



H1/Q2 2021 REPORT, HIGHLIGHTS AND FINANCIALS

17th August 2021

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Forward Looking Statements

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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	- Encouraging data from 2 rPhII trials suggest potential effective treatment option
AML	- <i>mOS</i> preliminary data are encouraging, regulatory alignment is ongoing
NSCLC	- On going Ph II in CPI refractory patients, data pending
Tilvestamab	- Ongoing Phase Ib
Regulatory	- Active engagement with regulators seeking alignment for AML and COVID-19 - FDA Fast Track designation awarded for 2L NSCLC
Partners	Ongoing discussions with Governments and Industry Partners
Cash	NOK 574m
Outlook	Clinical data in AML and COVID 19 is encouraging. Seeking Regulatory alignment for registration trials. Strong organization and well financed for current activities and immediate milestones.

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.

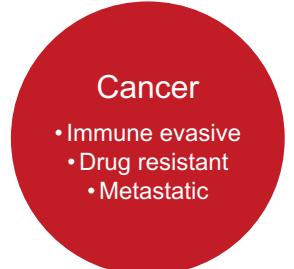
July
2021

- 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

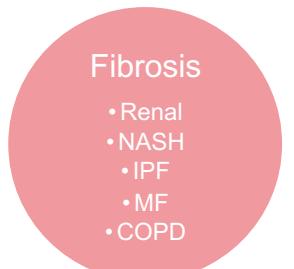
AXL signaling is upregulated by hostile cellular microenvironment and viral infection



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



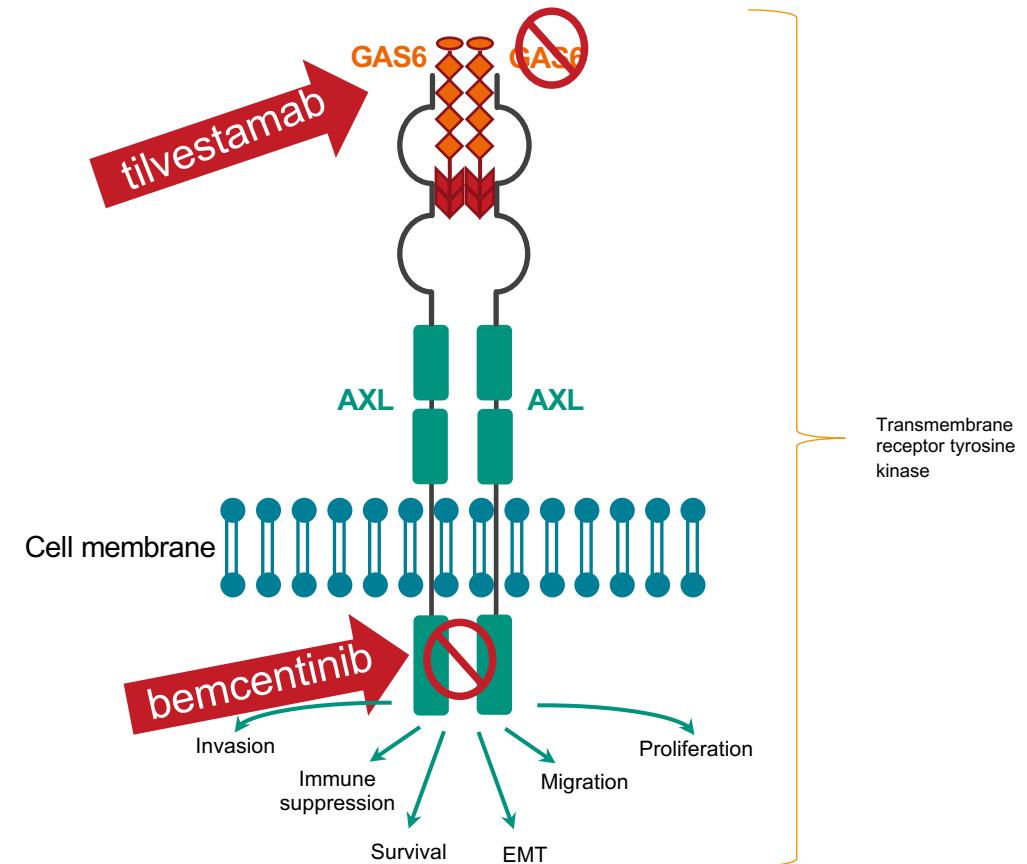
AXL mediates viral entry to cells and dampening of viral immune response



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*



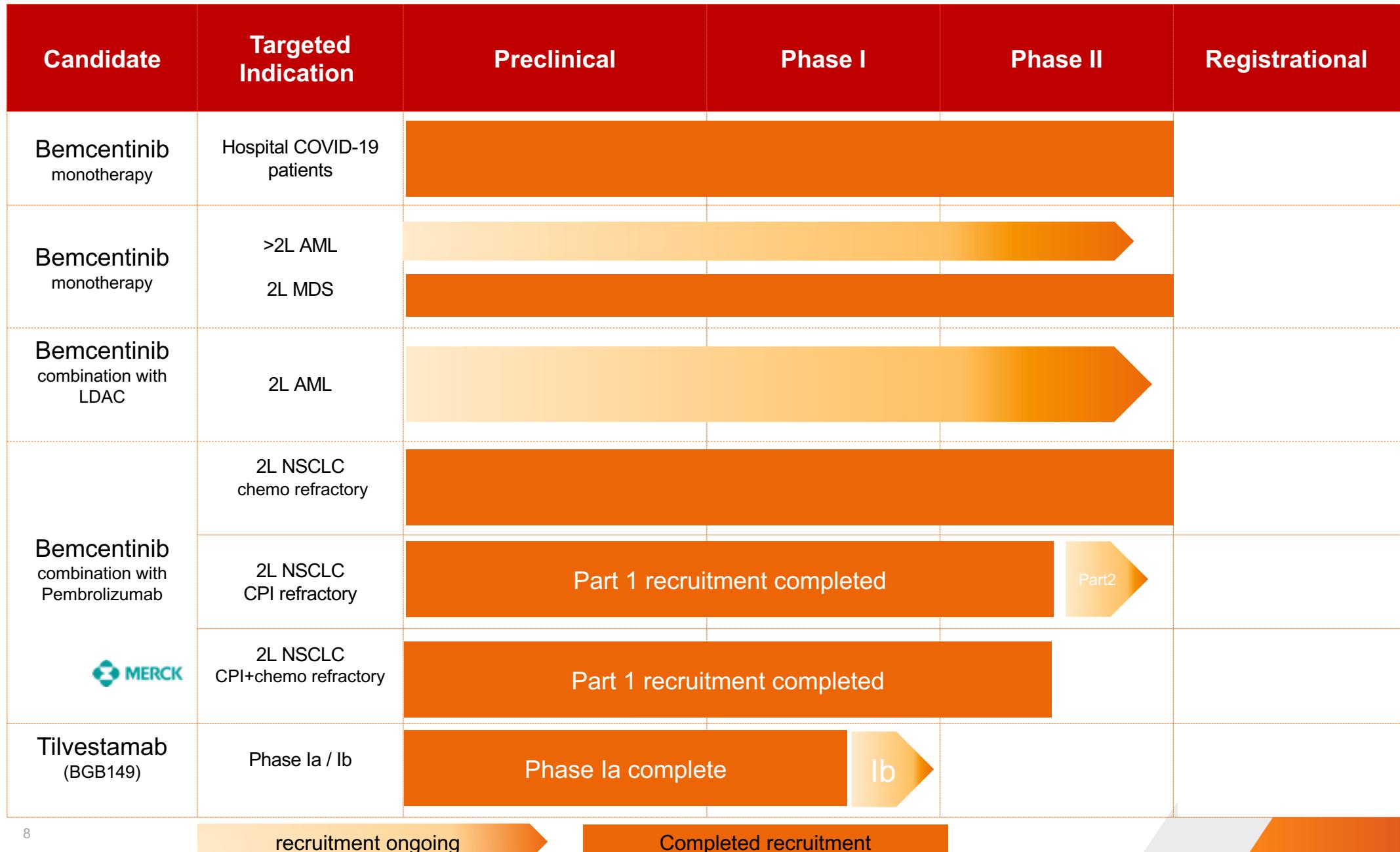
- Oral, once a day
- Size 0 capsule
- Stable simple drug product
- Favorable Safety and tolerability confirmed >400 patients
- Combines well with other drugs
- Phase III ready

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/Ila ongoing
 - Serial biopsies to confirm PK-PD

Pipeline of sponsored clinical trials

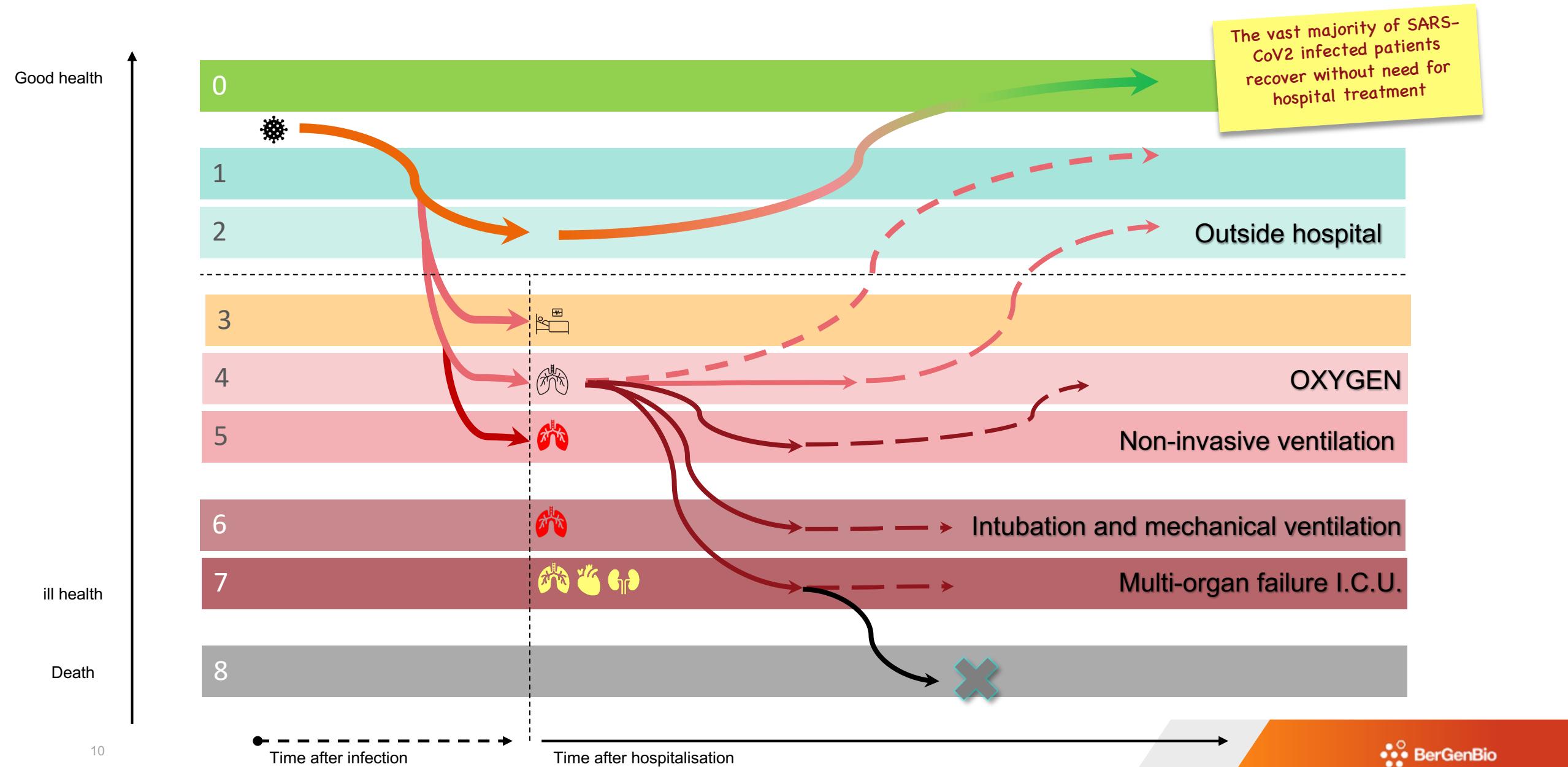


TWO RANDOMISED PHASE II STUDIES ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

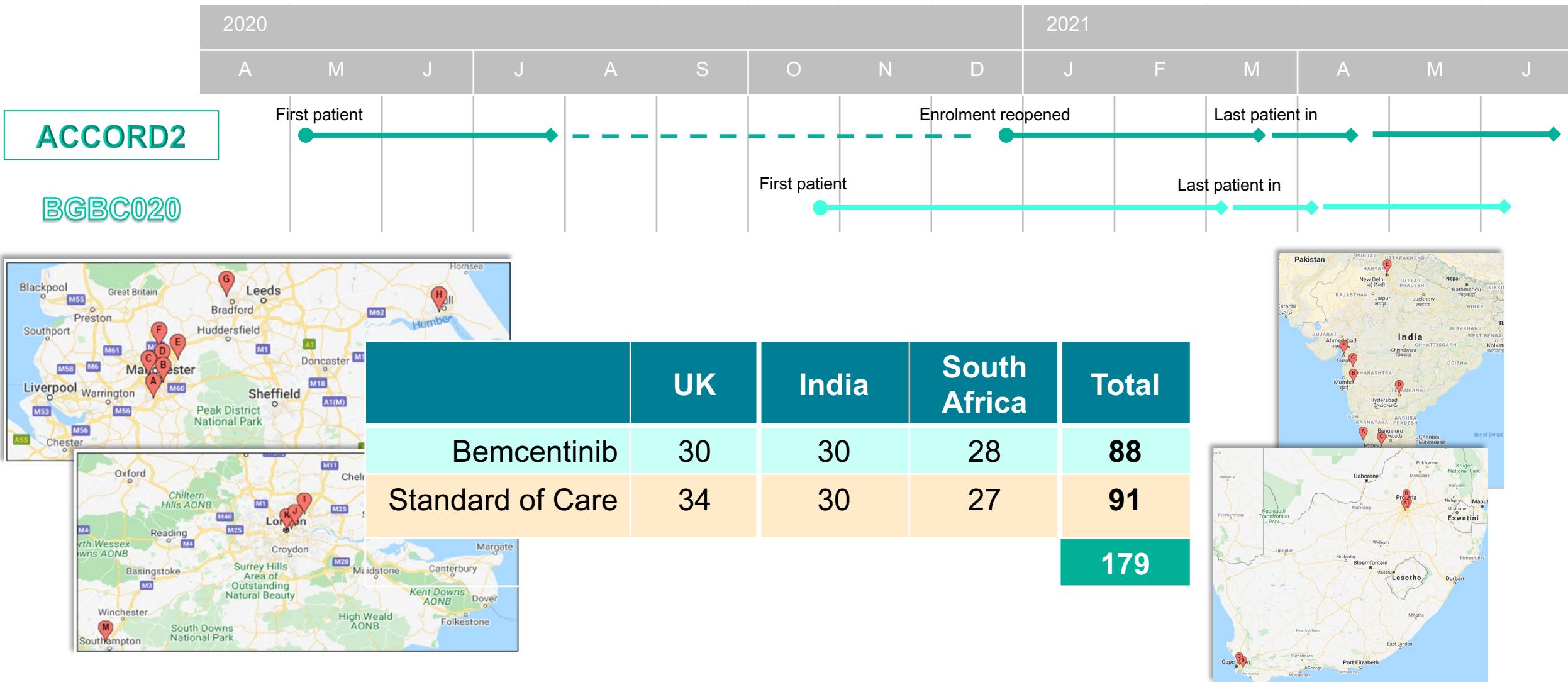
ECCMID 2021: European Congress of Clinical Microbiology and Infectious Diseases

- 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

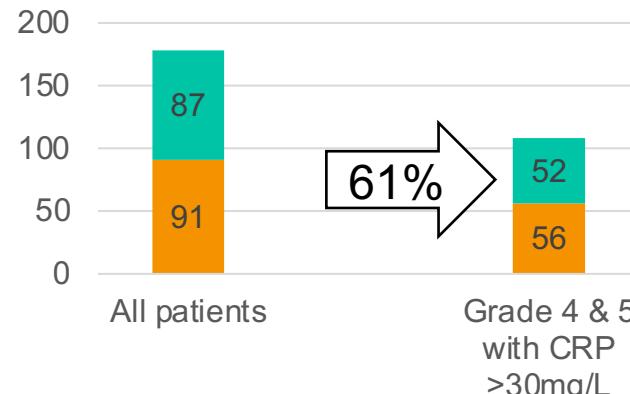


Baseline patient characteristics and Safety

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

Baseline WHO OCS	BGBC020			ACCORD2			
	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)

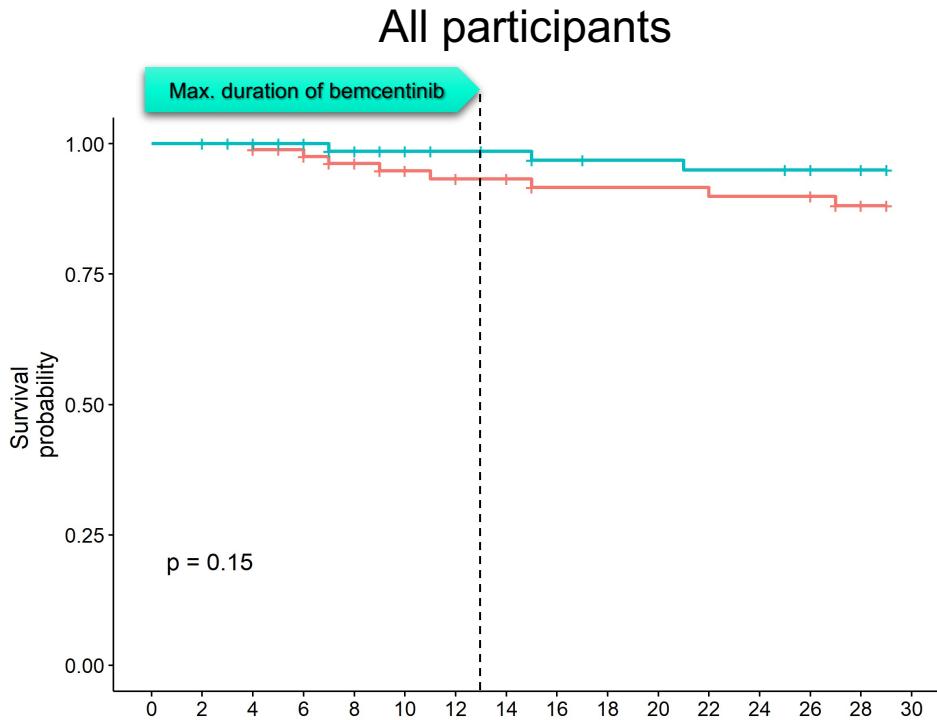
1 interrupted bemcentinib due to diarrhoea

No SUSAR

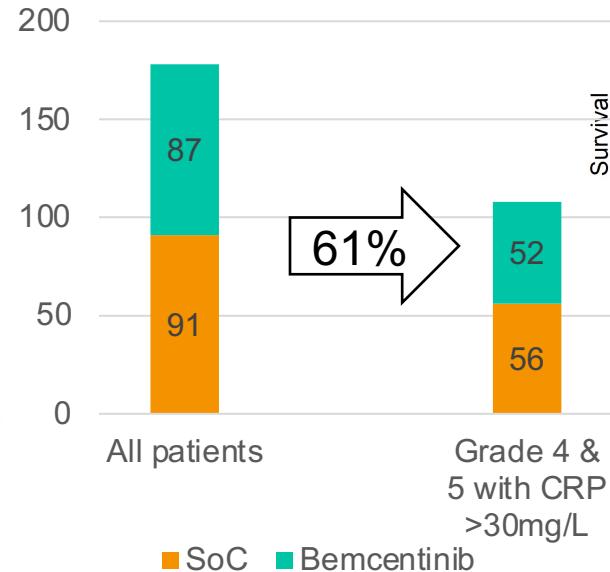
IDMC review; no safety or tolerability signal of concern for further development in this COVID19 patient population.

Survival (day 29 after enrolment)

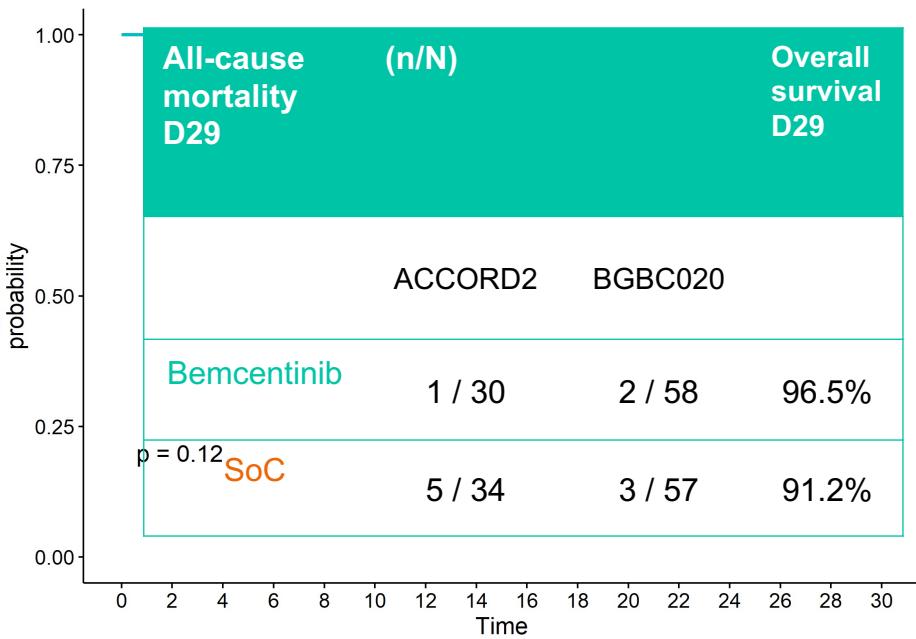
survival of 96.6% in bemcentinib arm vs. 91.2% in standard of care



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



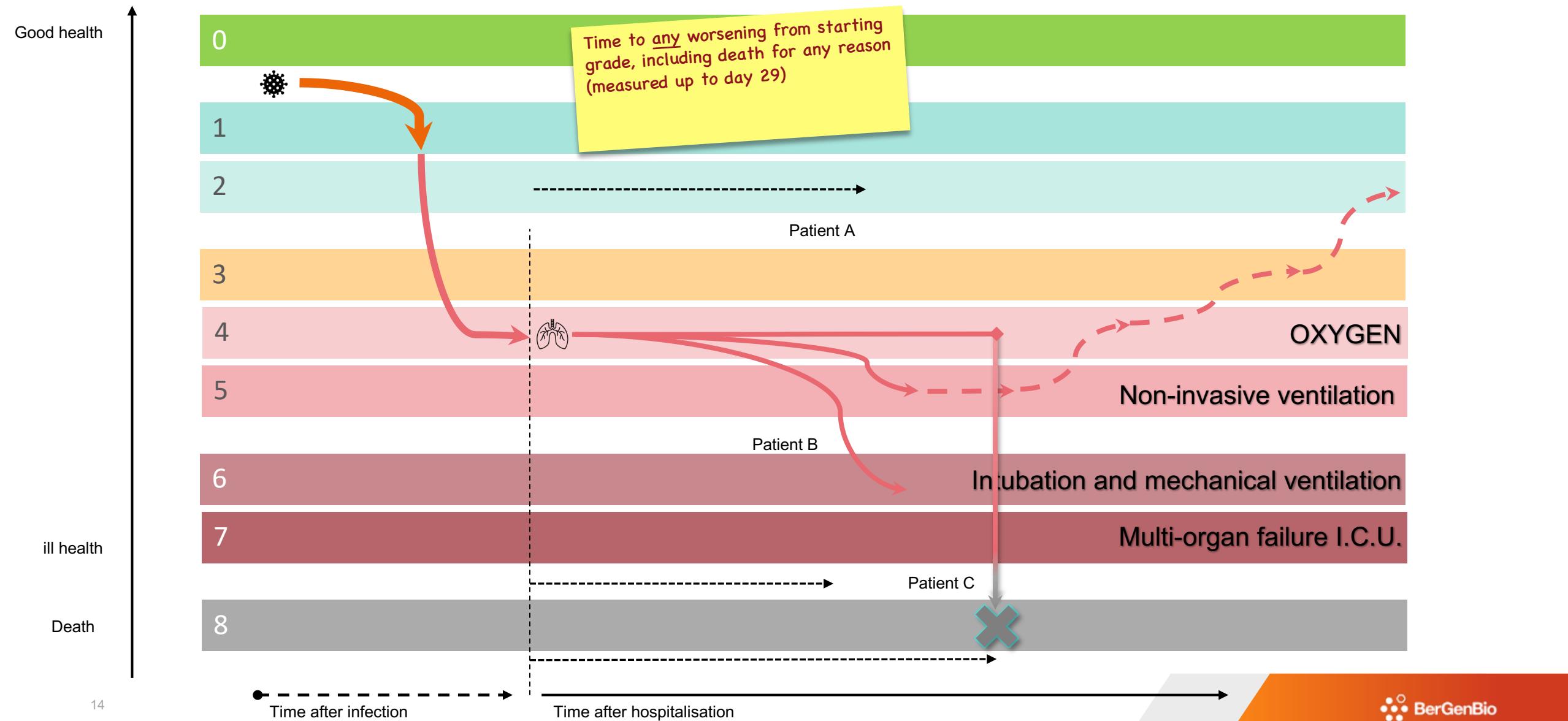
WHO scores of 4 & 5 at baseline
AND screening CRP \geq 30mg/L



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

■ SoC
■ Bemcentinib

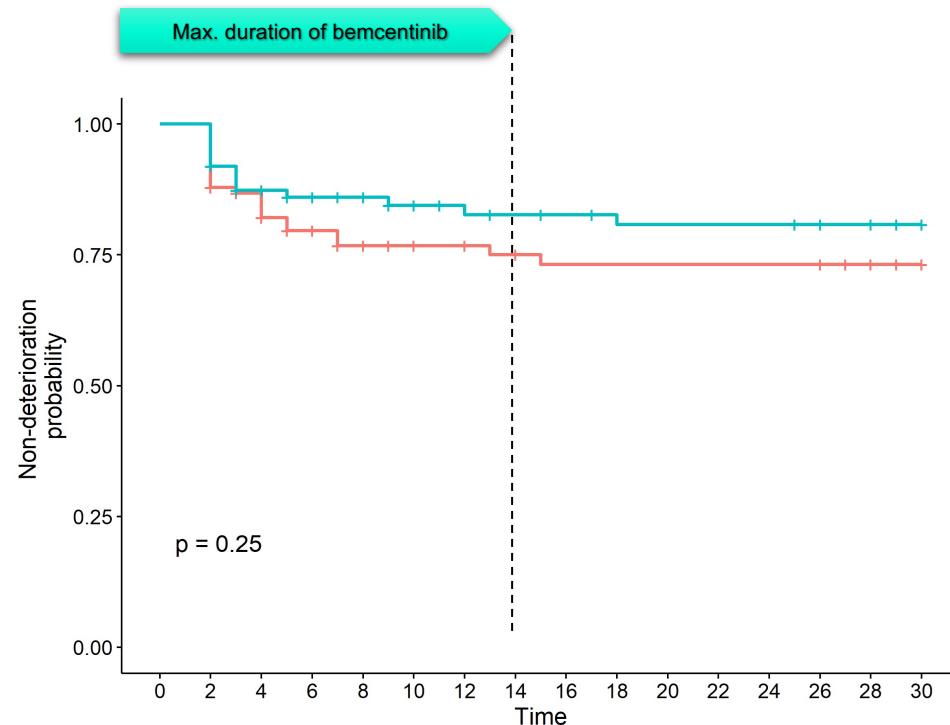
Key Secondary endpoint – time to any worsening (incl death)



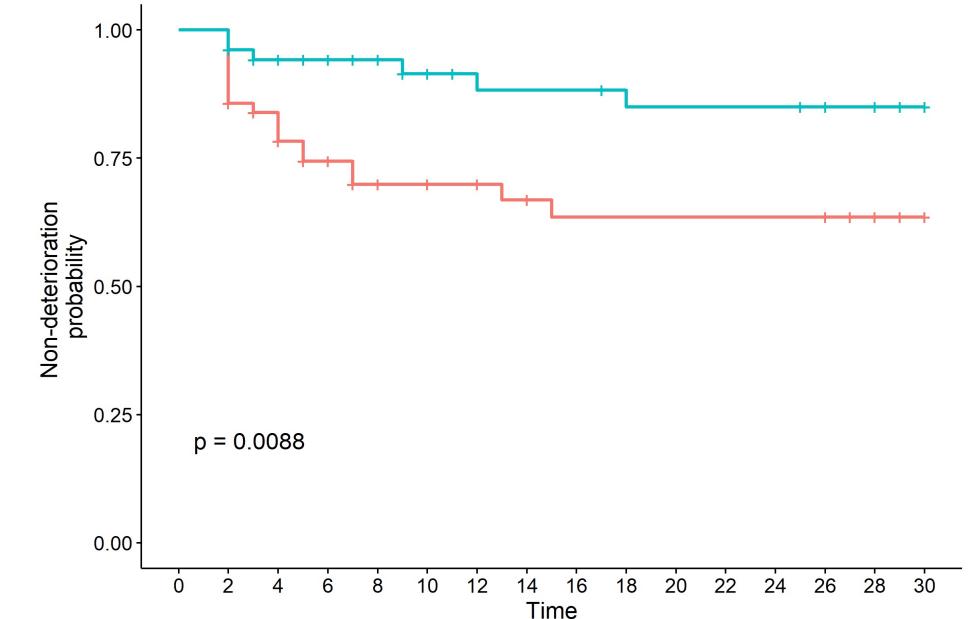
Time to worsening by ≥ 1 grade in WHO score

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

All participants



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



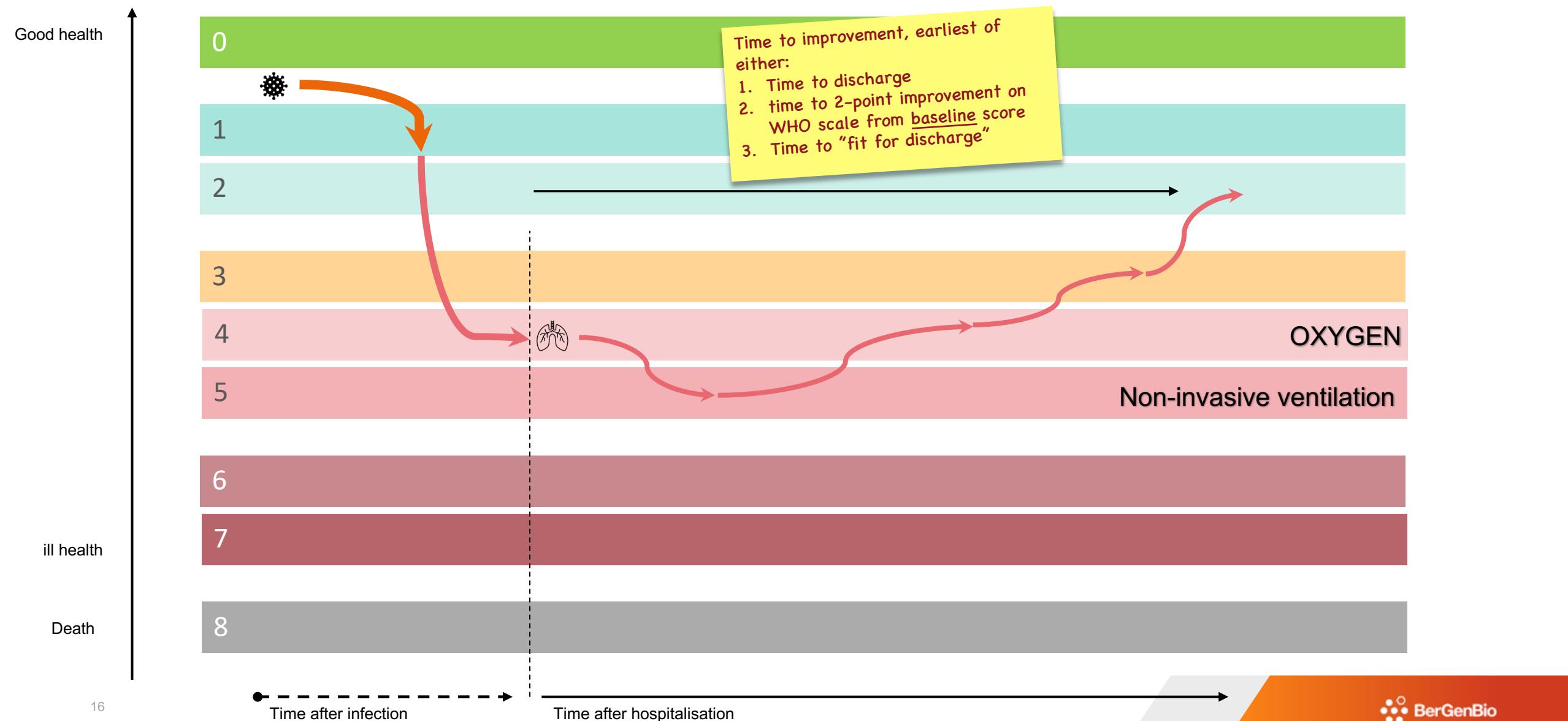
+

SoC

+

Bemcentinib

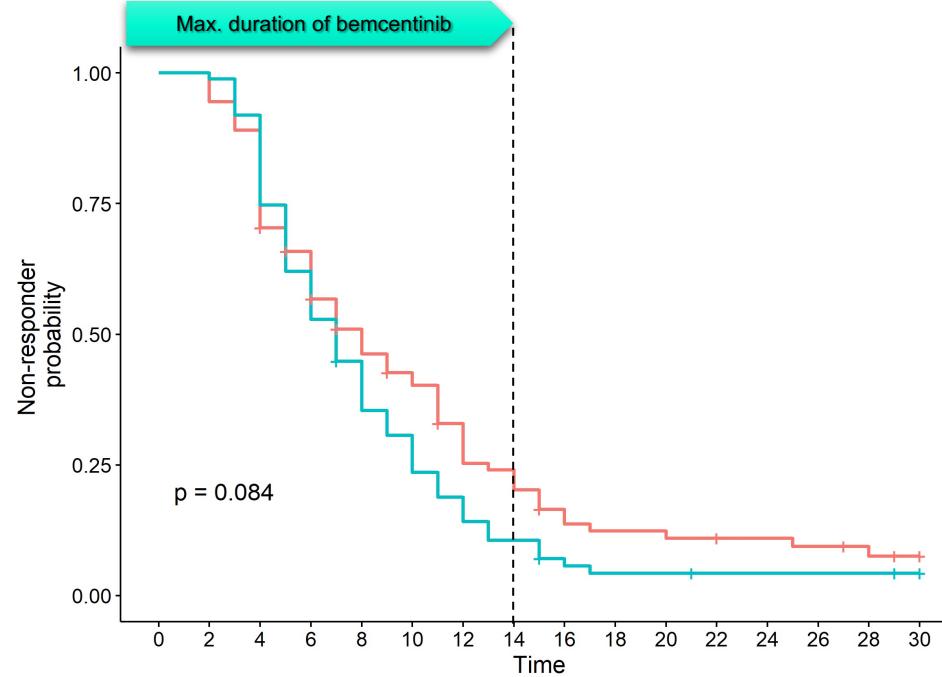
Primary endpoint – time to improvement (recovery or discharge)



Primary endpoint: time to recovery or discharge

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

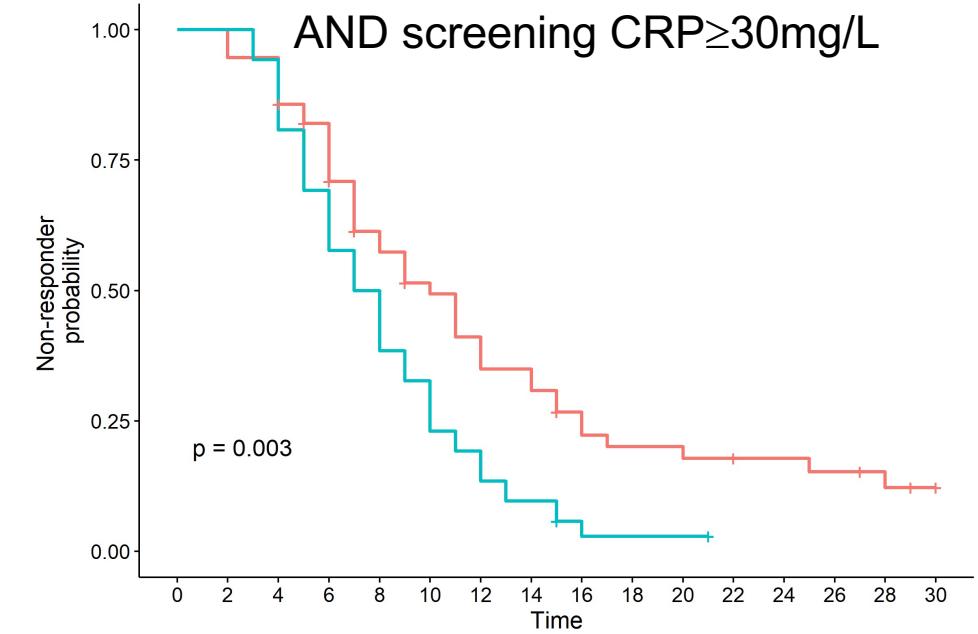
All participants



61%

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

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



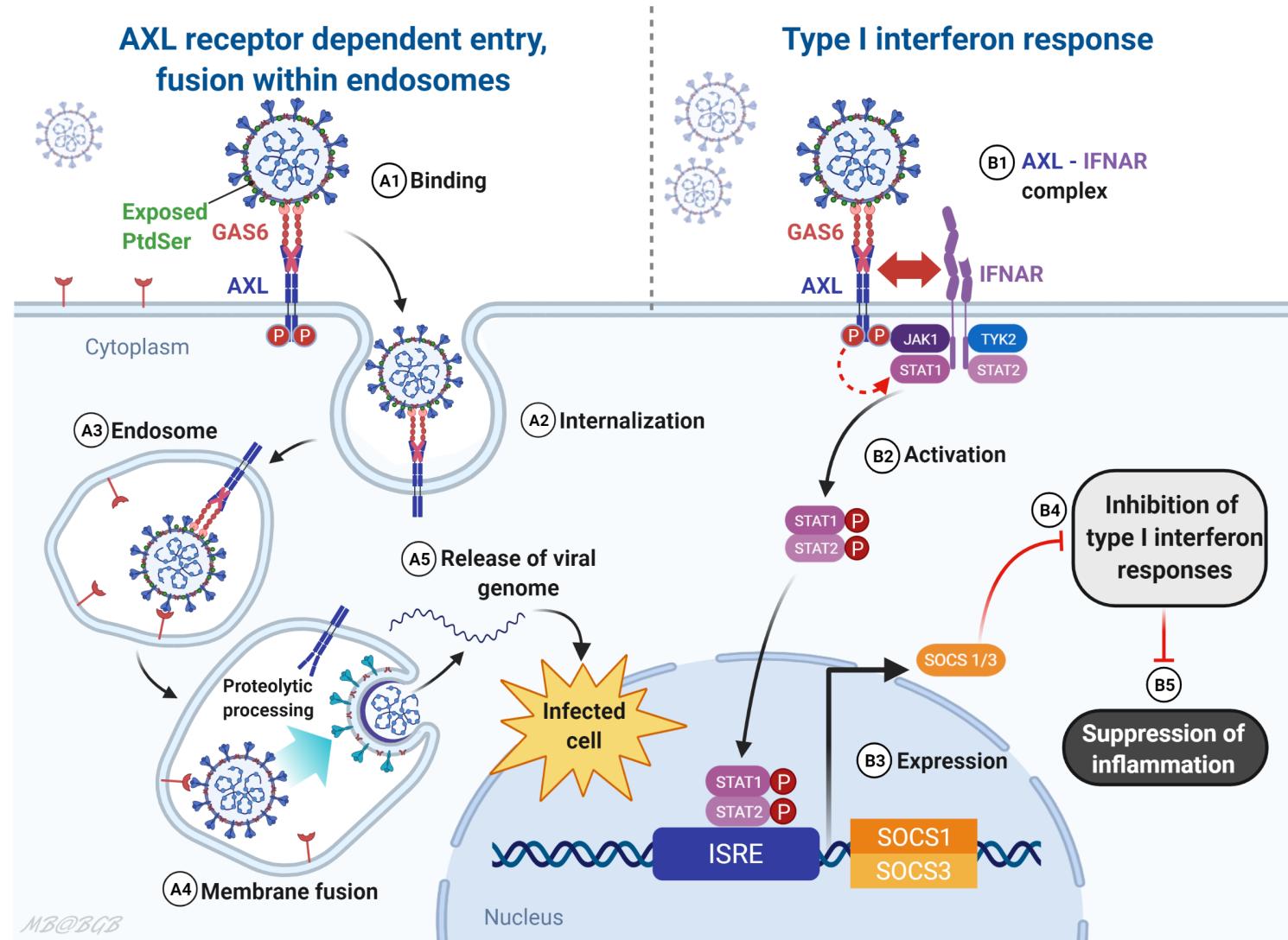
HR=1.884 95% C.I. (1.236, 2.871)

SoC
Bemcentinib

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

“apoptotic mimicry”

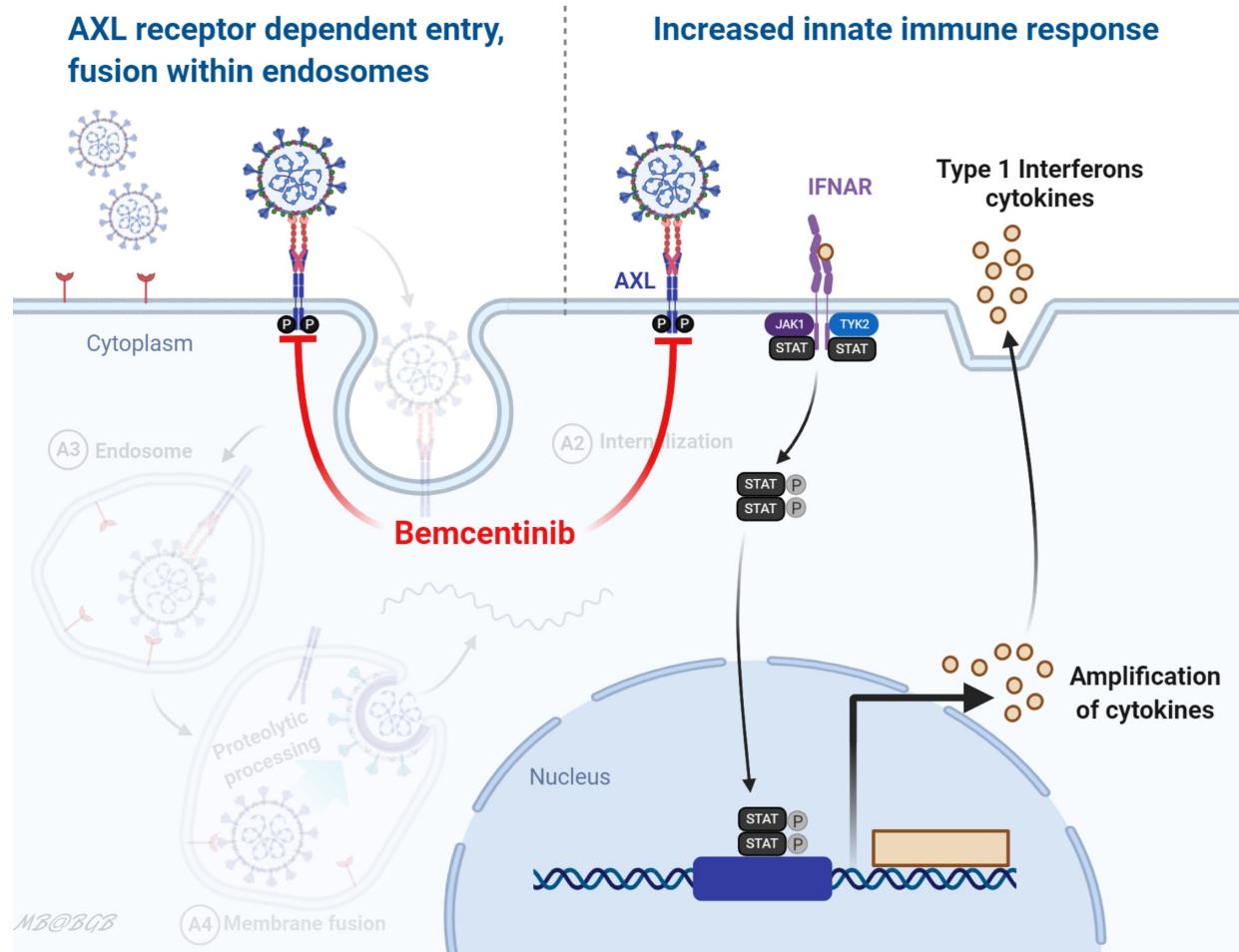
Enveloped viruses display phosphatidylserine, which is recognized by GAS6, the AXL receptor ligand, that mediates viral entry via endosomal pathway



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

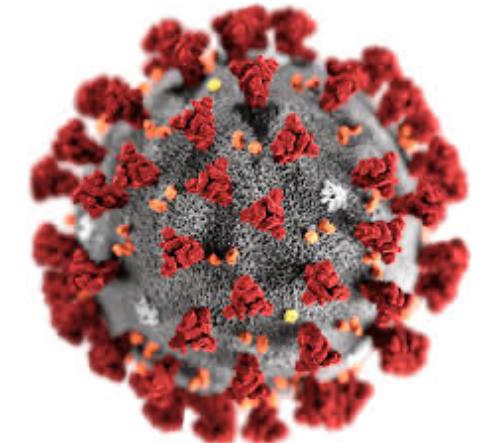


Bemcentinib:

- 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 adults¹

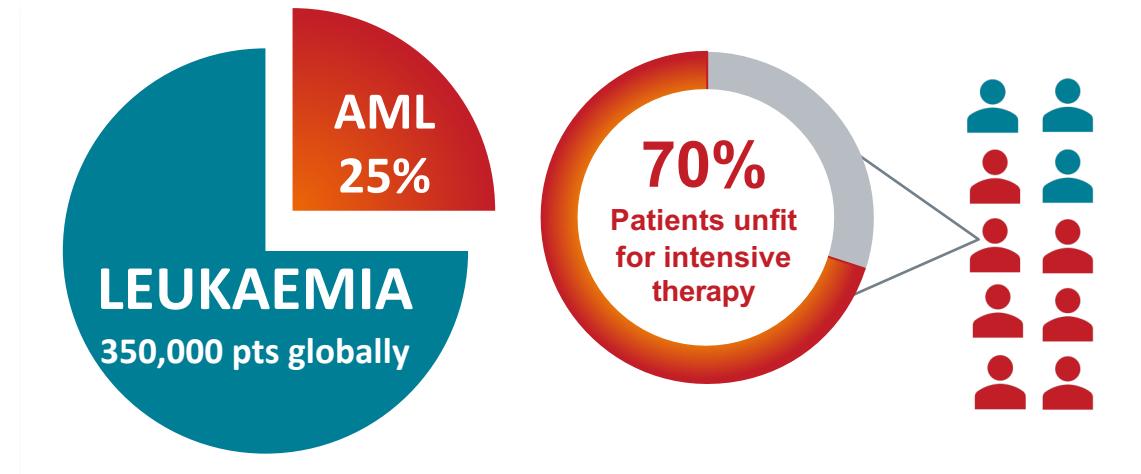
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018²

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 years⁶

Standard of Care:
1L: 66% CR/CRi, mOS 14.7mo.⁸
Relapse: mOS 4.7mo.⁹
5-year survival rates of 3-8% in patients over 60 years old⁷



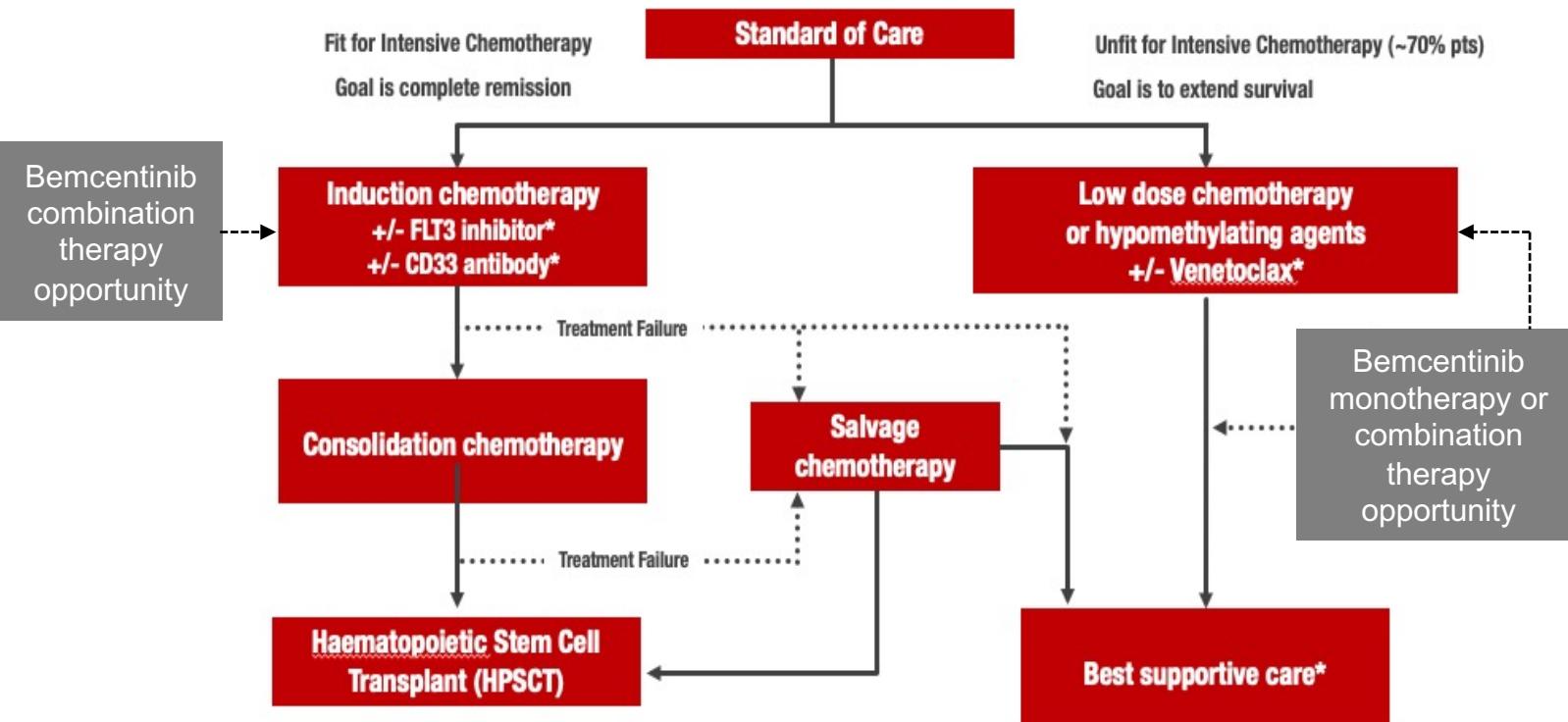
(1) Cancer.gov; (2) SEER; (3) https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble

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

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

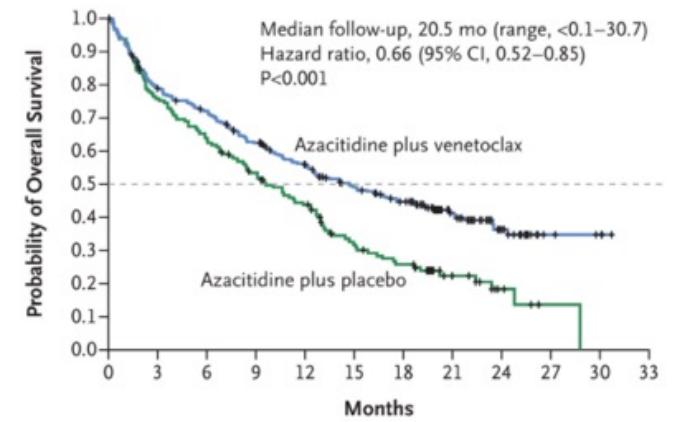
Relapse AML – the need for new treatment options

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 14.7mo¹
- Relapse patients mOS 4.7mo²



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 bencentinib 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

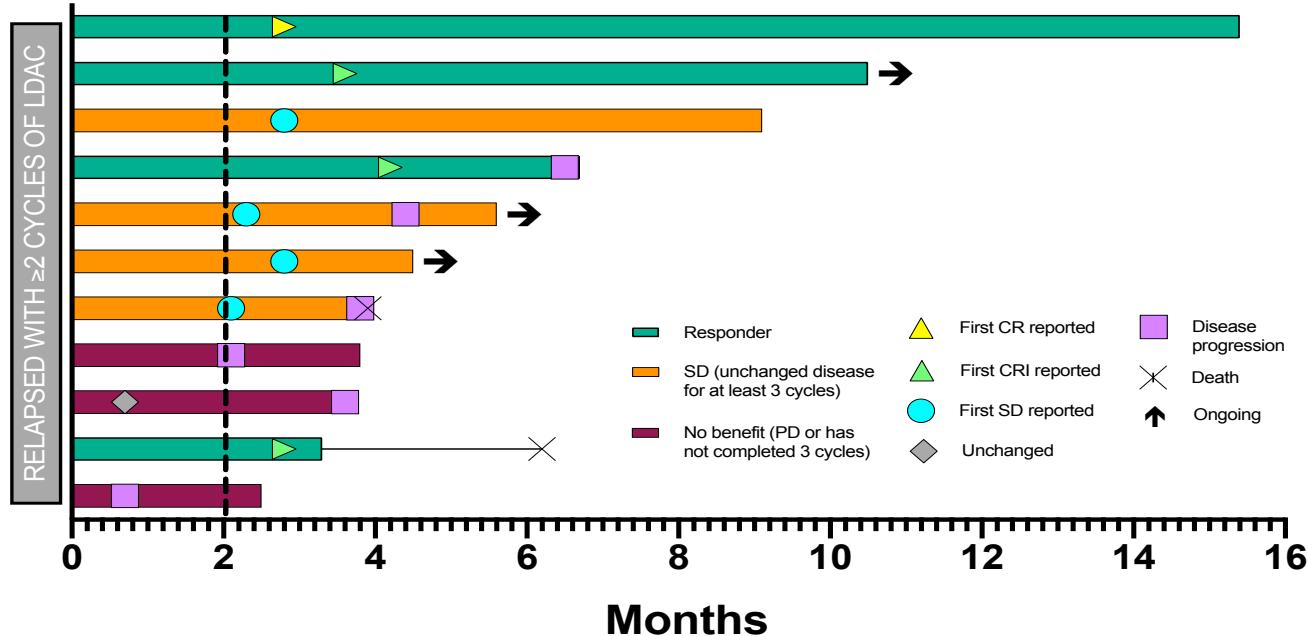
Cohort B4 n=14
Monotherapy MDS

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

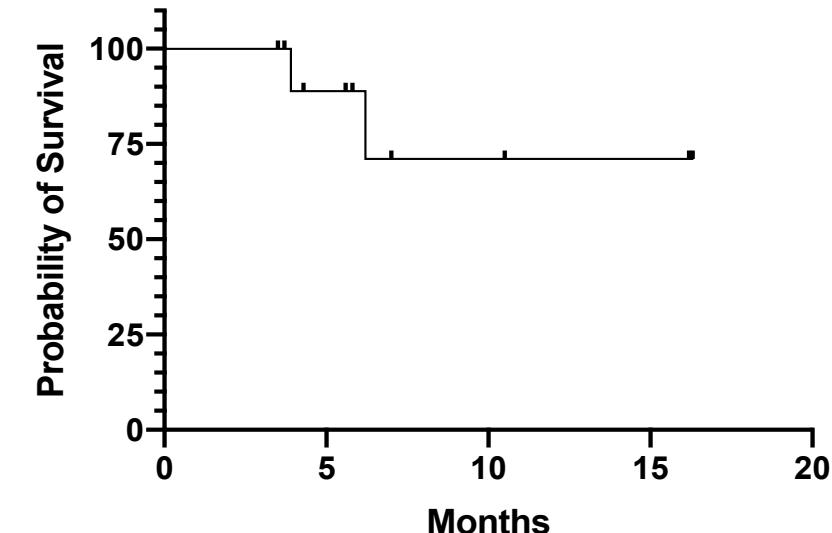
Preliminary Efficacy assessment for relapsed AML pts with ≥ 2 cycles of

Bemcentinib+LDAC (n=11*)

Time on Treatment



Overall survival



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

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

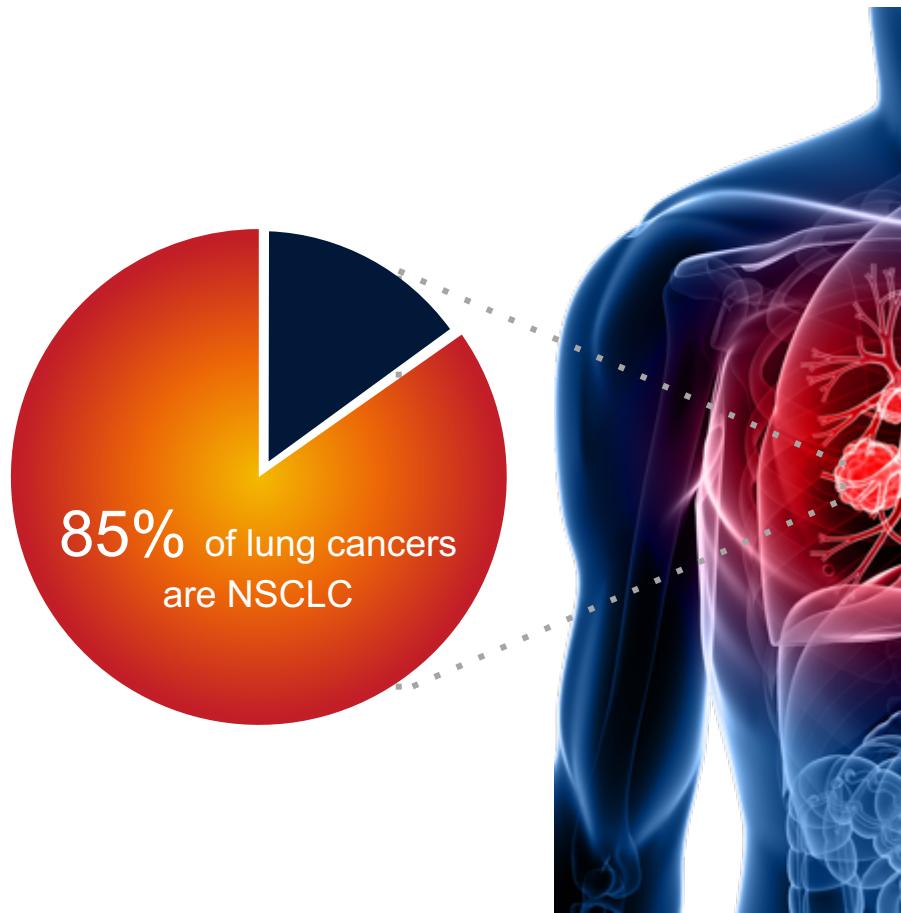
mOS not reached

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



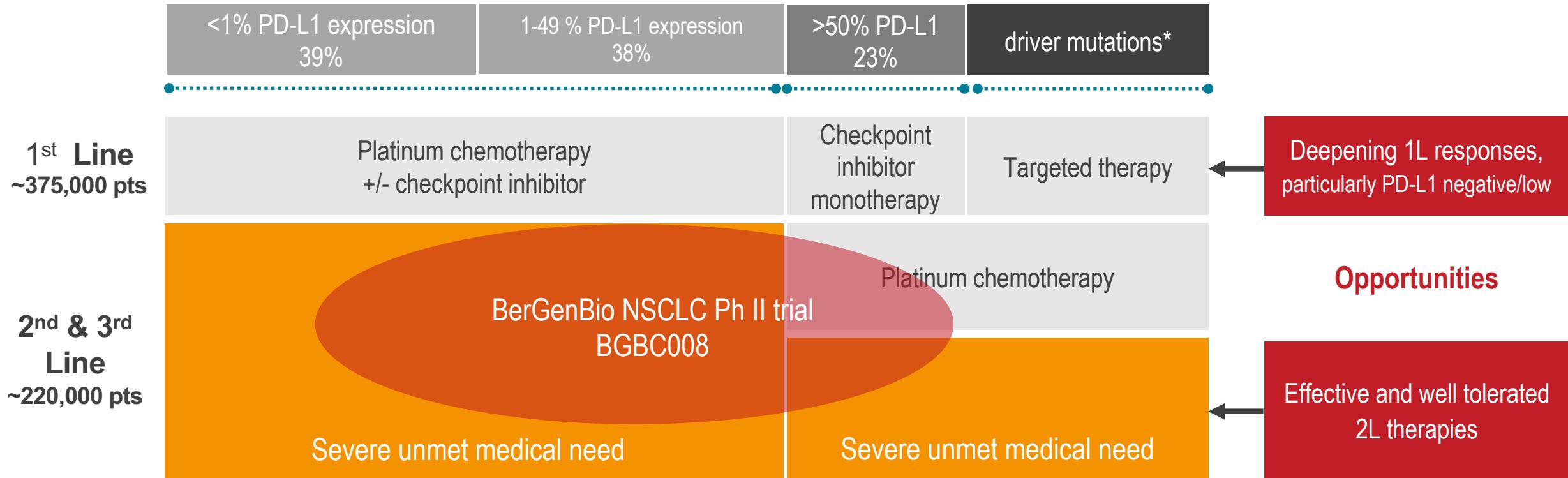
The largest cancer killer, most patients depend on drug therapy

- 2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases¹
- 1.76 million lung cancer deaths/yr worldwide¹
- NSCLC market opportunity \$39bn
- In the U.S, 5-year survival rate is approximately 18.6%, and 4.7% in patients with distant metastases²

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



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⁺

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

Recruitment ONGOING

Stage 2

N=29 patients

➤ Encouraging mPFS in cAXL⁺

Cohort C

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

Interim Analysis

Stage 1 N=13 patients

Pending

Stage 2

N=29 patients

➤ ORR and biomarker data pending

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

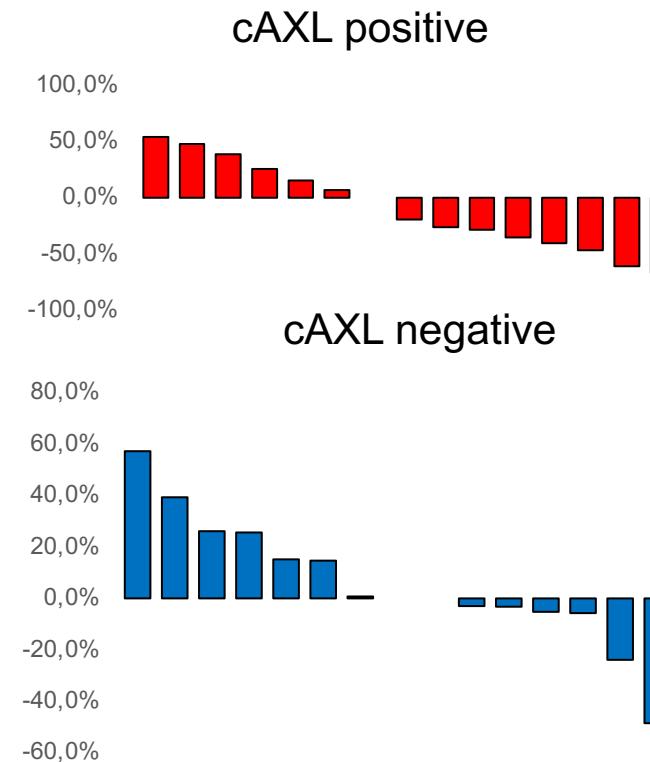
- ✓ The first formal recognition by a regulator of AXL-positive patients as a discernible patient population
- ✓ BerGenBio has developed proprietary biomarkers and companion diagnostic assays for selection of AXL positive patients, the cAXL assay is validated for clinical trial use
- ✓ Retrospective 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

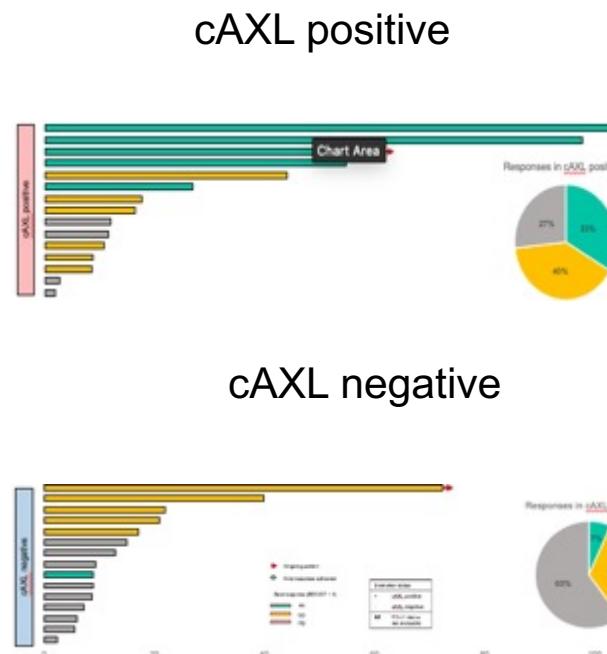


cAXL predicts response and survival benefit with Bemcentinib + Pembrolizumab in 2L NSCLC CPI naïve patients

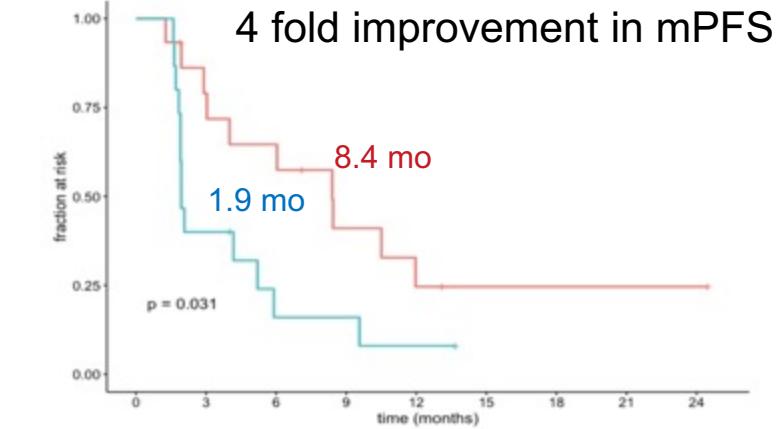
Change in tumor size



Duration of response



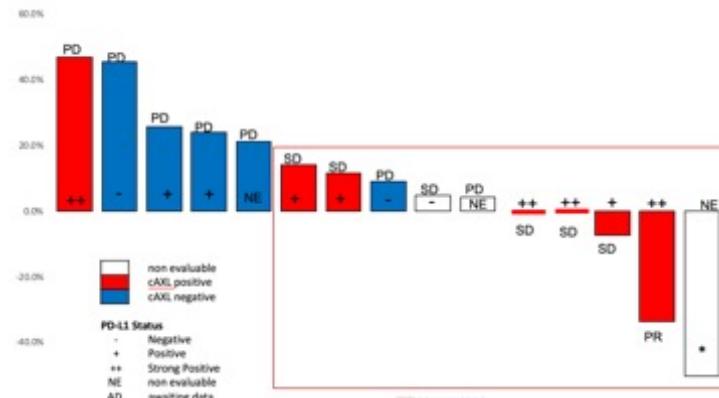
Survival benefit



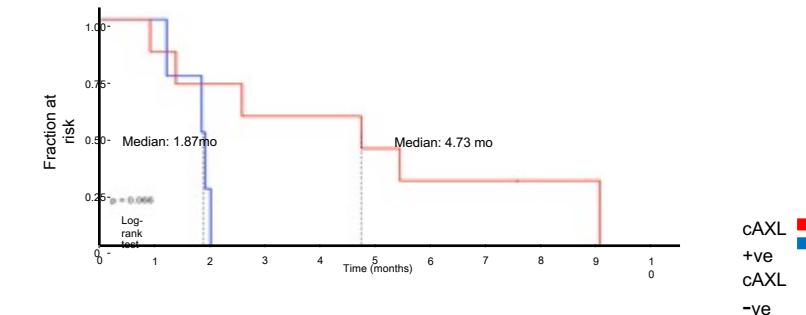
Cohort	mOS	12-mo OS
Cohort A – cAXL +ve pts**	17.3 mo*	79%
Cohort A – cAXL -ve pts**	12.4 mo*	60%
BGB Cohort A – all pts**	12.6 mo*	64%* (up to 67%)
CheckMate-057 (Opdivo)	12.2 mo	51%
KEYNOTE-010 (Keytruda)	10.4 mo	43.2%

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

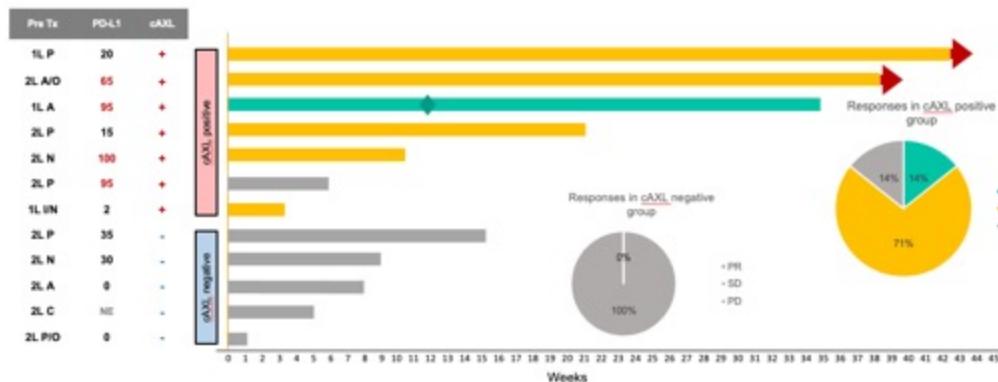
Change in tumour size



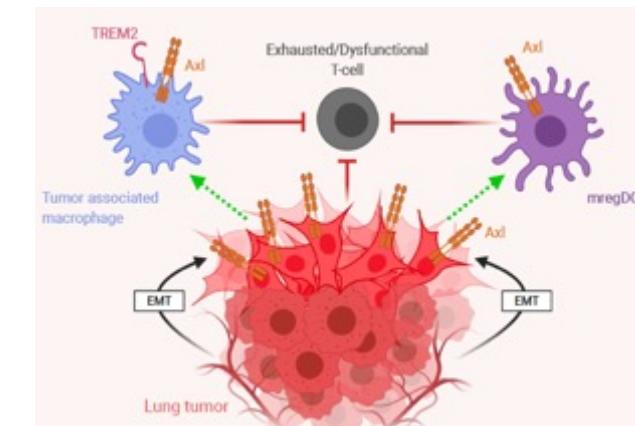
2.5 fold improvement in median progression free survival



Duration of response

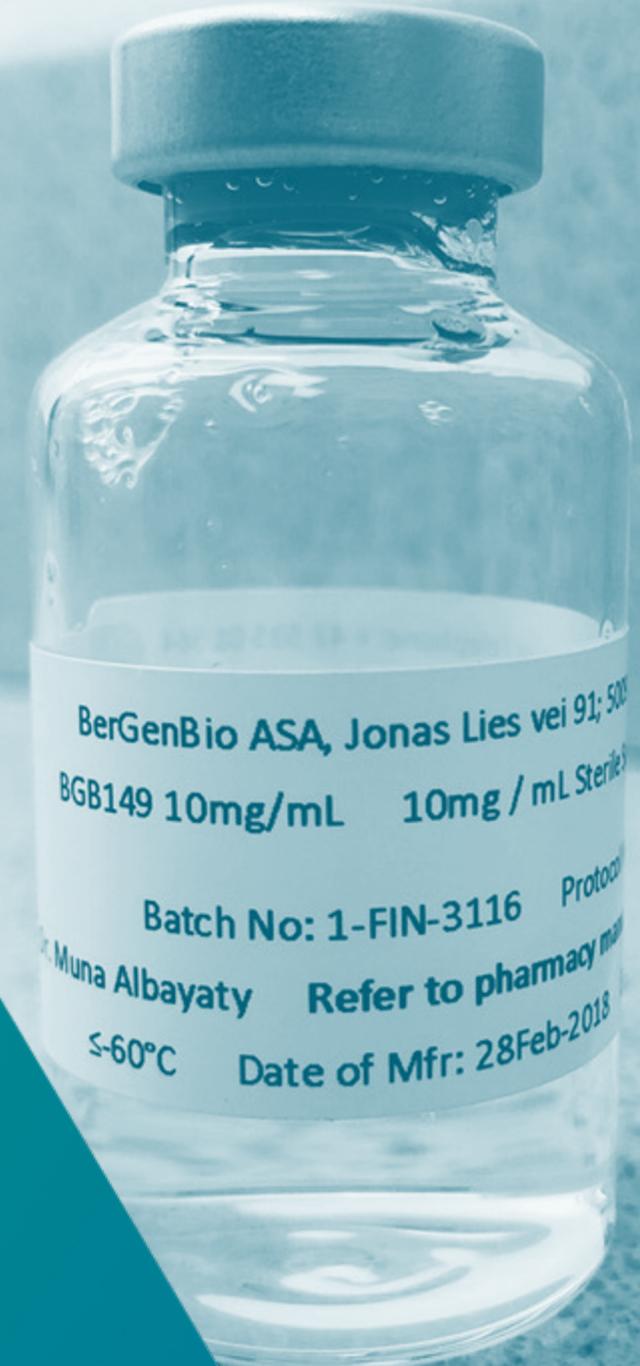


AXL^{+ve} immune suppressive cells identified

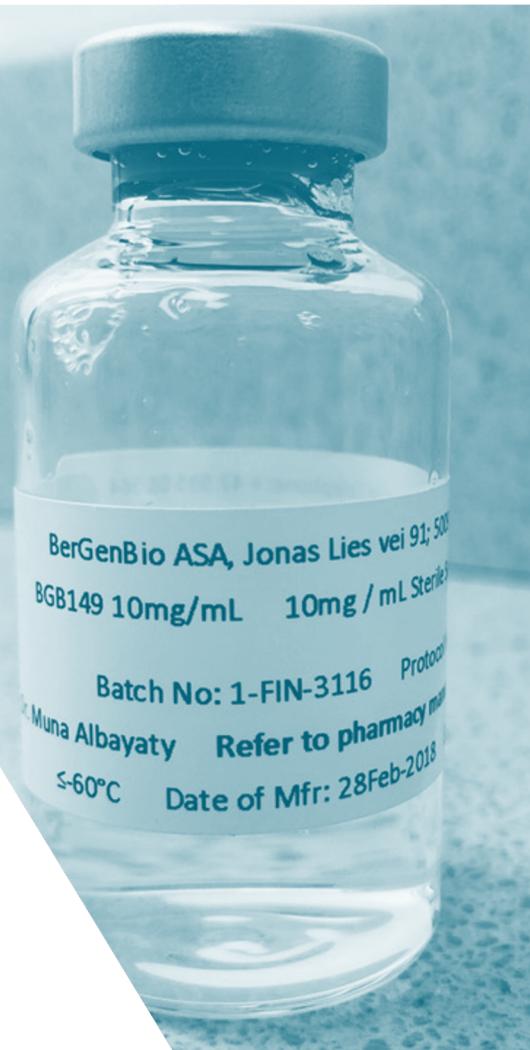




Tilvestamab (BGB149) anti-AXL monoclonal antibody



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

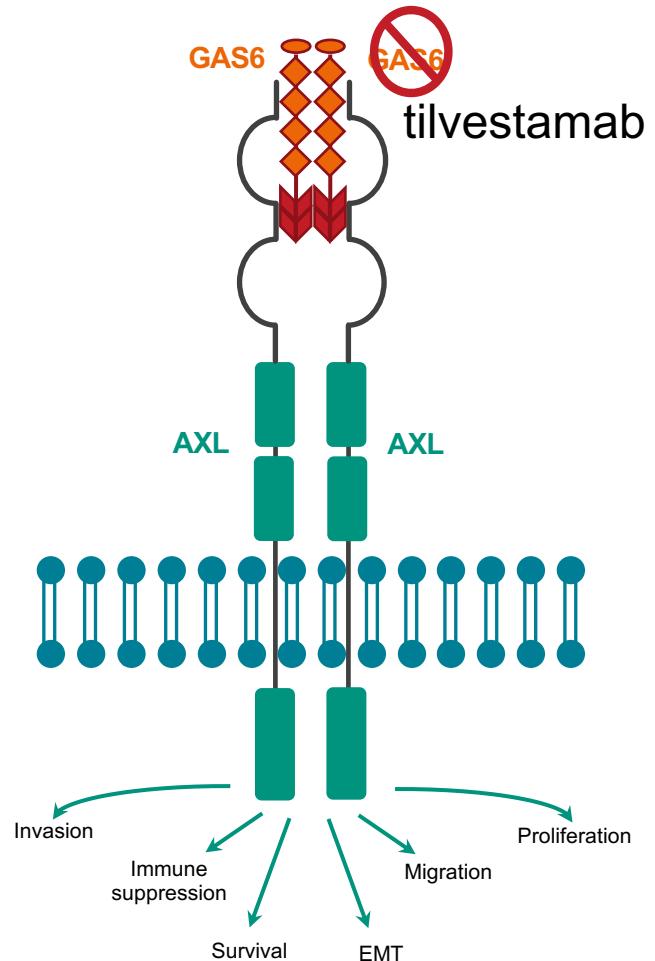
Phase Ia healthy volunteer SAD study complete

Safety – no dose limiting toxicity seen up to 3mg/kg dose

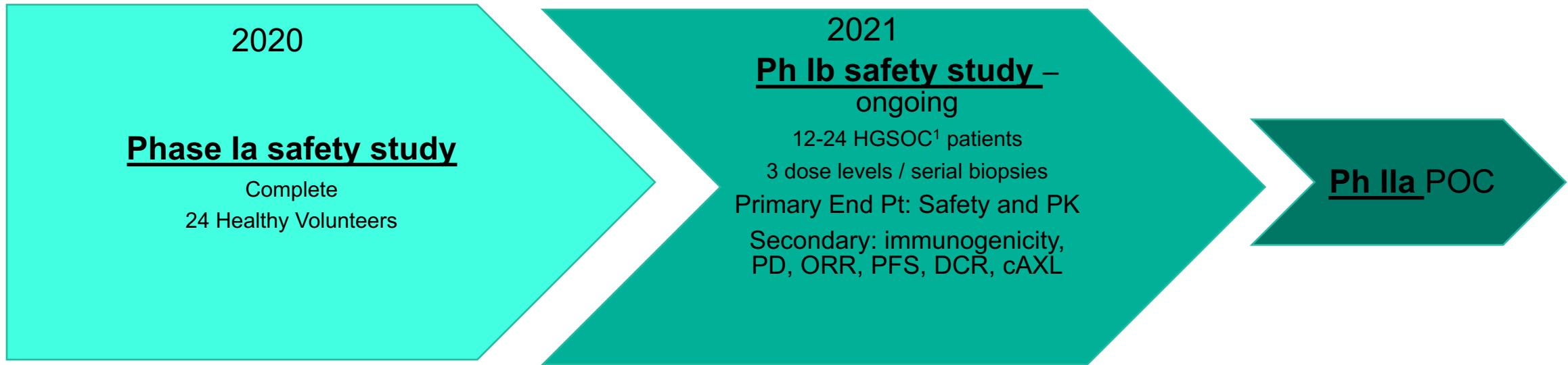
Pharmacokinetics - exposure predictable with dose
proportional Cmax increase

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

Phase I SAD trial complete
Phase Ib/Ila MAD ongoing



Tilvestamab development plan



Safety – no dose limiting toxicity seen up to 3mg/kg dose

Pharmacokinetics - exposure predictable with dose proportional Cmax increase

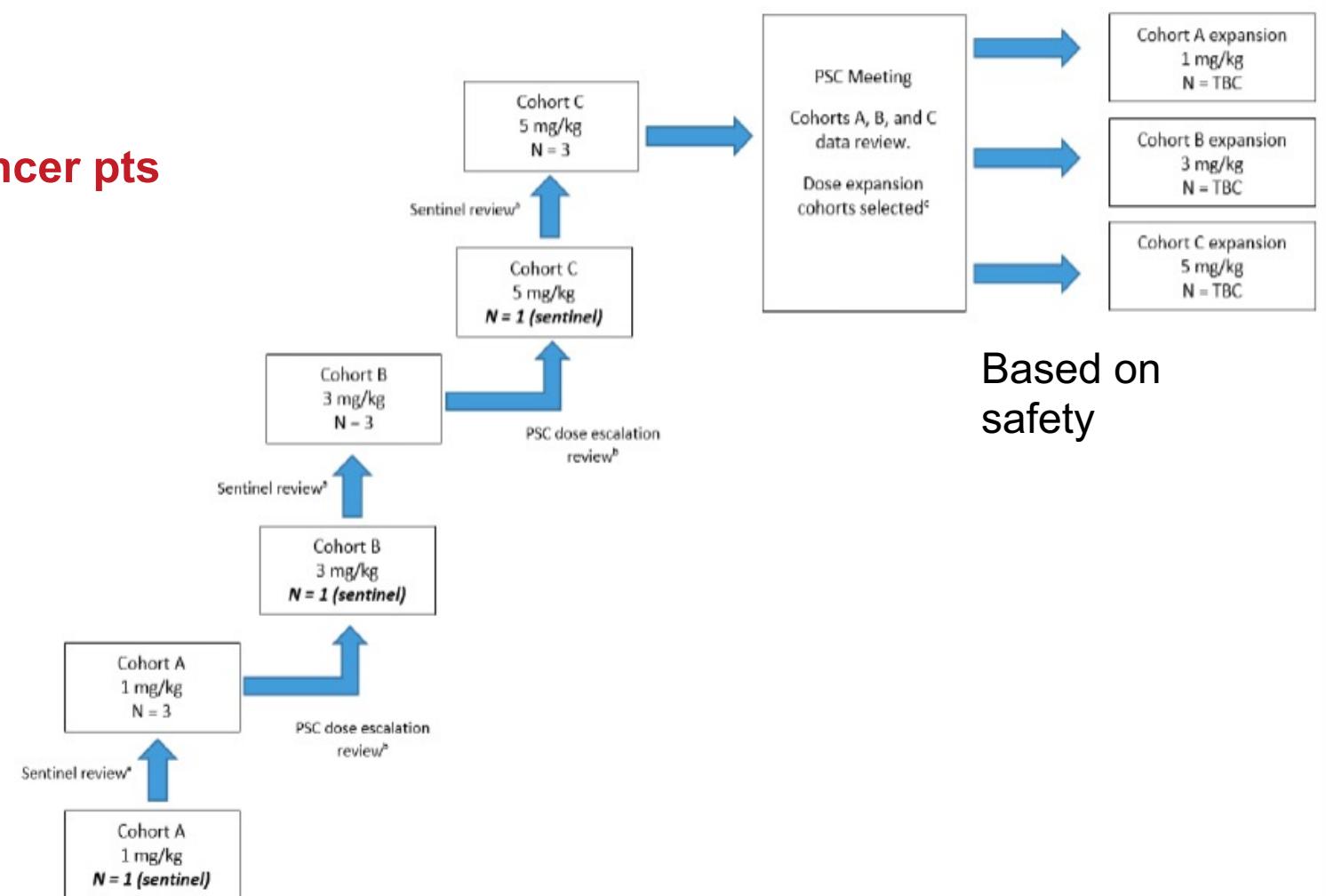
Confirmatory evidence of *in vivo* target engagement with sAXL -- stabilisation in circulation

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



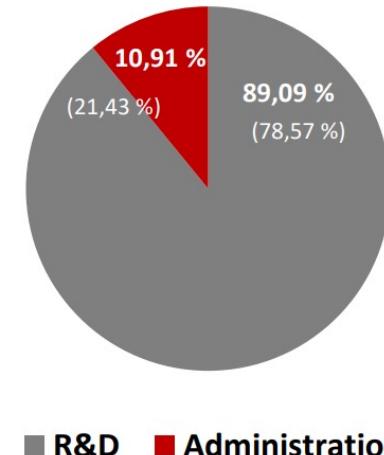
Finance Report

CFO Rune Skeie

Key financial figures

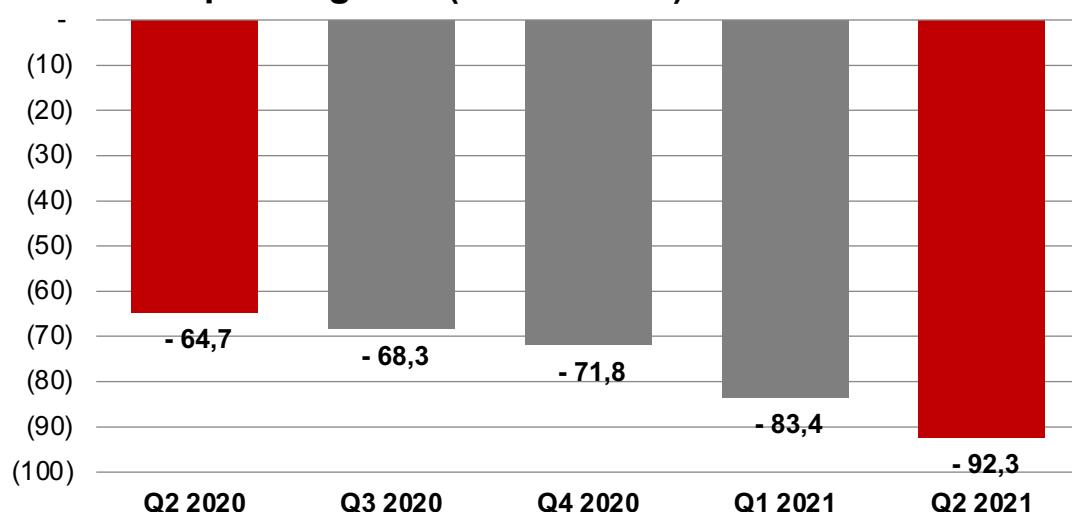
(NOK million)	Q2 2021	Q2 2020	YTD 2021	YTD 2020	FY 2020
Operating revenues	0,0	0,0	0,0	0,0	0,6
Operating expenses	92,3	64,7	175,7	121,0	261,7
Operating profit (-loss)	-92,3	-64,7	-175,7	-121,0	-261,1
Profit (-loss) after tax	-88,9	-67,3	-170,1	115,8	-257,0
Basic and diluted earnings (loss) per share (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)



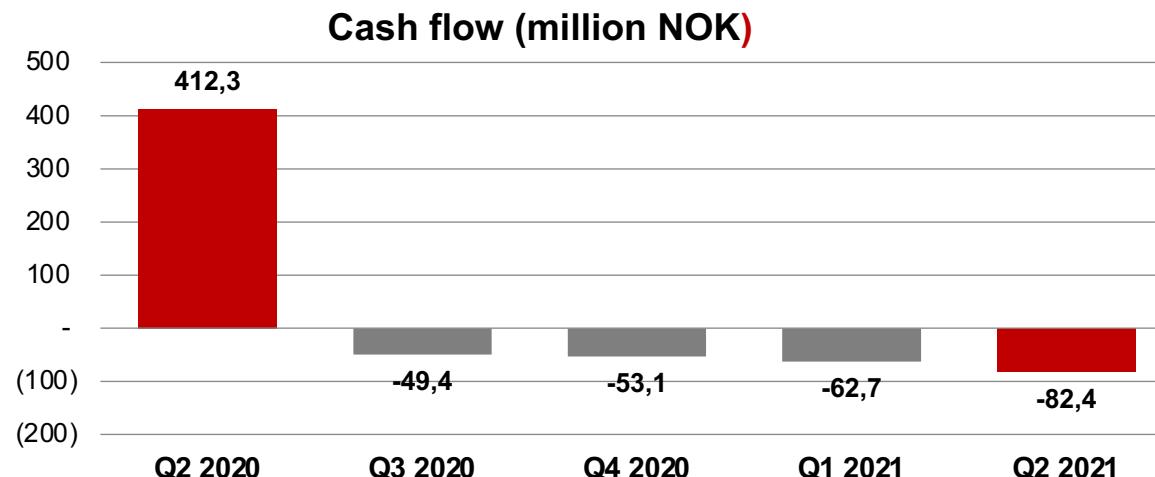
■ R&D ■ Administration

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

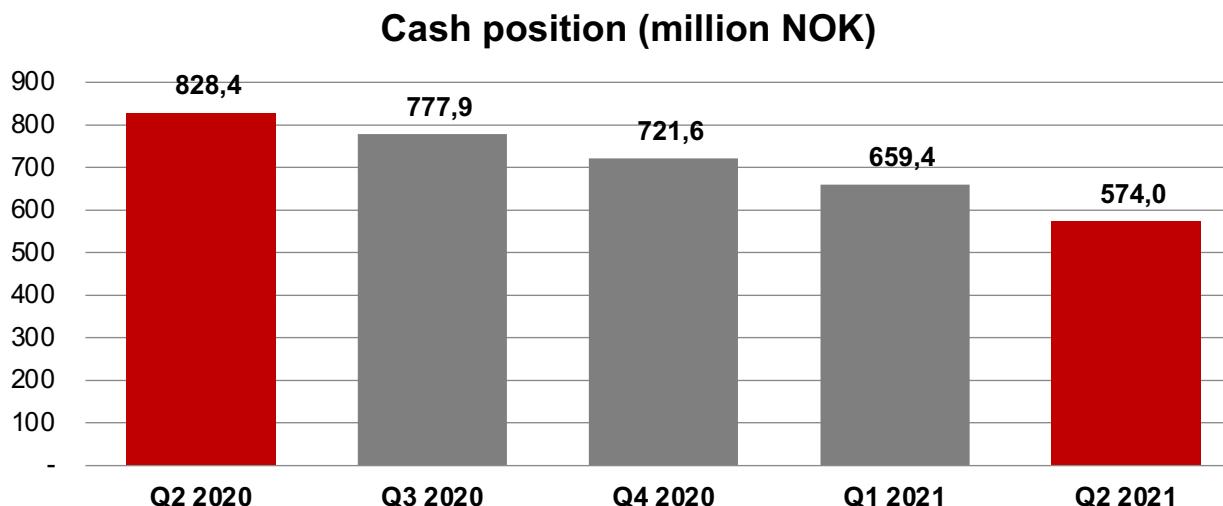
84.4 / 10.0

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



2L NSCLC data



Relapse AML
and MDS data



Tilvestamab
Phase Ia/Ib

2021



Data COVID-19
Phase II



COVID-19
Development



AML mOS data
& regulatory
alignment



Tilvestamab
Ph II

Two rPh II
- UK
- India & South
Africa

Interim data
- 2.5 x mPFS in
cAXL patients

Preliminary data
confirms a new
significant patient
population

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

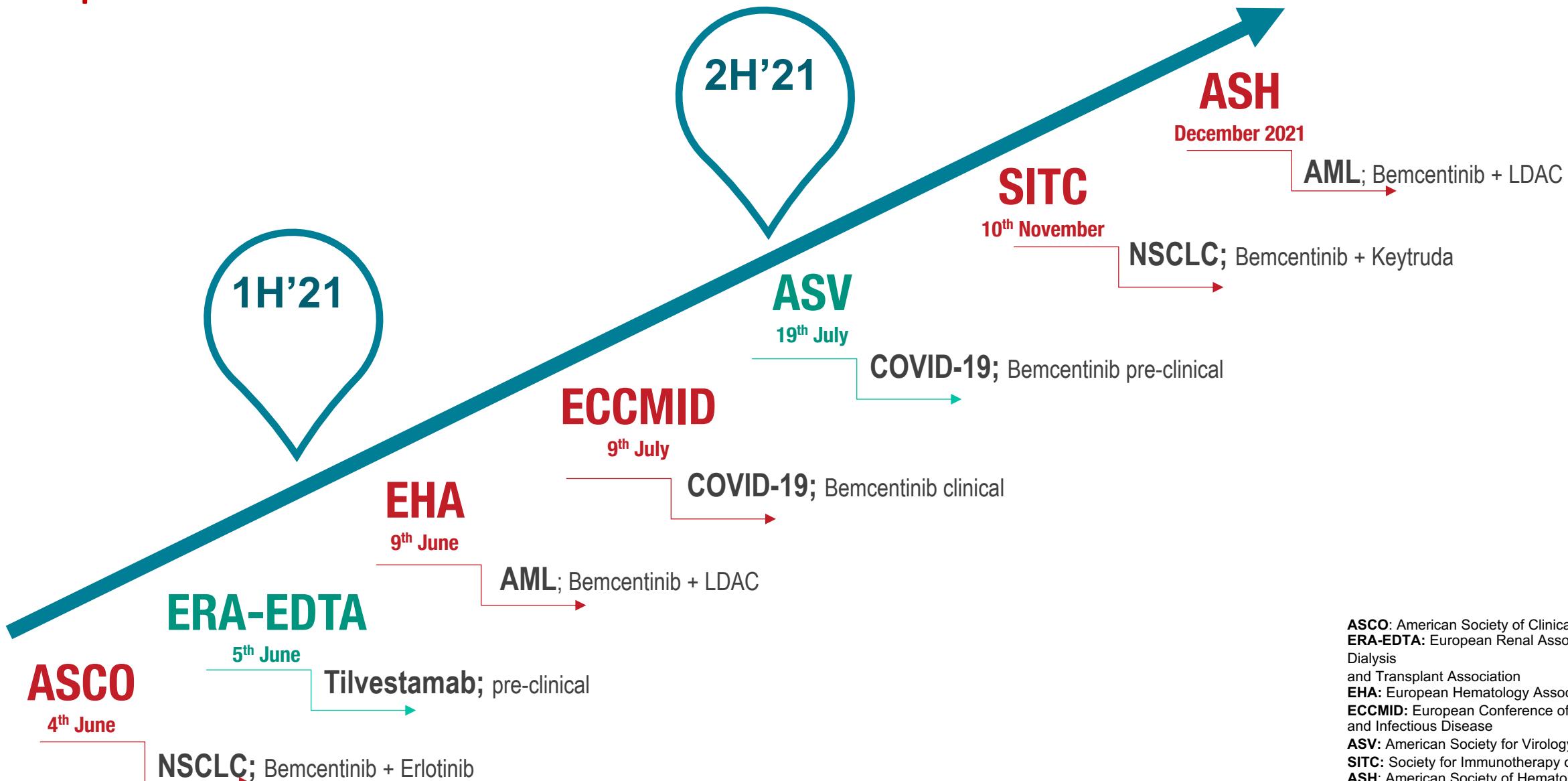
Top line data

Determine
development &
regulatory options

- Survival data
- Regulatory
alignment

- Prepare to
Initiate Ph II

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
SITC: Society for Immunotherapy of Cancer
ASH: American Society of Hematology

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