



# BerGenBio

## Q1 2020 REPORT HIGHLIGHTS AND FINANCIALS

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19<sup>th</sup> May 2020

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# BerGenBio corporate over view



## World leaders in understanding AXL biology

AXL tyrosine kinase mediates aggressive disease: immune evasion, therapy resistance & metastatic cancer, fibrosis and viral infection

Selective AXL inhibitors have the potential to treat many serious unmet medical needs

**Pipeline opportunities in multiple aggressive diseases**



## 2 selective AXL inhibitors in clinical development

Bemcentinib (oral once a day pill)  
Tilvestamab (mAb)

Bemcentinib broad Phase II program  
Monotherapy and combos with CPI, targeted & chemo

Biomarker correlation, parallel CDx development

Bemcentinib clinical data points 2020:  
**AML** (chemo-combo)  
**NSCLC** (KEYTRUDA combo) **COVID19** (mono)



## Resourced to deliver milestones

Listed on Oslo Børs: BGBIO

Clinical trial collaborations  
Merck, UKRI, and leading academic centres EU & USA

40 staff at two locations:  
HQ & R&D in Bergen, Norway;  
Clinical Development in Oxford, UK

**Cash Q1'20 NOK419m,**  
**(Plus PIPE NOK500m May'20)**

## Recent highlights

Dec  
2019

Presented preliminary clinical data from Ph II combination trial of bemcentinib and LDAC in AML patients at ASH conference

Complete responses (CR) reported with long duration

Jan  
2020

Met Primary end point of ORR in phase II clinical trial in NSCLC (cohort B) in 2L IO refractory patients

Bemcentinib in combination with KEYTRUDA<sup>®</sup> meets primary end point and progress to stage 2 of the study cohort

Jan  
2020

Private placement NOK220m

May  
2020

COVID19 rPhII ACCORD-2 trial

UK Govt selected bemcentinib as first experimental compound to enter fully funded seamless platform trial for efficacy and safety

May  
2020

Private placement NOK500m



## Impact on operations of COVID-19 global crisis

### Staff wellbeing

- Extensive WFH and virtual communications
- Some furlough in Norway

### Patient treatment

- Unaffected - all patients remained on study and received medication and follow ups
- Additional medication provided to limit visits to hospital pharmacy

### Patient recruitment

- Many (but not all) hospitals stopped enrolment of new patients on to trials
- Will impact time lines and data read outs

### Translational data

- Sample collection and processing slightly affected
- No impact on revised read-out time lines

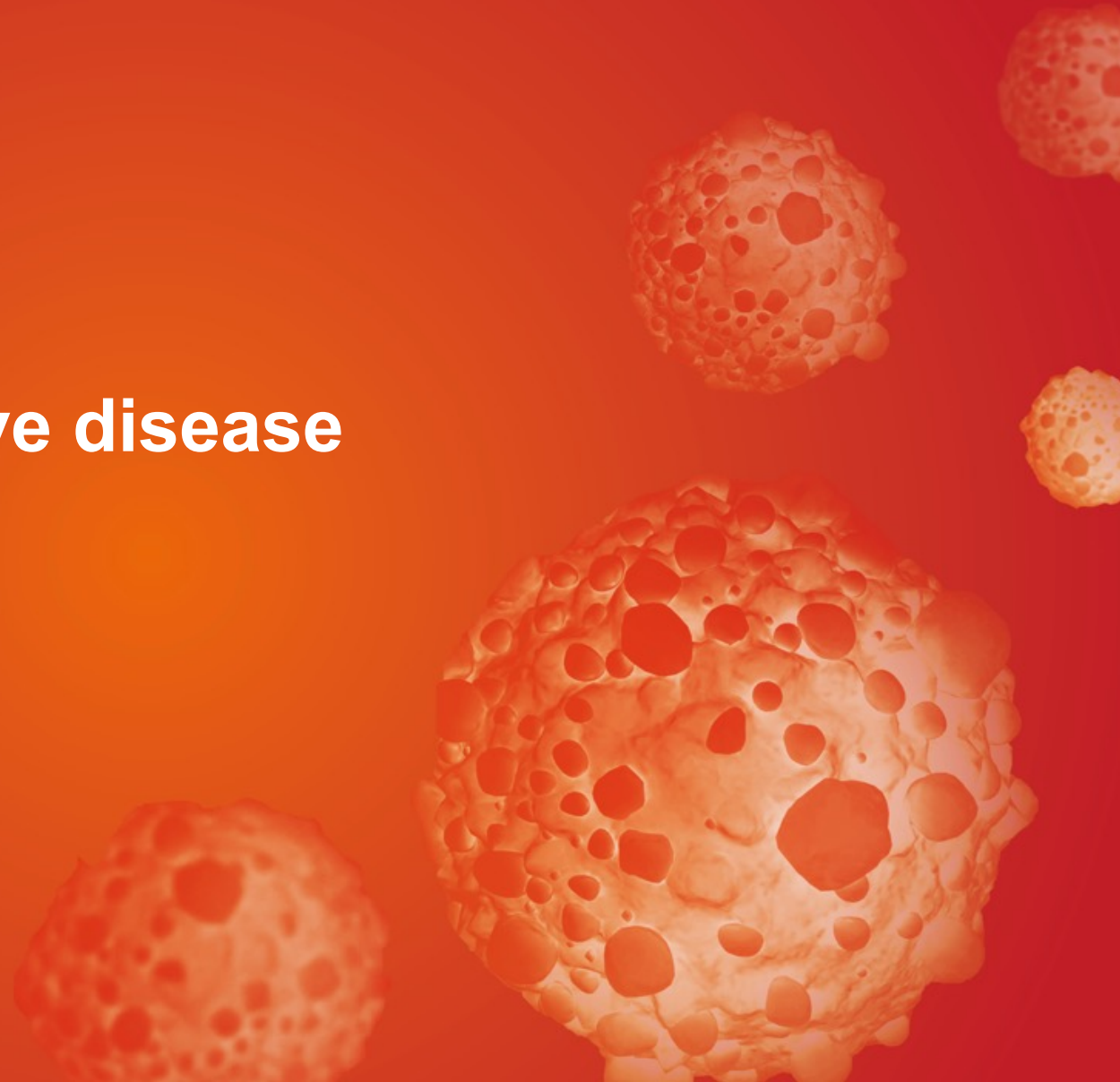
### Research operations

- Many collaborators research labs were closed and some projects are delayed
- IOWA University labs (SARS-CoV-2) remained open and productive

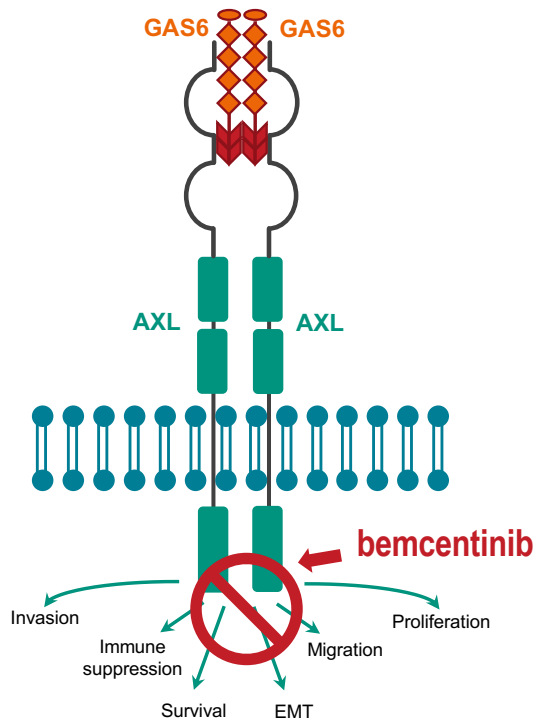
### Cash management

- Immediate actions taken to preserve cash and realigned project spend

**AXL drives aggressive disease**



# AXL Biology



- AXL mediates multiple survival mechanisms used by cancers:
  - Chemo drug resistance, immune evasion, metastasis
- AXL facilitates viral entry to host cells and reduces anti-viral immunity

- AXL a receptor tyrosine kinase that is important for regulating innate immune cells.<sup>1</sup>
- AXL levels are elevated by cellular stress and is strongly associated with inflammatory diseases including cancer and fibrosis.<sup>2</sup>
- It functions as a homeostatic regulator in adult tissues and organ systems that are subject to continuous challenge and renewal throughout life – immune, nervous, vascular and reproductive
- AXL drives cancer progression, immune evasion, and resistance to targeted therapies.<sup>3</sup>
- AXL is a key suppressor of the type I interferon response and is targeted by viruses to block the anti-viral immunity.<sup>4</sup>
- AXL is used by several different enveloped viruses (e.g. Ebola, Zika) to enter cells.<sup>5</sup>

Very low expression under healthy physiological conditions

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

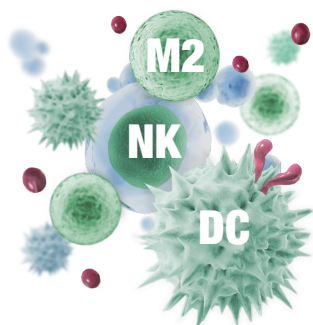
<sup>1</sup>Lemke Cold Spring Harb Perspect Biol 2013; <sup>2</sup>Zagórska Nat Immunol 2014, Ludwig Cancer Res 2018, Espindola, Am J Respir Crit Care Med. 2018; <sup>3</sup>Gay, Br J Cancer 2013; <sup>4</sup>Chen Nat Microbiol 2018; <sup>5</sup>Moller-Tank Virology 2014;

# AXL is a key survival mechanism 'hijacked' by aggressive cancers and drives drug resistance, immune-suppression & metastasis

very low expression under healthy physiological conditions

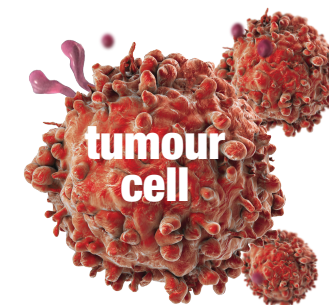
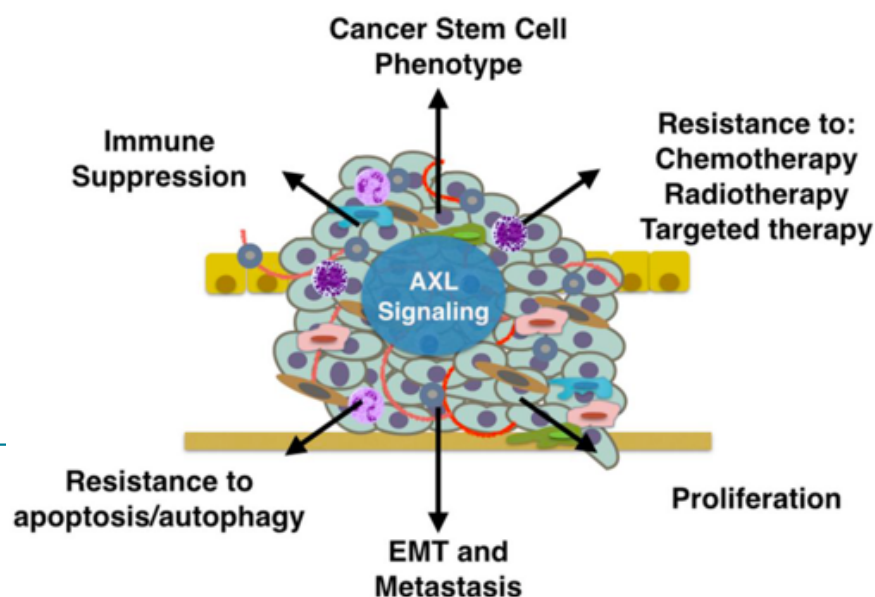
overexpressed in response to hypoxia, inflammation, cellular stress & drug treatment

overexpression correlates with worse prognosis in most cancers



AXL increases on immune cells and suppresses the innate immune response

- M1 to M2 macrophage polarisation<sup>1</sup>
- Decreased antigen presentation by DCs<sup>2</sup>
- Prevent CD8+ T cell mediated cell death<sup>3</sup>
- Activates Treg cells



AXL increases on the tumor cell and causes cancer escape and survival

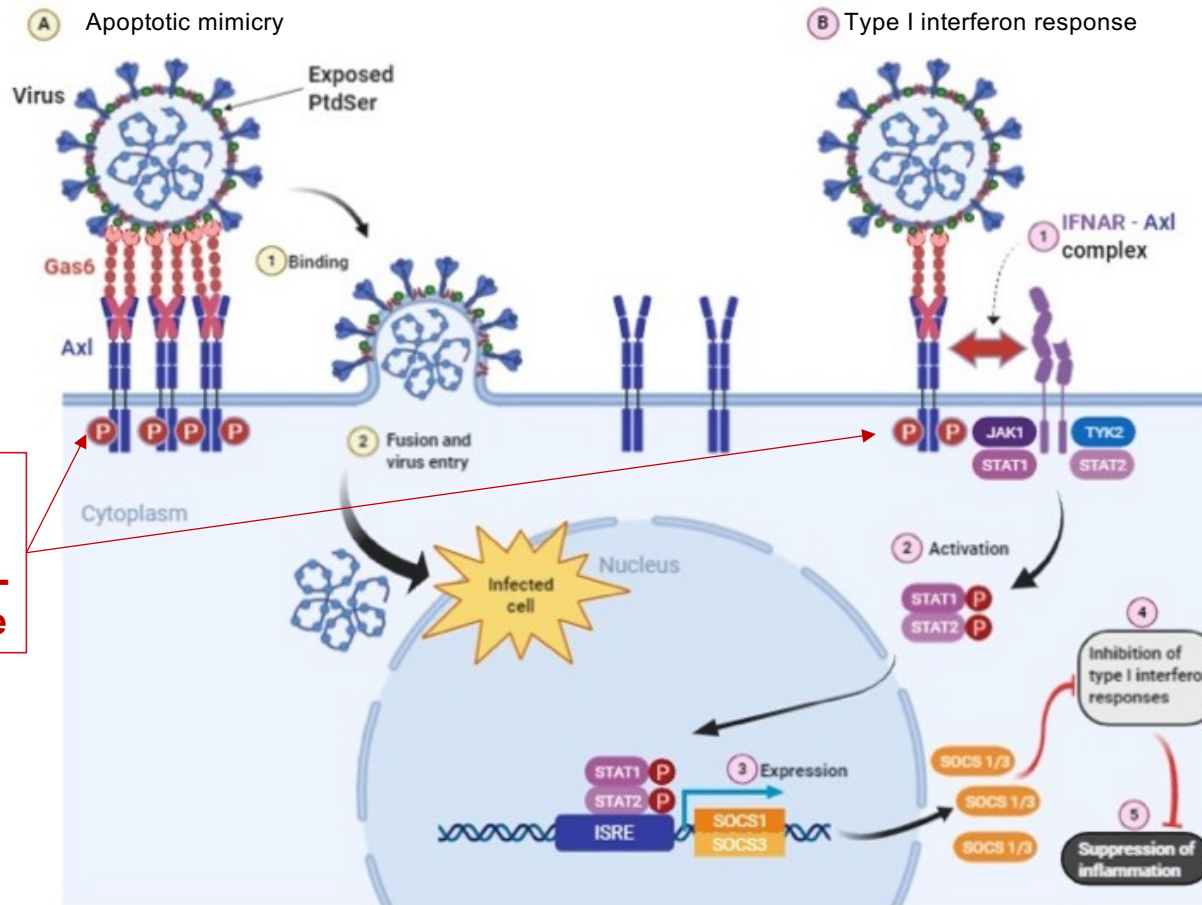
- AXL is a unique type I interferon (IFN) response checkpoint
- Acquired drug resistance
- Immune cell death resistant
- Metastasis

DC- dendritic cells Treg – Regulatory T Cell

8 1.Ludvig et al Can Res, 2018; Davidsen et al., submitted 2.Kurowska-Stolarska et al Nature Comm 2017; Rothlin et al Cell 2007 3.Ludvig et al Can Res, 2018, Davidsen et al., submitted

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

Enveloped viruses display phosphatidylserine that is recognized by GAS6, the AXL receptor ligand, that mediates viral entry through “apoptotic mimicry”.



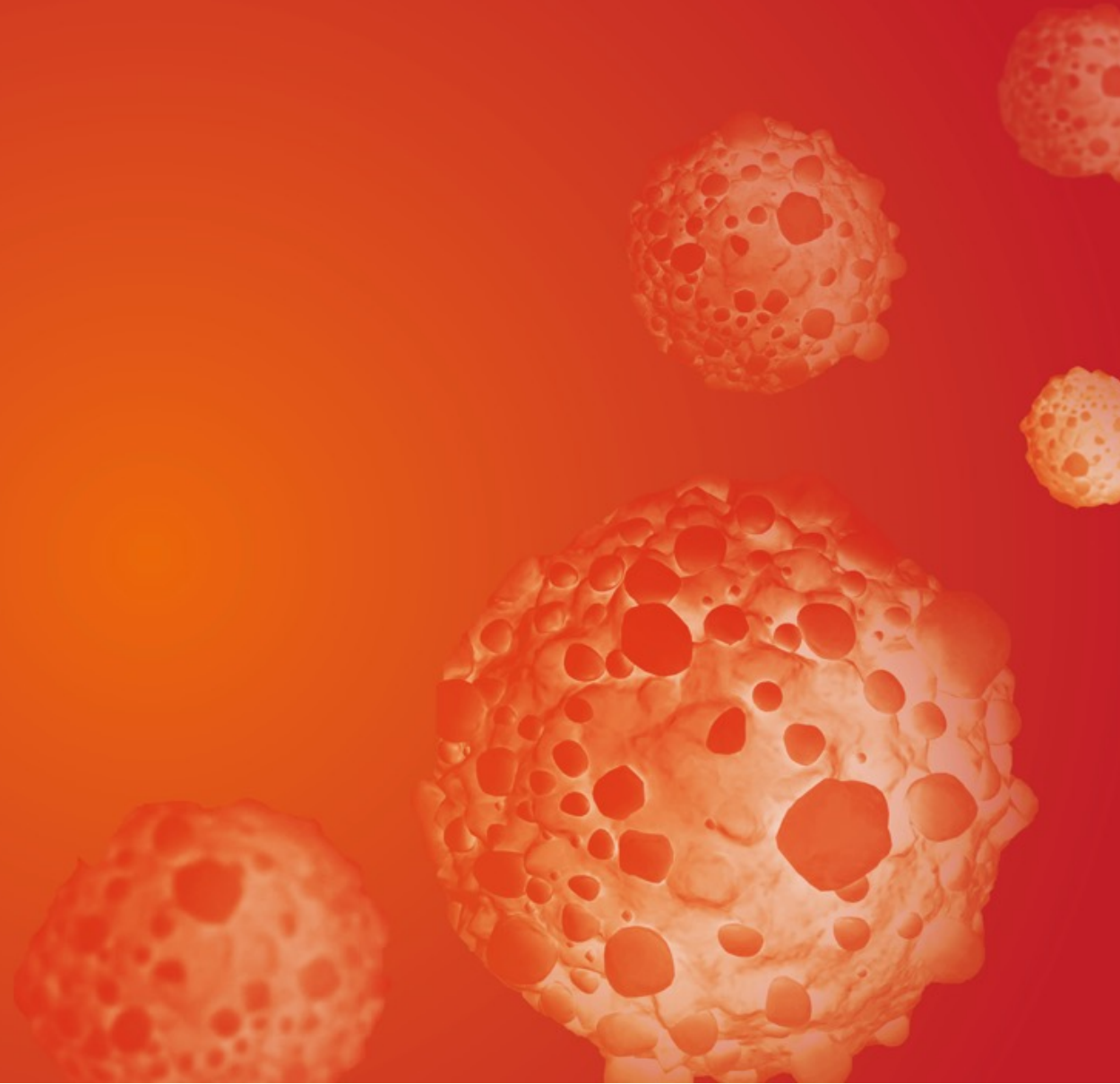
Viral-mediated AXL receptor activation dampens type I interferon responses, a key anti-viral defence mechanism for all cells

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

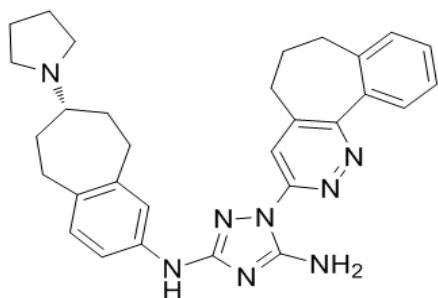
**Bemcentinib potently inhibits SARS-CoV-2 infection of cells.<sup>1</sup>**



# Bemcentininb



# Bemcentinib, a first-in-class, potent, oral, highly selective AXL inhibitor




- ✓  $IC_{50} = 14$  nM
- ✓ Uniquely selective for AXL
  - ✓ 50-100 fold selective *cf.* TAM kinases

- ✓ Manufacturing at increased scale for late stage regulatory filing
- ✓ Size 0 100mg HPMC capsules
- ✓ 3 years stability confirmed

- ✓ Once daily oral dosing
- ✓ Extensive Phase I & II experience
  - ✓ >350 patients
- ✓ Favourable safety profile supports use in first line, high risk fragile patients
- ✓ Safety and tolerability profile supports use in combination with other drugs
- ✓ MOA is synergistic with other therapies, enhancing response
- ✓ Global regulatory exposure with Fast Track Designation by FDA
- ✓ IMP available in stock for immediate clinical trial use



## BerGenBio pipeline of sponsored clinical trials and near term news flow

Candidate	Targeted Indication	Discovery	Preclinical	Phase I	Phase II	Registrational	Next expected news**
Bemcentinib monotherapy	>2L AML	Ph II safety and POC efficacy demonstrated in 39 patient trial					
Bemcentinib combination with LDAC	2L AML	Ph IIb Safety demonstrated, efficacy POC expansion study- 20 pts.					Q4'20 Update clinical & translational data <sup>1</sup>
Bemcentinib combination with Keytruda 	2L NSCLC chemo refractory	Ph II POC efficacy demonstrated in 50 patient trial, end points met					Q2'20 Updated Survival data <sup>2</sup>
	2L NSCLC CPI refractory	Ph II stage 1, 13 pts. met ORR proof of concept end point			Expansion 16 pts.		Q2'20 Stage 1 clinical and translational data <sup>2</sup>
	2L NSCLC CPI+chemo refractory	Ph II POC study ongoing 29 pts					Q4'20 Stage 1 preliminary interim clinical and translational data <sup>3/4</sup>
Tilvestamab (BGB149)	TBA	Ph Ia HV complete		Ph Ib in set up			
BGB601*		Ph I Terminated (change in clinical plan and drug supply)					Update by collaborators

\*Development Out licensed to ADCT

\*\* Increased uncertainty due to COVID crisis

CPI – checkpoint inhibitor

mOS – median overall survival




1 ASH – American Society of Hematology (Dec 5-8)

2 Next Gen Immuno Oncology (25<sup>th</sup> June)

3 SITC – Society of Immunotherapy of Cancer (Nov10-15)

4 WCLC – World Congress of Lung Cancer (Jan 26-29 2021)

# BerGenBio pipeline of Investigator Sponsored Trials (ISTs)

Candidate	Sponsor	Targeted Indication	Dimensions	Phase I	Phase II	Registrational	Next expected news*
Bemcentinib	Uni. Hospital Southampton / UKRI funded 	COVID19	Monotherapy	Randomised Phase II – 15 day treatment			Stage 1 Q3/4
	European MDS Cooperative Group	2L AML	Monotherapy	open-label, single-arm , phase II study.			Fully recruited. Q4'20 ASH
		2L MDS	Monotherapy	open-label, single-arm , phase II study			
	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins	Recurrent Glioblastoma	Monotherapy	Set up			FPI* [recruitment on hold due to COVID-19]
	University of Leicester  	Relapse Mesothelioma	+ pembrolizumab	Set up			FPI * [recruitment on hold due to COVID-19]
	Haukeland University Hospital	1L Metastatic Melanoma	+ pembrolizumab or +Dabrafenib/Trametinib	Randomised Phase II			Biomarker Analysis Q3
	UT Southwestern Medical Center	2-4L Stage 4 NSCLC	+ docetaxel	Ph I safety study			RP2D * [recruitment on hold due to COVID-19]
	UT Southwestern Medical Center	1L metastatic or recurrent PDAC	+ Nab-paclitaxel+ Gemcitabine+ Cisplatin	Ph I safety study			[recruitment on hold due to COVID-19]

# Bemcentinib clinical development in COVID19

## *ACCORD-2* trial

To evaluate the efficacy and safety in hospitalized COVID19 patients

First compound selected by UK Govt. COVID19 Therapeutic Task Force

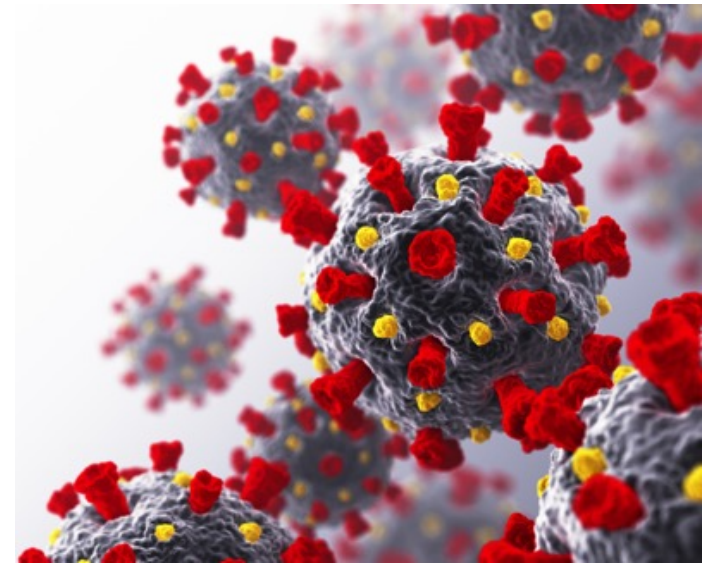
Trial funded by UK Govt.

A multicentre, randomised Phase II (120 patients) seamless Phase III transition option



## BerGenBio's bemcentinib selected to be fast-tracked as a potential treatment for COVID-19

- Preclinical data suggest that bemcentinib is potentially useful for the treatment of early SARS-CoV-2 infection, as it selectively inhibits AXL kinase activity
- Bemcentinib selected as the first candidate to be fast-tracked in a new UK national multi-centre randomised Phase II clinical trial initiative to investigate potential treatments for hospitalised COVID-19 patients
- ACCORD (**A**ccelerating **C**oVID-19 **R**esearch & **D**evelopment platform) is an Investigator Sponsored Trial, is funded by the UK Department of Health and Social Care and UK Research and Innovation
- National Institute for Health Research (NIHR) Southampton Biomedical Research Centre is the sponsor, Professor Tom Wilkinson is the Chief Investigator of ACCORD-2
- Study is a collaboration between the UK Government Scientific Office, the NIHR's Biomedical Research centres and clinical research company IQVIA
- The study will test 120 patients across 6 UK NHS hospital trusts.



# Protocol title: A Multicentre, Seamless, Phase 2 Adaptive Randomisation Study to Assess the Efficacy and Safety of Multiple Candidate Agents for the Treatment of COVID-19 in Hospitalised Patients

## Rationale:

There are currently no approved therapeutic agents available to treat coronaviruses such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19 disease, and there is an urgent public health need for rapid development of such interventions. This adaptive platform study is designed to rapidly assess multiple candidate agents as treatments for COVID-19. Candidate drugs that are initially assessed as being efficacious will be moved from an evaluation (pilot) stage to a confirmatory stage, with candidate agents being added to and removed from the study on an ongoing basis, depending on the results of their evaluation. Patients to be included in the study will be hospitalised and may require either supplemental oxygen, noninvasive ventilation or high flow oxygen devices, or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO).

## Objectives:

Stage 1: To evaluate the efficacy of candidate agents as add-on therapies to standard of care (SoC) in patients hospitalised with COVID-19 in a screening stage.

Stage 2: To confirm the efficacy of identified efficacious candidate agents in patients hospitalised with COVID-19 in an expansion stage.

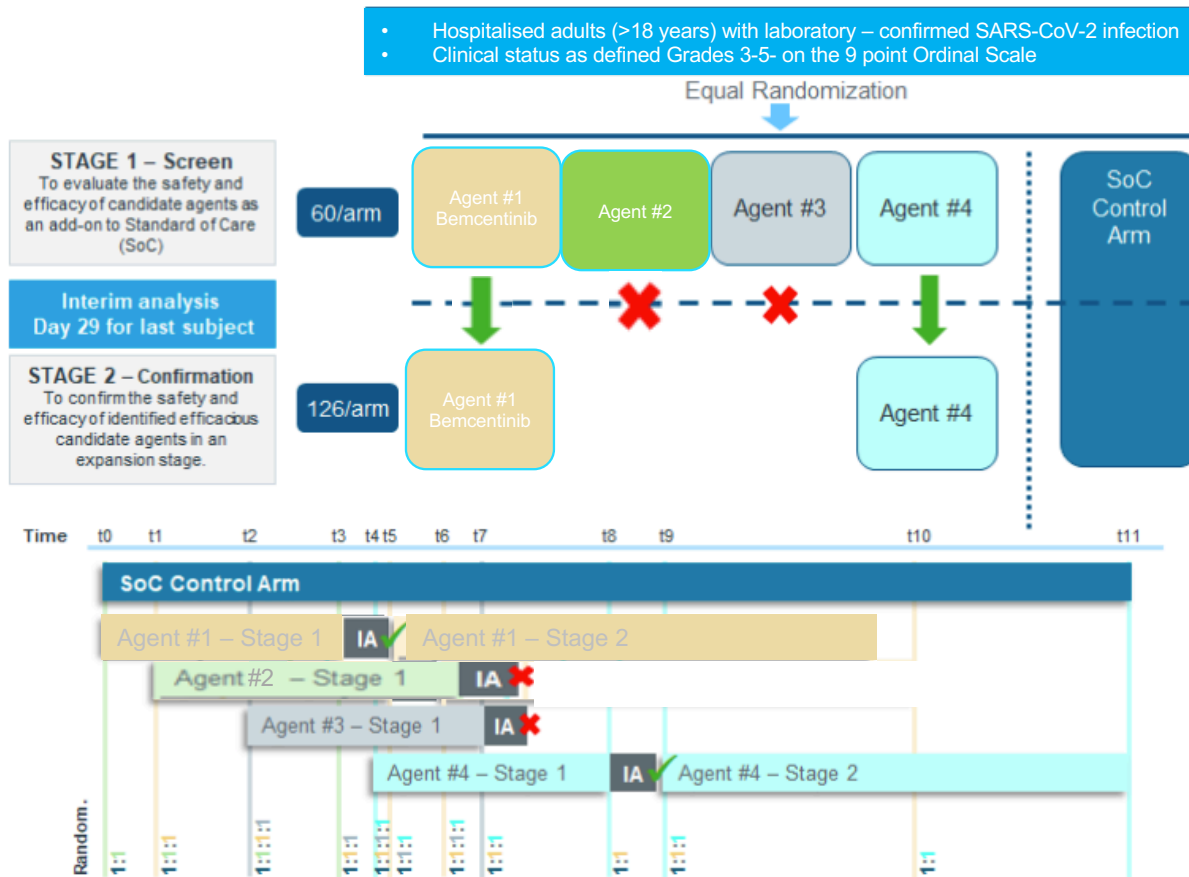
## Endpoints:

- Time to clinical improvement of at least 2 points (from randomisation) of patients stage 3, 4 or 5 on a 9-point category ordinal scale, or live discharge from the hospital, whichever comes first (this will also define the “responder” for the response rate analyses).

### 9-Point Category Ordinal Scale:

0. Uninfected, no clinical or virological evidence of infection
1. Ambulatory, no limitation of activities
2. Ambulatory, limitation of activities
3. Hospitalised – mild disease, no oxygen therapy
4. Hospitalised – mild disease, oxygen by mask or nasal prongs
5. Hospitalised – severe disease, noninvasive ventilation or high flow oxygen
6. Hospitalised – severe disease, intubation and mechanical ventilation
7. Hospitalised – severe disease, ventilation and additional organ support – pressors, renal replacement therapy (RRT), extracorporeal membrane oxygenation (ECMO)
8. Death

# ACCORD-2 Platform Study overview



IA=interim analysis; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; SoC=standard of care.  
 Note: This figure shows a hypothetical situation, where in Stage 1 of the study there are 4 candidate agents being compared with the SoC, of which 2 candidate agents progress to Stage 2.

Bemcentinib ACCORD study :

- 8 NHS sites across UK
- Randomized Phase II
- 120 patients
  - ( 60 receive bemcentinib, 60 in SoC control group)
- IQVIA are the CRO
- Standard bemcentinib dosing
- 15 day dosing schedule
- Independent Data monitoring Committee
- Seamless transition to stage 2 (phase III) subject to compelling data

# ACCORD-2 bemcentinib Update



#	Hospital	City	Status 14 <sup>th</sup> May
1	Southampton General Hospital (SPONSOR)	Southampton	Active / Screening
2	Royal London Hospital	London	Active / Screening
3	Whipps Cross hospital	London	In Set Up
4	St Thomas' Hospital	London	Active / Screening
5	Manchester Royal Infirmary	Manchester	Active
6	Wythenshawe Hospital	Manchester	Active
7	Royal Victoria Hospital	Belfast	In set up
8	Royal Gwent Hospital	Newport	Active / Screening



Ref. BGBC003 / NCT02488408

# Bemcentinib clinical development in Acute Myeloid Leukemia (AML) and Myelodysplastic syndromes (MDS)

Objective: to evaluate the safety and efficacy of bemcentinib in AML and MDS

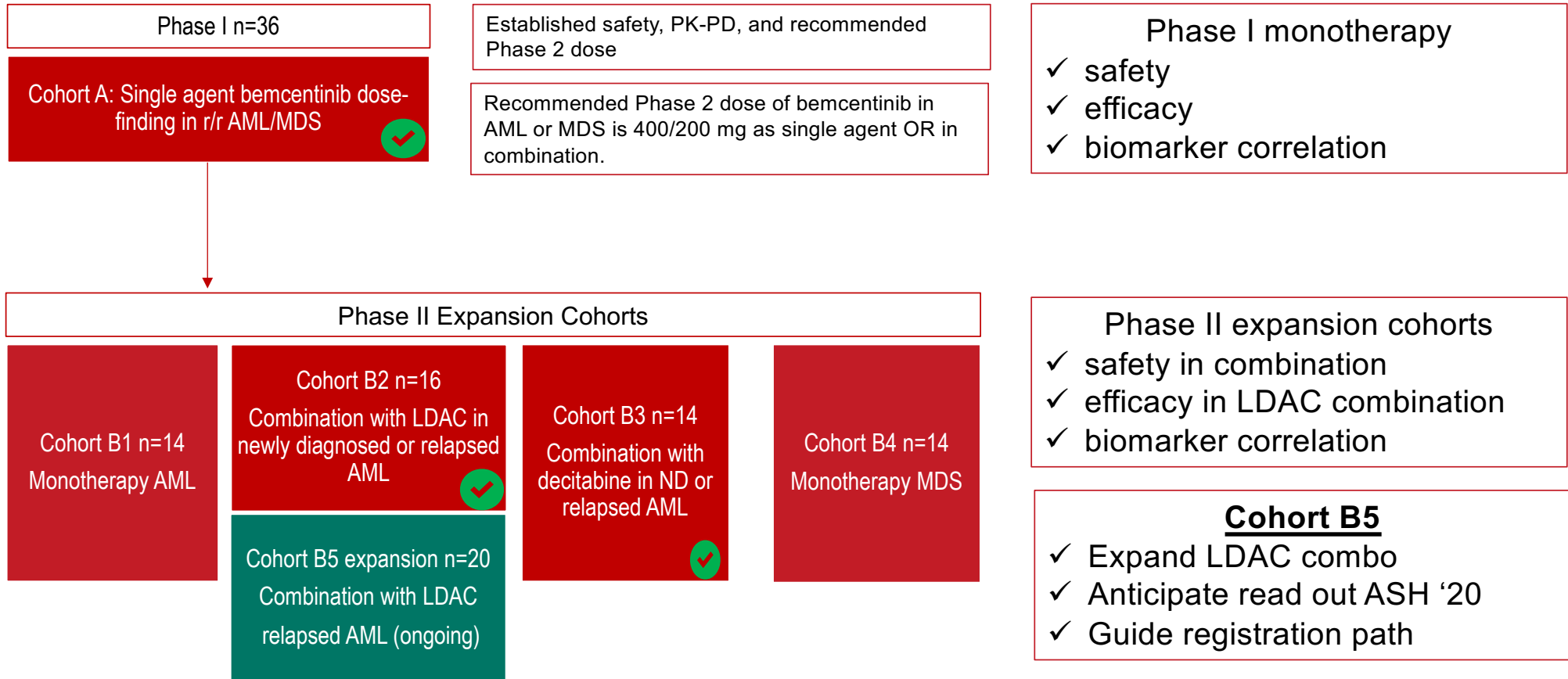
Bemcentinib monotherapy in patients relapsed AML or MDS ✓

Bemcentinib in combination with low-dose cytarabine (LDAC) in 1L newly diagnosed or relapsed patients with AML ✓

Bemcentinib in combination with LDAC in 2L relapsed patients with AML **Expansion On going**



# Bemcentinib clinical development in Acute Myeloid Leukemia / Myeloid Dysplastic Syndrome elderly >75 years, r/r patients, with no approved SoC.



Ref. BGBC008 / NCT03184571

# Bemcentinib clinical development in Non Small Cell Lung Cancer (NSCLC)

Objective: to improve the effectiveness of immune check point inhibitor (CPI) (pembrolizumab/Keytruda) refractory NSCLC patients, with a well tolerated, effective, and convenient drug

Chemotherapy refractory patients



CPI +/- chemotherapy refractory patients **On going**

CPI + Chemotherapy refractory patients **On going**



# Bemcentinib + KEYTRUDA in refractory/relapsed NSCLC

## Phase II Study Design



**BGBC008**  
Phase II 2-stage study of bemcentinib (BGB324) in combination with pembrolizumab

**Inclusion criteria**

- Adenocarcinoma histology
- Measurable disease
- Fresh tumor tissue
- AXL and PD-L1 All comers

**Assessments**

**Efficacy**

- **Primary endpoint**
  - Objective Response Rate
- **Secondary endpoints**
  - Duration of Response
  - Disease Control Rate
  - Time to Progression
  - Survival at 12 months
  - Response by Biomarker expression

**Safety**  
PK

**Regimen**

- Pembrolizumab 200mg fixed
- Bemcentinib 400mg loading dose, then 200mg OD

### Cohort A

- Previously treated with a platinum containing chemotherapy
- 2<sup>nd</sup> line advanced adeno NSCLC

### Cohort B

- Previously treated with a checkpoint inhibitor (PD-L1 or PD-1 inhibitor)
- No more than 2 previous lines of treatment
- Must have had disease control for ≥12 weeks followed by progression
- 2<sup>nd</sup> or 3<sup>rd</sup> line advanced adeno NSCLC

### Cohort C

- Previously treated 1<sup>st</sup> line with a checkpoint inhibitor- containing regimen in combination with a platinum-containing chemotherapy
- Disease control on 1<sup>st</sup> line therapy for ≥12 weeks followed by progression
- 2<sup>nd</sup> line advanced adeno NSCLC

COMPLETED: INFORMS 1L OPPORTUNITY	
<p><b>Interim Analysis</b> ✓</p> <p><b>Stage 1</b> N=24 patients (each patient has the potential for at least 24 weeks follow-up)</p> <p>Stop at this stage for: Futility (H0:15% if ≤3 responses) Or unfavorable risk/benefit</p>	<p><b>Final Analysis</b> ✓</p> <p><b>Stage 2</b> N=50 patients total (each patient has the potential for at least 24 weeks follow-up)</p>
<p><b>Interim Analysis</b> ✓</p> <p><b>Stage 1</b> N=13 patients/cohort (each patient has the potential for at least 24 weeks follow-up)</p> <p>Stop at this stage for: Futility (H0:15% if 0 responses) Or unfavorable risk/benefit</p>	<p><b>Final Analysis</b> Recruiting</p> <p><b>Stage 2</b> N=29 patients/cohort (each patient has the potential for at least 24 weeks follow-up)</p>
<p><b>Interim Analysis</b> Recruiting</p> <p><b>Stage 1</b> N=13 patients/cohort (each patient has the potential for at least 24 weeks follow-up)</p> <p>Stop at this stage for: Futility (H0:15% if 0 responses) Or unfavorable risk/benefit</p>	<p><b>Final Analysis</b></p> <p><b>Stage 2</b> N=29 patients/cohort (each patient has the potential for at least 24 weeks follow-up)</p>
ONGOING WILL INFORM 2L PIVOTAL STUDY	



## **Cohort A:** stage 1 + 2 data (n=50)

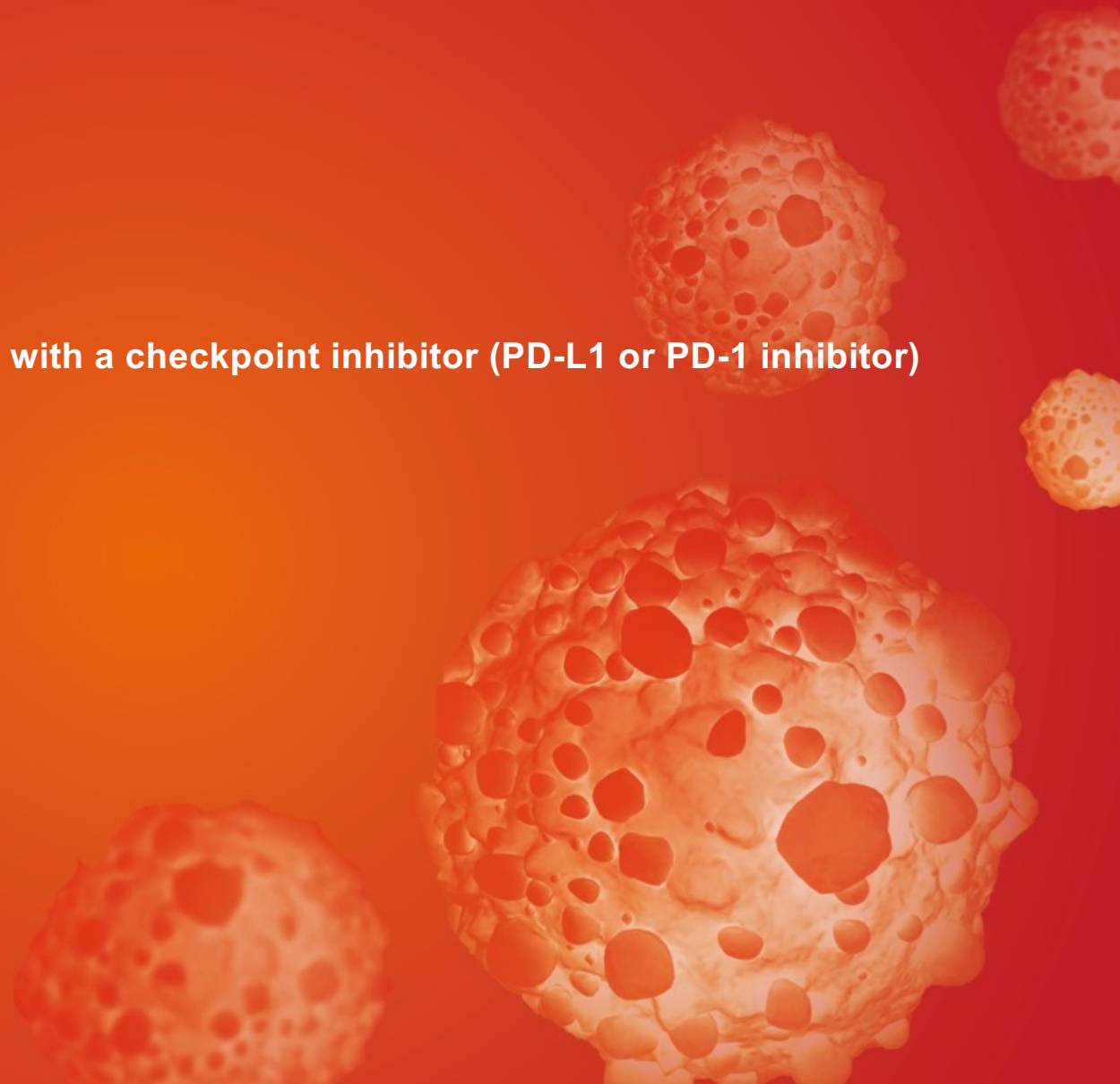
NSCLC patients previously treated with a platinum containing chemotherapy

**50% of patients are cAXL +ve :**

- ✓ - **ORR cAXL +ve patients 5 X cAXL -ve patients**
- ✓ - **442% increase in mPFS in cAXL +ve patients**
- ✓ - **73% Clinical Benefit Rate in cAXL +ve patients**
- ✓ - **independent of PD-L1 status**

# Cohort B:

NSCLC patients previously treated with a checkpoint inhibitor (PD-L1 or PD-1 inhibitor)



## Cohort B: Bemcentinib + KEYTRUDA in CPI refractory patients

### CHECK POINT INHIBITOR REFRACTORY PATIENTS: precise and specific definition

- Patients must have reported an initial clinical benefit (CR, PR or SD) for at least 12 weeks
- Subsequently progressed on treatment with an anti-PD1/L1 monoclonal antibody (mAb)
- PD-1 treatment progression is defined by meeting all of the following criteria:
  - received at least 2 doses of an approved anti-PD-1/L1 mAb
  - demonstrated disease progression after PD-1/L1 as defined by RECIST v1.1.
  - initial evidence of disease progression (PD) is to be confirmed by a second assessment no less than four weeks from the date of the first documented PD,
- Progressive disease has been documented within 12 weeks from the last dose of anti-PD-1/L1 mAb.
- Other therapies not to be administered between last dose of anti PD-1/L1 mAb and commence of clinical trial agent

Jan 2020



Interim Analysis Cohort B stage 1

met ORR end point

stage 2 (n=16 pts) initiated.

Clinical and Translational data will be presented at :

Next Gen-Immuno-Oncology Congress

25<sup>th</sup> June 2020

Virtual event



# Finance Report

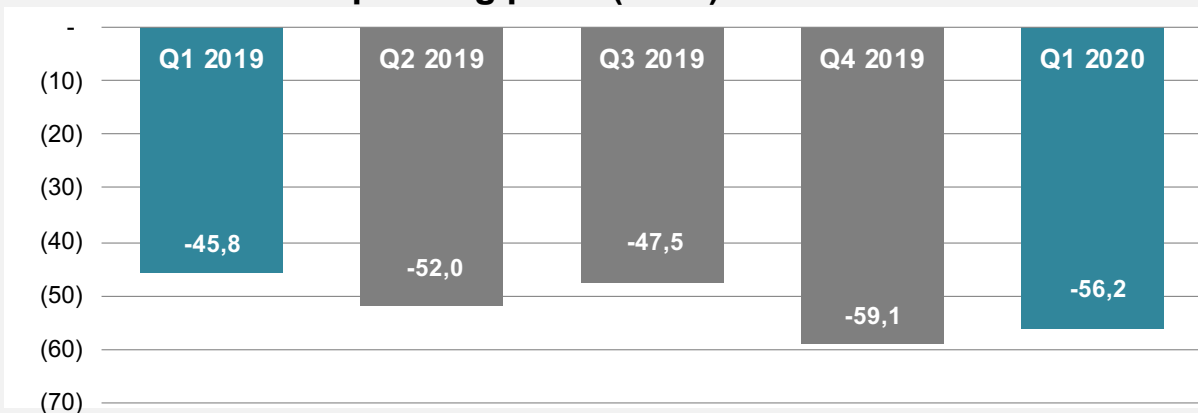
Rune Skeie - CFO



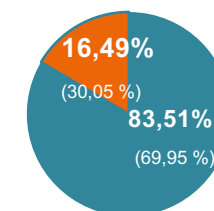
## Key financial figures

(NOK million)	Q1 2020	Q1 2019	FY 2019
Operating revenues	0,0	8,7	8,9
Operating expenses	56,2	54,5	213,3
Operating profit (-loss)	-56,2	-45,8	-204,4
Profit (-loss) after tax	-48,6	-44,3	-199,3
Basic and diluted earnings (loss) per share (NOK)	-0,73	-0,81	-3,43
Net cash flow in the period	158,9	-54,2	-107,2
Cash position end of period	419,4	306,7	253,6

Operating profit (-loss) million NOK



Operating expenses Q1 2020  
( Q1 2019)

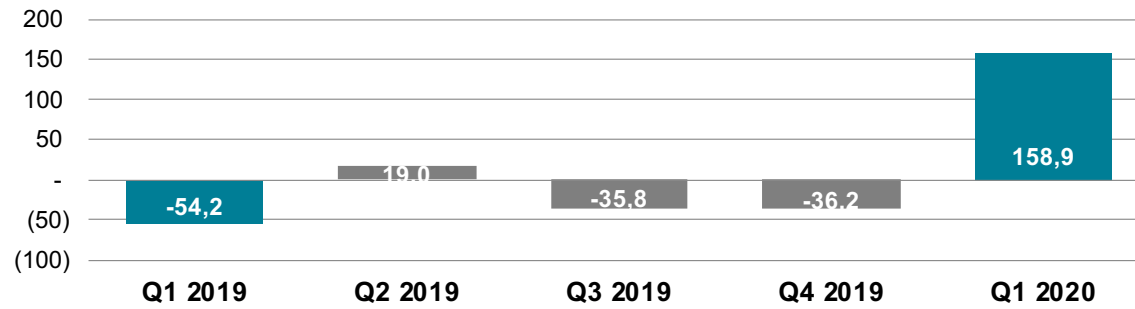


■ R&D ■ Administration

- Increase in operation expenses is a result of organisational expansion in preparation for late stage clinical development. Specifically the clinical and regulatory teams have been enlarged.
- Well managed overhead costs.
- 83,51 % of operating expenses Q1 2020 (Q1 2019: 69,95 %) is attributable to Research & Development activities.

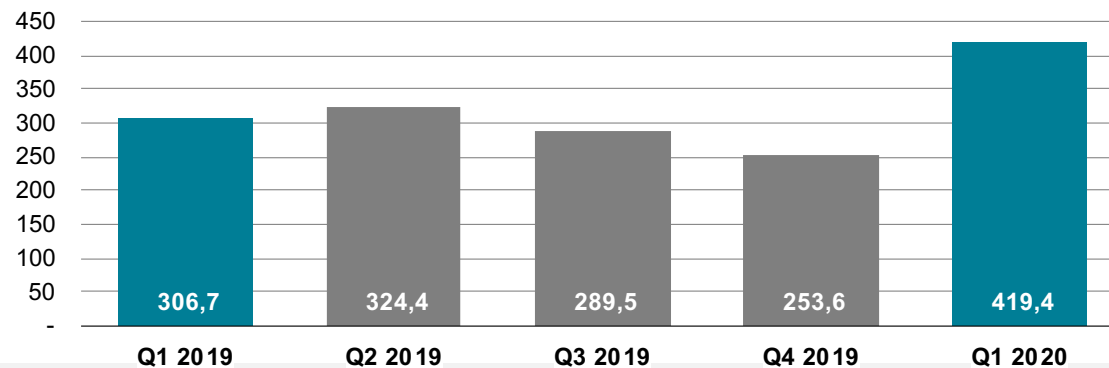
## Cash flow and cash position

Cash flow (million NOK)



- Q1 cash flow include proceed from Private Placement in January/February raising gross NOK 219.9m.
- Quarterly average cash burn (Q419 – Q420) NOK 49.6m (USD 5.6m)

Cash position (million NOK)



- Cash position Q1 2020 NOK 419.4 million (USD 39.9m).
- Private Placement May 2020 additional cash NOK 500.0m (USD 48.3m).

## Private Placement and subsequent repair offering: May 2020

- Subscription and issue of 13,325,000 offer shares at NOK 37.50 per share completed. Gross proceeds NOK 500 million.
- Number of shares after the private placement is 86,725,805.
- Subsequent Repair offering:
  - Issue up to 1,500,000 shares
  - Directed to eligible shareholders:
    - shareholder at 4 May registered at 6 May (record date),
    - were not allocated shares in the private placement 4 May,
    - are not resident in a jurisdiction where such offering would be unlawful and
    - at the record date have a shareholding below 150,000 shares in the Company.
  - Non tradable subscription rights will be allocated to eligible shareholders at a later time.
  - Completion of subsequent repair offering is subject to an Extraordinary General meeting approval, approval of a Prospectus and share price development.

## Analyst coverage



### H.C. Wainwright & Co

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### Sponsored research:

Link to reports from Trinity Delta:

<https://www.bergenbio.com/investors/analyst-coverage/>

Q1 Summary &  
News Flow 2020



## Recent highlights

Dec  
2019

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COVID19 rPhII ACCORD-2 trial

UK Govt selected bemcentinib as first experimental compound to enter fully funded seamless platform trial for efficacy and safety

May  
2020

Private placement NOK500m



# Expected Newsflow\*

## 2020

**Next-Gen**  
25<sup>th</sup> June  
**NSCLC**  
Bem + KEYTRUDA

**SITC**  
10-15 Nov  
**NSCLC**  
Bem + KEYTRUDA

**WCLC**  
26-29 Jan  
**NSCLC**  
Bem + KEYTRUDA

2020 | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC | 2021

  
**ACCORD-2**

**ASH**  
5-8 Dec  
**AML**  
Bem + LDAC  
update

\* Conditional on impact of global COVID crisis  
ASH – American Society of Heamatology (Dec 5-8)  
Next Gen Immuno Oncology (25<sup>th</sup> June)  
SITC – Society of Immunotherapy of Cancer (Nov10-15)  
WCLC – World Congress of Lung Cancer (Jan 26-29 2021)

**Questions**

