



BerGenBio

Q1 2021 REPORT, HIGHLIGHTS AND FINANCIALS

19th May 2021

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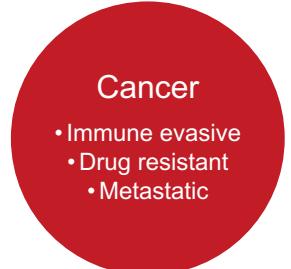
AGENDA

1. AXL inhibitors
2. Q1 and Recent Highlights
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

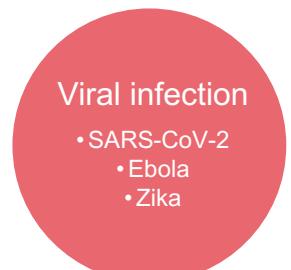
AXL mediates aggressive disease

Very low expression under healthy physiological conditions

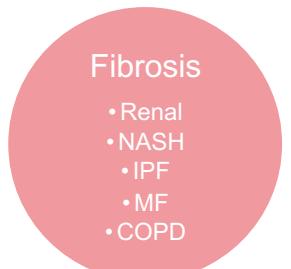
AXL signaling is upregulated by hostile cellular microenvironment and viral infection



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



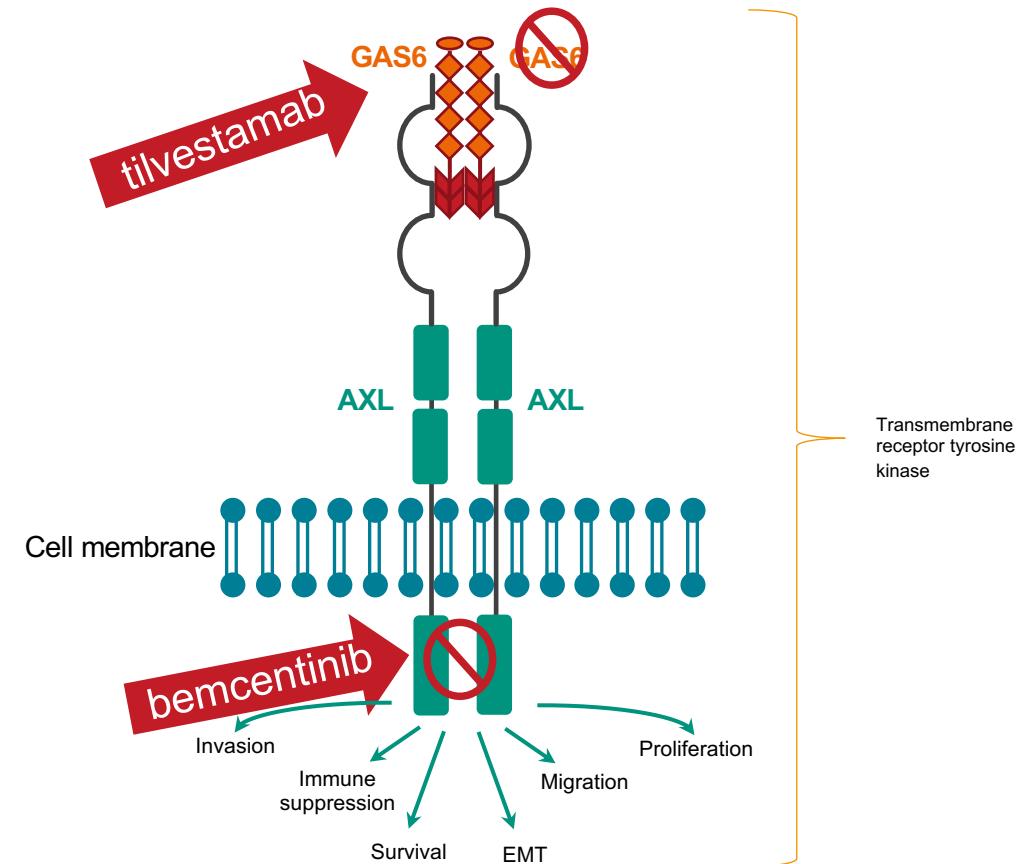
AXL mediates viral entry to cells and dampening of viral immune response



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

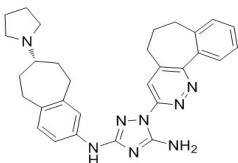


Two first-in-class, potent, highly selective AXL inhibitors in clinical development

Bemcentinib*

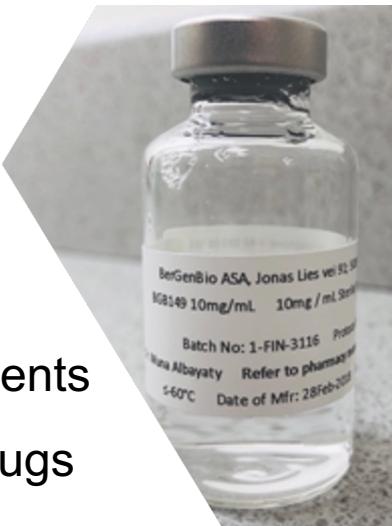


- Oral, once a day
- Size 0 capsule
- Stable simple drug product
- Favorable Safety and tolerability confirmed >400 patients
- Combines well with other drugs
- Phase III ready



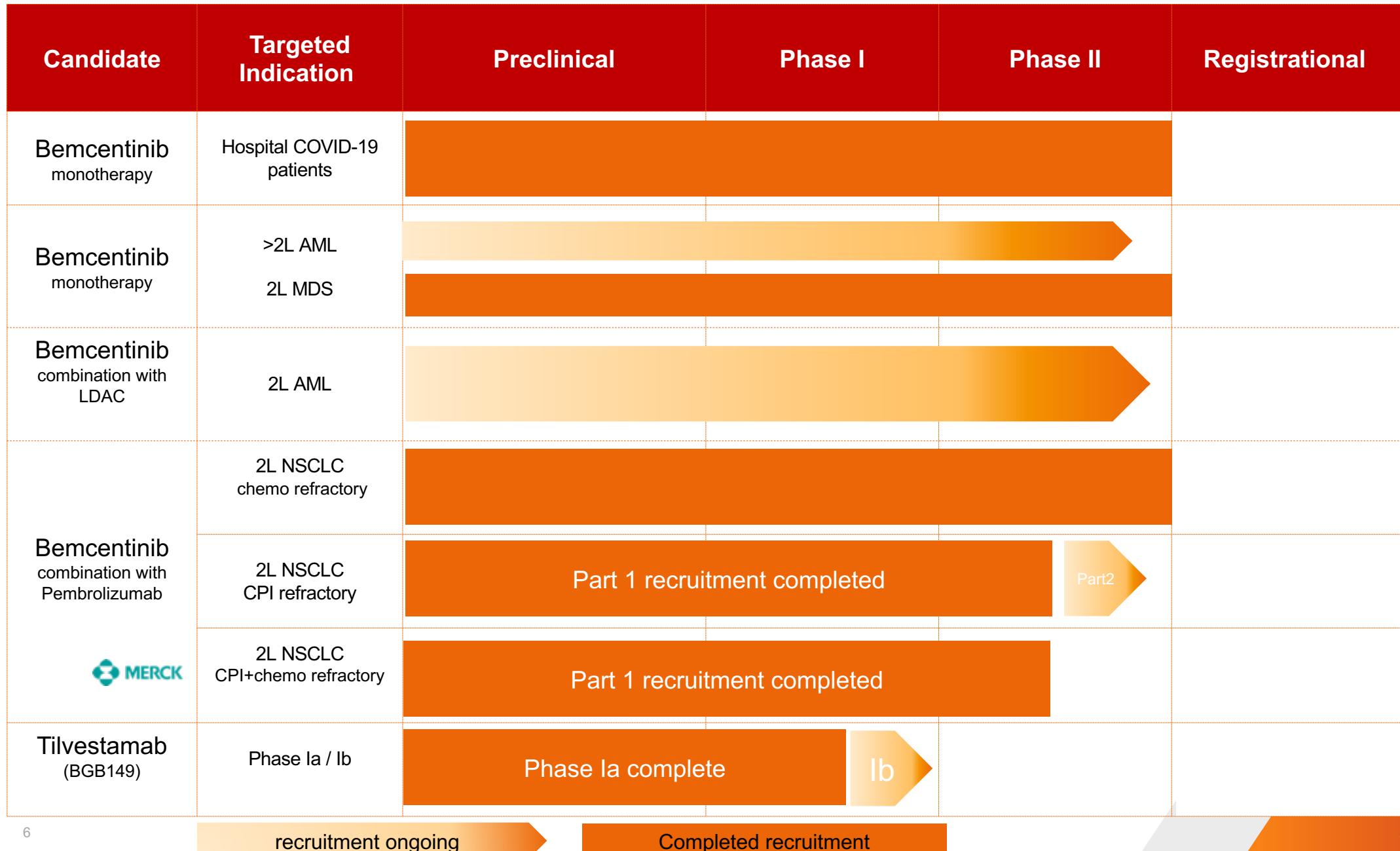
- Nano-molar potency
- 50-100 selective for Axl

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



Q1 and recent highlights

Jan
2021

Updated data from Phase II bemcentinib combination study (BGBC008) in refractory non-small cell lung cancer (NSCLC) presented at World Conference on Lung Cancer

Feb
2021

Recruitment closed and independent Data Monitoring Committees recommend continuation of BGBC020 trial assessing bemcentinib in COVID-19, with a total of 115 patients enrolled in the Phase II study

Mar
2021

First patient dosed in Phase Ib trial of anti-AXL antibody tilvestamab (BGB149)

Senior management presented at HC Wainwright, Sachs European Life Sciences and Carnegie investor conferences

Preclinical bemcentinib COVID-19 data presented at Conference on Retroviruses and Opportunistic Infections (CROI)

Completed enrolment of latest cohort in Phase II bemcentinib/pembrolizumab combination study in refractory NSCLC

Apr
2021

Update from investigational 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 COVID-19 data presented at Virtual Immunology 2021

Top Line data from phase II trial assessing bemcentinib in hospitalised COVID-19 patients

Experienced Executive Leadership Team — welcome Nigel McCracken CSO



Richard Godfrey, MRPharmS, MBA

Chief Executive Officer



Rune Skeie

Chief Financial Officer



Professor Hani Gabra, MD, PhD, FRCPE, FRCP

Chief Medical Officer



Alison Messon, PhD

Director of Clinical Operations



Nigel McCracken, MSc, PhD,

Chief Scientific Officer



James Barnes, PhD

Director of Operations



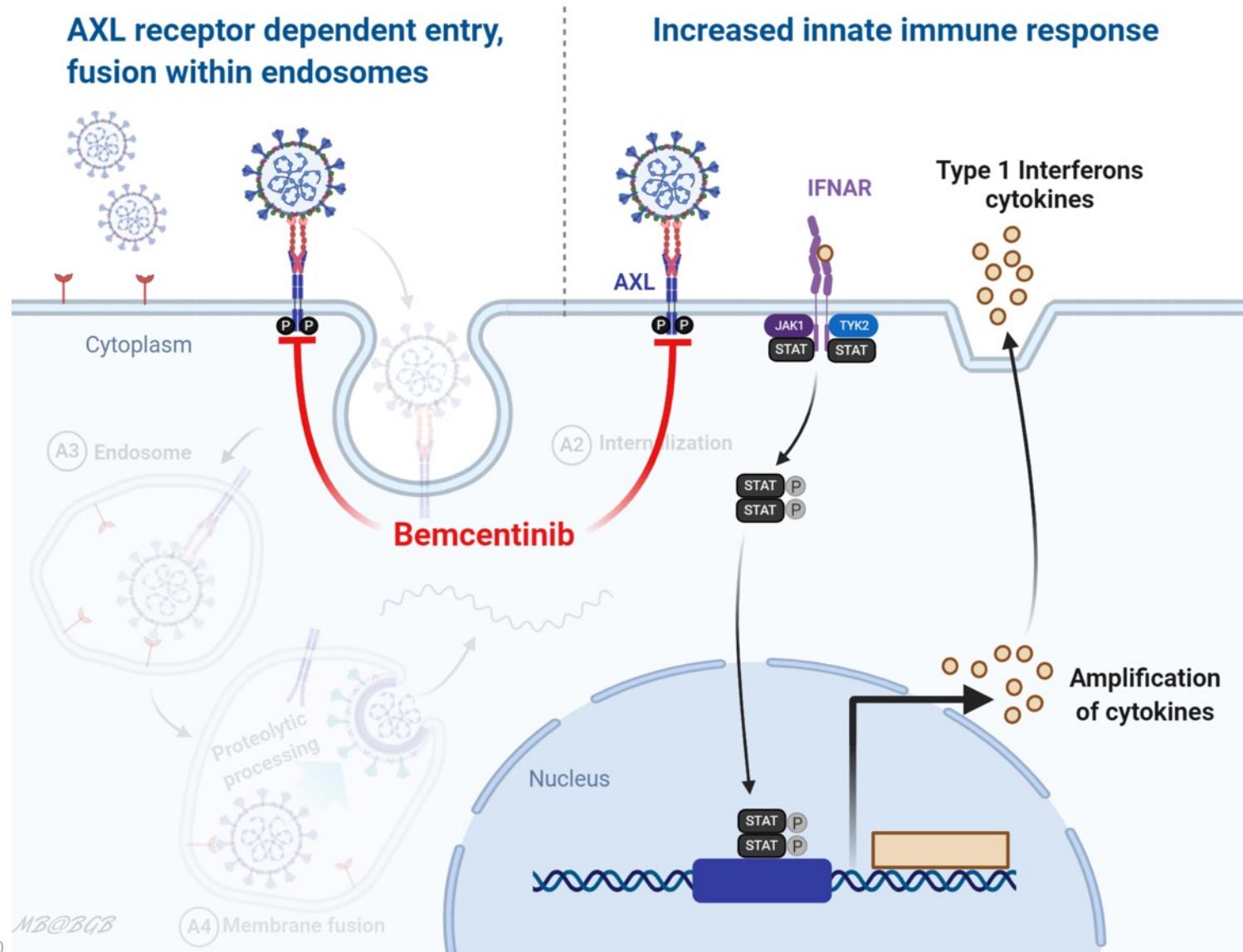
PHASE II TRIAL ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

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

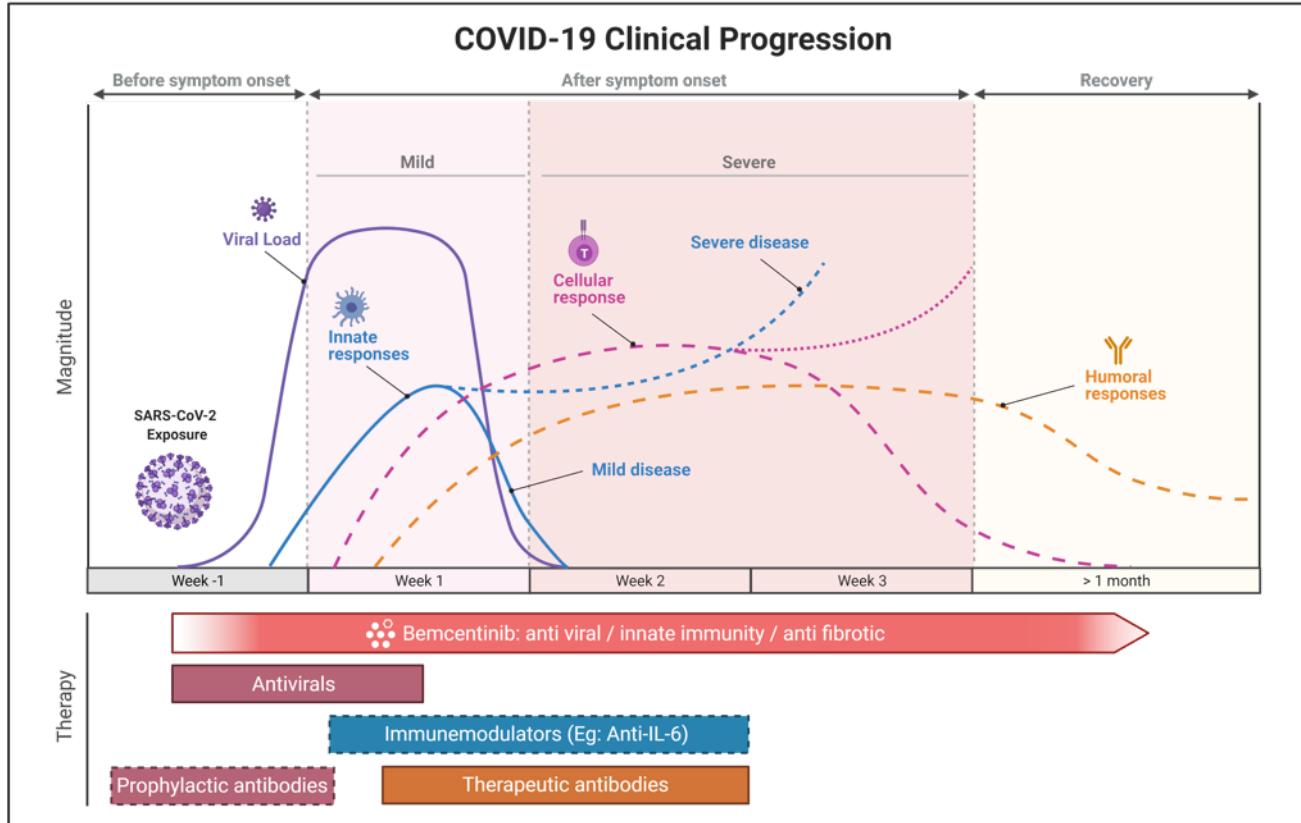
Prevents viral infection and promotes innate immunity



Bemcentinib:

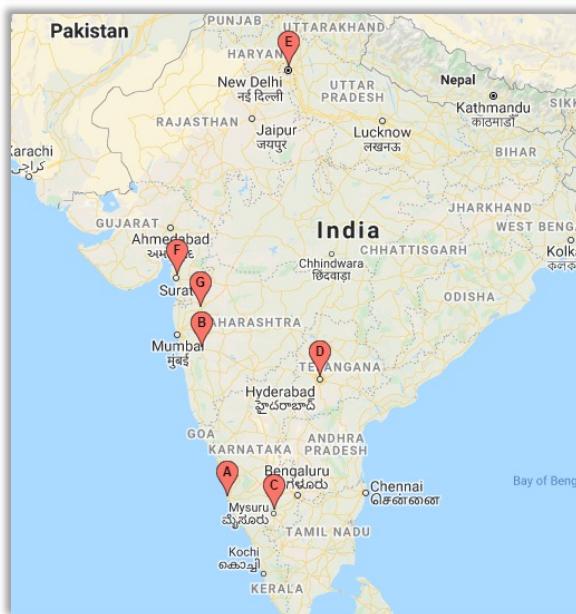
- **Blocks AXL-dependent viral entry**
- **Enhances anti-viral interferon response**
- **Mode of action is independent of spike protein (or mutations)**

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

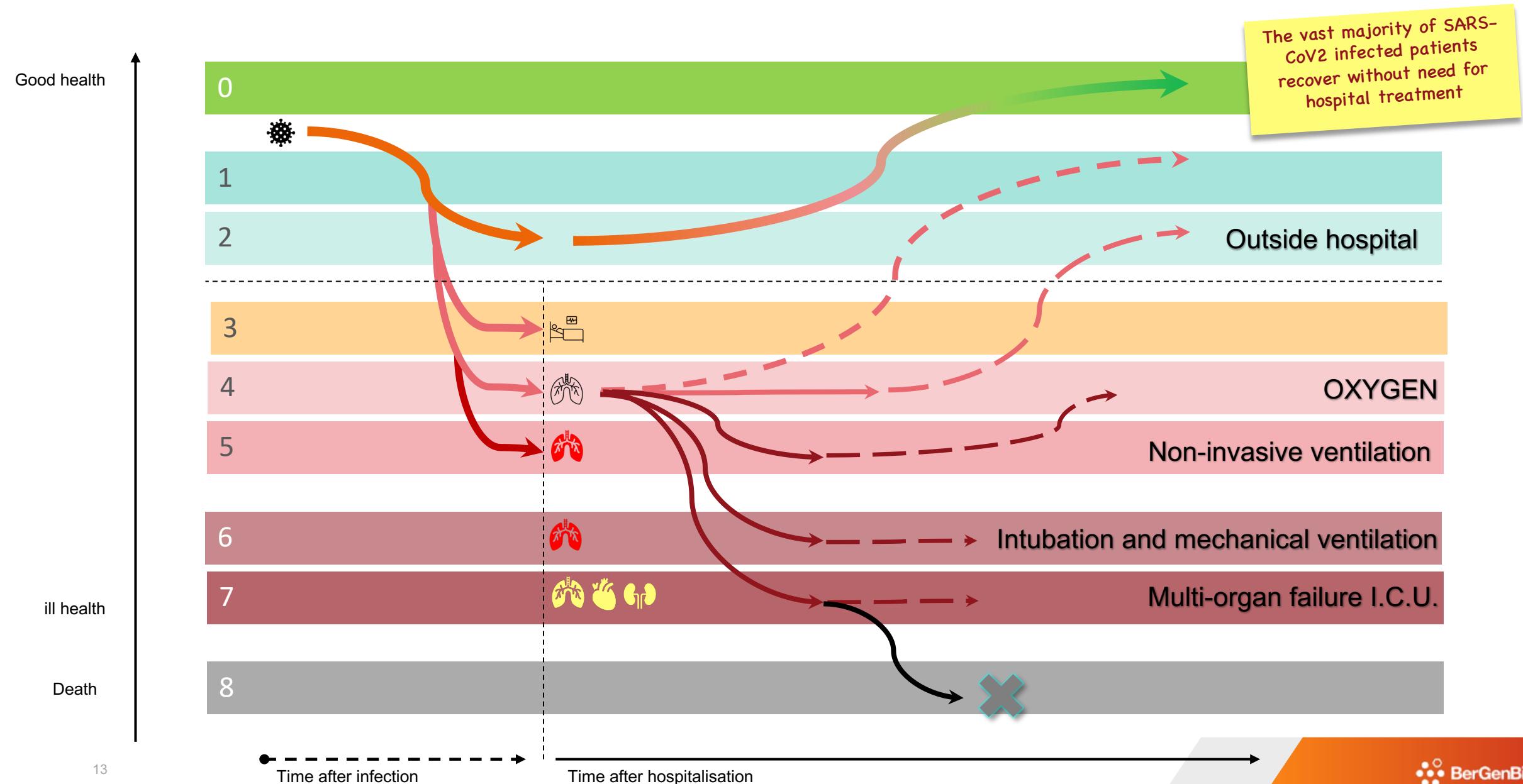
Bemcentinib studied in COVID-19 across 3 countries



Patient Accrual 3/24	India	South Africa	UK	Total
Bemcentinib	30	28	30	88
SoC	30	27	32	89
				177



WHO 9-point scale – graded increase in pulmonary support



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

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

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)

GOALS of COVID19 therapy

1. Preventing death
2. Preventing progression to 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

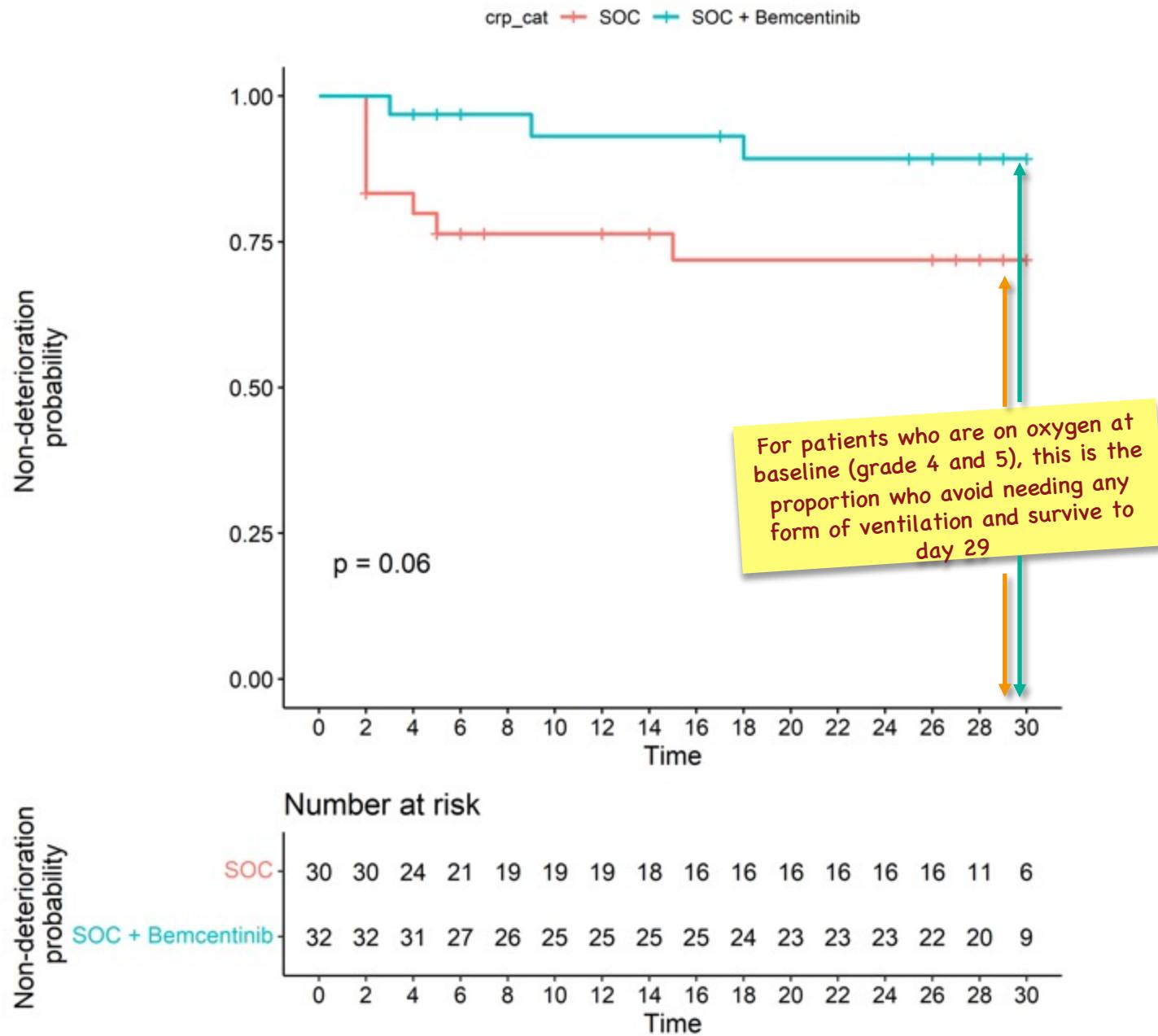
Clinically meaningful endpoint for:

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%)

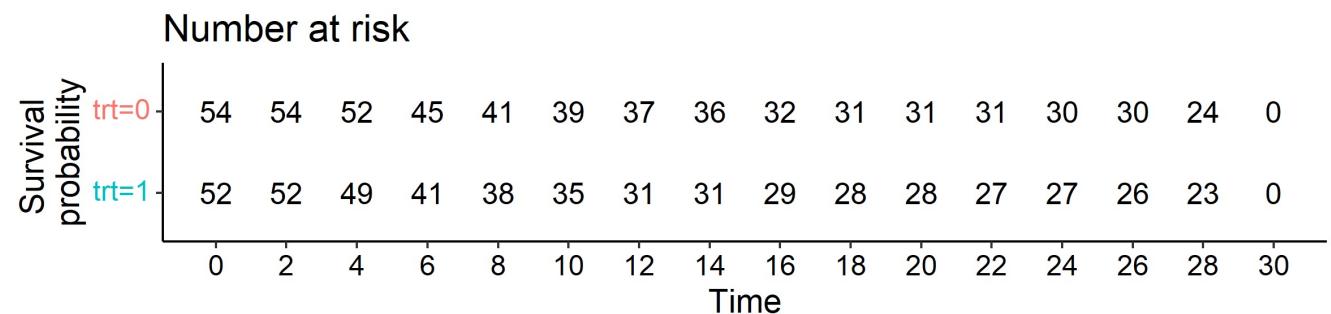
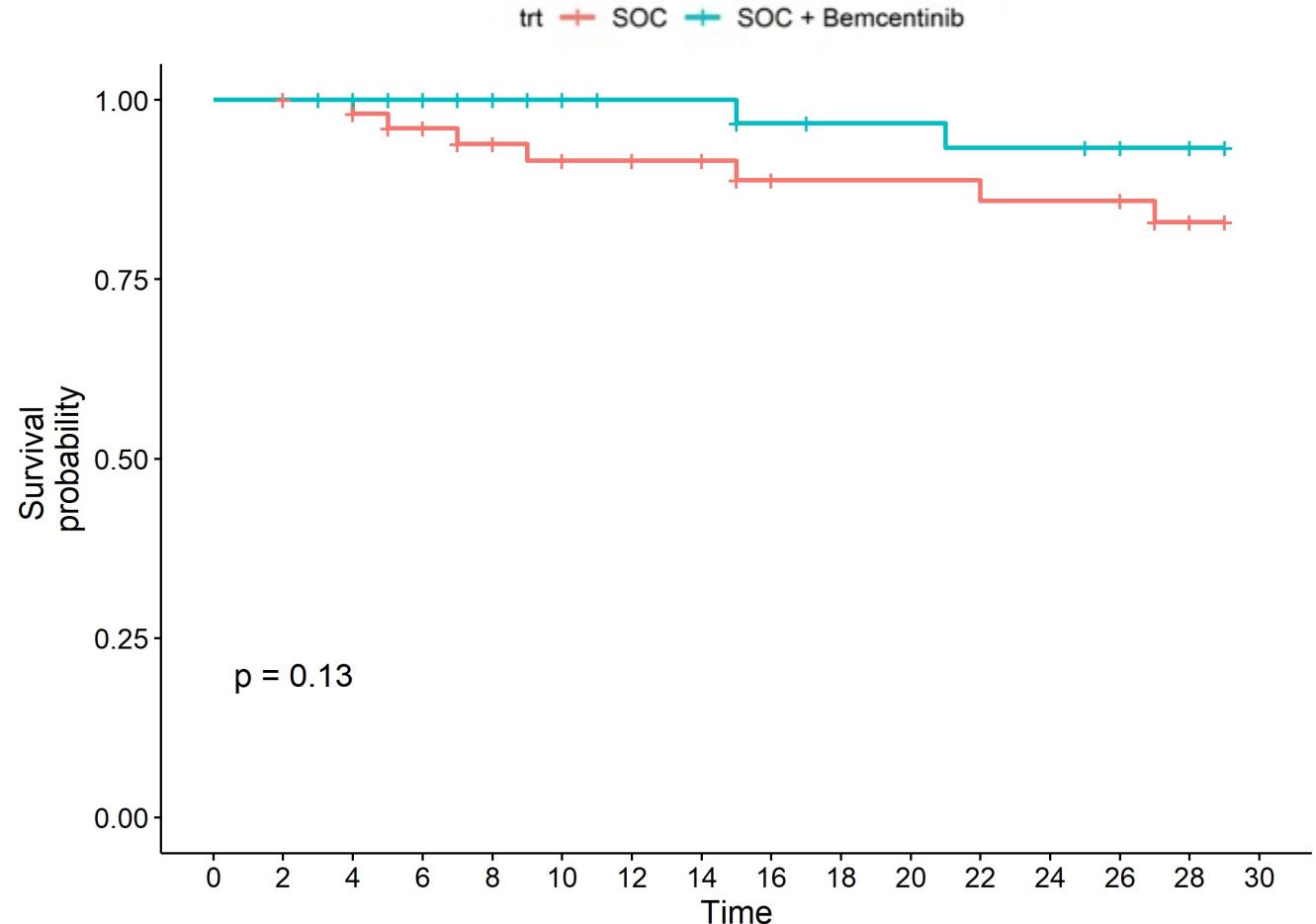


Survival at day 29

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 adults¹

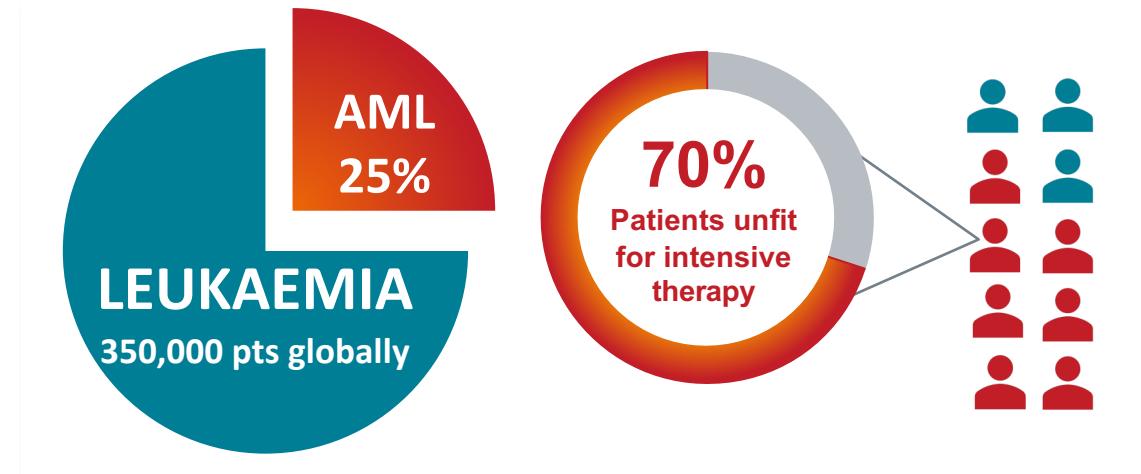
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

~ 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



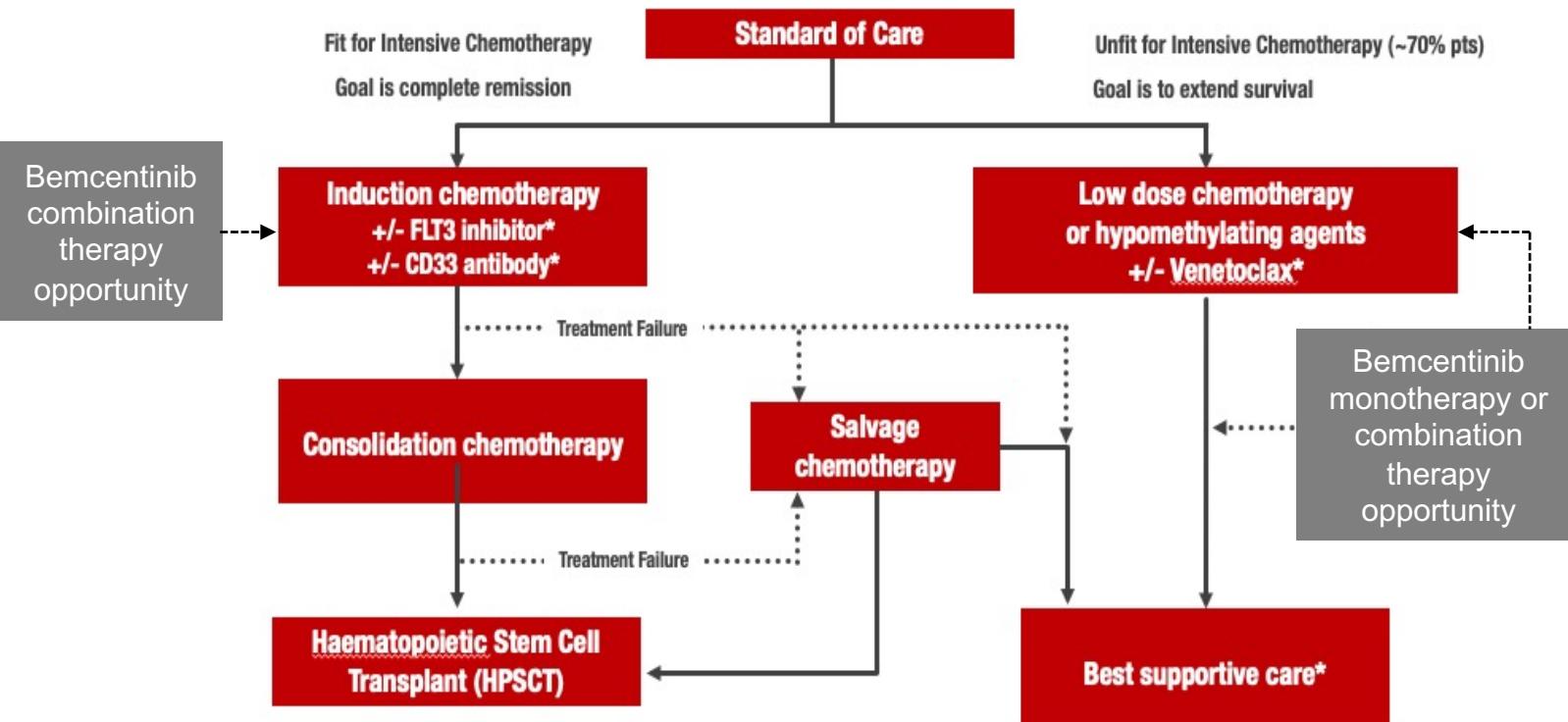
(1) Cancer.gov; (2) SEER; (3) https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble

(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

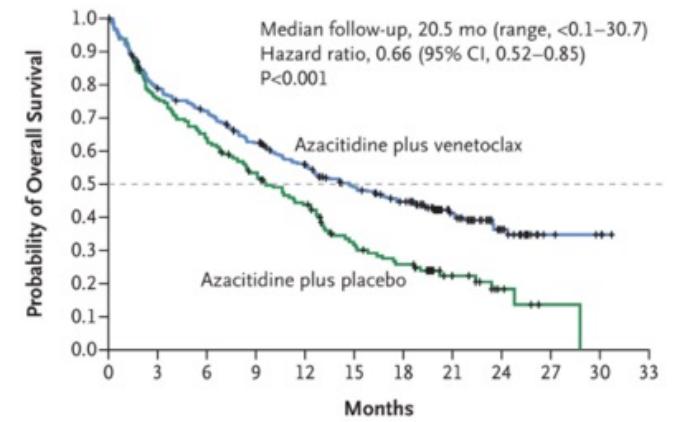
Relapse AML – the need for new treatment options

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)

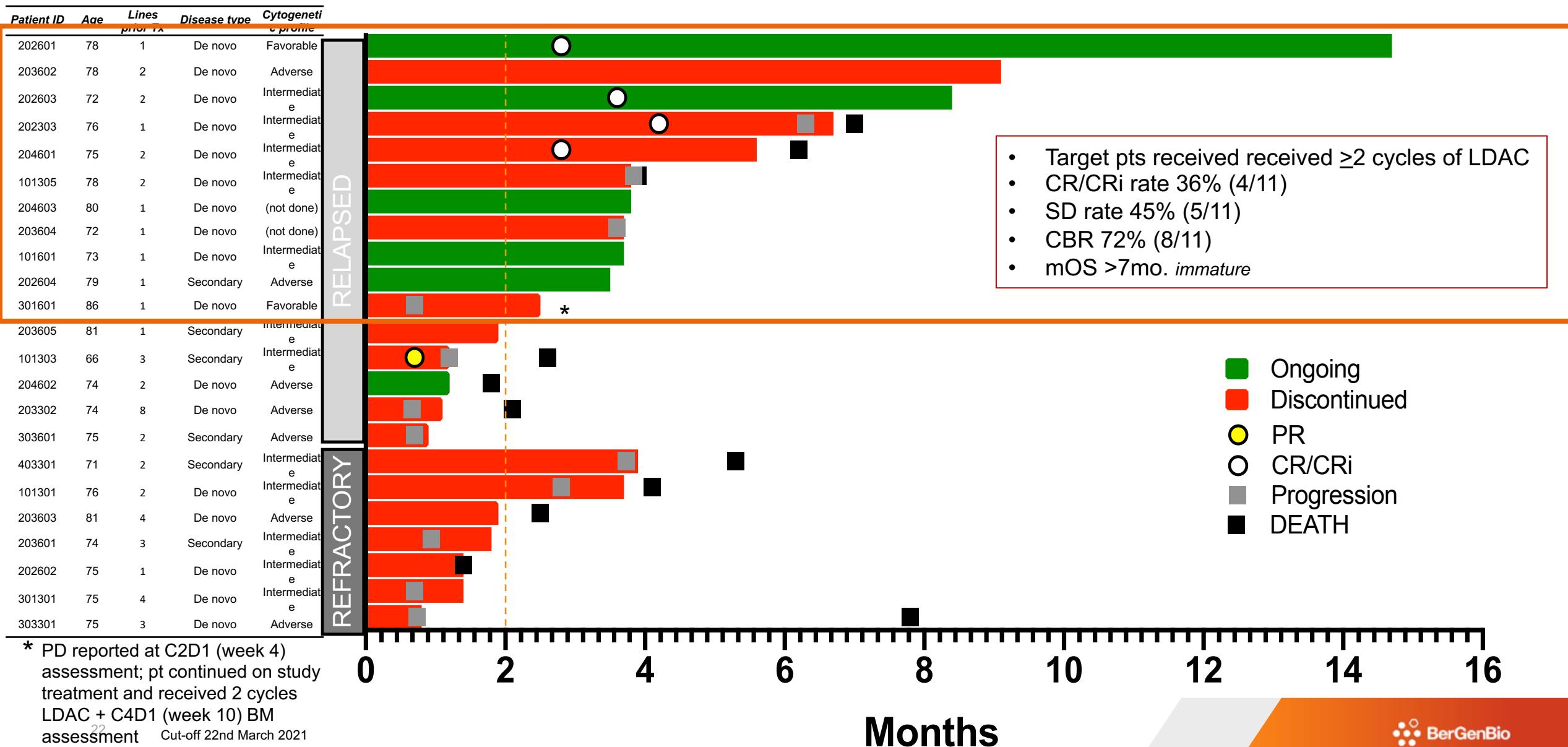
Cohort B3 n=14
Combination with
decitabine in ND or
relapsed AML

Cohort B4 n=14
Monotherapy MDS

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

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

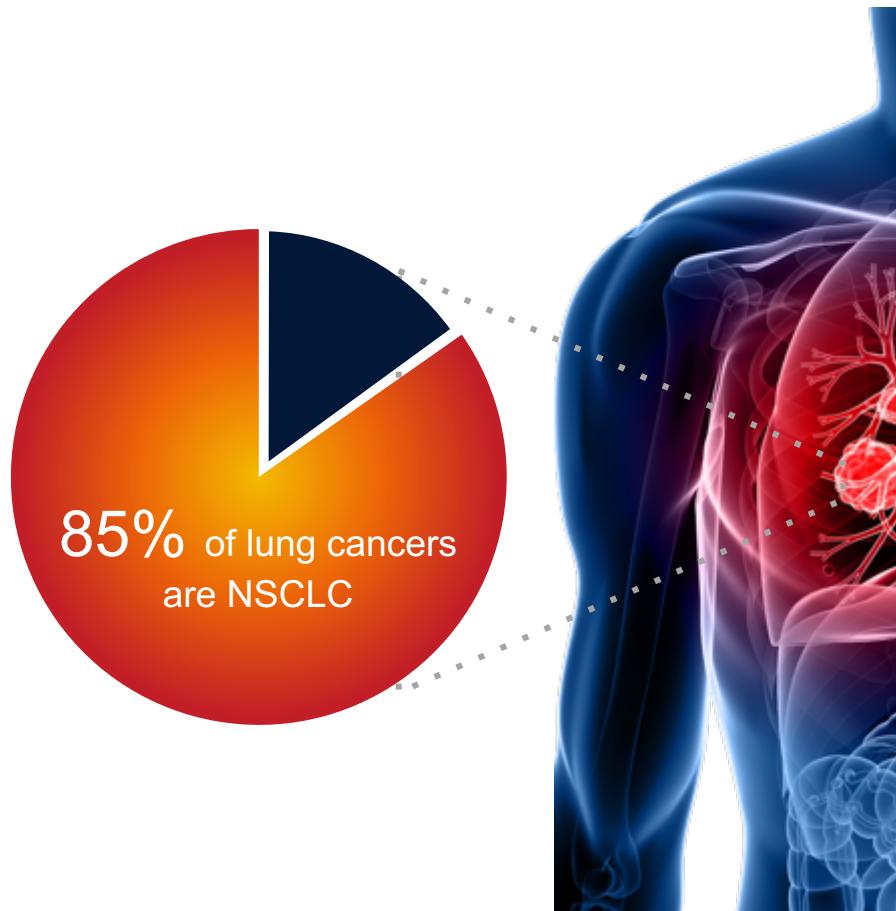
n=17 relapsed, n=7 refractory (16 evaluable) Ongoing study



Bemcentinib clinical development in:

**Refractory NSCLC with
bemcentinib/pembrolizumab combination**

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



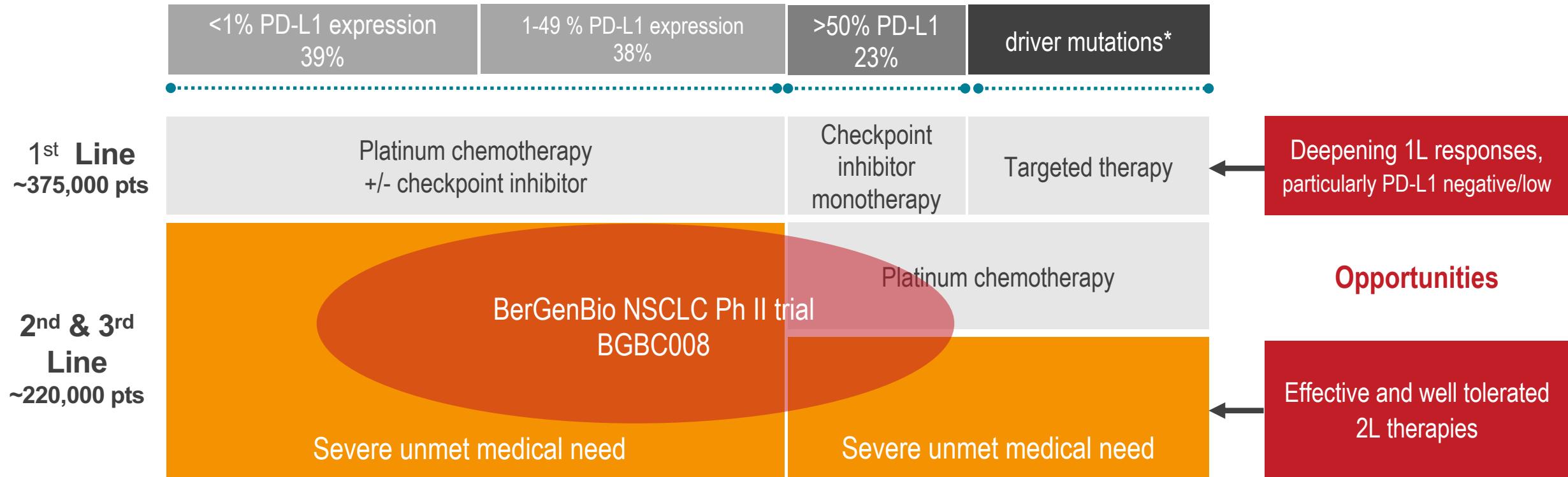
The largest cancer killer, most patients depend on drug therapy

- 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

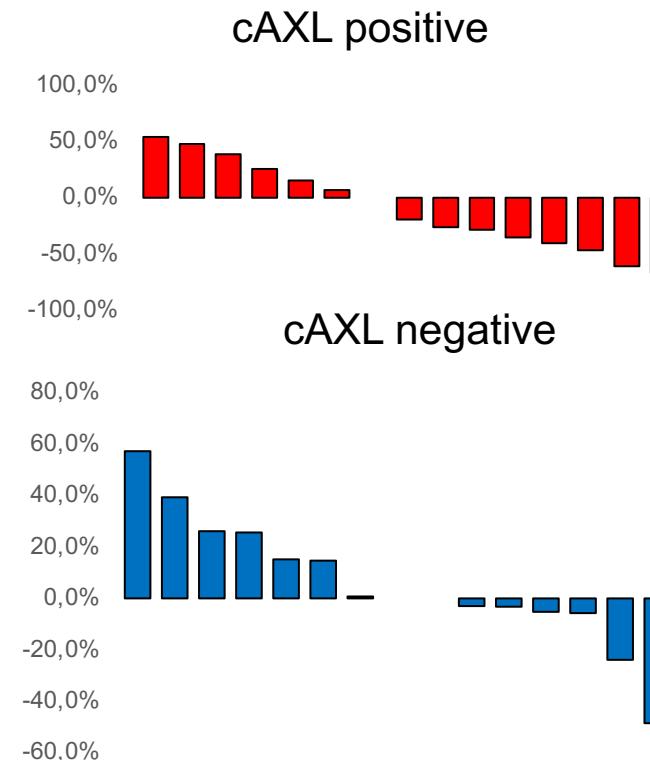
Stage 2

N=29 patients

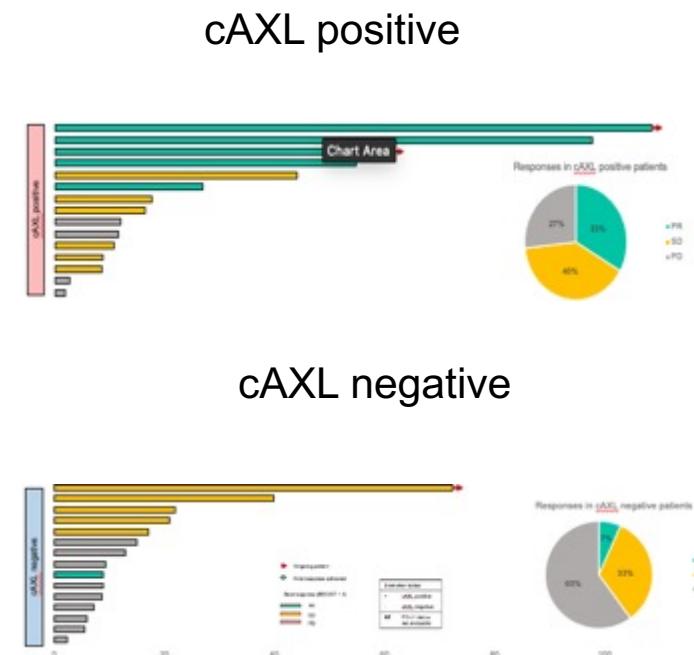
➤ ORR and biomarker data pending

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

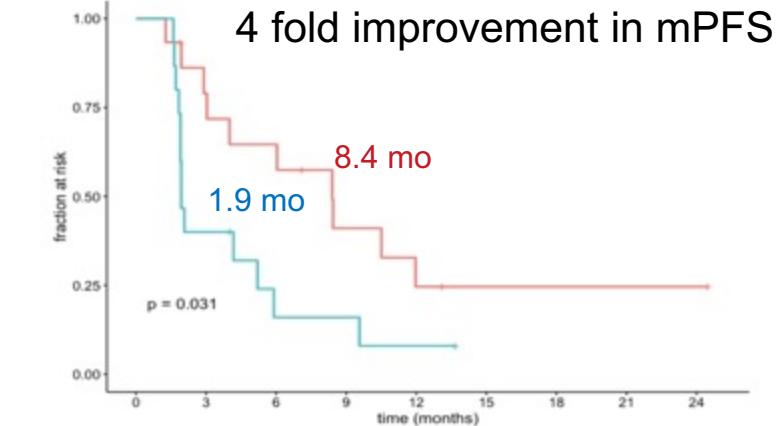
Change in tumor size



Duration of response



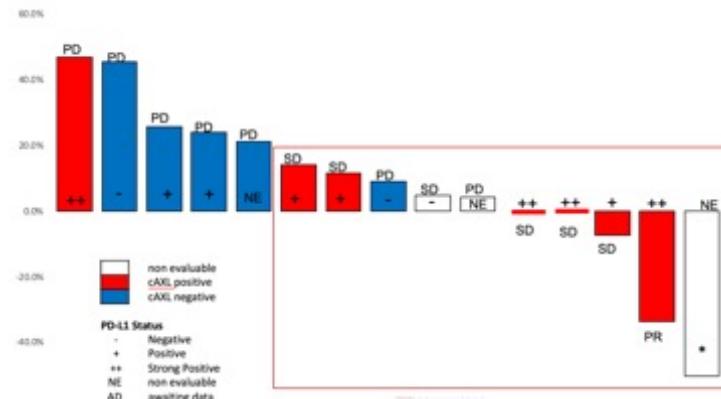
Survival benefit



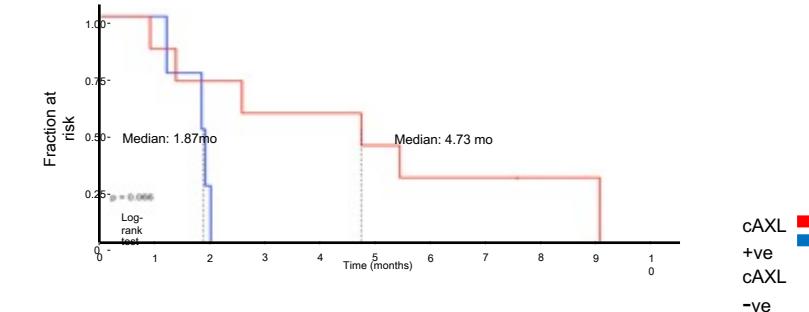
Cohort	mOS	12-mo OS
Cohort A – cAXL +ve pts**	17.3 mo*	79%
Cohort A – cAXL -ve pts**	12.4 mo*	60%
BGB Cohort A – all pts**	12.6 mo*	64%* (up to 67%)
CheckMate-057 (Opdivo)	12.2 mo	51%
KEYNOTE-010 (Keytruda)	10.4 mo	43.2%

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

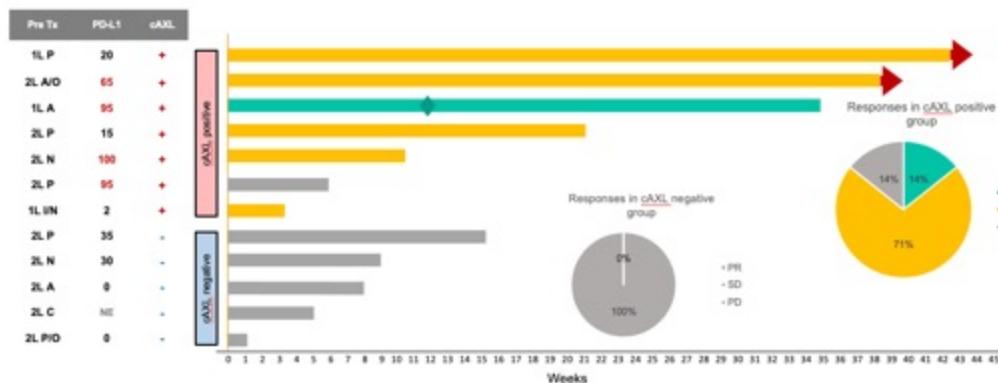
Change in tumour size



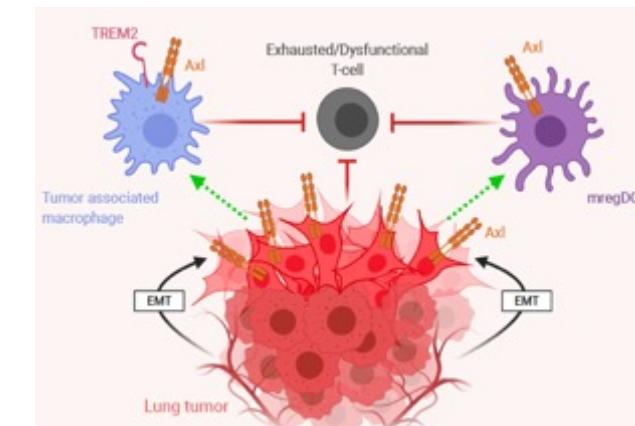
2.5 fold improvement in median progression free survival



Duration of response

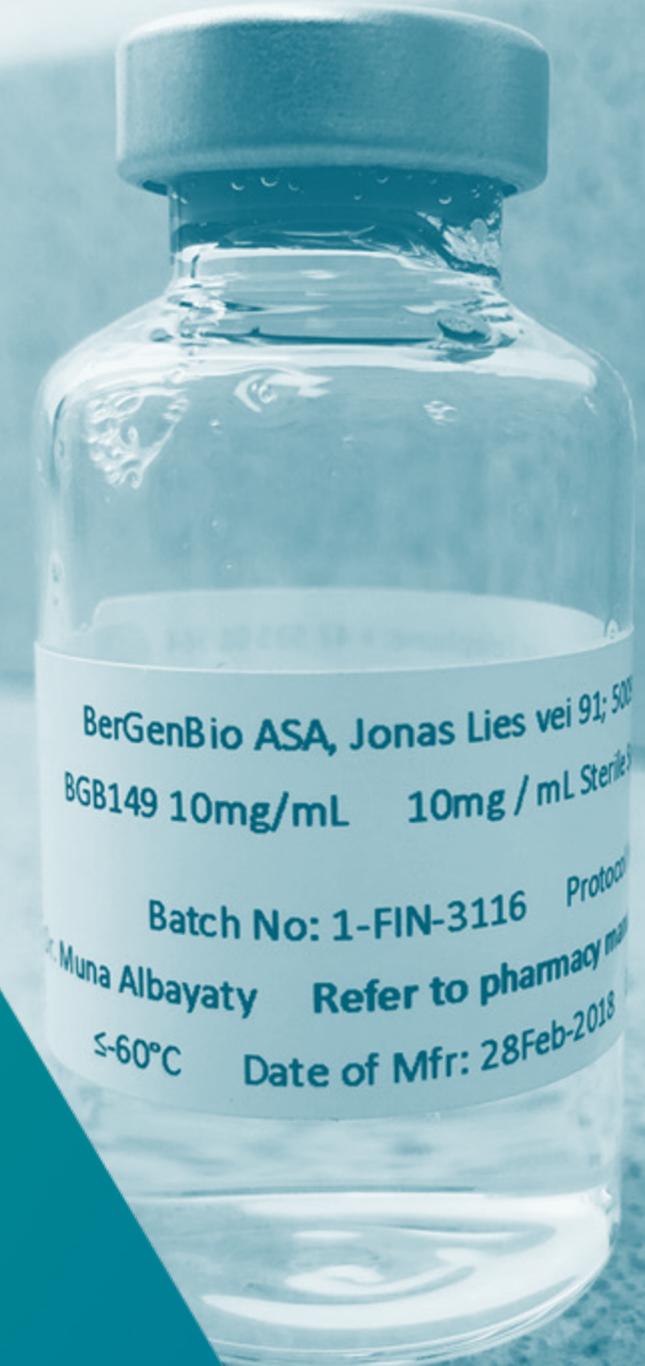


AXL+ve immune suppressive cells identified

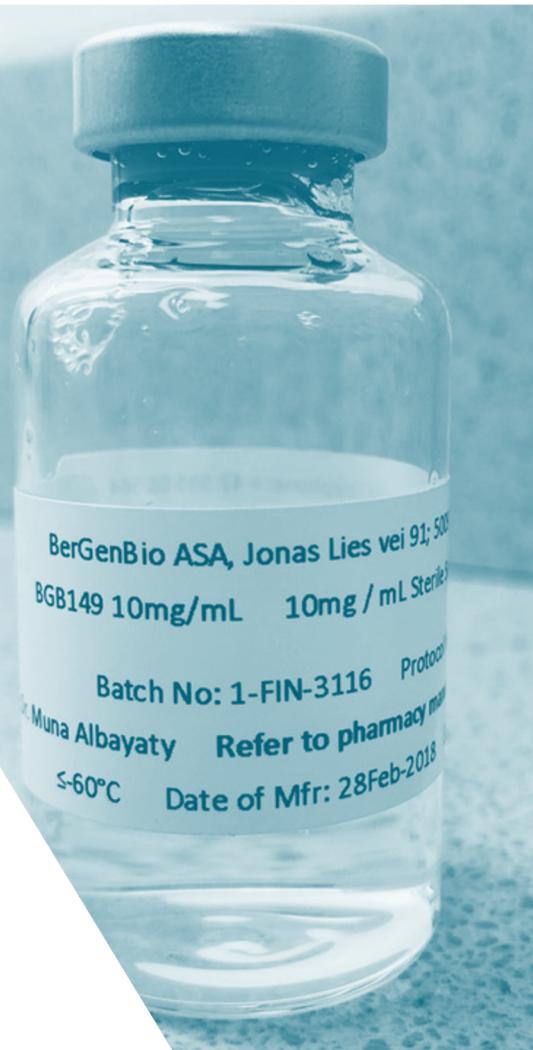




Tilvestamab (BGB149) anti-AXL monoclonal antibody



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

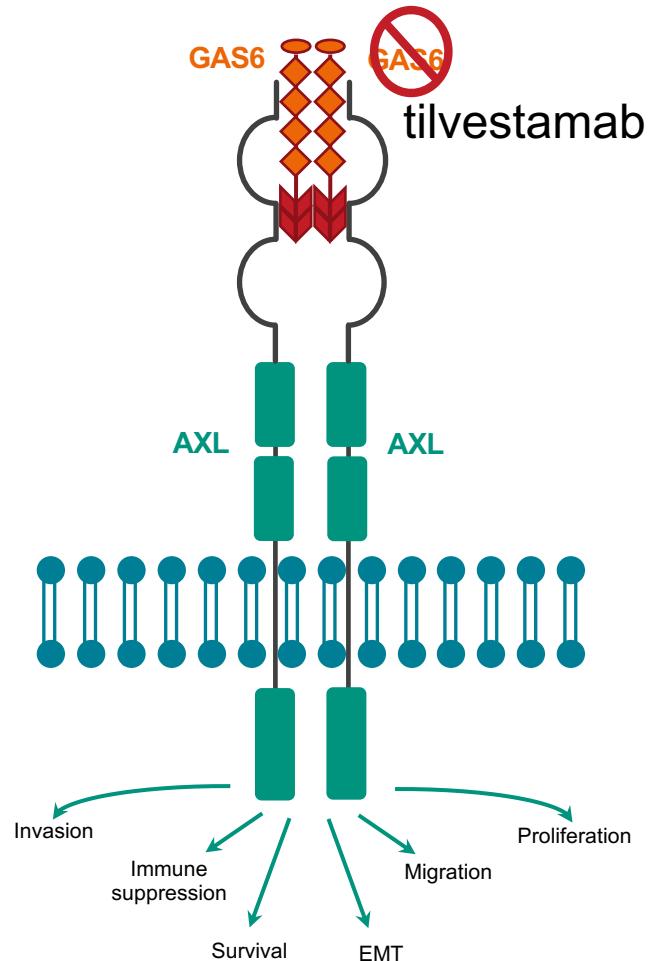
Phase Ia healthy volunteer SAD study complete

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 single dose pharmacokinetics was characterised in study BGB149-101 – Complete

Single ascending dose study in healthy volunteers



Study design

- Single IV dose at day 1
- 84 day observation with intensive PK over days 1-7
- 24 healthy volunteers
- Ascending dose cohort with randomised sentinel dosing 1:1
- Protocol Steering Committee (PSC) review prior to dose escalation

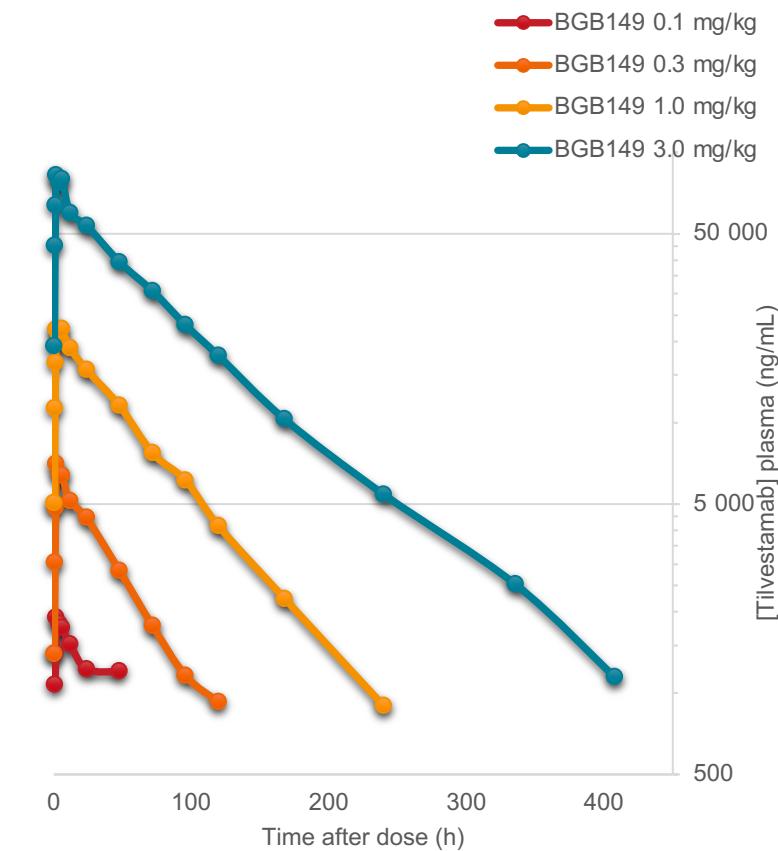
Tilvestamab was generally well tolerated at all doses studied, up to 3.0 mg/kg IV.

Safety:

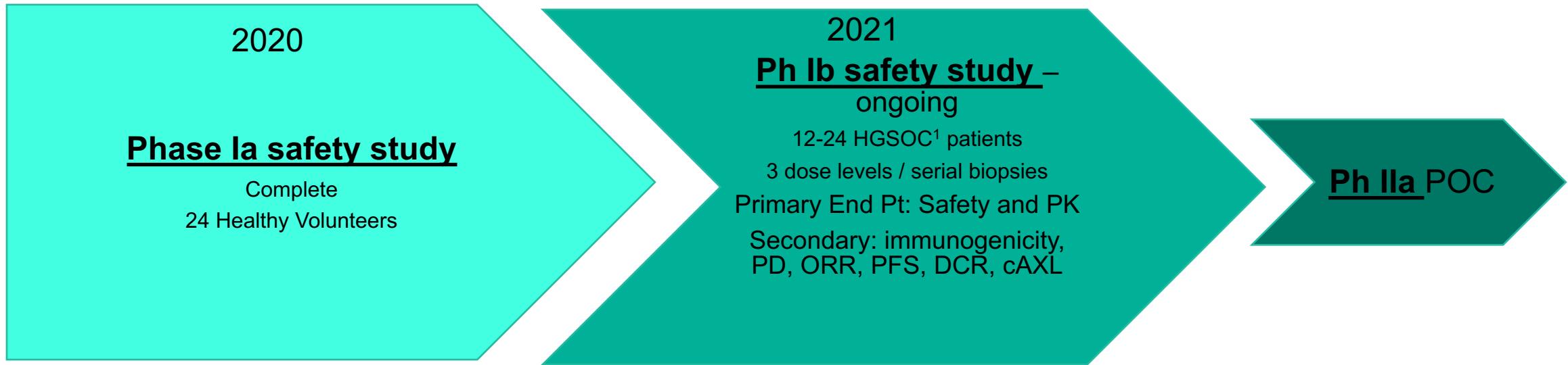
- Adverse events, mild transient and comparable to placebo
- No observed immunogenicity
- No observed stimulation of cytokines or raised inflammatory markers - c-reactive protein (CRP)

Pharmacokinetics

- Above dose-proportional increase in overall plasma exposure with ascending dose
- Detectable antibody at biologically relevant concentrations >18 day after single dose of 3 mg/kg
- Potential for 3 weekly dose interval in later phase clinical studies



Tilvestamab development plan



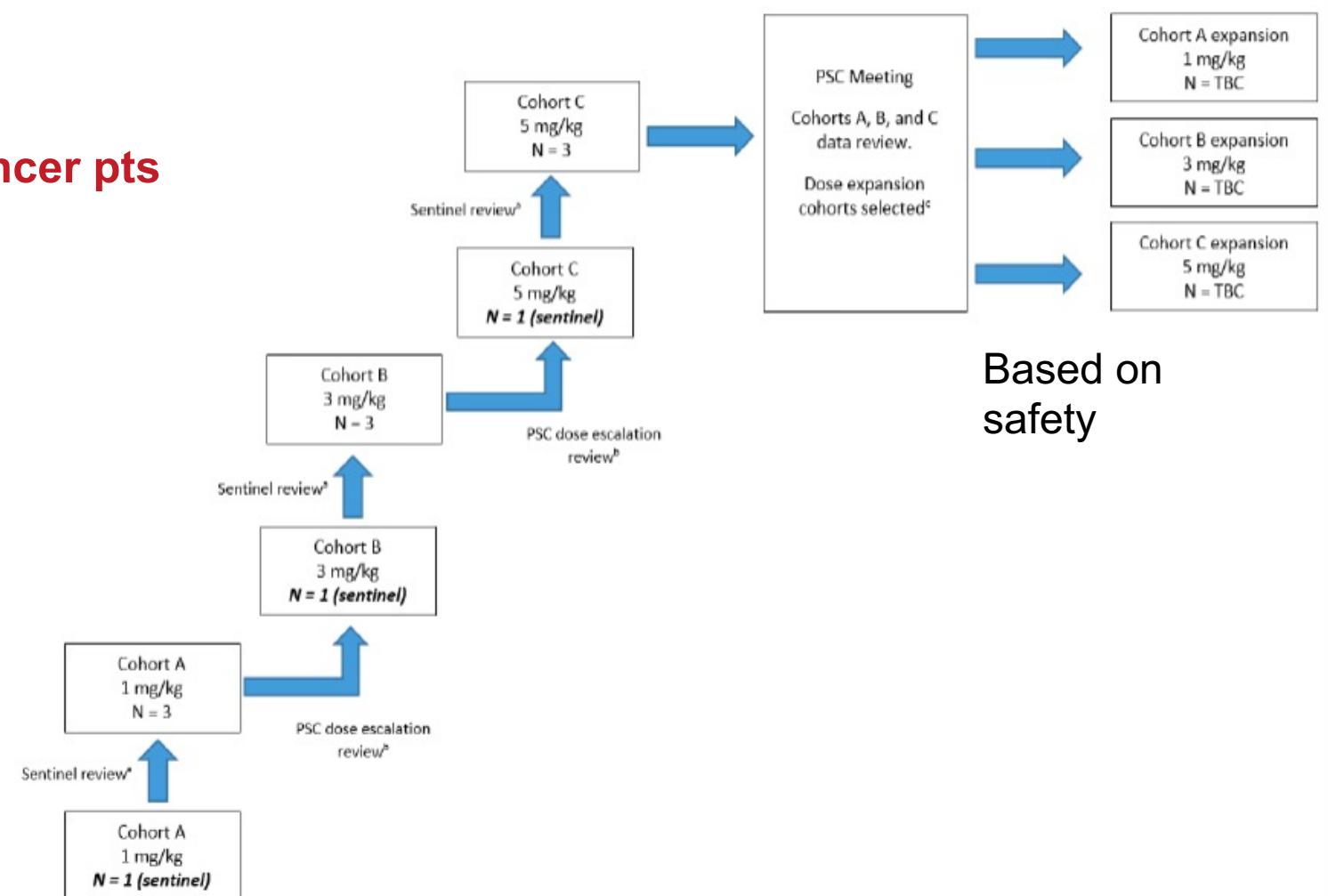
Safety – no dose limiting toxicity seen up to 3mg/kg dose
Pharmacokinetics - exposure predictable with dose proportional Cmax increase
Confirmatory evidence of *in vivo* target engagement with sAXL -- stabilisation in circulation

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



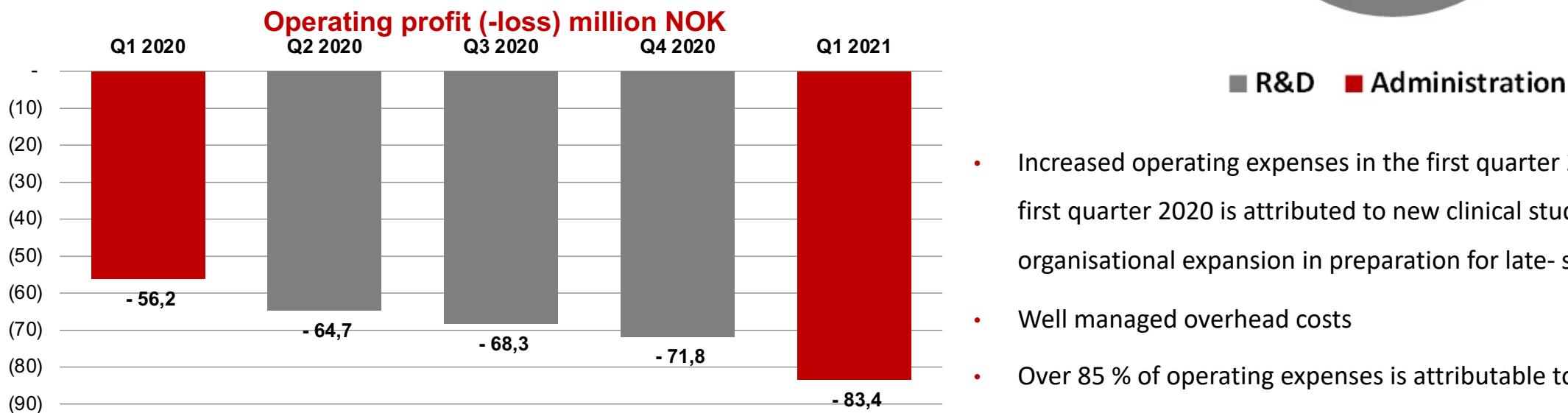
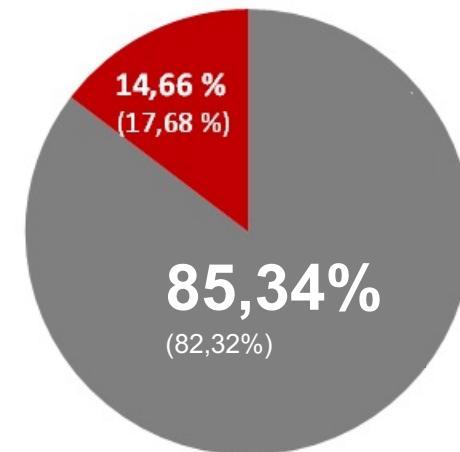
Finance Report

CFO Rune Skeie

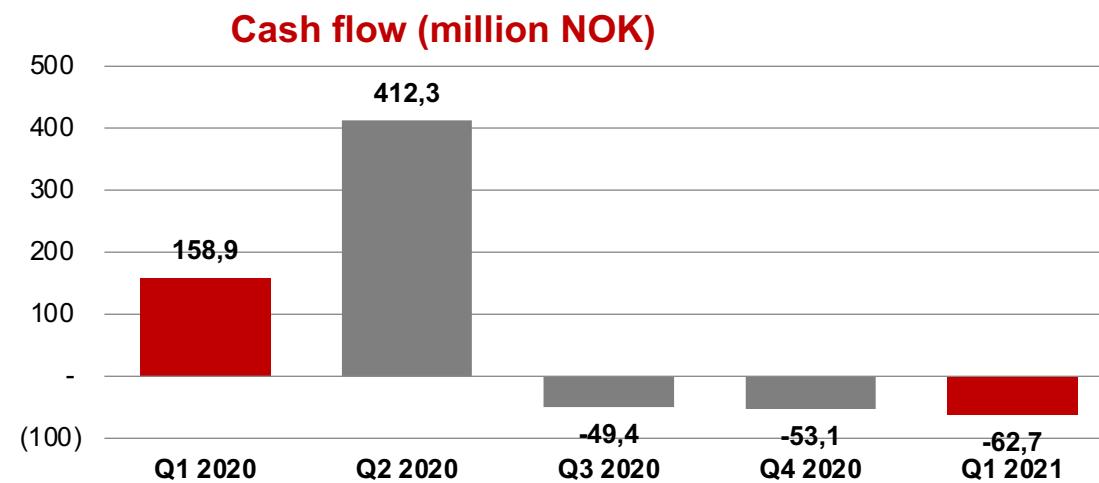
Key financial figures

(NOK million)	Q1 2021	Q1 2020	FY 2020
Operating revenues	0.0	0,0	0.6
Operating expenses	83.4	56.2	261.7
Operating profit (-loss)	(83.4)	(56.2)	(261.1)
Profit (-loss) after tax	(81.2)	(48.6)	(257.0)
Basic and diluted earnings (loss) per share (NOK)	(0.93)	(0.73)	(3.43)
Net cash flow in the period	(62.7)	(158.9)	468.8
Cash position end of period	659.4	419.4	721.6

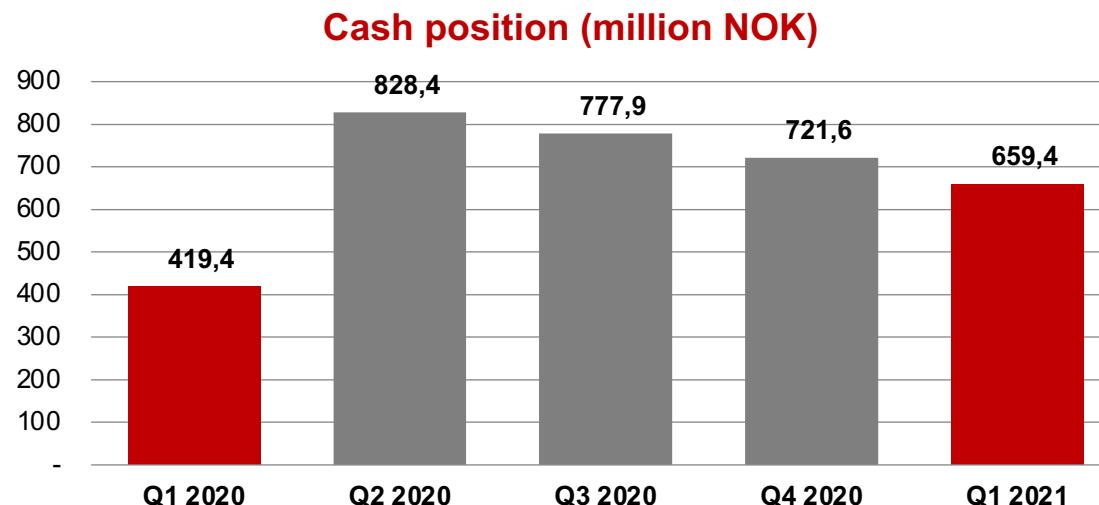
Operating expenses Q1 2021
(FY 2020)



Cash flow and cash position



Cash burn operating activities Q1 2021
70.8 / 8.3
NOK million USD million



Quarterly average cash burn (Q1 2020-Q1 2021)
57.3 / 6.3
NOK million USD million

Cash position Q1 2021
659.4 / 77.3
NOK million USD million

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Financial Calendar 2021

19 May 2021: Quarterly Report Q1 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

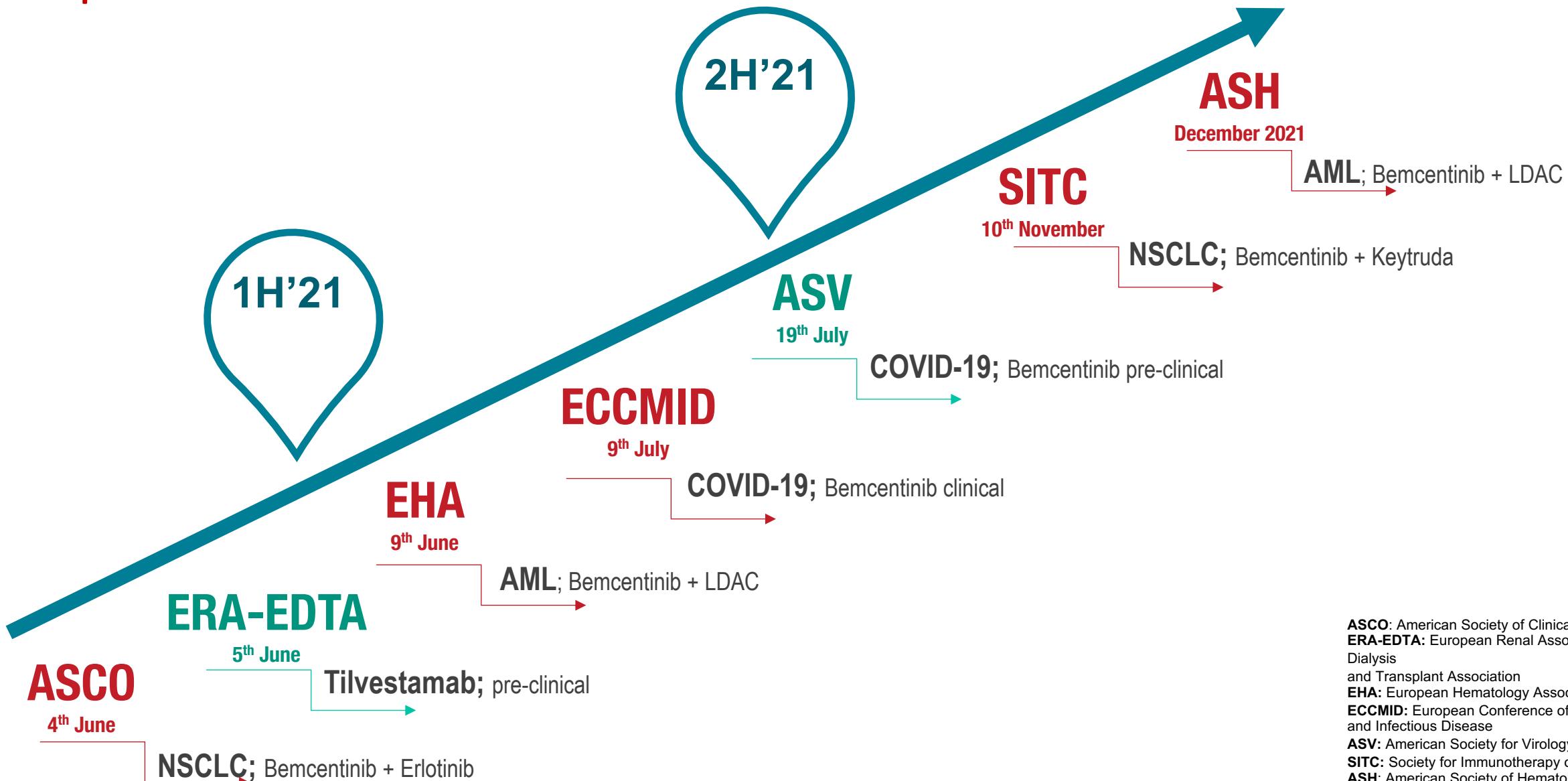
Top line data

Determine
development &
regulatory options

- Survival data
- Regulatory
alignment

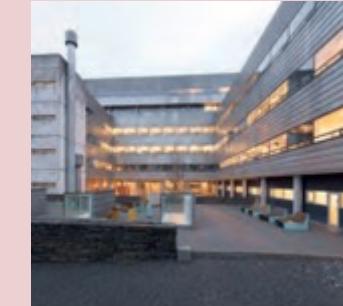
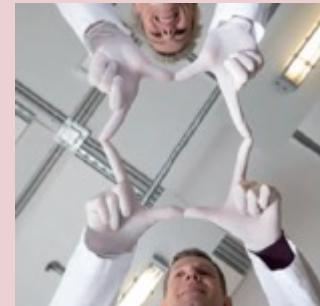
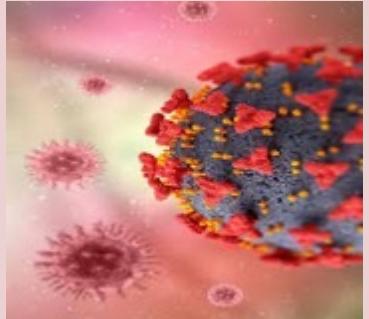
- Prepare to
Initiate Ph II

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



PhII COVID-19

Top line data:

- ✓ Safety
- ✓ Fewer deaths
- ✓ Increased ventilator free survival
- ✓ 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