

SACHS ASSOCIATES

7th ANNUAL IMMUNO-ONCOLOGY INNOVATION FORUM
18th - 20th of May 2021

BerGenBio ASA

Business update presentation



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Forward Looking Statements

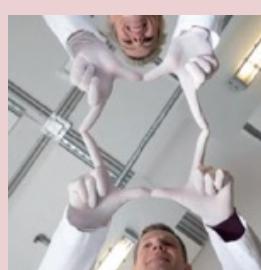
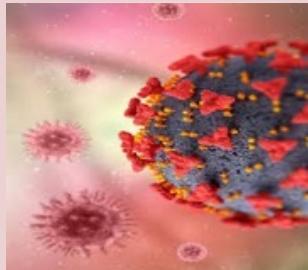
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BerGenBio – Developing first in class AXL inhibitors for aggressive disease

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

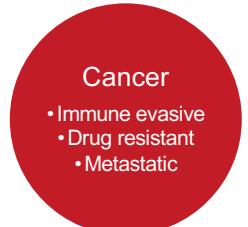
Industry & academic partnership and collaborations

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

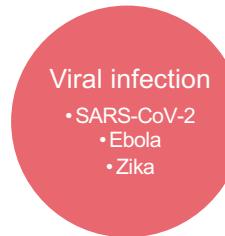
AXL mediates aggressive disease

Very low expression under healthy physiological conditions

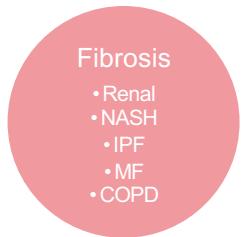
AXL signaling is upregulated by hostile cellular microenvironment and viral infection



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



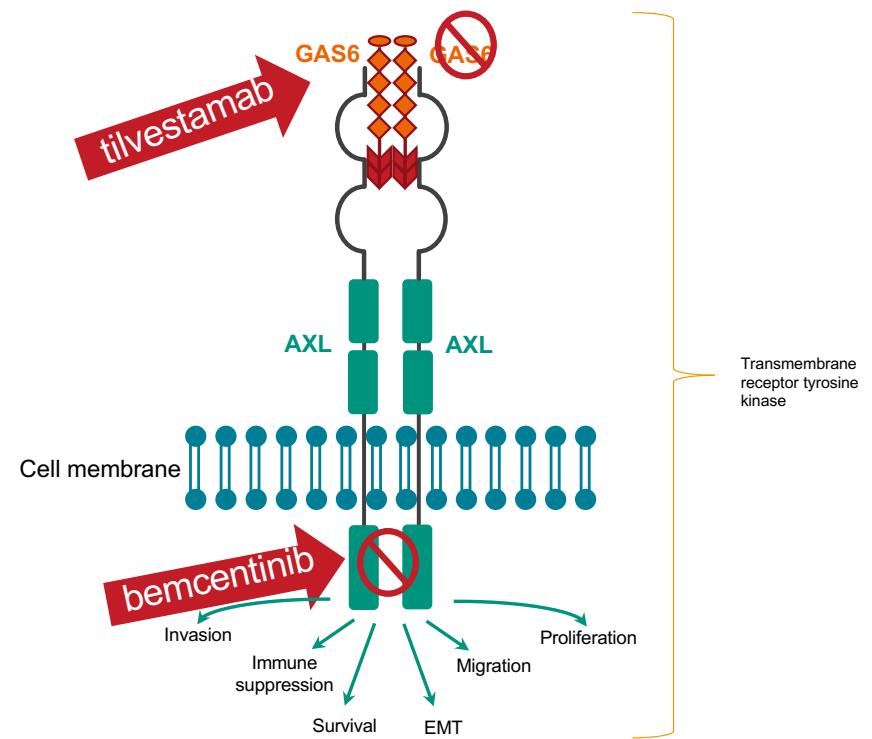
AXL mediates viral entry to cells and dampening of viral immune response



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

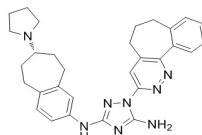


Two first-in-class, potent, highly selective AXL inhibitors in clinical development

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



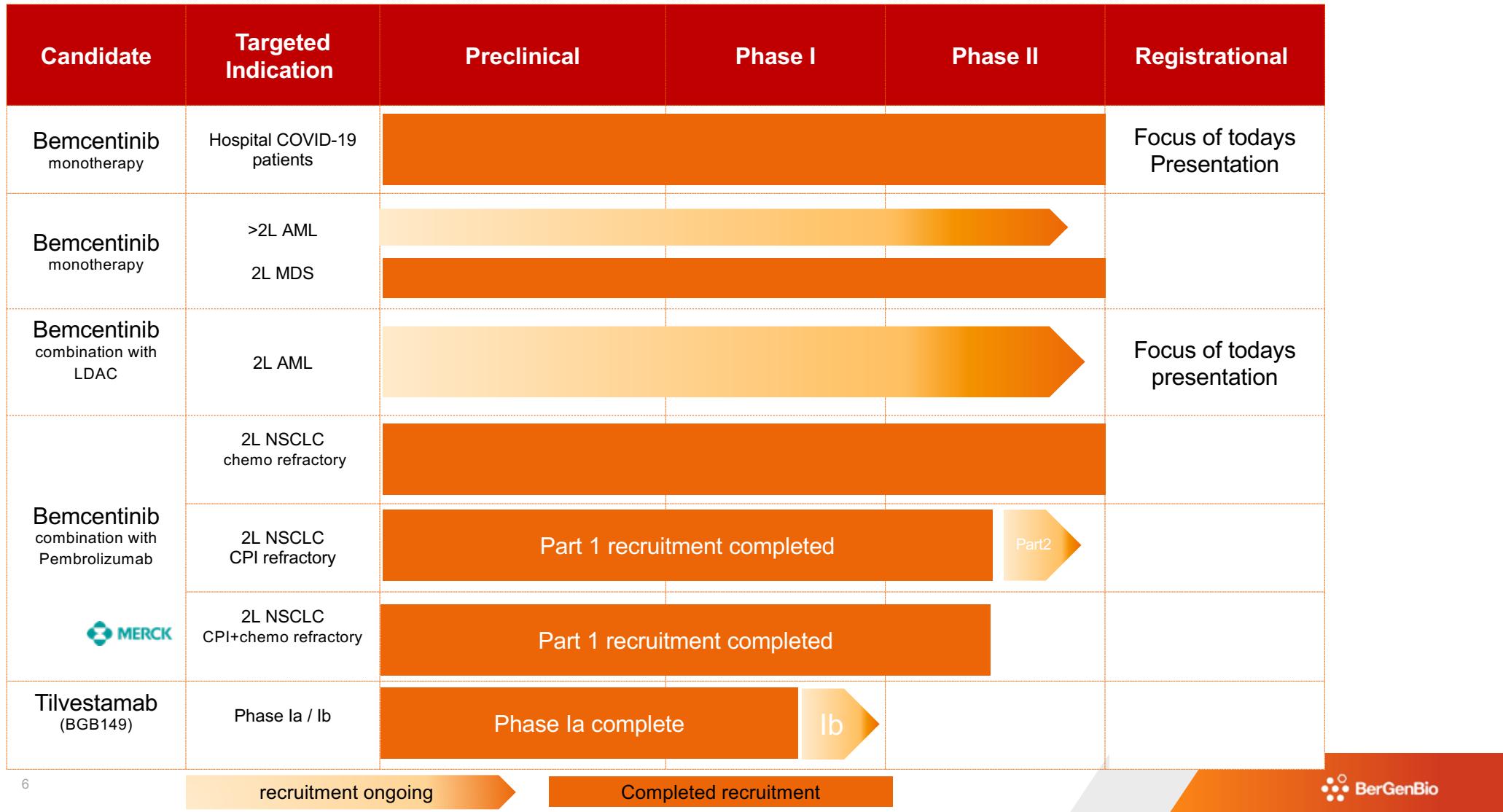
- Nano-molar potency
- 50-100 selective for Axl

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



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 path

- Survival data
- Regulatory
alignment

- Prepare to
Initiate Ph II

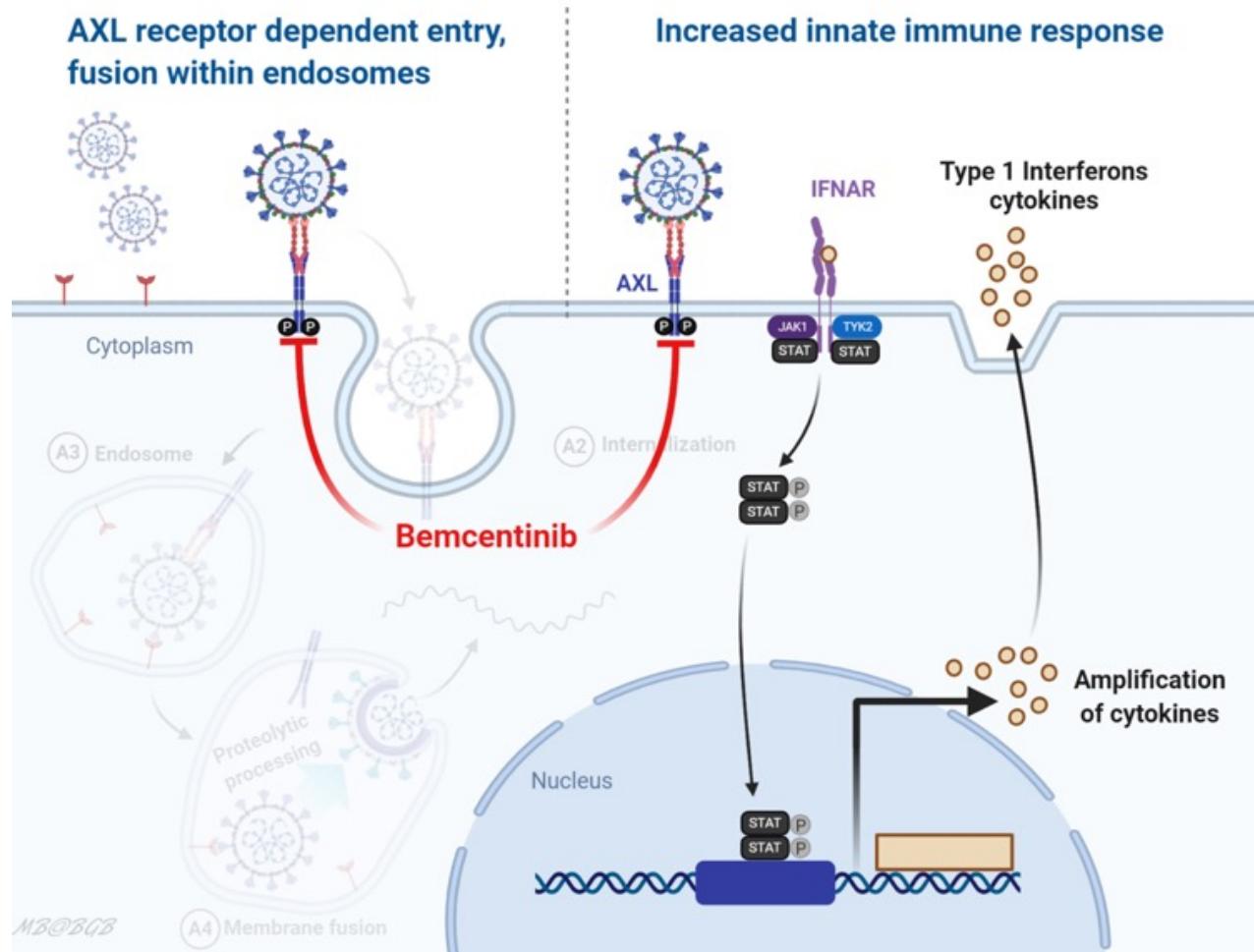
BEMCENTINIB CLINICAL DEVELOPMENT IN HOSPITALISED COVID-19 PATIENTS

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

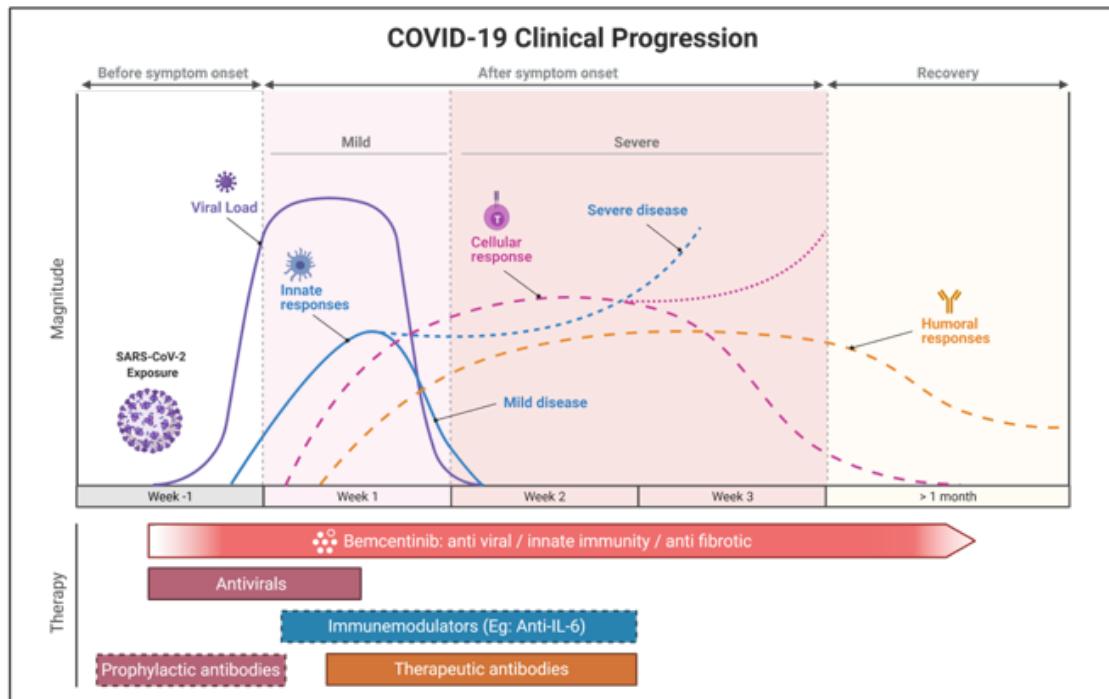
Prevents viral infection and promotes innate immunity



Bemcentinib:

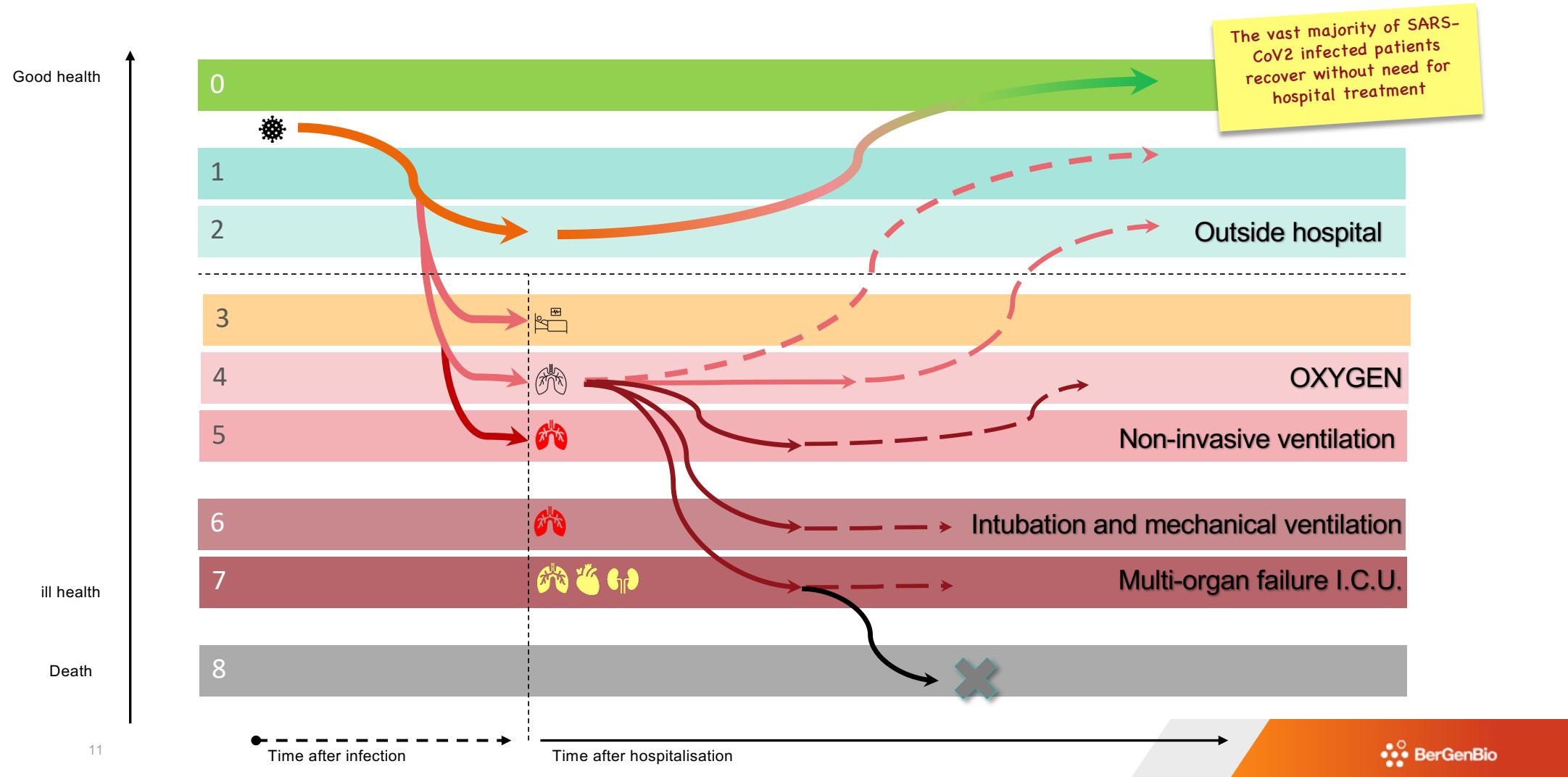
- **blocks AXL-dependent viral entry**
- **enhances anti-viral interferon response**
- **Mode of action is independent of spike protein (or mutations)**

Summary of bemcentinib as a COVID-19 therapy



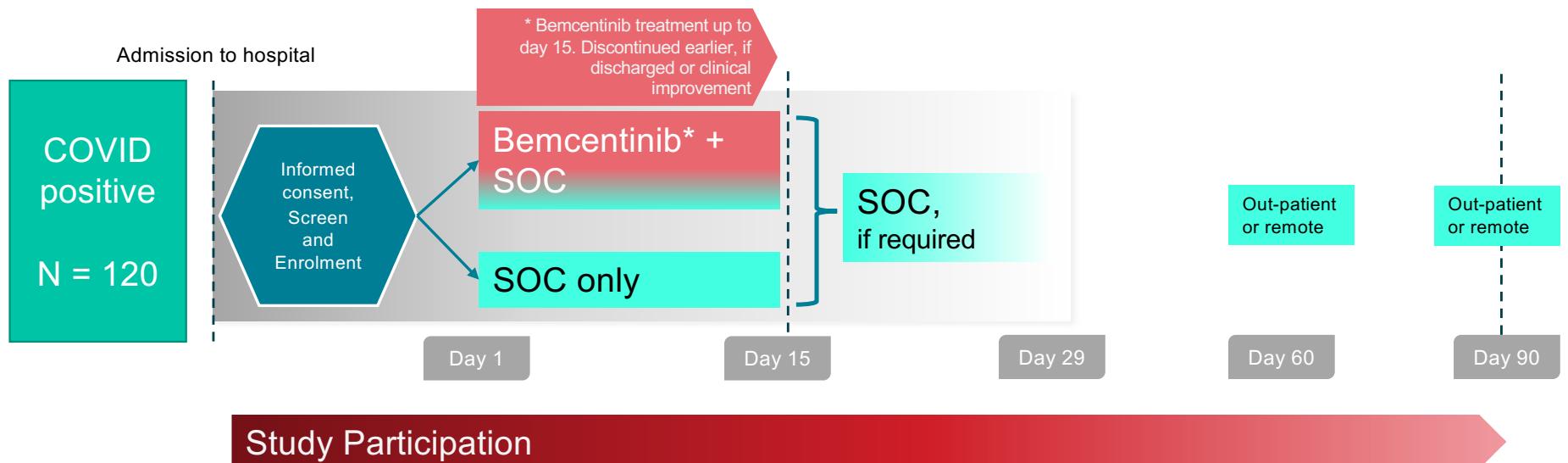
- **Bemcentinib acts on two host pathways**
 - Prevents viral infection
 - Promotes innate immunity
- **Bemcentinib inhibits viral entry by inhibiting AXL**
 - AXL is independent of viral spike protein and should remain effective against current and future variants
 - Ongoing work will confirm viral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

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 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:

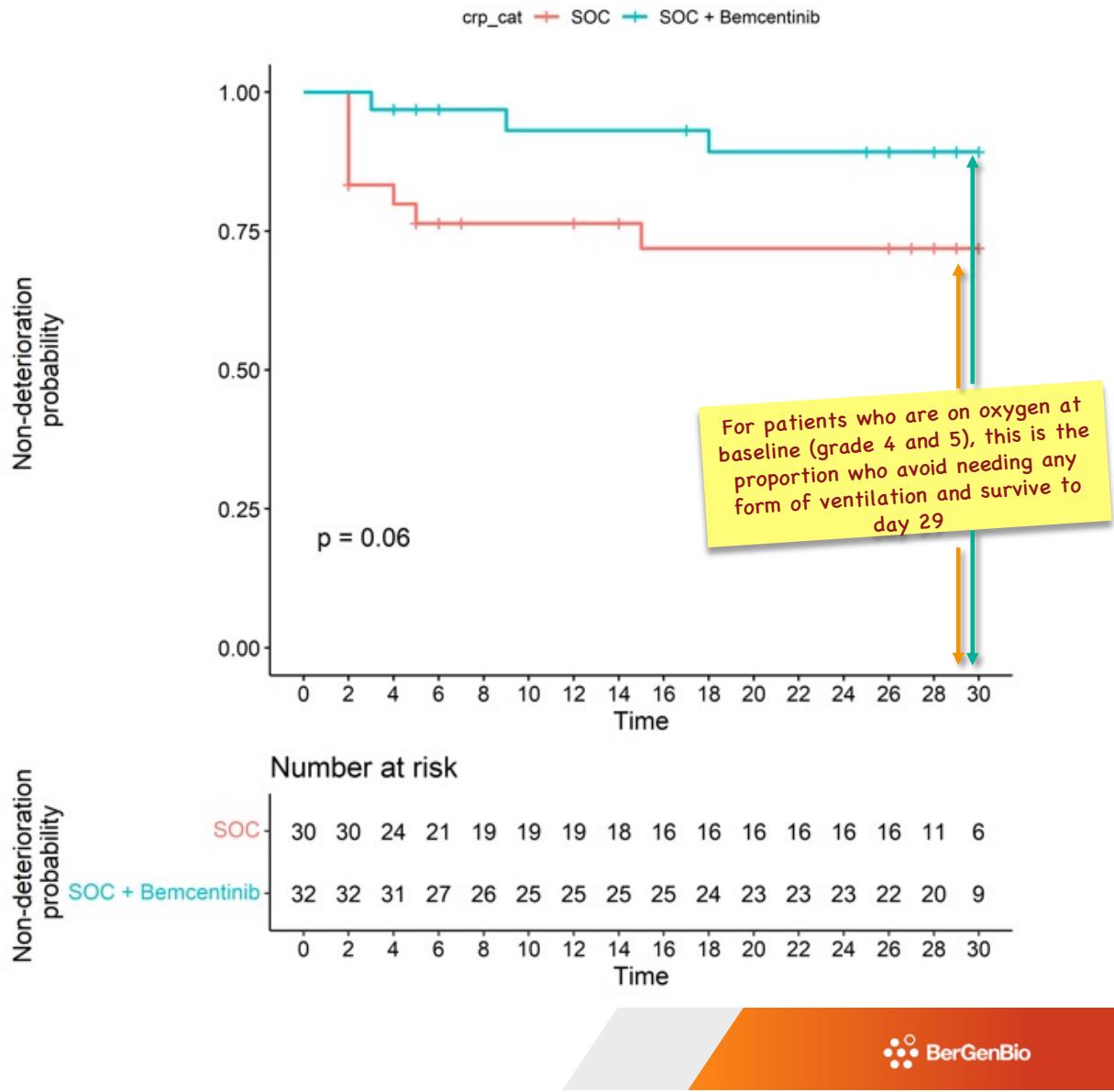
1. Individual Patient health – both acute, and long-term
2. Healthcare system; resource constraints

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%)

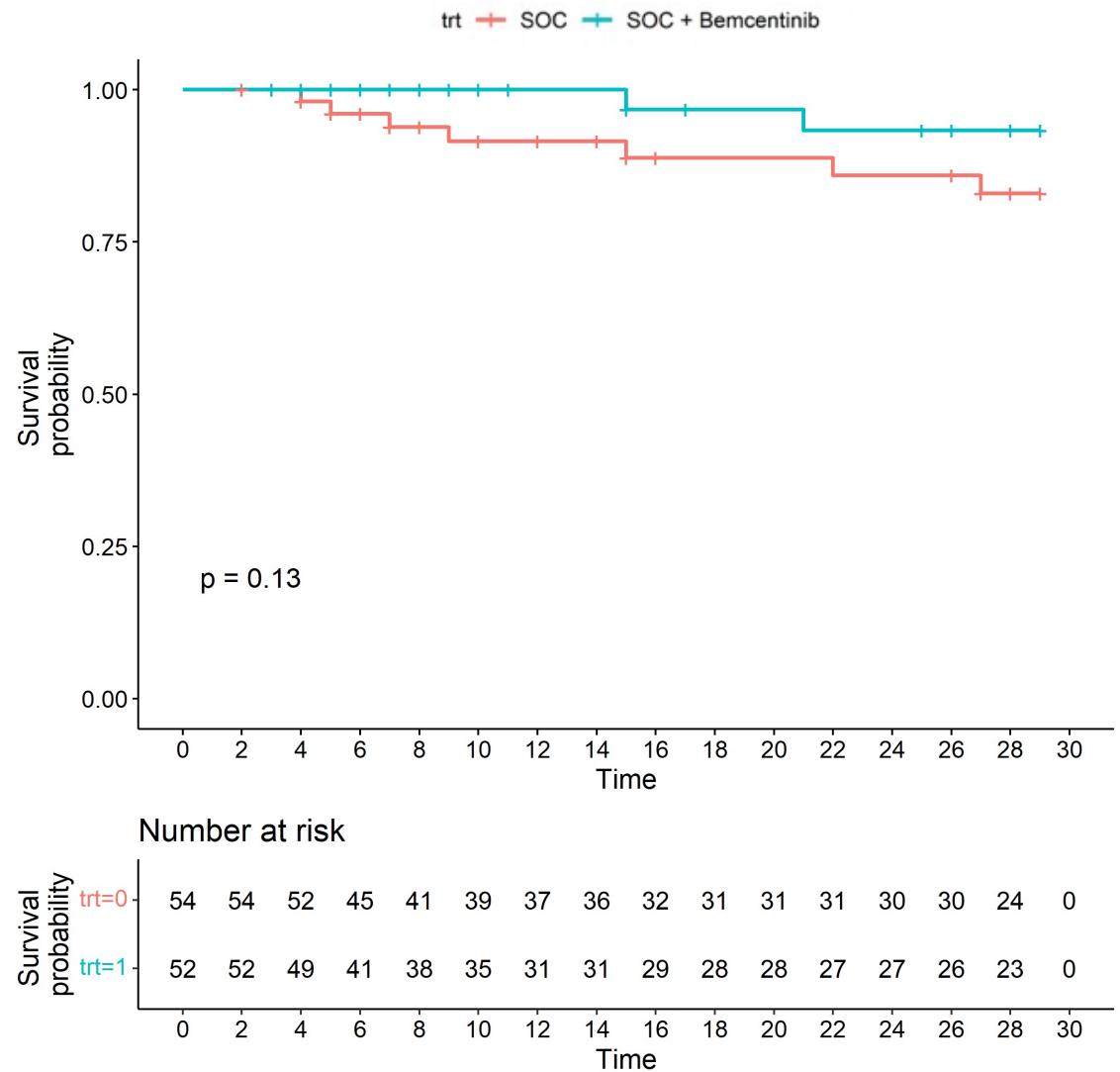


Survival at day 29

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 adults¹

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

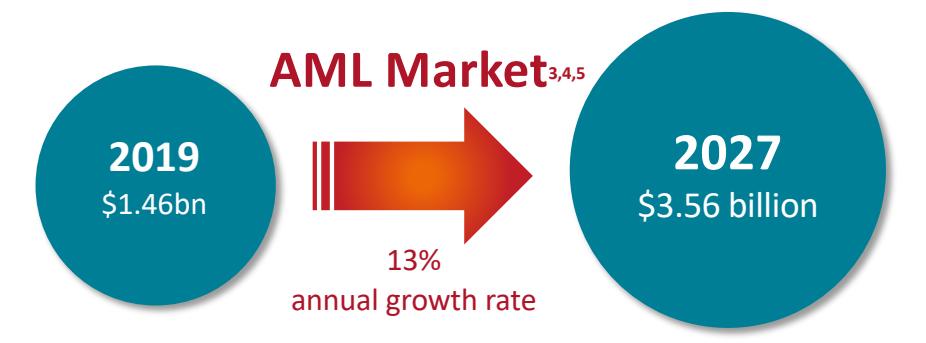
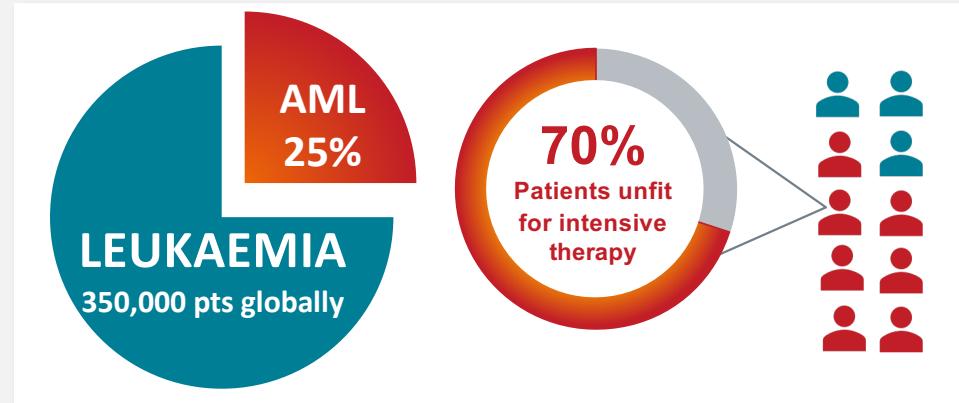
~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018²

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

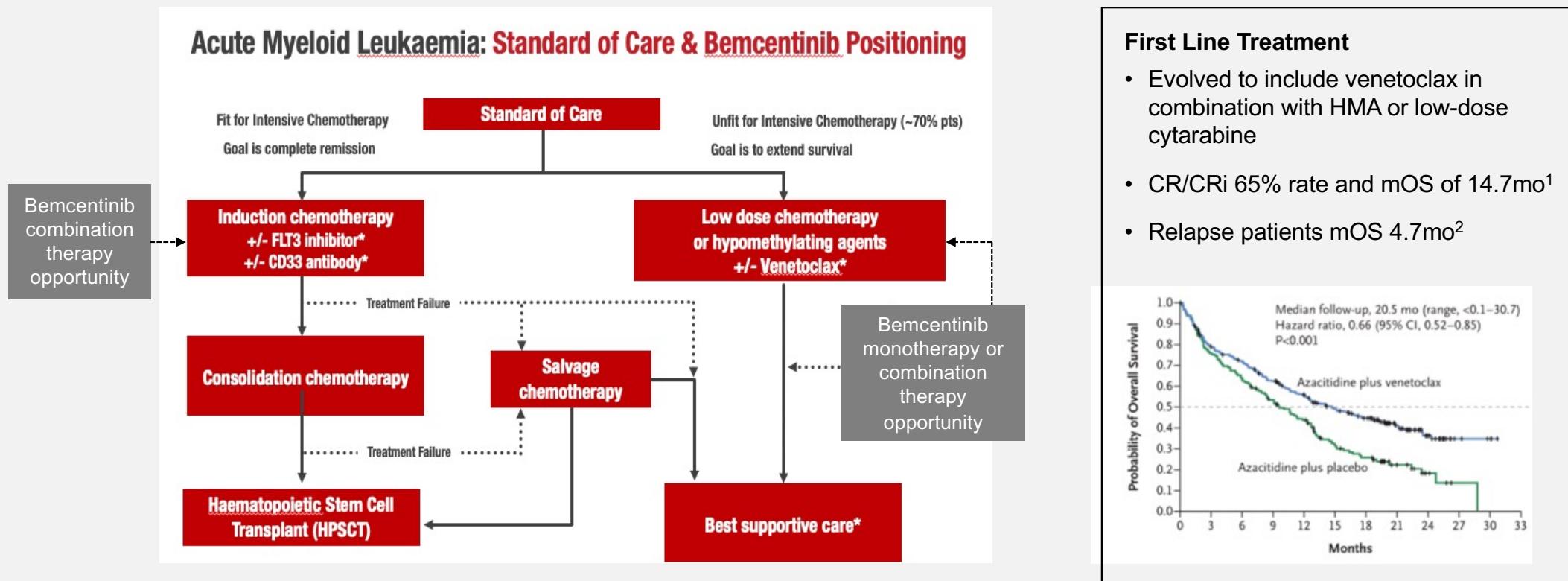


(1) Cancer.gov; (2) SEER; (3) https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble

(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



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 B3 n=14
Combination with decitabine in AML

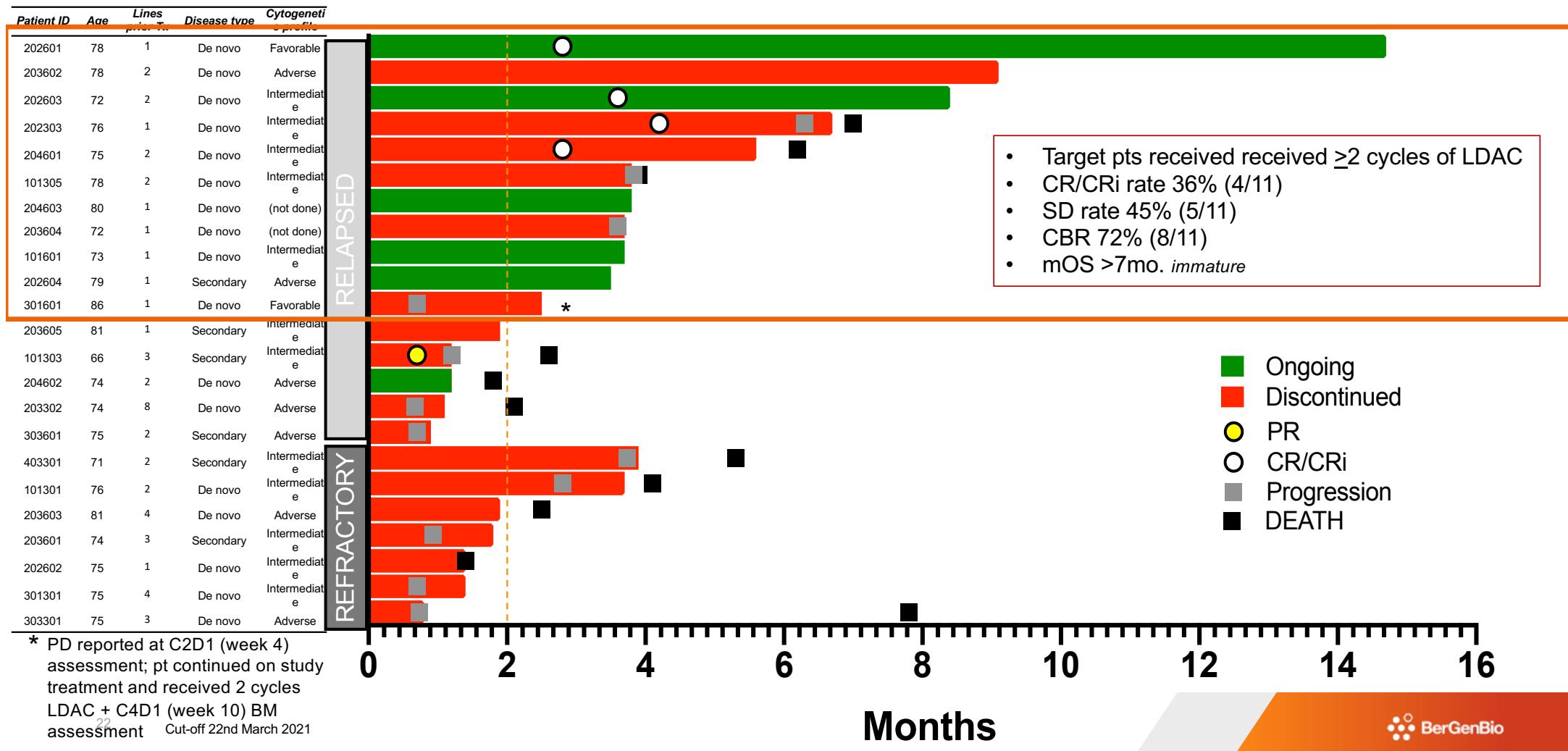
Cohort B4 n=14
Monotherapy MDS

Cohort B5 expansion
Combination with LDAC
relapsed AML (ongoing)

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



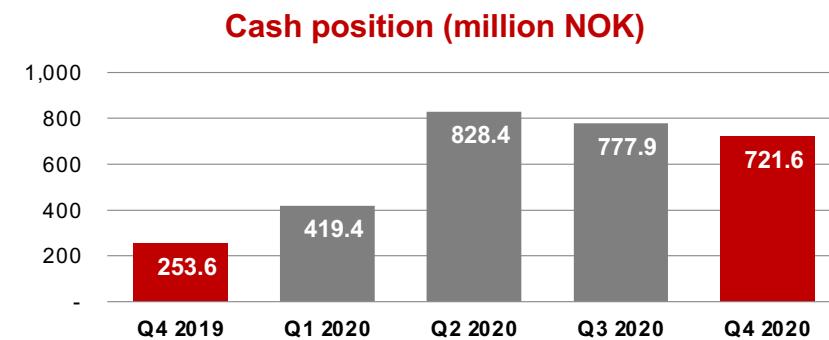
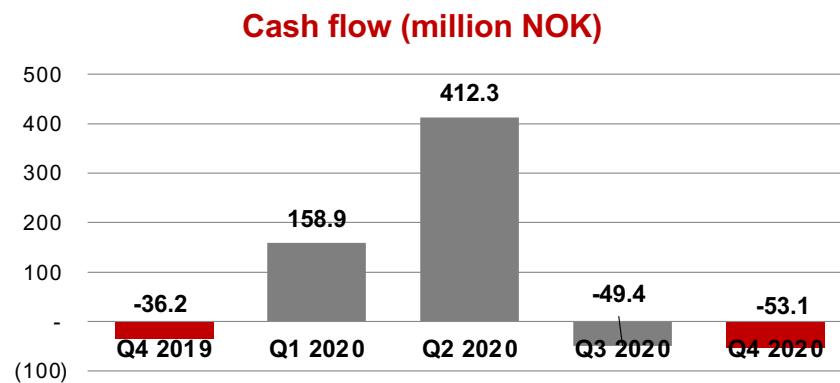


Well positioned for continued success....

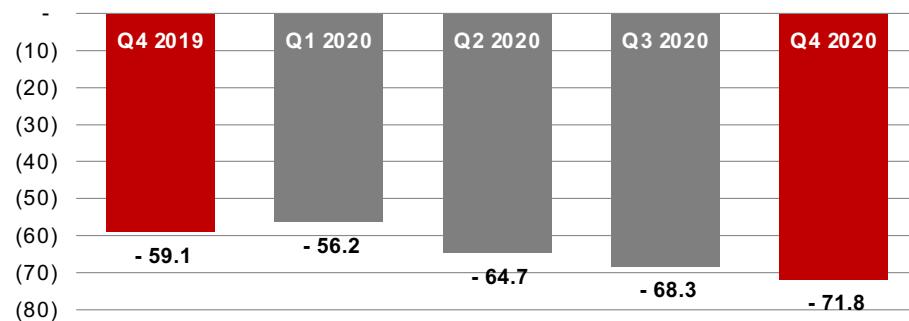


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Cash flow and cash position Q4'20

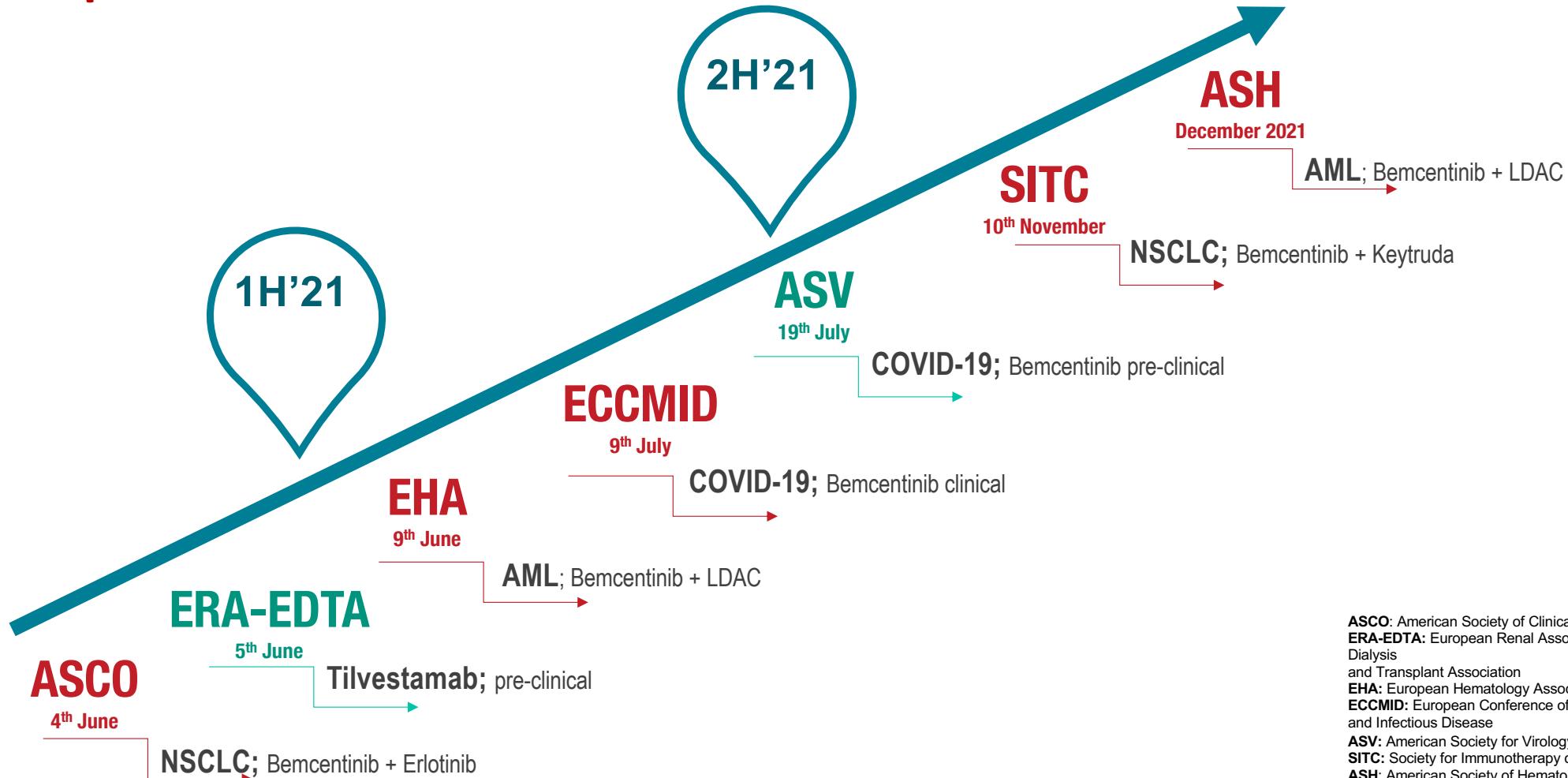


Operating profit (-loss) million NOK



- Cash position Q4 2020 NOK 721.6 million (USD 84.6m).
- Quarterly average cash burn (Q419 – Q420) NOK 54.0m (USD 5.8m)

Expected news flow at conferences in 2021



ASCO: American Society of Clinical Oncology
ERA-EDTA: European Renal Association & European Dialysis and Transplant Association
EHA: European Hematology Association
ECCMID: European Conference of Clinical Microbiology and Infectious Disease
ASV: American Society for Virology
SITC: Society for Immunotherapy of Cancer
ASH: American Society of Hematology