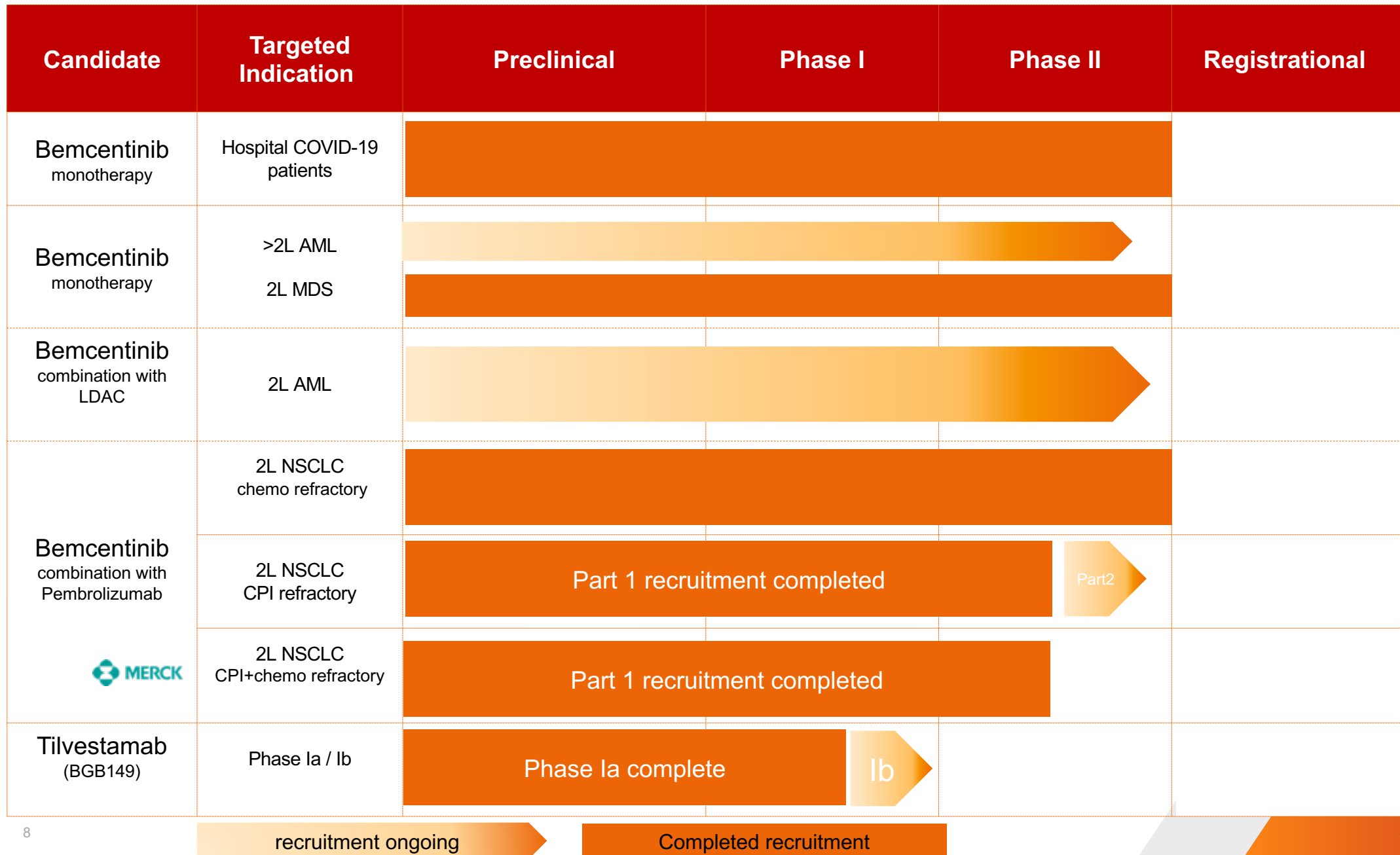
- Oral, once a day
- Size 0 capsule
- Stable simple drug product
- Favorable Safety and tolerability confirmed >400 patients
- Combines well with other drugs
- Phase III ready

## 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



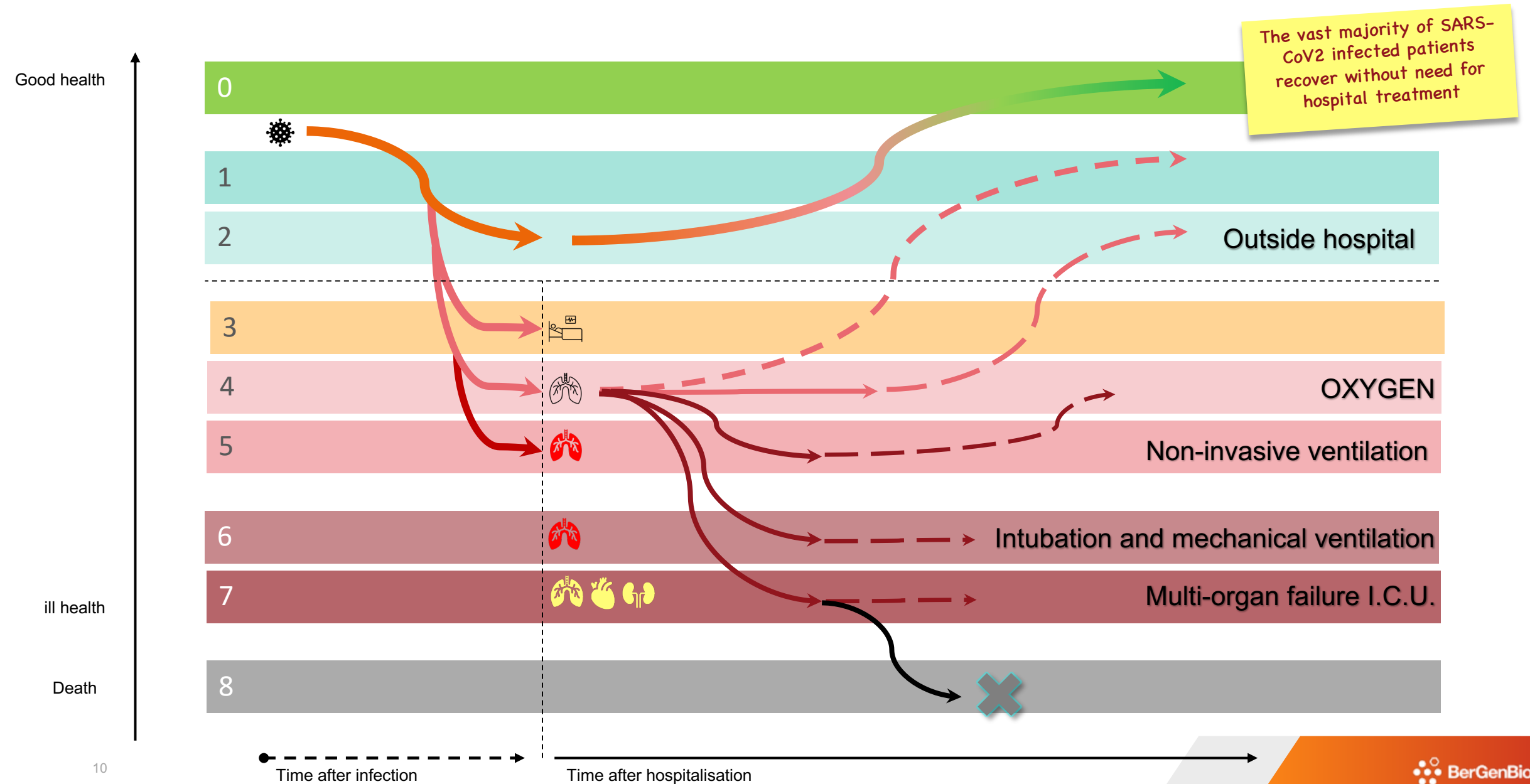


# TWO RANDOMISED PHASE II STUDIES ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

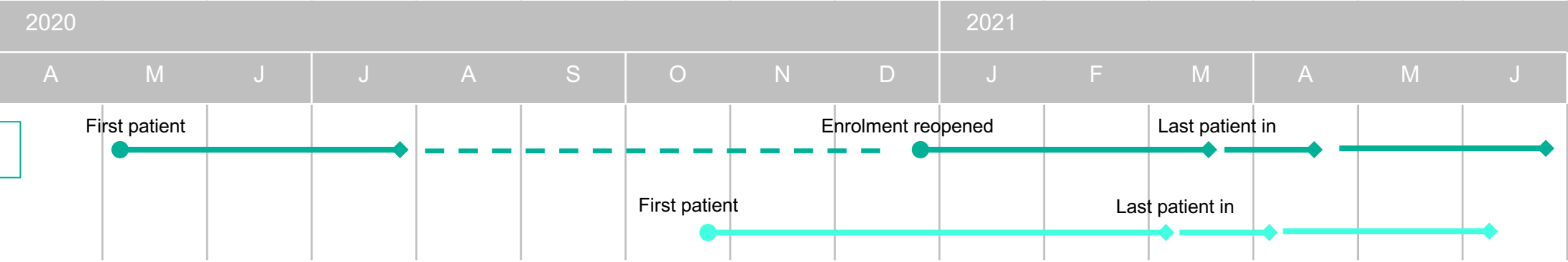
**ECCMID 2021:** European Congress of Clinical Microbiology and Infectious Diseases

- Survival to day 29 - 96.6% vs 91.2% with SoC alone
- Reduced likelihood of progression of pulmonary distress to require ventilation – 69% lower than SoC in higher severity patients
- Increased likelihood of shorter time to recovery or discharge – 88% greater than SoC in higher severity patients

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



# Bemcentinib: two exploratory phase 2 COVID19 studies



	UK	India	South Africa	Total
Bemcentinib	30	30	28	88
Standard of Care	34	30	27	91
				179

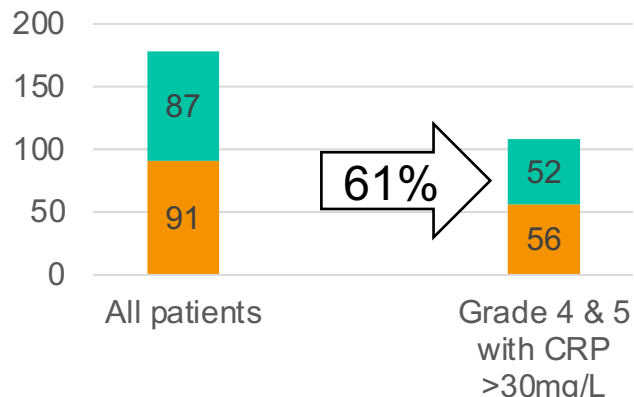


# Baseline patient characteristics and Safety

Post-hoc exploratory analysis identified 61% subset of patients affected by more severe disease, benefited from bemcentinib

BGBC020				ACCORD2			
Baseline WHO OCS	Baseline Intent to use steroid	Bemcentinib	SOC	Total	Bemcentinib	SOC	Total
3	N/A	6	5	11	3	0	3
4	No	11	10	21			
	Yes	36	36	72	21	25	46
5	No	1	1	2			
	Yes	4	5	9	5	8	13
Total		58	57	115	29	33	62

CRP	>30mg/L	27	30	57	22	26	48
Proportion of patients				50%	77%		



## 5 Most Commonly reported Adverse Event (by PT)

Preferred Term	Bemcentinib +SoC n=86		SoC n=89		Total N=175	
	n	%	n	%	n	%
Diarrhoea	8	9	2	2	10	6
ALT increased	8	9	1	1	9	5
Hyperglycaemia	4	5	3	3	7	4
Headache	4	5	2	2	6	3
Pulmonary embolism	1	1	5	6	6	3

4 patients discontinued bemcentinib due to adverse events (myocardial infarction - 1, raised ALT - 1, prolonged QTc - 1, septic shock and acute renal failure - 1)  
1 interrupted bemcentinib due to diarrhoea

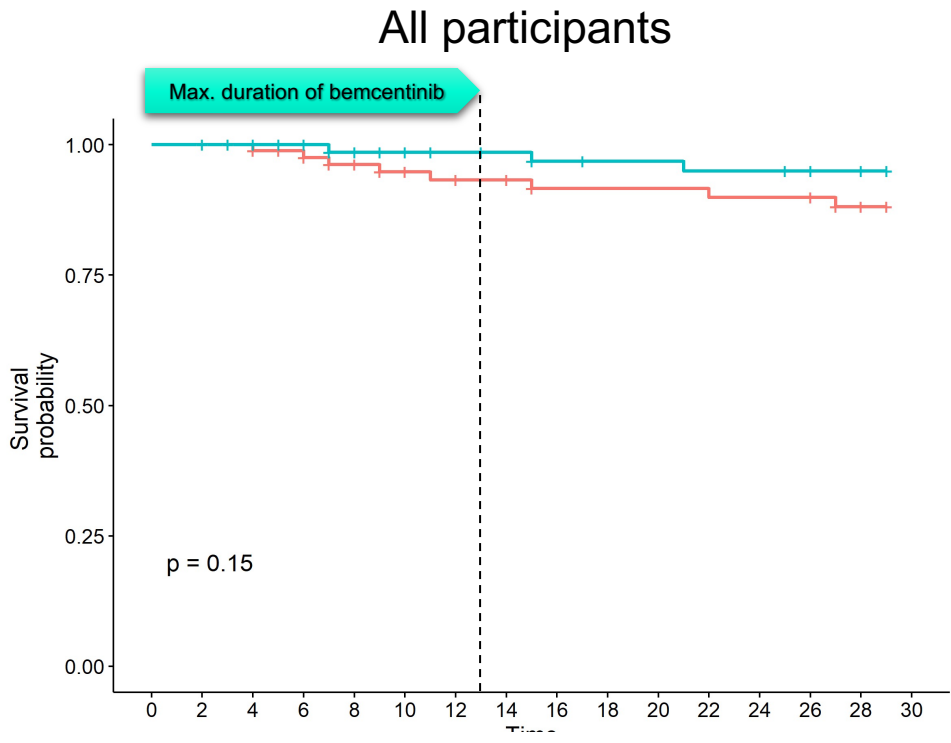
No SUSAR

IDMC review; no safety or tolerability signal of concern for further development in this COVID19 patient population.

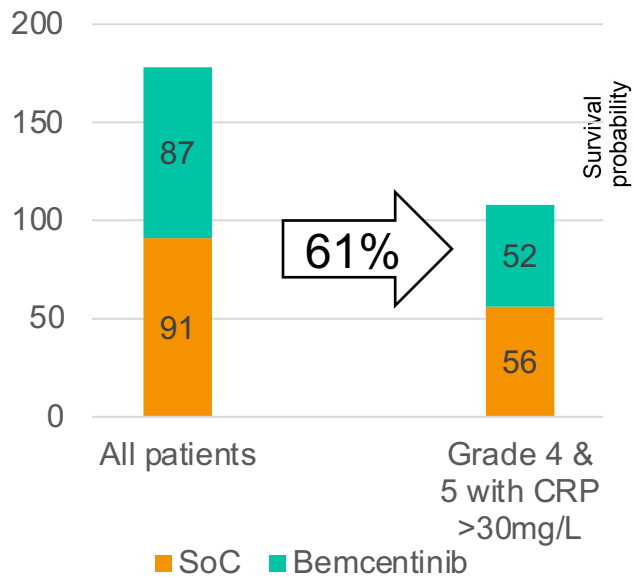


# Survival (day 29 after enrolment)

survival of 96.6% in bemcentinib arm vs. 91.2% in standard of care



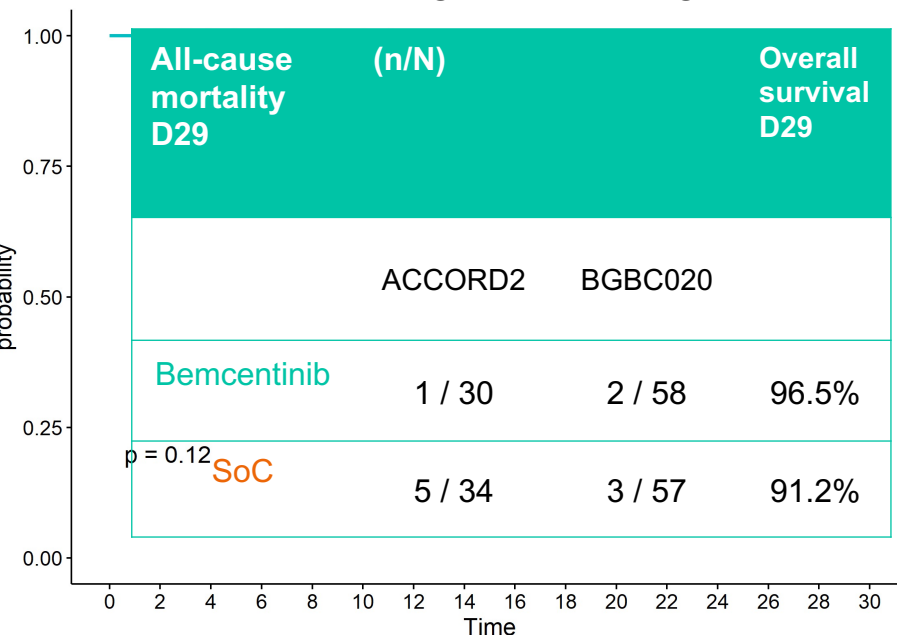
HR=0.388 95% C.I.(0.103, 1.462)



—+— SoC

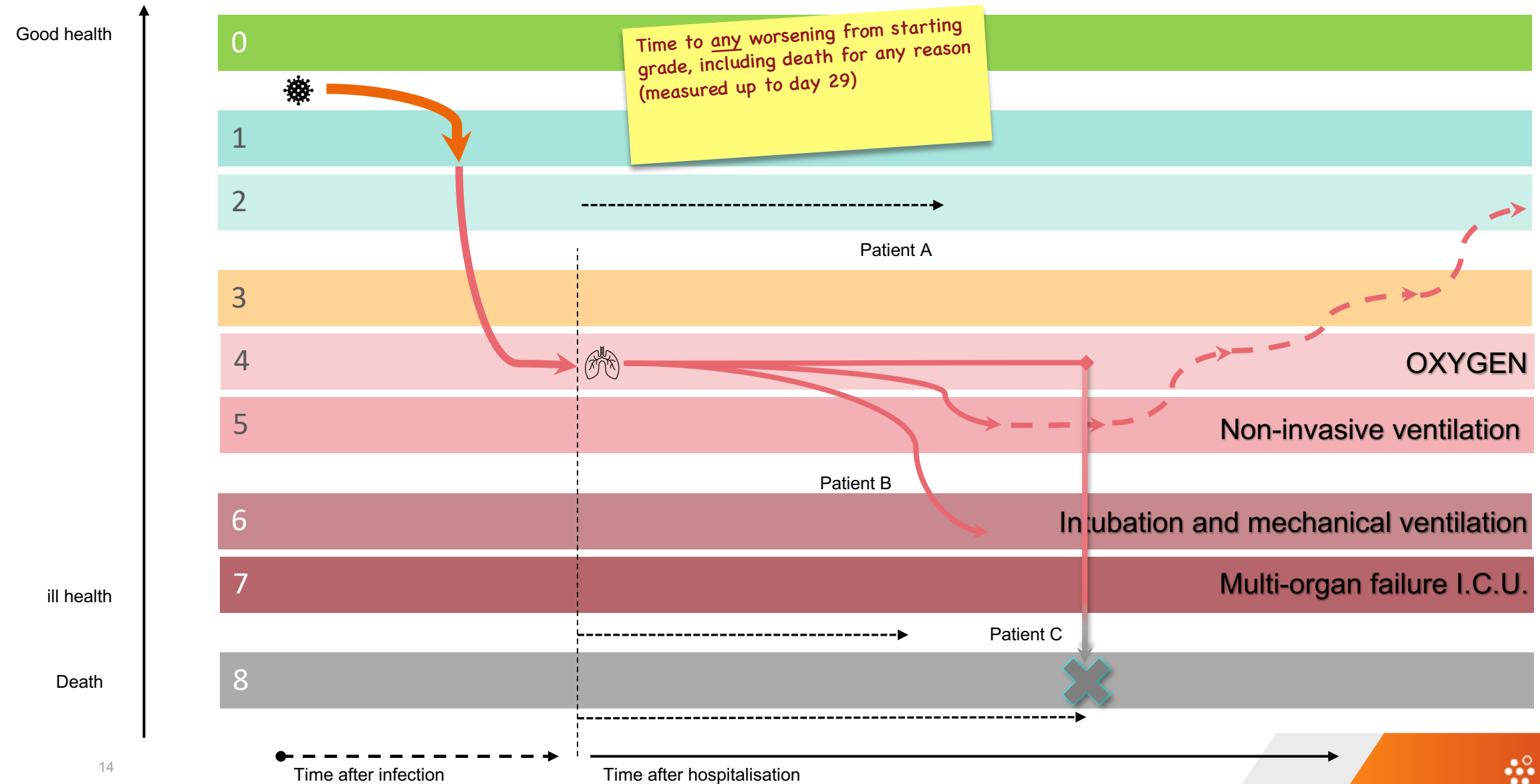
—+— Bemcentinib

WHO scores of 4 & 5 at baseline  
AND screening CRP≥30mg/L



HR=0.306 95% C.I. (0.063, 1.472)

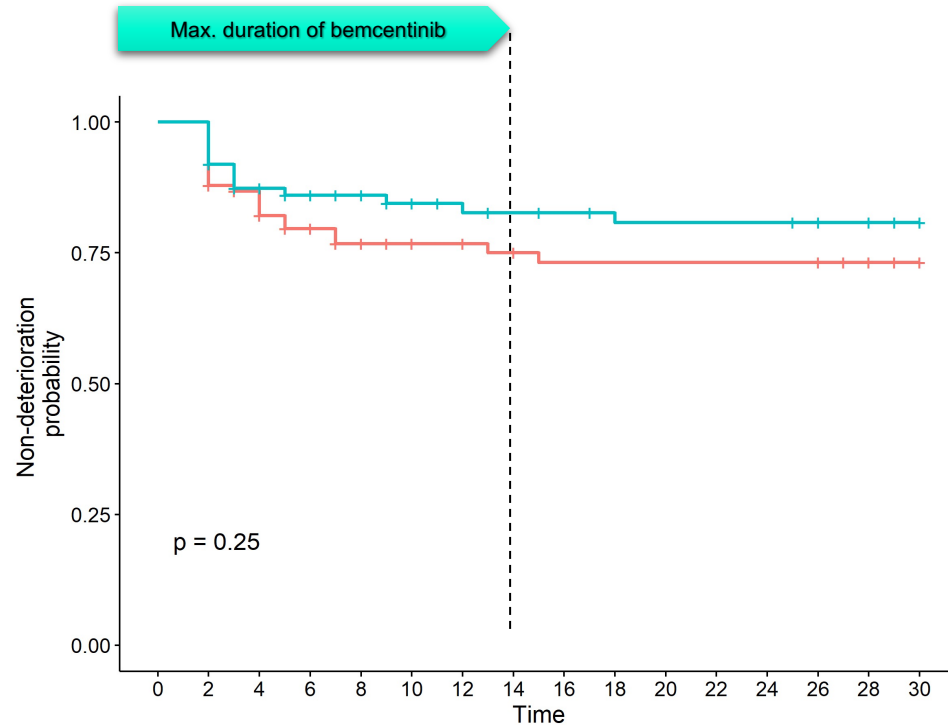
**Key Secondary endpoint – time to any worsening (incl death)**



# Time to worsening by $\geq 1$ grade in WHO score

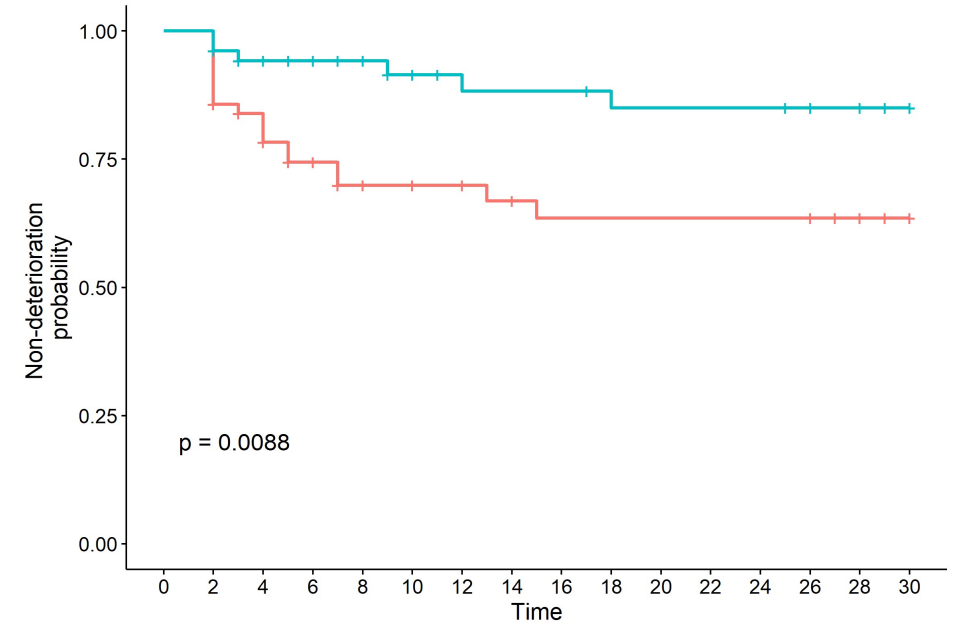
Significantly reduced likelihood (69%) of progression to ventilation in higher severity pts.

All participants



HR=0.679 95% C.I. (0.352, 1.309)

WHO scores of 4 & 5 at baseline  
AND screening CRP  $\geq 30$ mg/L

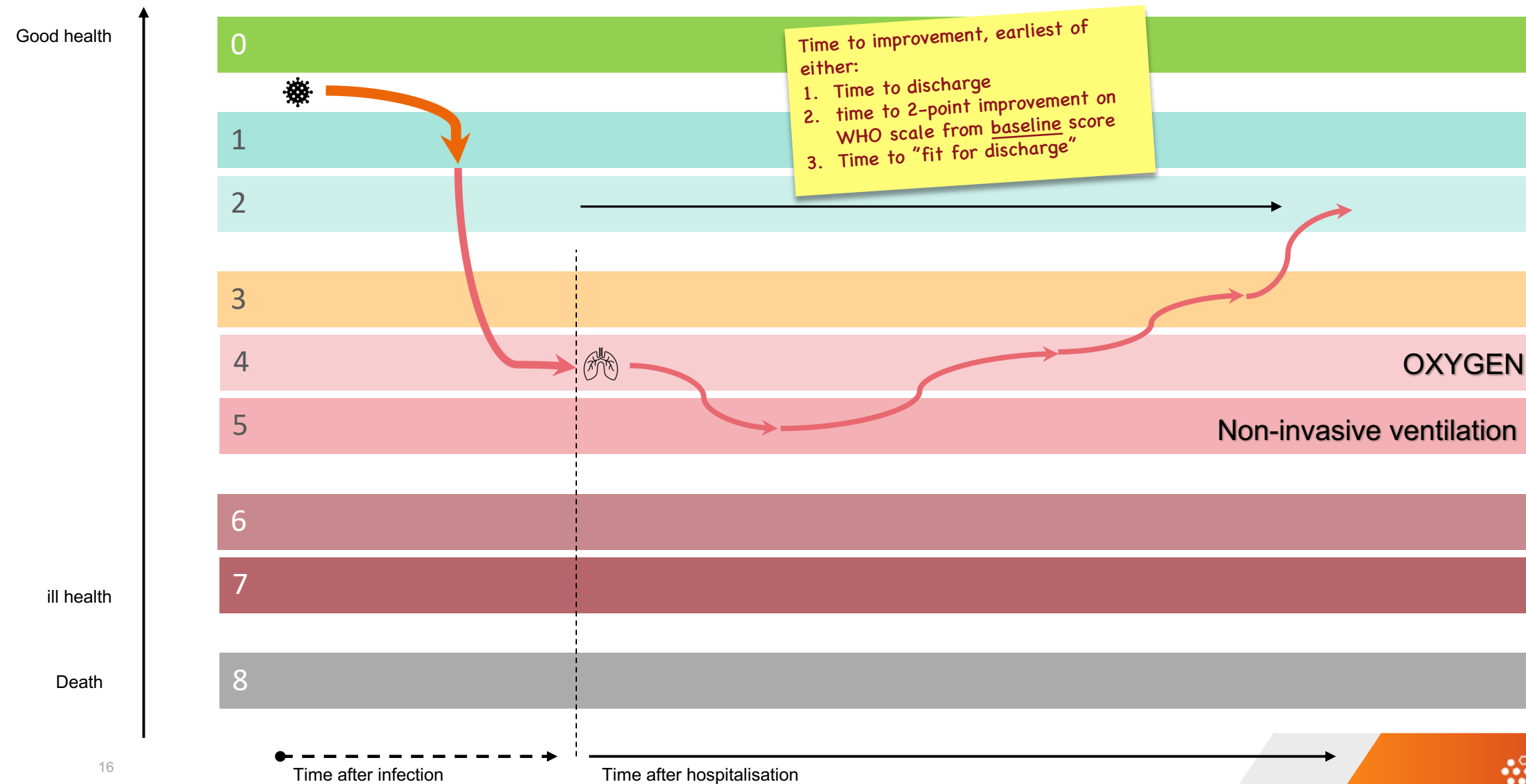


HR=0.310 95% C.I. (0.123, 0.781)

61%

+ SoC  
+ Bemcentinib

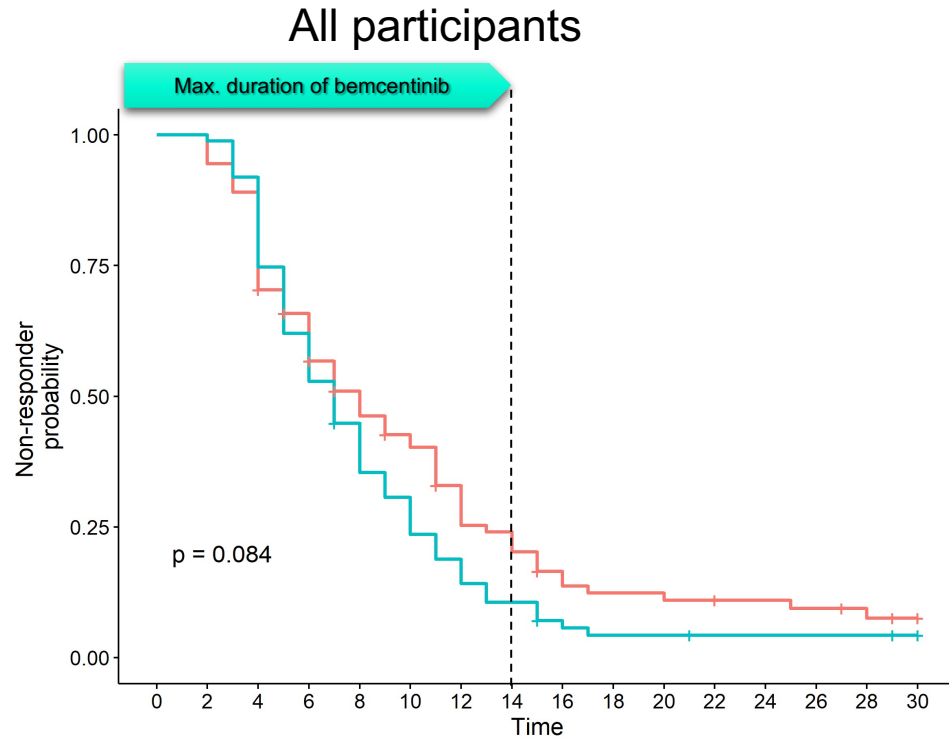
# Primary endpoint – time to improvement (recovery or discharge)





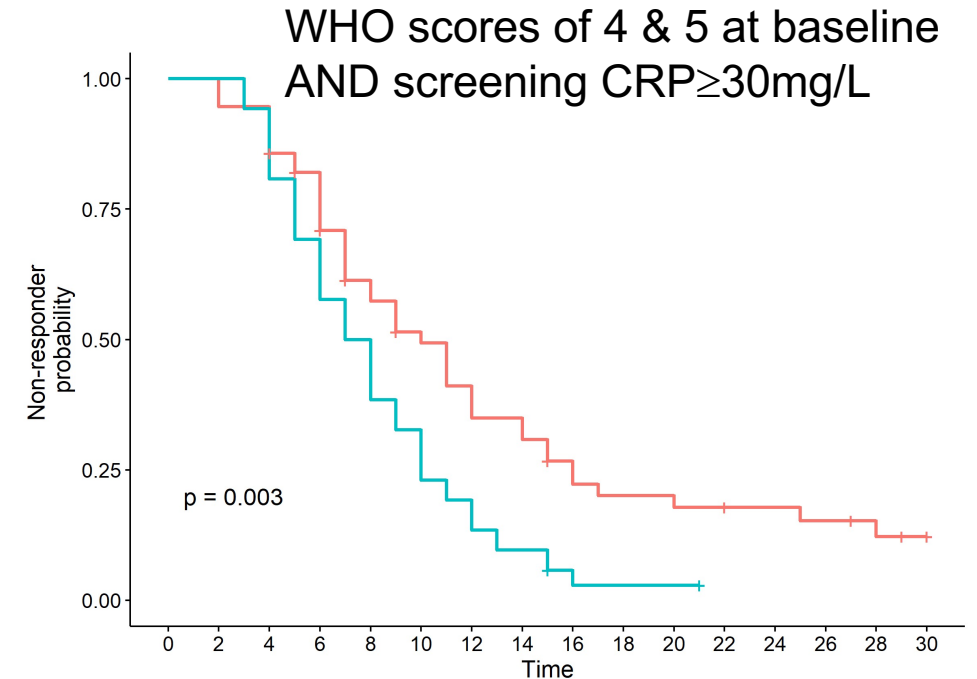
# Primary endpoint: time to recovery or discharge

Significantly increased likelihood (88%) of shorter time to recovery or discharge in higher severity pts.



HR=1.318 95% C.I. (0.964, 1.802)

61%



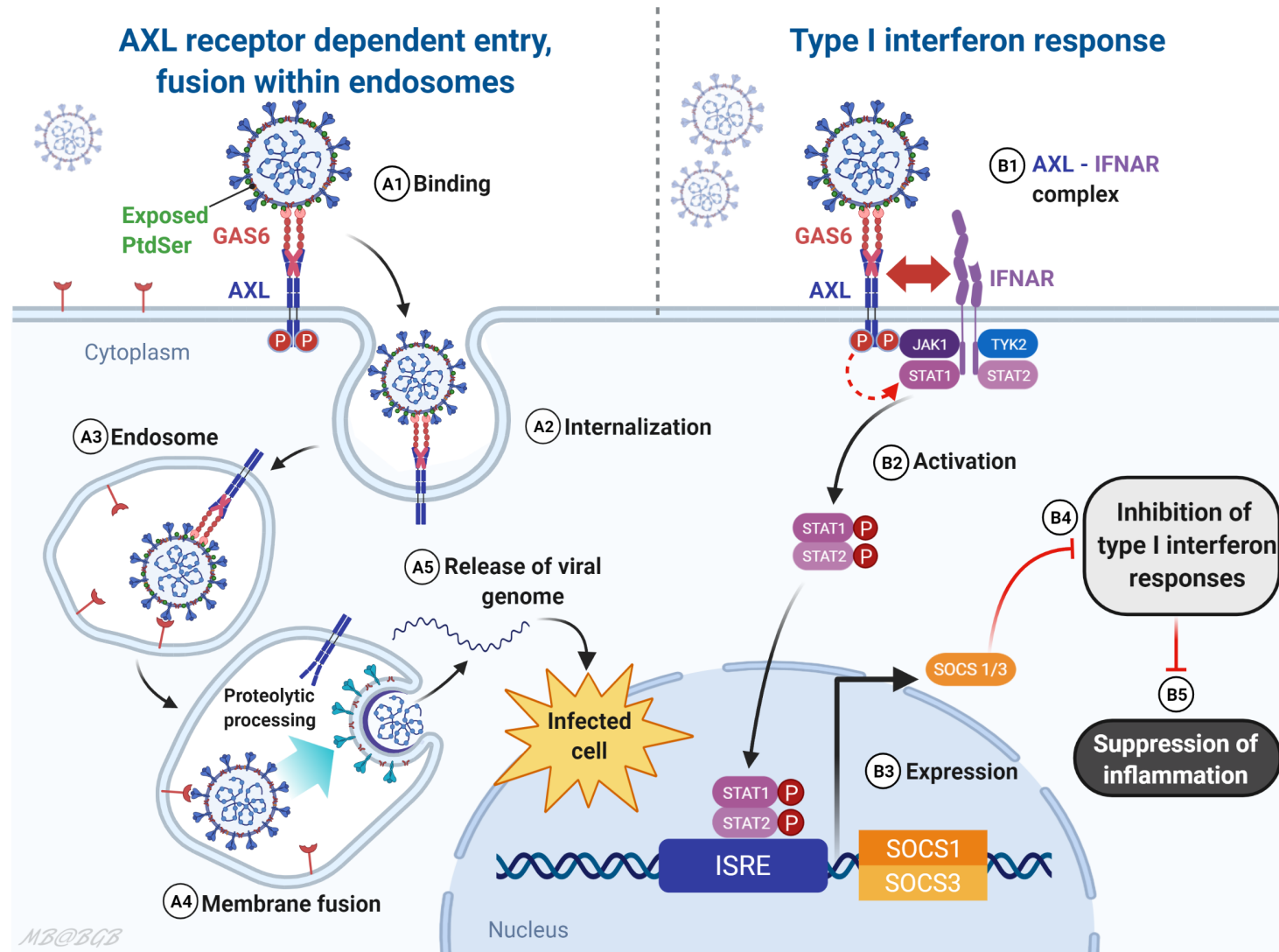
HR=1.884 95% C.I. (1.236, 2.871)

—+— SoC  
—+— Bemcentinib

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

## *“apoptotic mimicry”*

Enveloped viruses display phosphatidylserine, which is recognized by GAS6, the AXL receptor ligand, that mediates viral entry via endosomal pathway

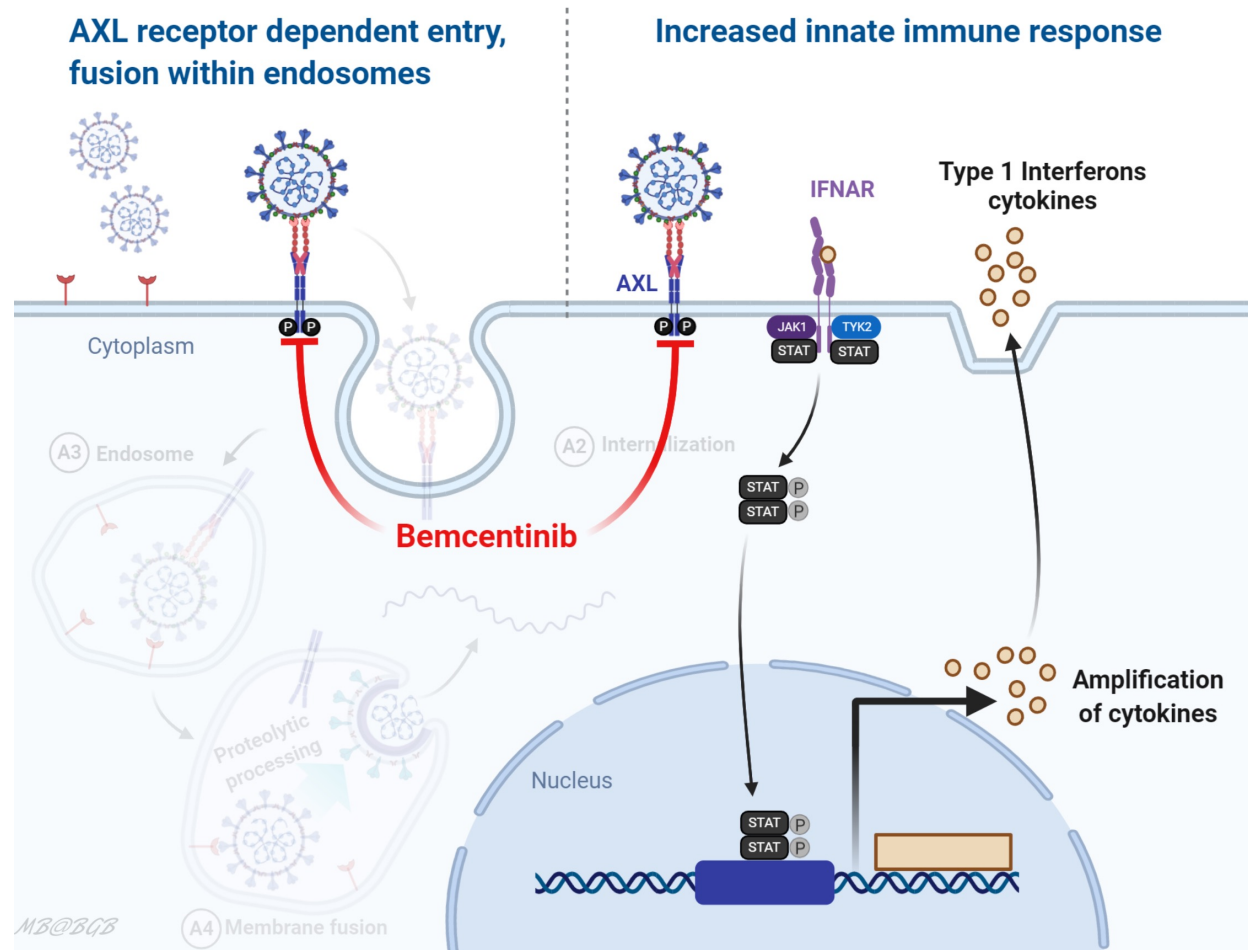


Viral-mediated AXL receptor activation dampens type I interferon responses, key to cellular anti-viral defence mechanism

BerGenBio R&D day, Nov 2020; Prof Wendy Maury 1h9min

<https://vimeo.com/477021607>

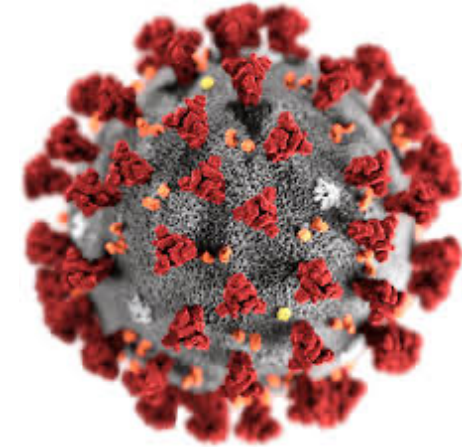
# Bemcentinib acts on two host pathways prevents viral infection and promotes innate immunity



## Bemcentinib:

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

# Summary Bemcentinib potential treatment for COVID-19



In **hospitalised** patients, **requiring oxygen** but not intubated across a diverse range of healthcare scenarios in three continents

When added to corticosteroid based standard-of-care therapy, a finite course of daily oral therapy with bemcentinib:

Showed evidence for therapeutic benefit on meaningful clinical endpoints

- Survival to day 29 - 96.6% vs 91.2% with SoC alone
- Reduced likelihood of progression of pulmonary distress to require ventilation – 69% lower than SoC in higher severity patients
- Increased likelihood of shorter time to recovery or discharge – 88% greater than SoC in higher severity patients

Clinical data adds support to pre-clinical evidence for bemcentinib - host-targeted anti-viral mechanism of action on SARS-CoV2:

- Impairing viral cell entry
- Enhancing innate type-1 IFN immune response to virus
- Independent of variant(s)

This signal of therapeutic benefit, requires confirmation in a prospectively designed placebo RCT – magnitude of effect indicates the requisite study population for statistical power, would likely be of modest size.

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
- ✓ EHA conference

# 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

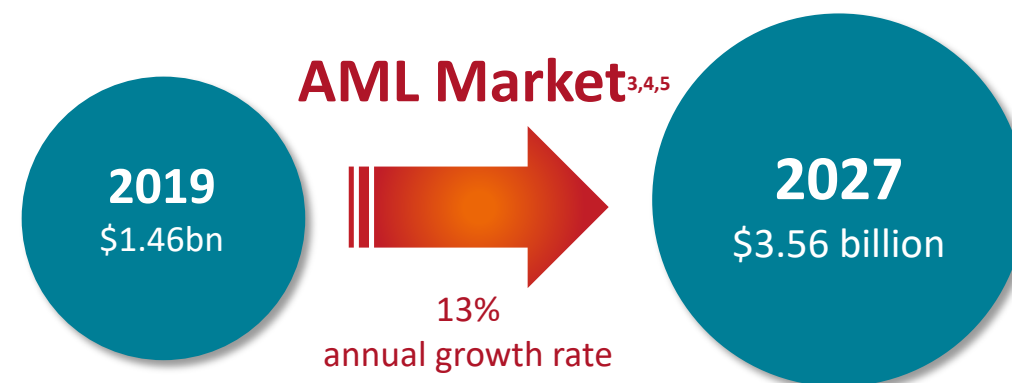
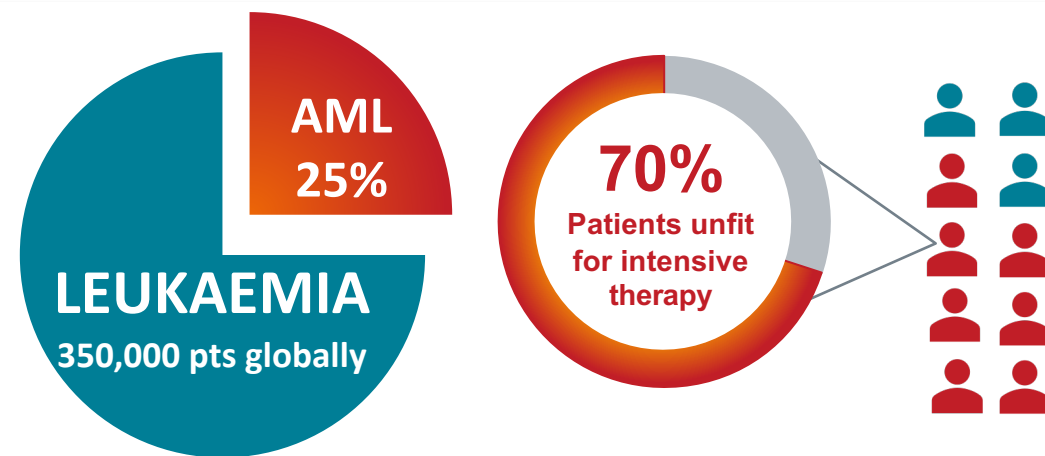
Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years<sup>6</sup>

## 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)

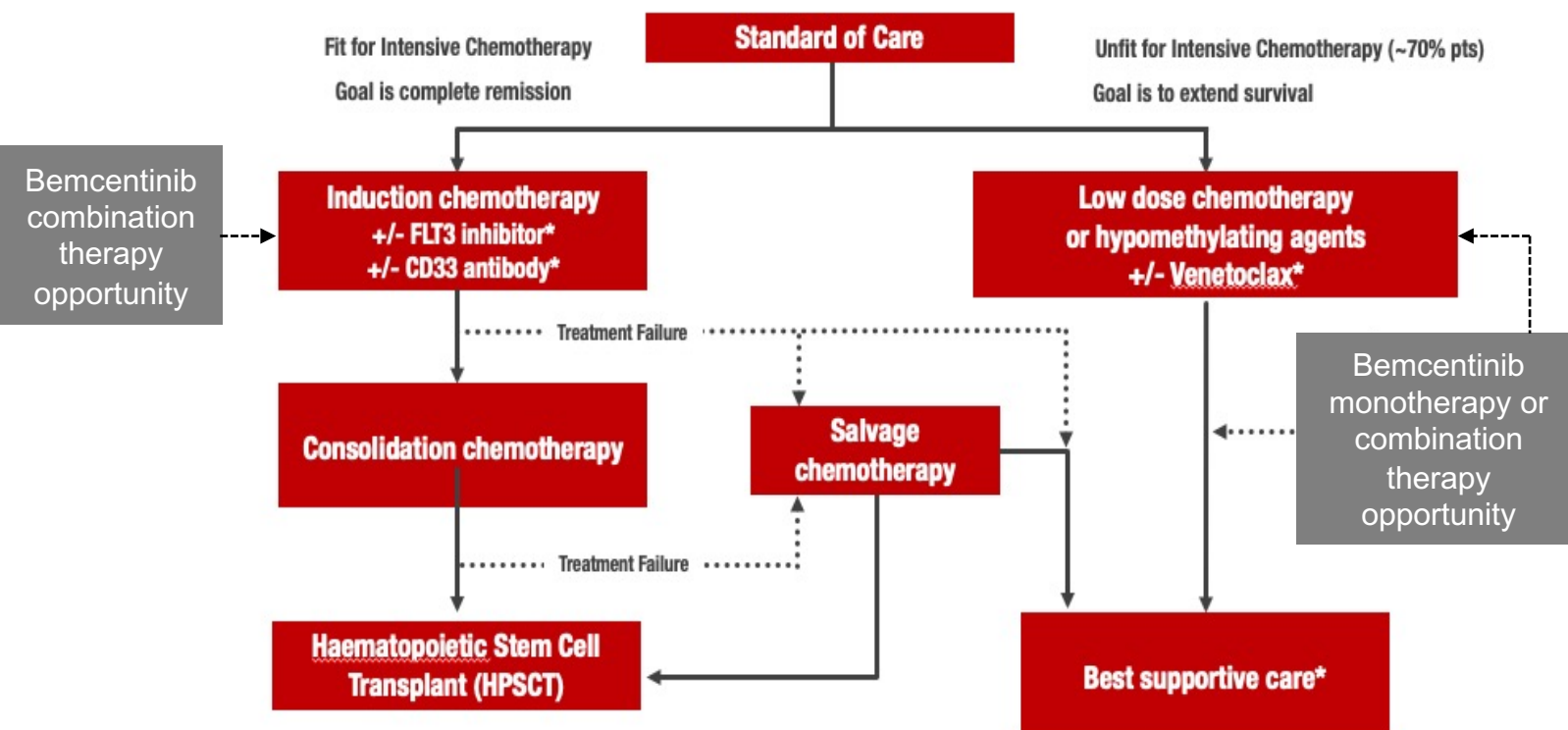
(4) <https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics> (5) <https://www.businesswire.com/news/home/20190319005442/en/> (6)

<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

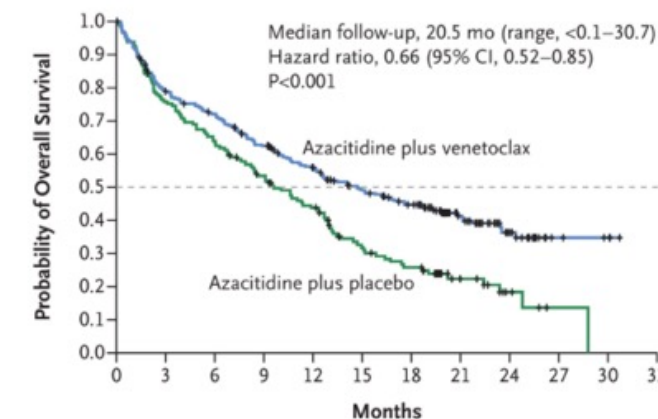
# Relapse AML – the need for new treatment options

## 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  
r/r 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  
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

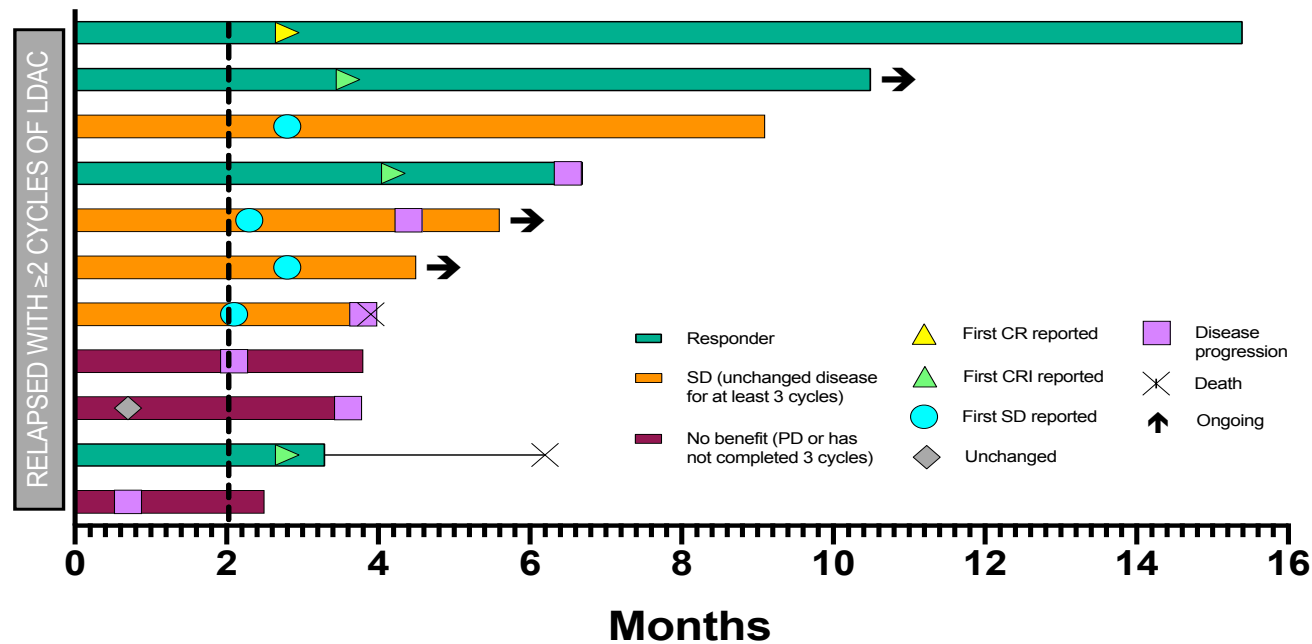
**Cohort B4 n=14**  
Monotherapy MDS

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

# Preliminary Efficacy assessment for relapsed AML pts with $\geq 2$ cycles of

## Bemcentinib+LDAC (n=11\*)

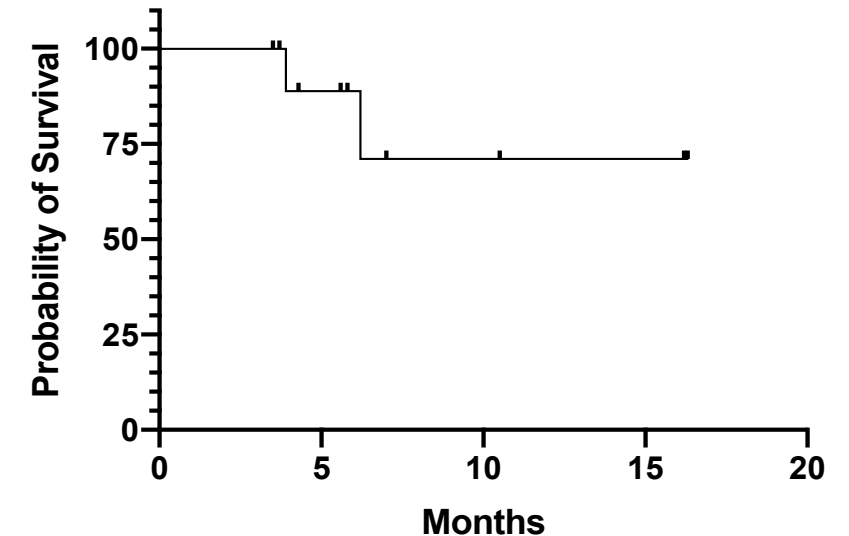
### Time on Treatment



\*Subset of patients who demonstrated increased clinical benefit and response rates had the following characteristics:

- Continued treatment beyond 8 weeks (56 days), and
- received  $\geq 2$  cycles of Bem+LDAC
- BM assessment beyond 8 weeks

### Overall survival



### mOS not reached

6 months OS = 70%  
12 months OS = 70%



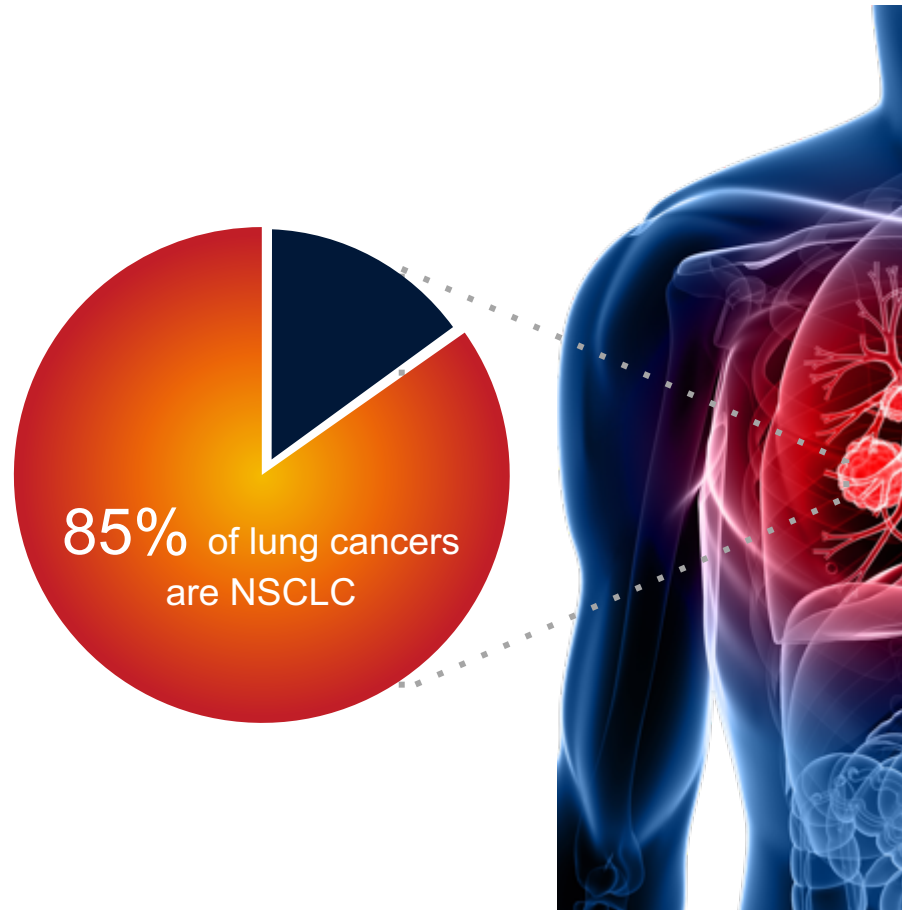
**Bemcentinib clinical development in:**

**Refractory NSCLC with  
bemcentinib/pembrolizumab combination**





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



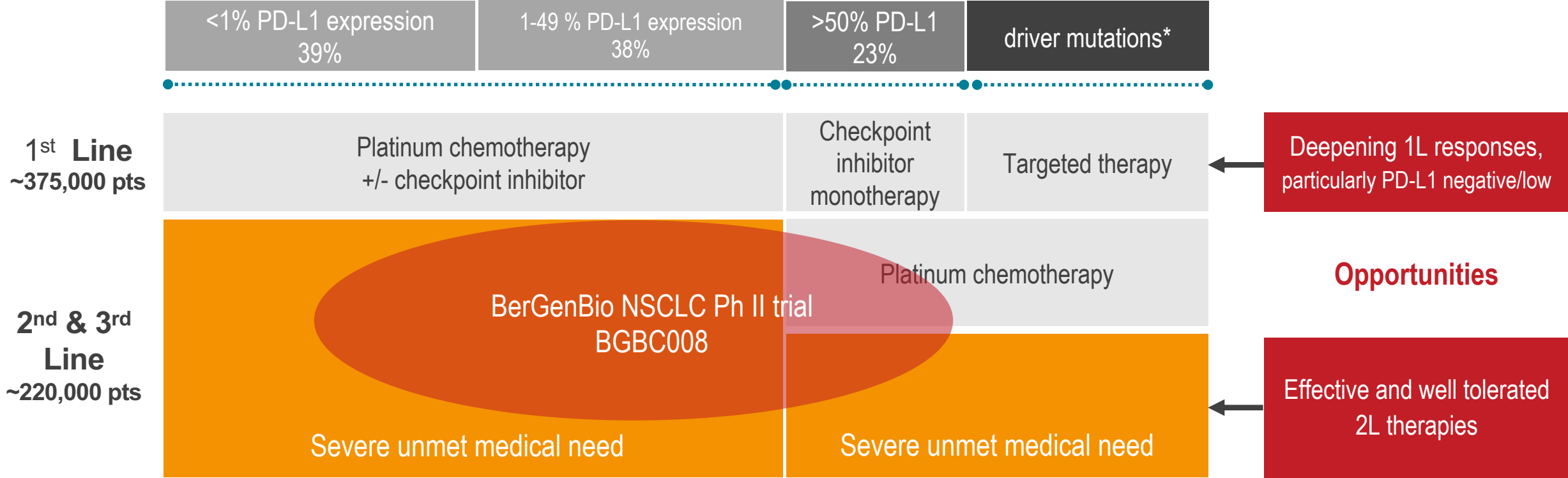
## The largest cancer killer, most patients depend on drug therapy

- 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



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

# 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

### Pending

Stage 2

N=29 patients

# U.S. Food and Drug Administration (FDA) has granted Fast Track designation for bemcentinib in combination with an anti-PD-(L)1 agent for the treatment of patients with AXL -positive advanced/metastatic non-small cell lung cancer (NSCLC)

## Recognition

- ✓ The first formal recognition by a regulator of AXL-positive patients as a discernible patient population
- ✓ BerGenBio has developed proprietary biomarkers and companion diagnostic assays for selection of AXL positive patients, the cAXL assay is validated for clinical trial use
- ✓ Retrospective analysis of patients in clinical trials suggest approximately 50% of patients are cAXL positive, and it is these patients that achieve the clinical responses and extended survival benefit previously reported.

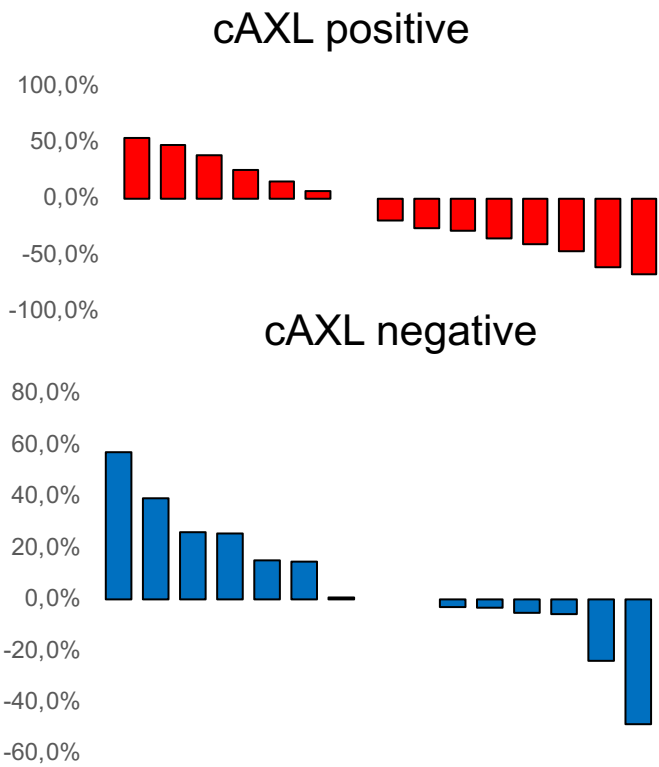
## Benefits of Fast Track



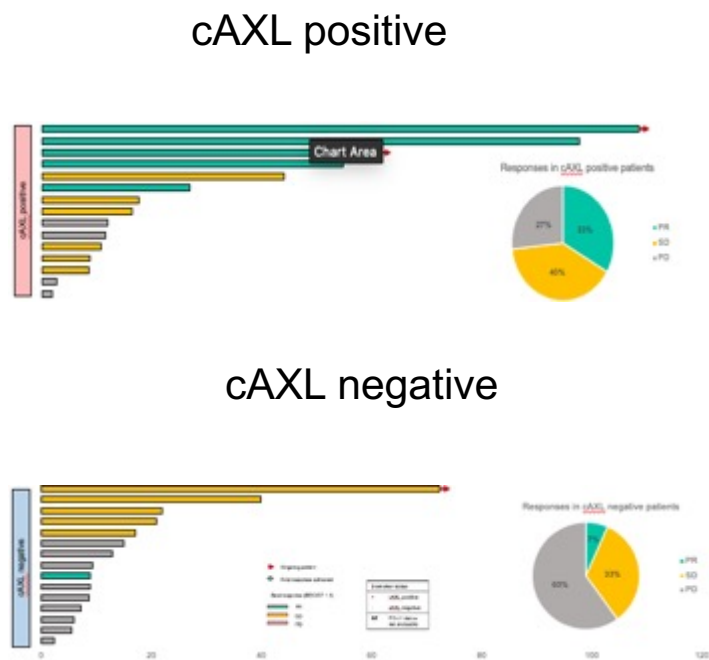
Kalkine Image (Source: FDA)

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

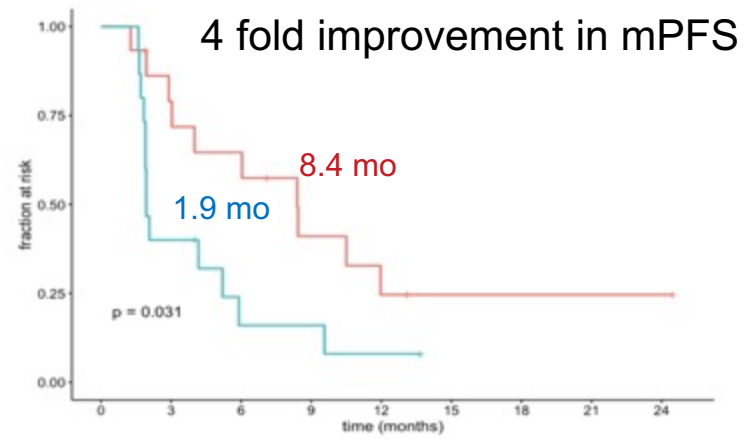
## Change in tumor size



## Duration of response



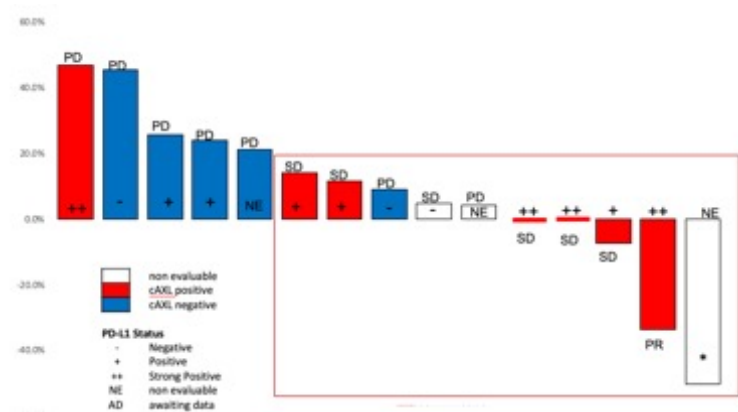
## Survival benefit



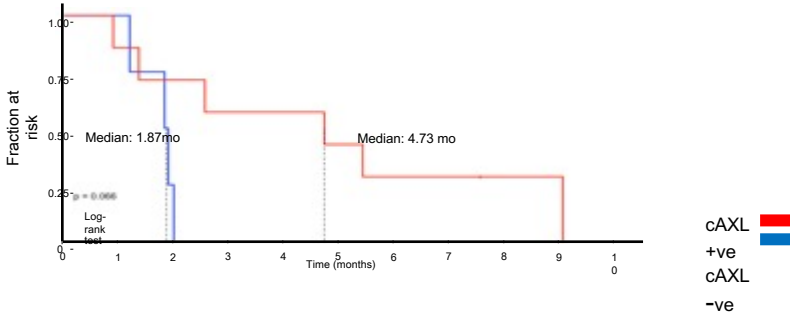
Cohort	mOS	12-mo OS
Cohort A – cAXL +ve pts**	17.3 mo*	79%
Cohort A – cAXL -ve pts**	12.4 mo*	60%
BGB Cohort A – all pts**	12.6 mo*	64%* (up to 67%)
CheckMate-057 (Opdivo)	12.2 mo	51%
KEYNOTE-010 (Keytruda)	10.4 mo	43.2%

# cAXL predicts improved patient outcomes from Bemcentinib + Pembrolizumab in 2L NSCLC CPI refractory patients

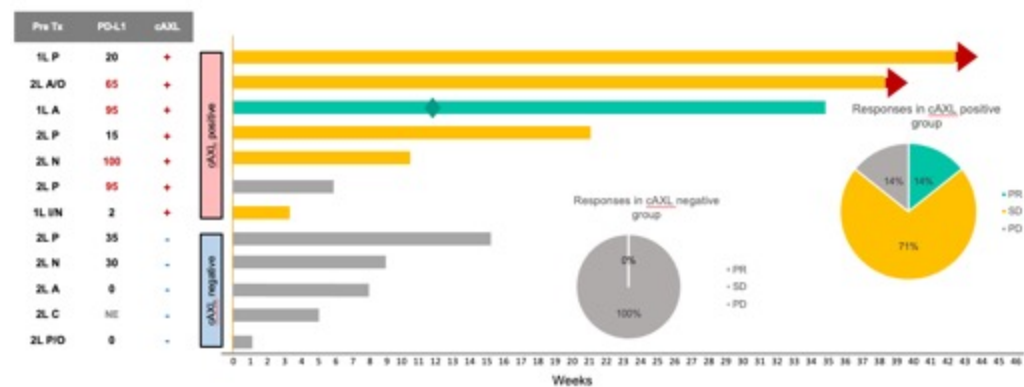
## Change in tumour size



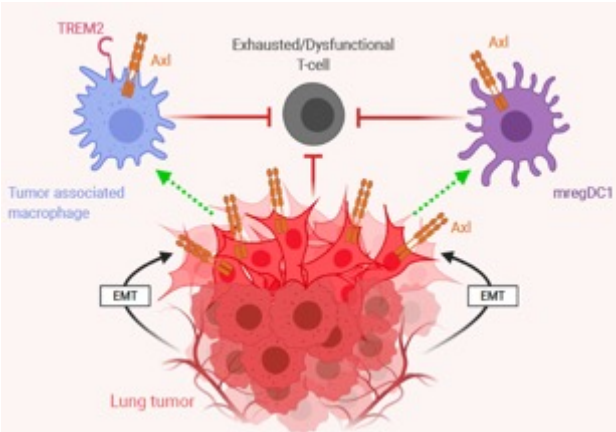
## 2.5 fold improvement in median progression free survival



## Duration of response



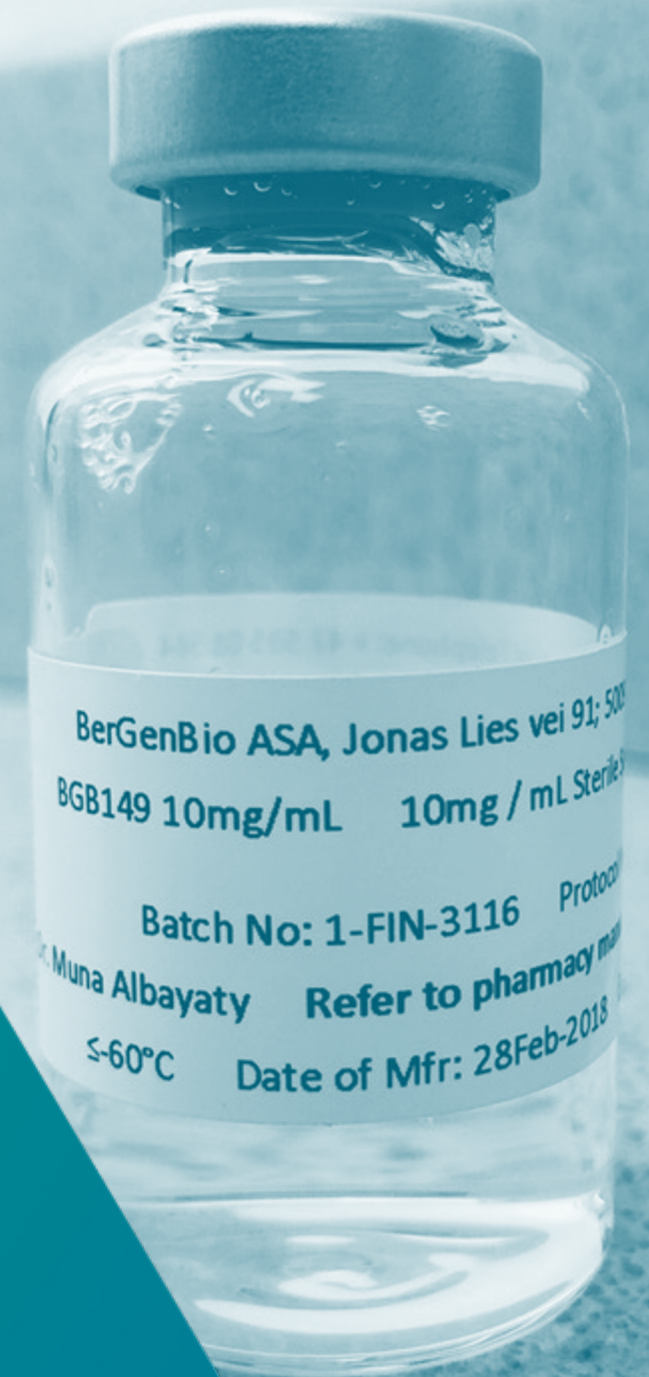
## AXL<sup>+</sup>ve immune suppressive cells identified



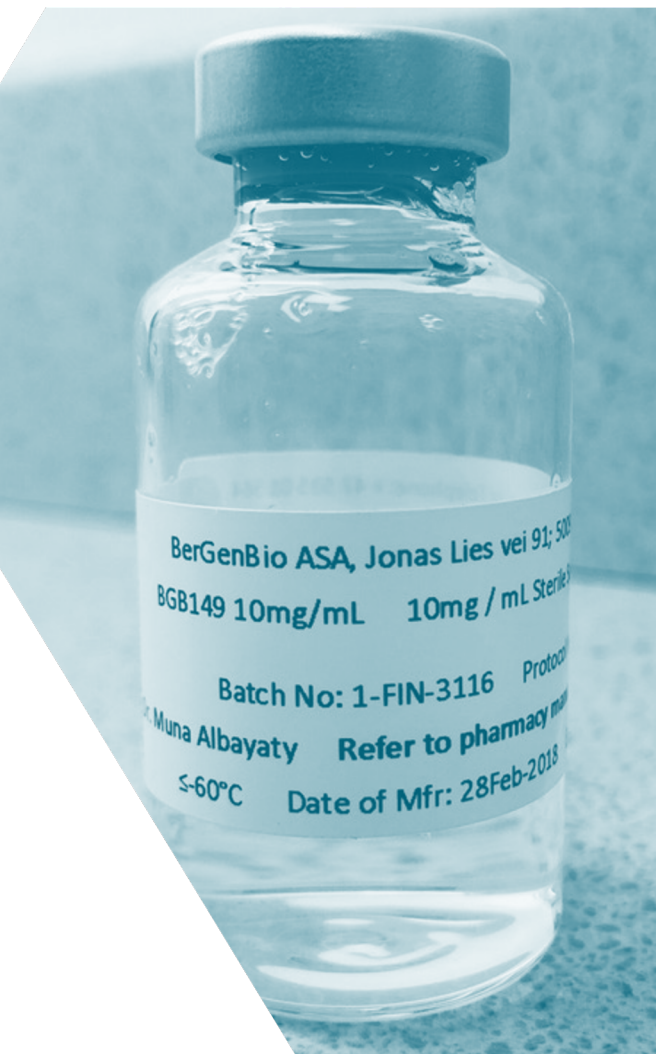




# Tilvestamab (BGB149) anti-AXL monoclonal antibody



# TILVESTAMAB: Anti-AXL monoclonal antibody



Functional blocking fully-humanised IgG1 monoclonal antibody

Binds human AXL, blocks AXL signalling

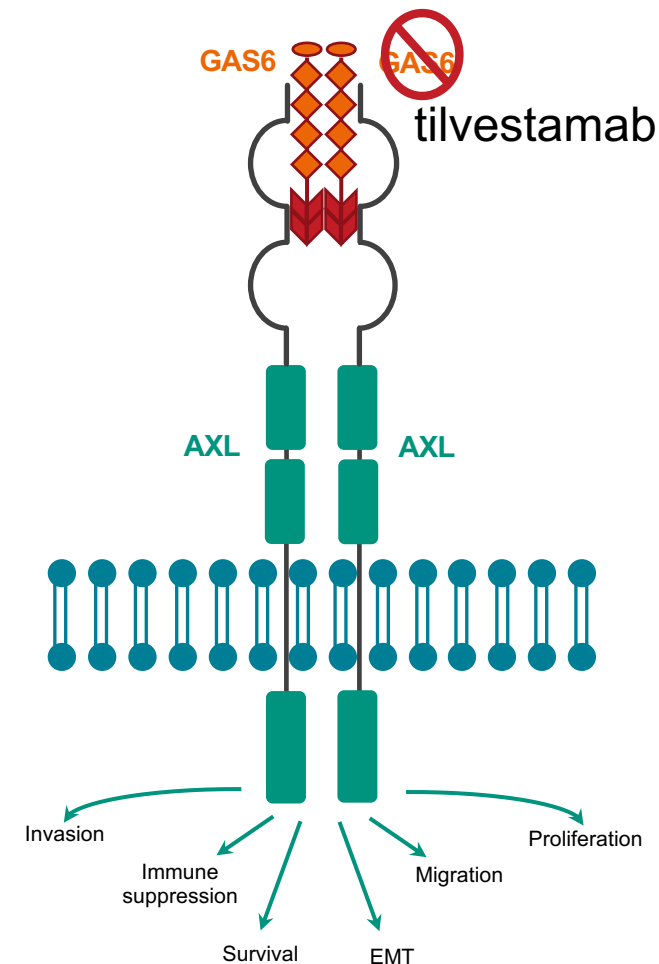
High affinity (KD: 500pM), displaces GAS6  
Anti-tumour efficacy demonstrated *in vivo*

Robust manufacturing process established,  
18 months stability

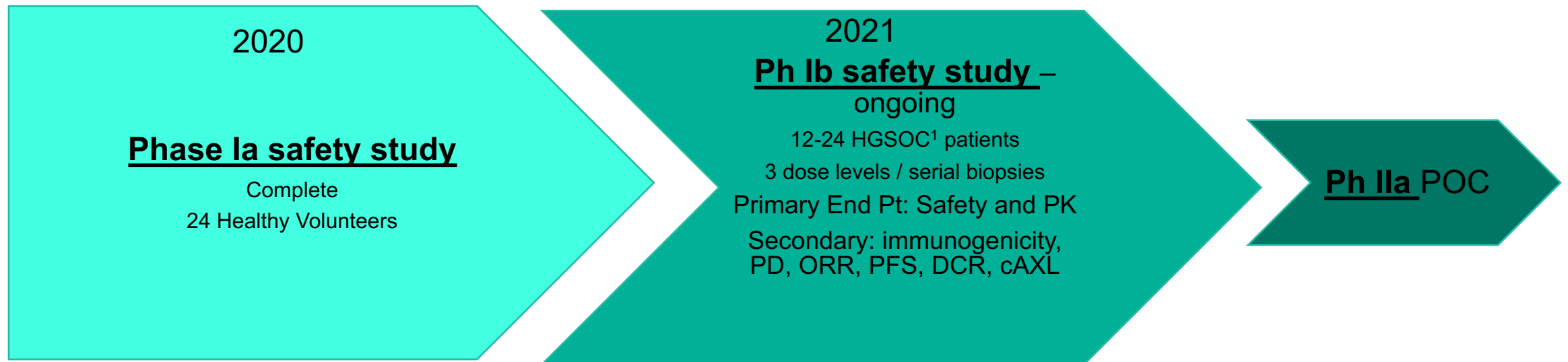
Phase Ia healthy volunteer SAD study complete

**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 I SAD trial complete  
Phase Ib/IIa MAD ongoing



# Tilvestamab development plan



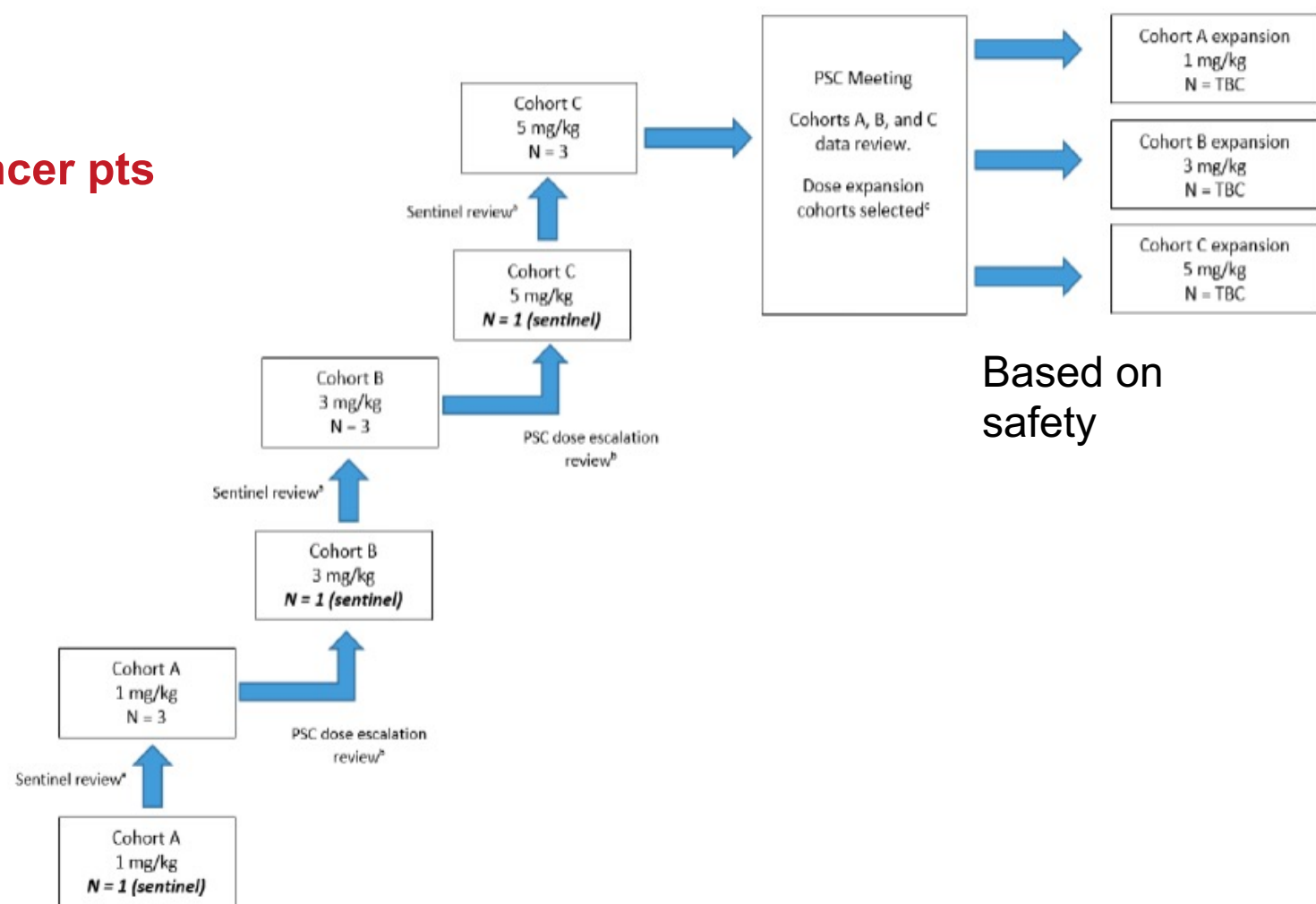
**Safety** – no dose limiting toxicity seen up to 3mg/kg dose  
**Pharmacokinetics** - exposure predictable with dose proportional C<sub>max</sub> increase  
Confirmatory evidence of *in vivo* target engagement with sAXL -- stabilisation in circulation

# Tilvestamab multiple ascending dose finding safety and pharmacokinetics study

## BGB149-102

### Study in platinum resistant ovarian cancer pts

- High AXL in 70% of available OC population
- Biopsy patients selected up front – high success rate
- Good experience across global centres of mandatory sequential biopsy
- MAD study will ensure PK/PD across dose range to facilitate phase II dose confirmation
- Strong probability of success for Proof of Mechanism





# Finance Report

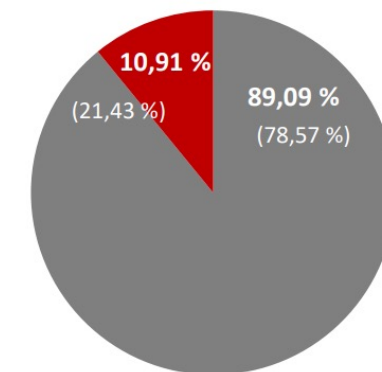
CFO Rune Skeie



# Key financial figures

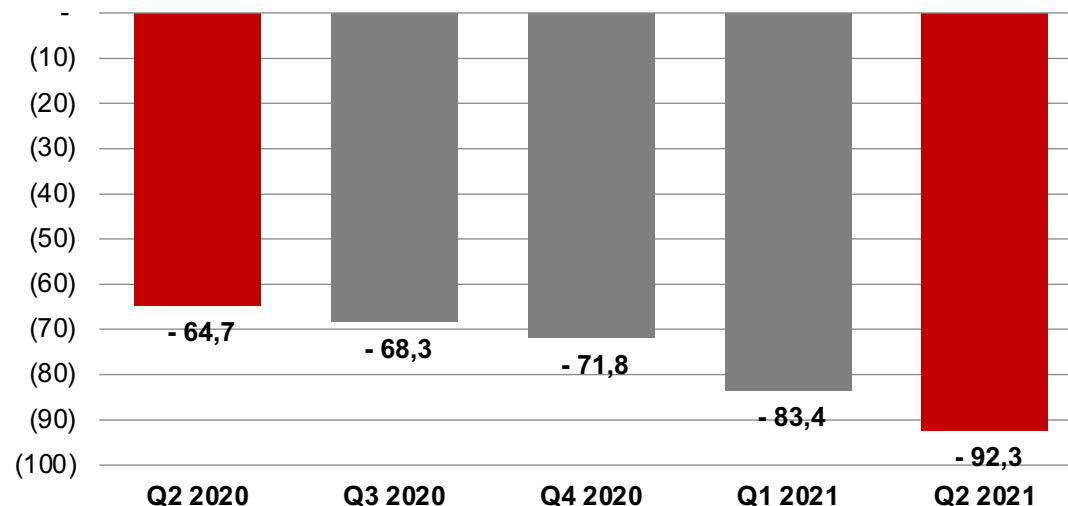
(NOK million)	Q2 2021	Q2 2020	YTD 2021	YTD 2020	FY 2020
Operating revenues	0,0	0,0	0,0	0,0	0,6
Operating expenses	92,3	64,7	175,7	121,0	261,7
Operating profit (-loss)	-92,3	-64,7	-175,7	-121,0	-261,1
Profit (-loss) after tax	-88,9	-67,3	-170,1	115,8	-257,0
Basic and diluted earnings (loss) per share (NOK)	-1.02	-0.86	-1.94	-1.59	-3.43
Net cash flow in the period	-82,4	412,3	-144,2	571,3	468,8
Cash position end of period	574,0	828,4	574,0	828,4	721,6

Operating expenses Q2 2021  
(Q2 2020)



■ R&D ■ Administration

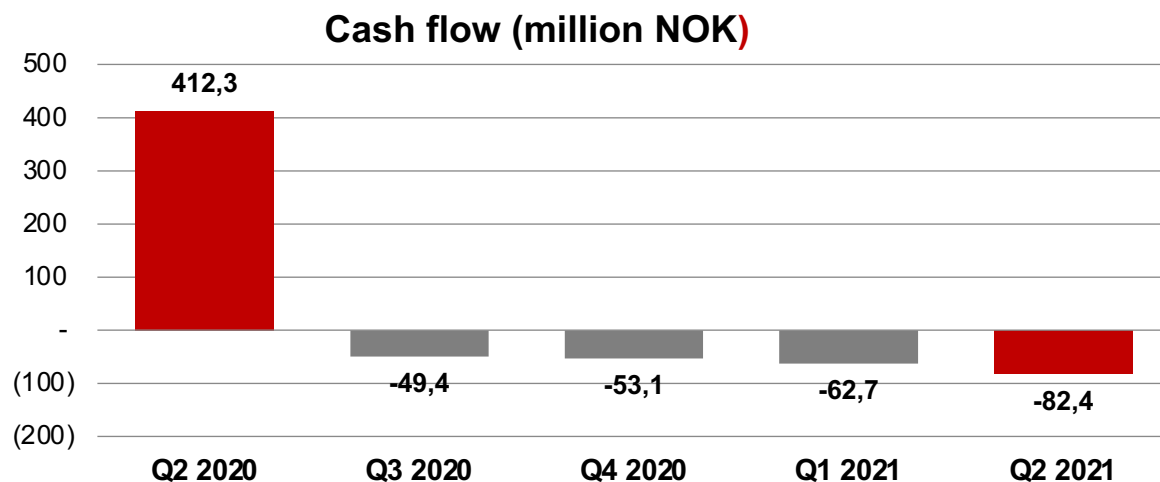
Operating loss (million NOK)



- Increased operating expenses in the second quarter 2021 compared to second quarter 2020 is attributed to new clinical studies and organisational expansion in preparation for late- stage development.
- Well managed overhead costs
- Over 89 % of operating expenses is attributable to Research & Development activities



# Cash flow and cash position



Cash burn operating activities Q2 2021

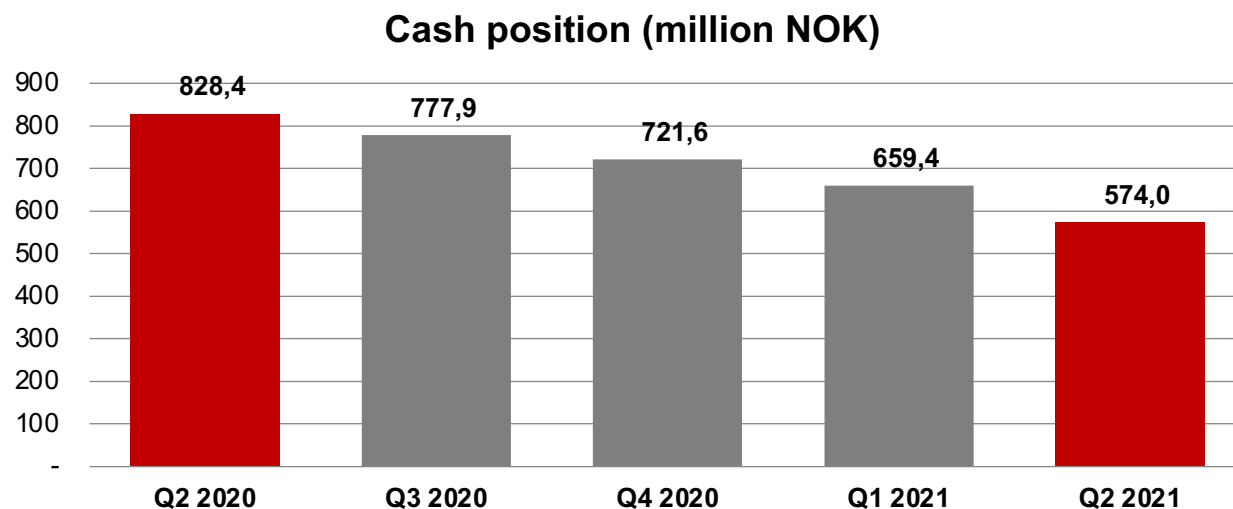
**84.4 / 10.0**

**NOK million    USD million**

Quarterly average cash burn (Q2 2020-Q2 2021)

**61.9 / 6.9**

**NOK million    USD million**



Cash position Q2 2021

**574.0 / 67.1**

**NOK million    USD million**

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## Financial Calendar 2021

**17 August 2021: Half-year report 2021**

**16 November 2021: Quarterly Report Q3 2021**

**15 February 2021: Quarterly Report Q4 2021**

# 2021 Highlights & Outlook

# 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 options



AML mOS data  
& regulatory  
alignment

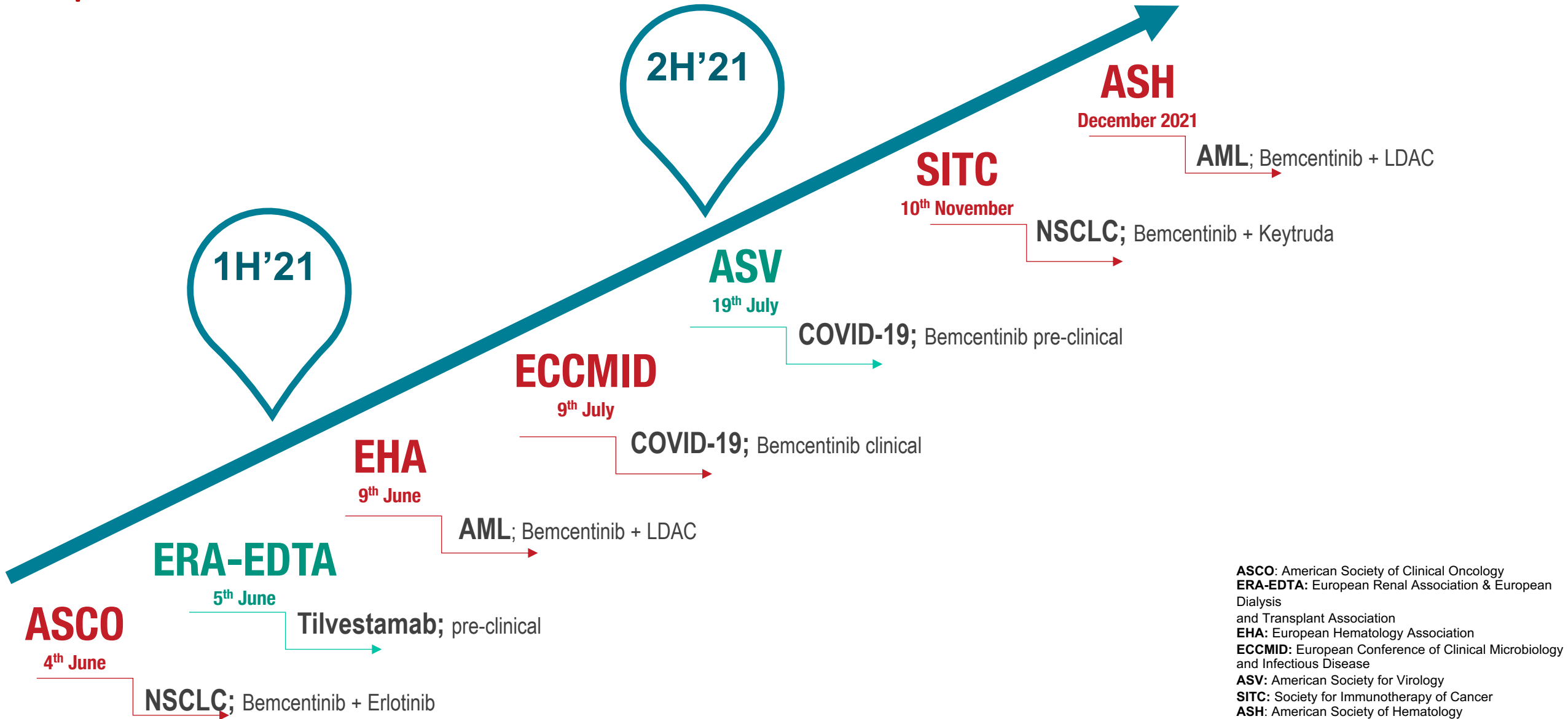
- Survival data  
- Regulatory  
alignment



Tilvestamab  
Ph II

- Prepare to  
Initiate Ph II

# Expected news flow at conferences in 2021



# BerGenBio – Investment highlights



## Near term milestones

Regulatory alignment:

COVID-19  
AML



## Diversified Clinical Pipeline

AML (FT/Orphan)  
Covid-19

NSCLC (FT)

MDS  
Multiple ISTs



## TWO first in class selective AXL inhibitors

Bemcentinib - oral  
once-a-day capsule

Tilvestamab –  
humanised functionally  
blocking mAb



## 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