



ABG Sundal Collier- Oncology Seminar

10th June 2020

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BerGenBio corporate overview



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[®] meets primary end point and progress to stage 2 of the study cohort

Jan
2020

Private placement NOK220m

May
2020

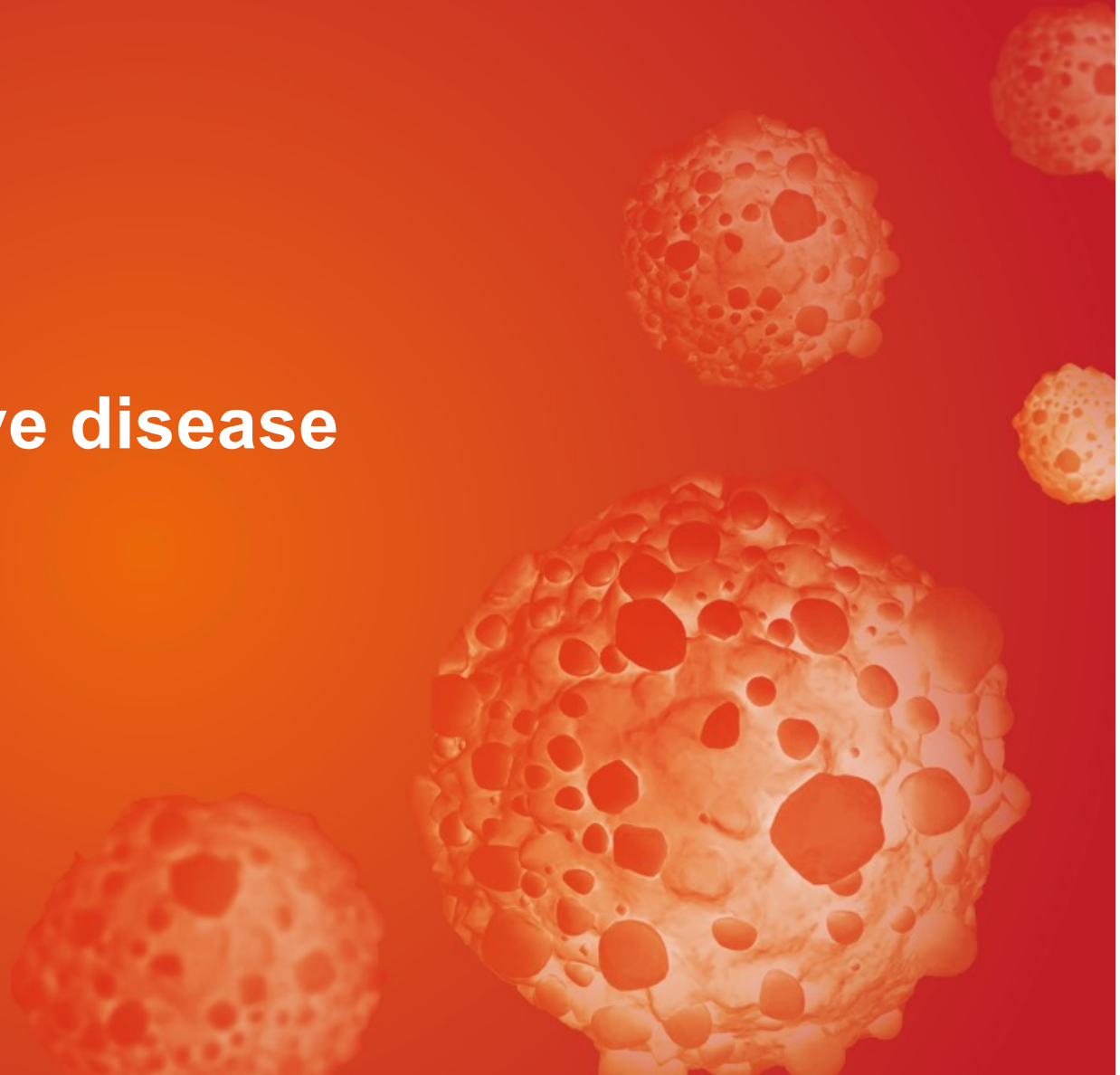
FPI COVID19 rPhII ACCORD-2 trial

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

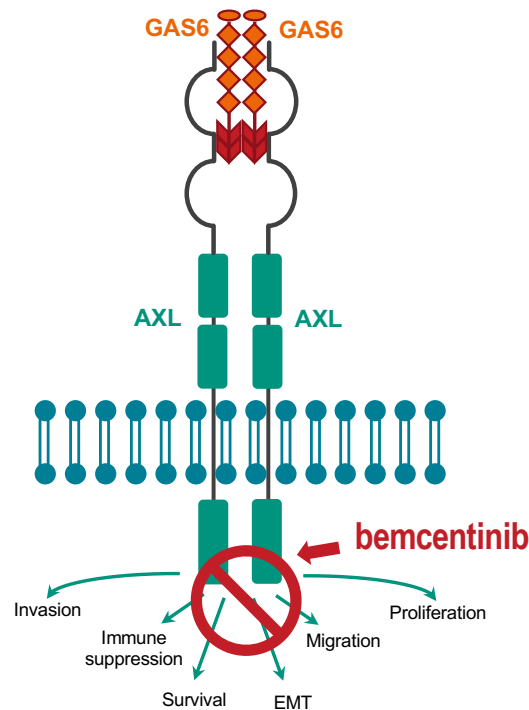
May
2020

Private placement NOK500m

AXL drives aggressive disease



AXL Biology



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

- AXL a receptor tyrosine kinase that is important for regulating innate immune cells.¹
- AXL levels are elevated by cellular stress and is strongly associated with inflammatory diseases including cancer and fibrosis.²
- 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.³
- AXL is a key suppressor of the type I interferon response and is targeted by viruses to block the anti-viral immunity.⁴
- AXL is used by several different enveloped viruses (e.g. Ebola, Zika) to enter cells.⁵

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

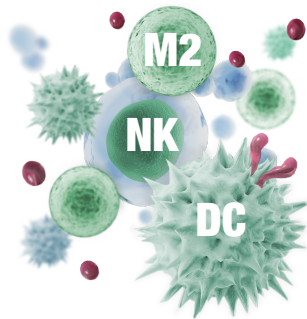
¹Lemke Cold Spring Harb Perspect Biol 2013; ²Zagórska Nat Immunol 2014, Ludwig Cancer Res 2018, Espindola, Am J Respir Crit Care Med. 2018;³Gay, Br J Cancer 2013; ⁴Chen Nat Microbiol 2018; ⁵Moller-Tank Virology 2014;

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

very low expression under healthy physiological conditions

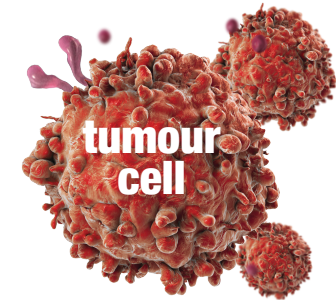
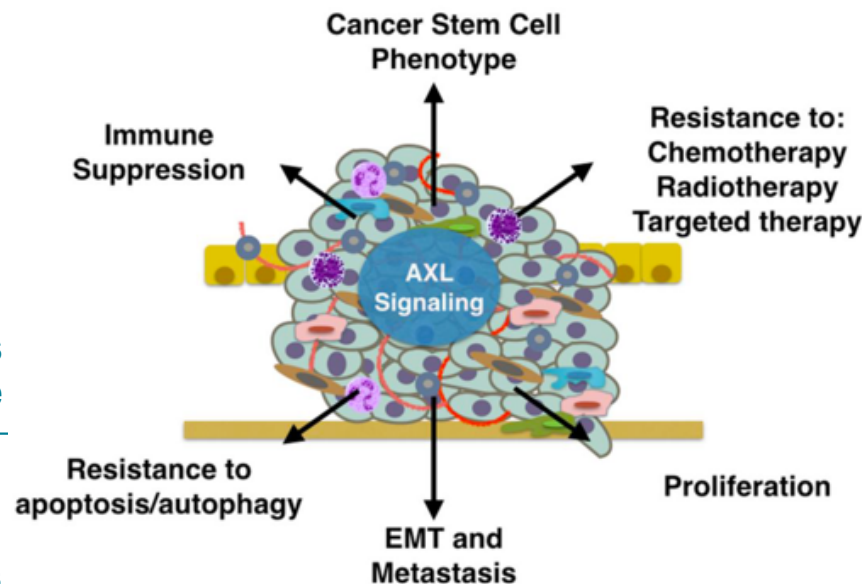
overexpressed in response to hypoxia, inflammation, cellular stress & drug treatment

overexpression correlates with worse prognosis in most cancers



AXL increases on immune cells and suppresses the innate immune response

- M1 to M2 macrophage polarisation¹
- Decreased antigen presentation by DCs²
- Prevent CD8+ T cell mediated cell death³
- Activates Treg cells



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

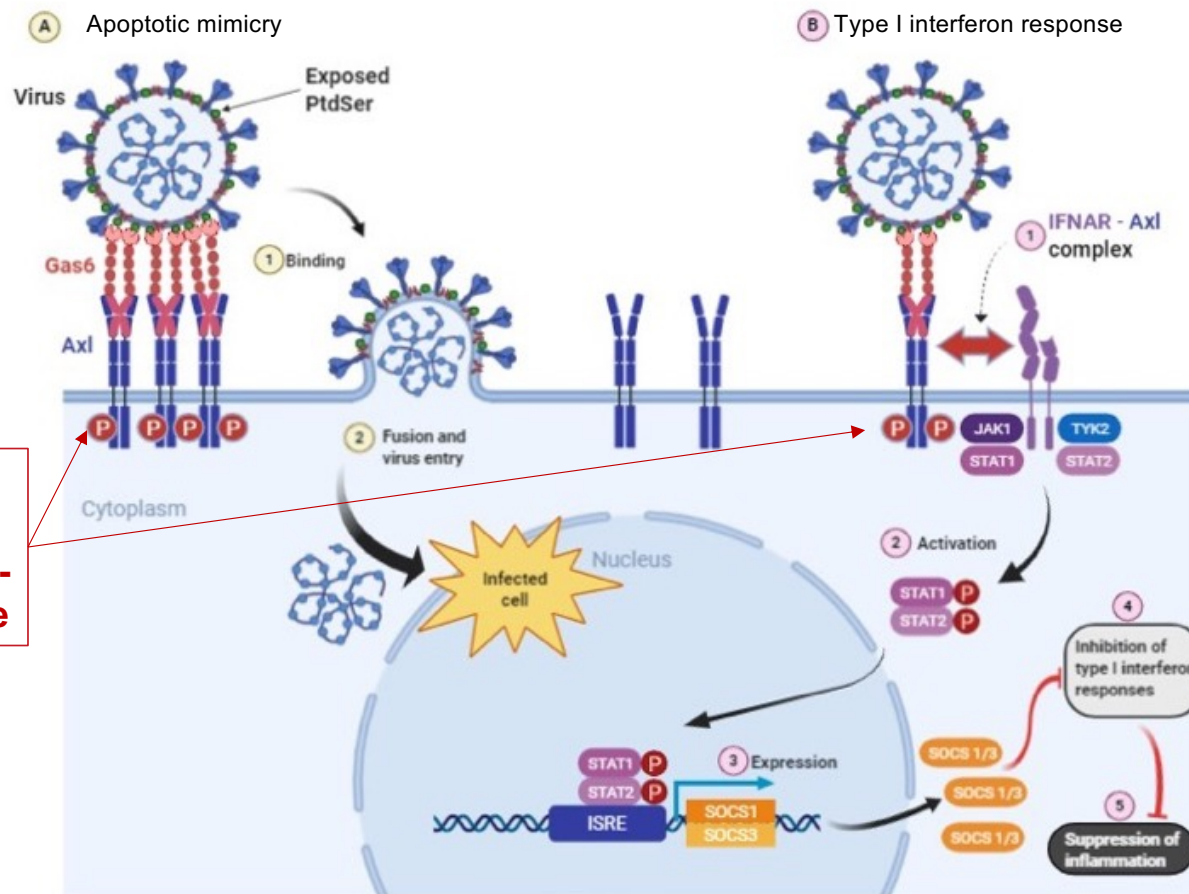
- AXL is a unique type I interferon (IFN) response checkpoint
- Acquired drug resistance
- Immune cell death resistant
- Metastasis

DC- dendritic cells Treg – Regulatory T Cell

⁷ 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”.

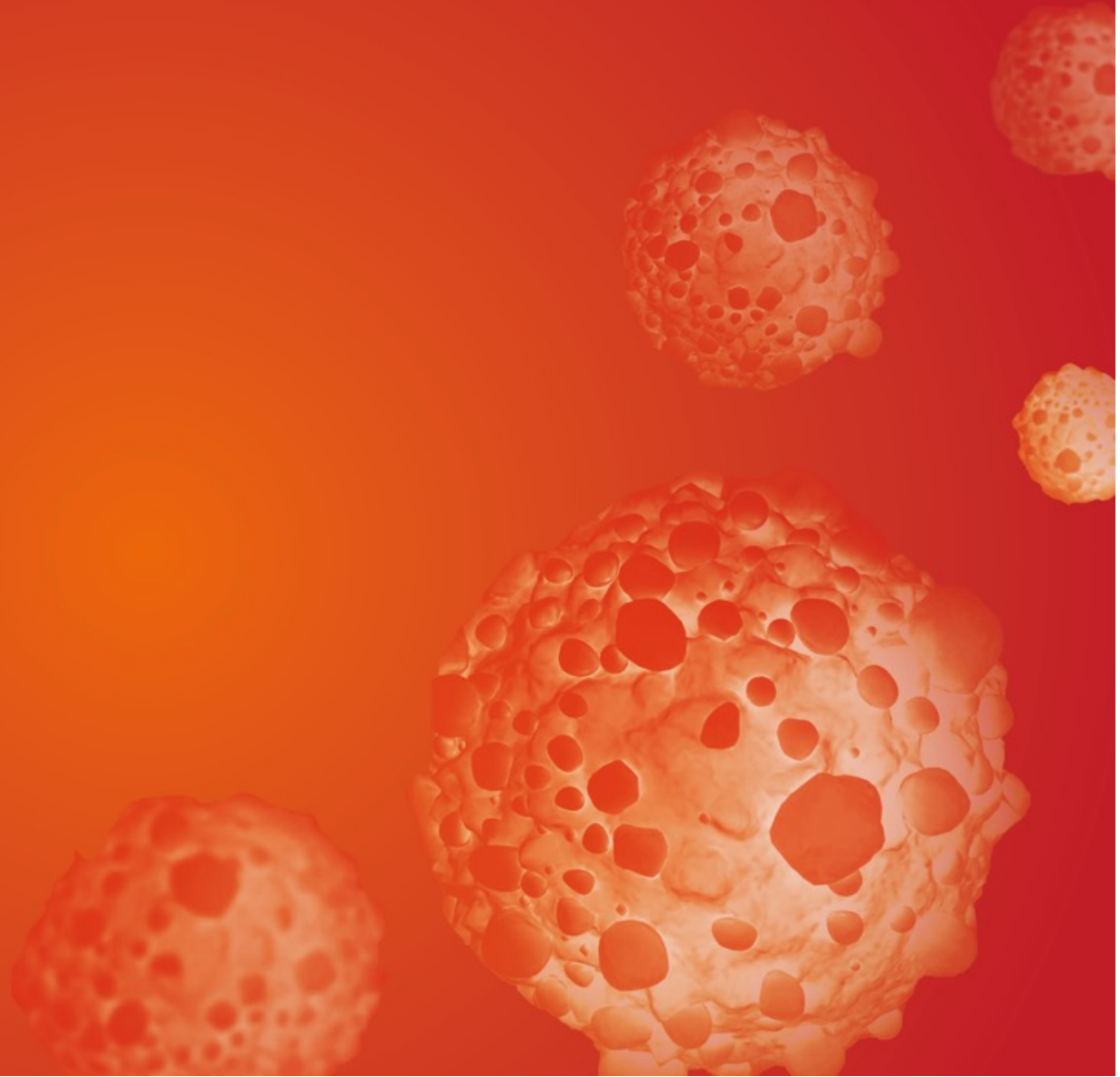


Viral-mediated AXL receptor activation dampens type I interferon responses, a key anti-viral defence mechanism for all cells

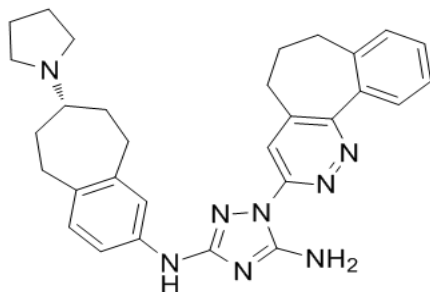
bemcentinib blocks AXL-dependent viral entry and enhances anti-viral interferon response

Bemcentinib potently inhibits SARS-CoV-2 infection of cells.¹

Bemcentinib




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



- ✓ $IC_{50} = 14 \text{ nM}$
- ✓ 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 ¹
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 ²
	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 ²
	2L NSCLC CPI+chemo refractory	Ph II POC study ongoing 29 pts					Q4'20 Stage 1 preliminary interim clinical and translational data ^{3/4}
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 (25th 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 IA Q3
	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 Q2 [recruitment of hold due to COVID-19]
	University of Leicester  	Relapse Mesothelioma	+ pembrolizumab	Set up			FPI Q2 [recruitment of 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 Q3 [recruitment of hold due to COVID-19]
	UT Southwestern Medical Center	1L metastatic or recurrent PDAC	+ Nab-paclitaxel+ Gemcitabine+ Cisplatin	Ph I safety study			[recruitment of 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

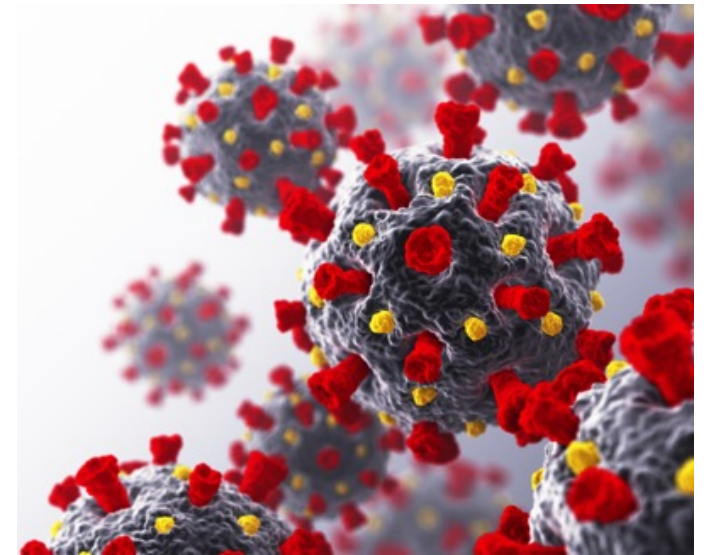
Trial funded by UK Govt.

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



BerGenBio's bemcentinib selected 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 (Accelerating CCOVID-19 Research & Development 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.



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, relapsed or refractory patients with AML

Bemcentinib in combination with LDAC in 2L relapsed patients with AML



Acute Myeloid Leukaemia (AML)

Most common type of acute leukaemia in adults¹

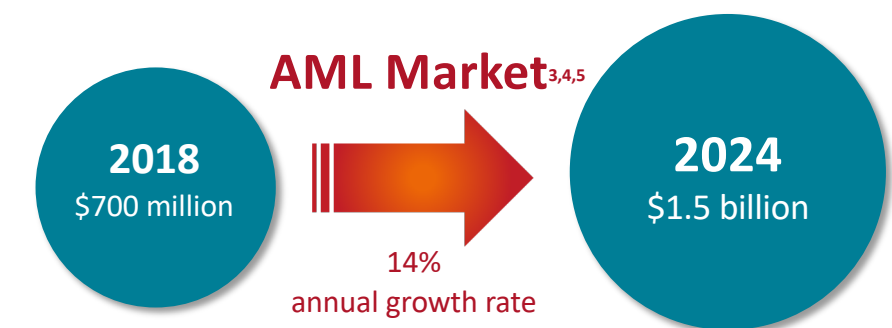
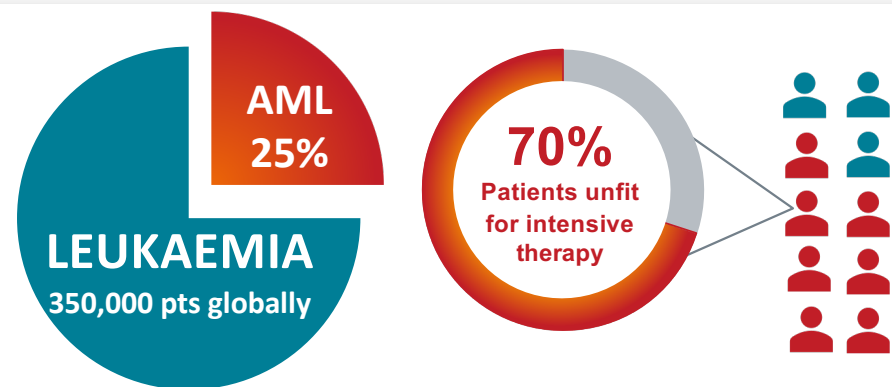
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

~ 21,000 new cases diagnosed and >11,000 deaths in the US in 2018²

AML makes up 32% of all adult leukaemia cases

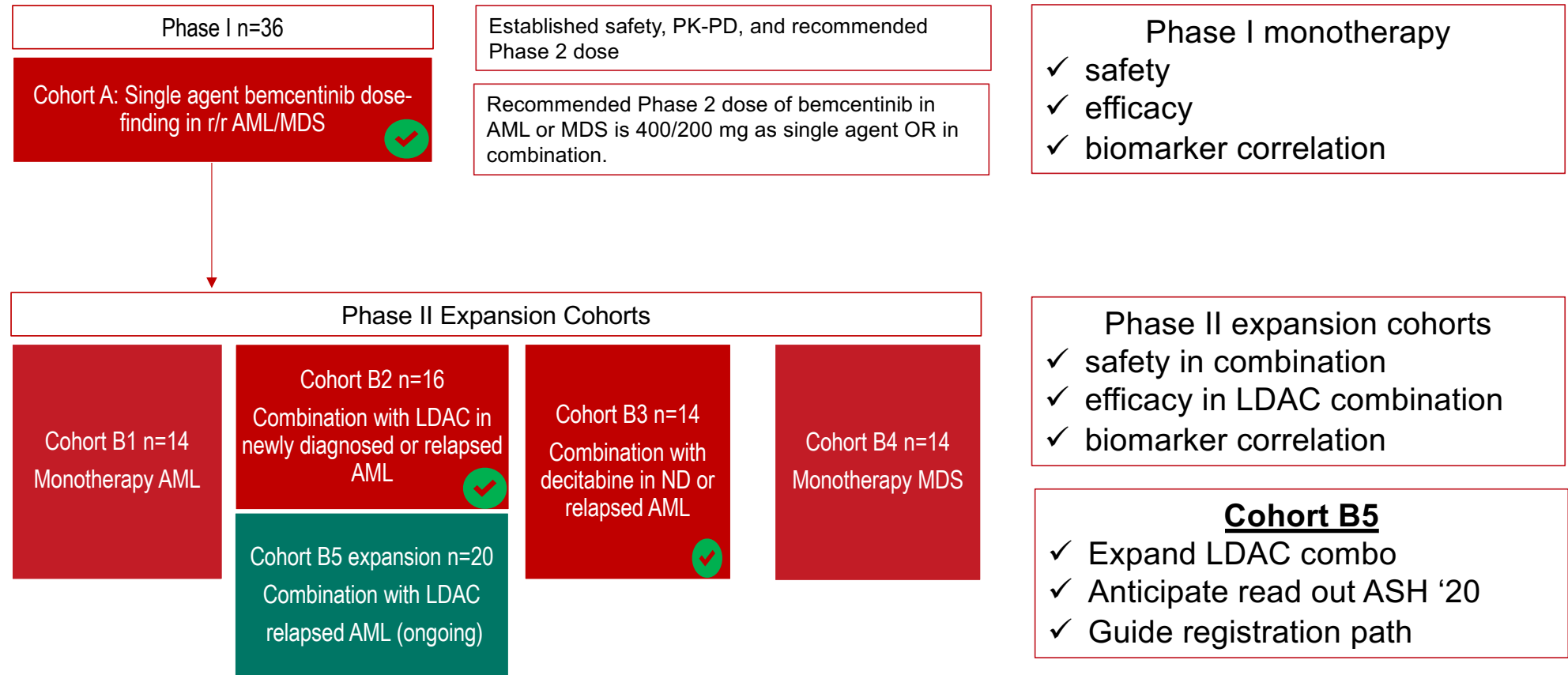
Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years⁶

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/>

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



Reported clinical efficacy in AML

Mono therapy r/r elderly AML n=27

ASH 2018

sAXL biomarker
sAXI low 14/27

52%

CR/Cri/CRp
sAXI low 6/14

43%

mDOR 3.1mo. (5.5*mo.)

*Historic controls***
CR/Cri/CRp: 24%
mOS: 6.7mo.

LDAC Combination 1L & 2L AML n=14

ASH 2019

1L
CR/Cri 4/6

66%

mDOR >12Mo.

2L R/R
CR/CriCRp 4/8

50%

mDOR 5Mo.

Responses occurred early, improved over time and included poor risk, previously treated patients. Bemcentinib appears well tolerated in combination with LDAC.

2L cohort expansion ongoing

Ref. BGBC008 / NCT03184571

Bemcentinib clinical development in 2L 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

- A) Chemotherapy refractory patients
- B) CPI refractory patients
- C) CPI + Chemotherapy refractory patients



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

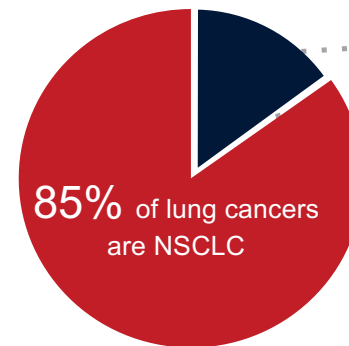
The largest cancer killer, most patients depend on drug therapy

The most common type of cancer

2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases¹

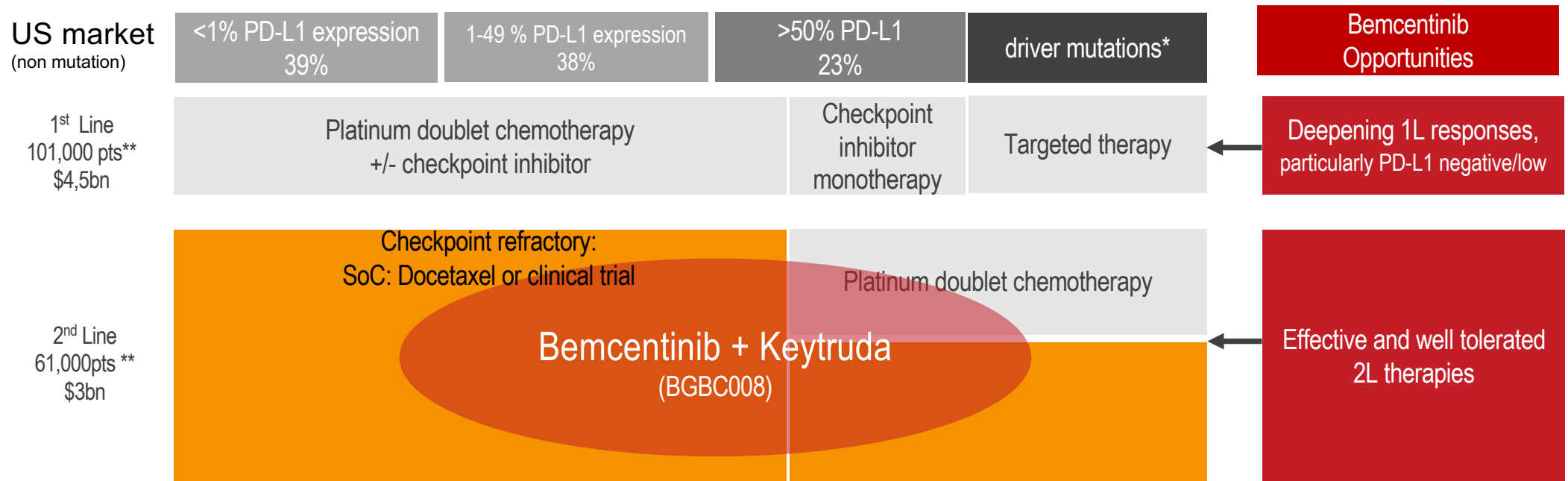
1.76 million lung cancer deaths/yr worldwide¹

5-year survival rate is 3.5% in patients with PD-L1 <1%, and **12.6%** in patients PD-L1 1-49%



Non- Small Cell Lung Cancer (NSCLC)

Rapidly evolving SoC creates opportunities for novel effective, chemo free well tolerated regimens



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
- 2nd 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
- 2nd or 3rd line advanced adeno NSCLC

Cohort C

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

COMPLETED: INFORMS 1L OPPORTUNITY	
<p>Interim Analysis </p> <p>Stage 1 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>Final Analysis </p> <p>Stage 2 N=50 patients total (each patient has the potential for at least 24 weeks follow-up)</p>
<p>Interim Analysis </p> <p>Stage 1 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>Final Analysis </p> <p>Stage 2 N=29 patients/cohort (each patient has the potential for at least 24 weeks follow-up)</p>
<p>Interim Analysis </p> <p>Stage 1 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>Final Analysis</p> <p>Stage 2 N=29 patients/cohort (each patient has the potential for at least 24 weeks follow-up)</p>
ONGOING WILL INFORM 2L PIVOTAL STUDY	

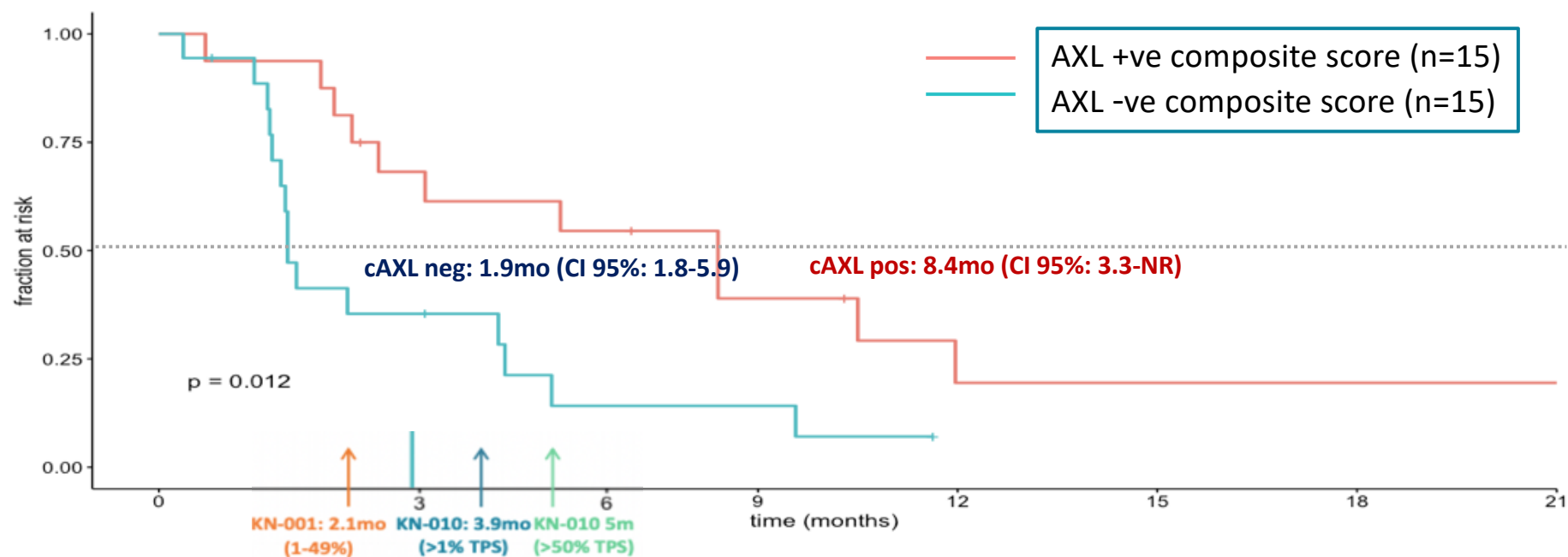
Cohort A: stage 1 + 2 data (n=50)

50% of patients are cAXL +ve :

- ORR cAXL +ve patients 5 X cAXL -ve patients
- mPFS >4 X in cAXL +ve patients
- independent of PD-L1 status

Survival Data

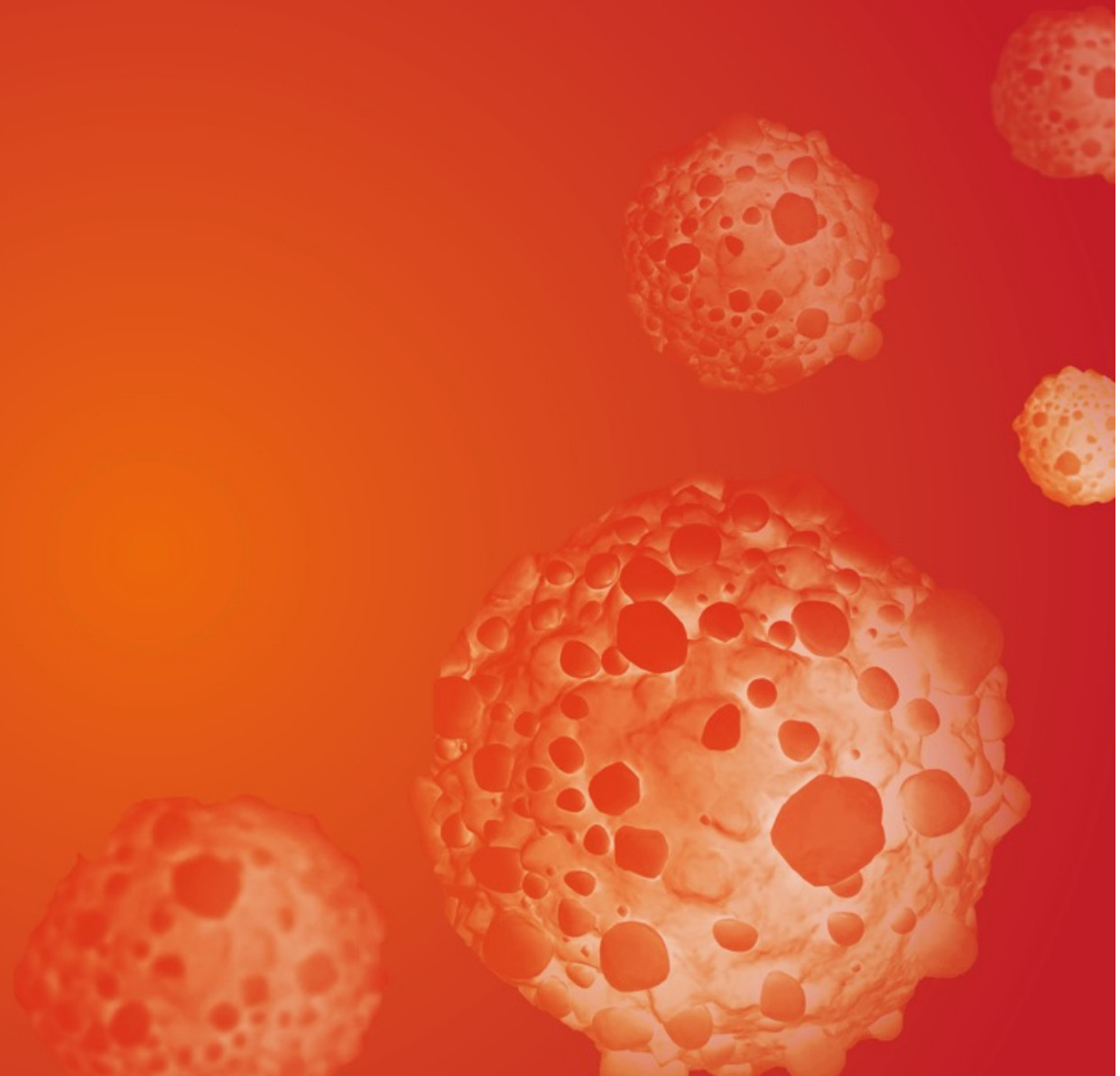
Cohort A: >4 X improvement in mPFS cAXL positive patients



- ✓ >4-fold improvement in cAXL +ve vs. cAXL -ve patients.
- ✓ 4-fold improvement in what might be expected in the same patient population with Keytruda monotherapy

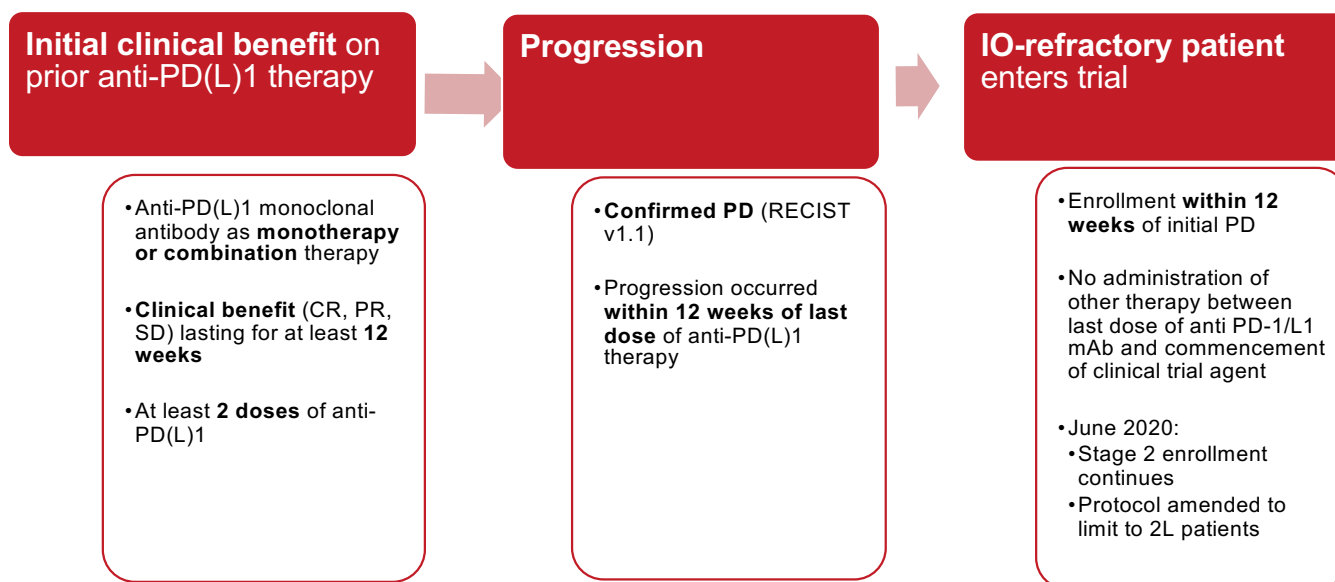
Cohort B

Part 1 data to be presented at :
Next Gen-Immuno-Oncology Congress
25th June 2020
Virtual event



Cohort B: Bemcentinib + KEYTRUDA in CPI refractory patients

CHECK POINT INHIBITOR REFRACTORY PATIENTS: precise and specific definition



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
25th June 2020
Virtual event

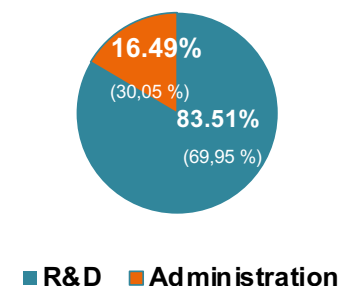
Finance & News Flow



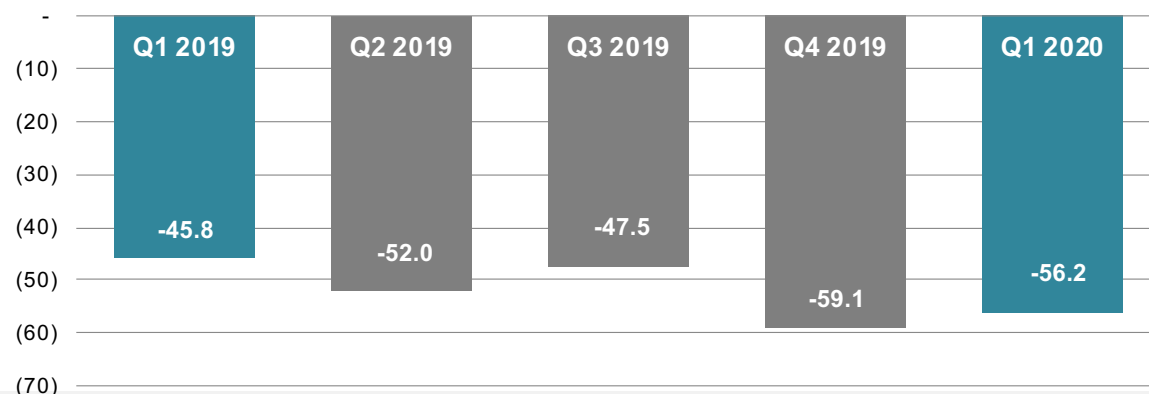
Key financial figures

(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 expenses Q1 2020
(Q1 2019)



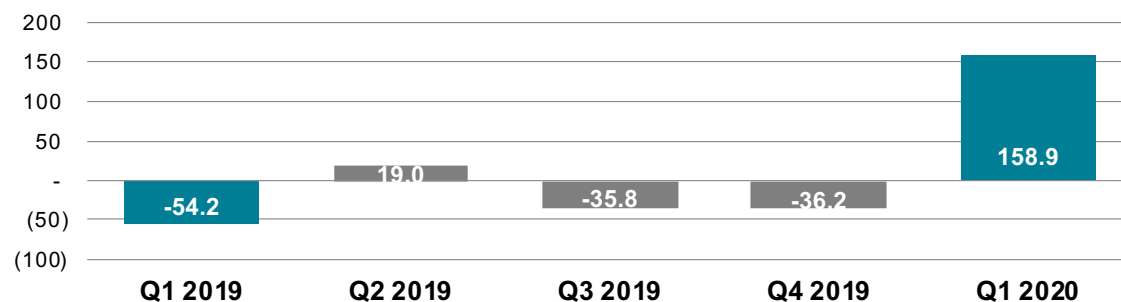
Operating profit (-loss) million NOK



- Increase in operation expenses is a result of increased head count as part of a planned organisational build out in preparation for late stage clinical development. Clinical team, regulatory team and supply chain team have been build out.
- Well managed overhead costs.
- 83,51 % of operating expenses Q1 2020 (Q1 2019: 69,95 %) attributable to Research & Development activities.

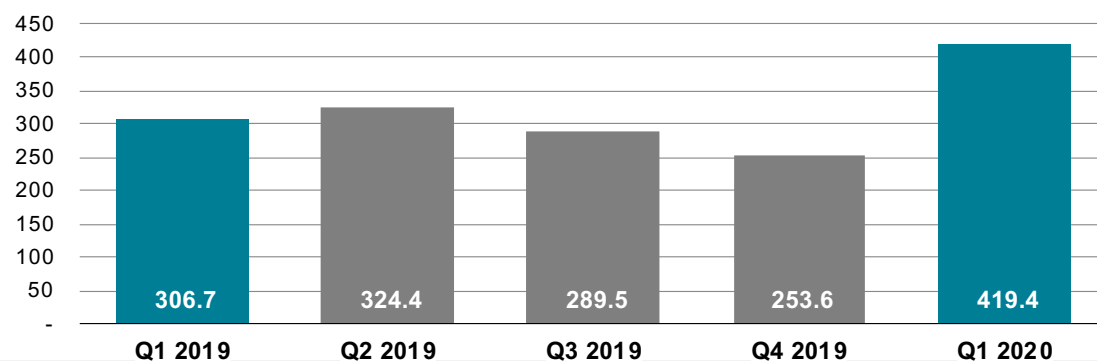
Cash flow and cash position

Cash flow (million NOK)



- Q1 cash flow include proceed from Private Placement in January/February raising gross NOK 229.9m.
- 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).
- Cash position gives runway to deliver key milestones from ongoing clinical trials.

Analyst coverage



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Link to reports from Trinity Delta:

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

Expected Newsflow 2020



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



ASCO-SITC: Clinical Immuno-Oncology symposium, San Francisco
ASCO: American Society of Clinical Oncology, Chicago
WCLC: World Conference of Lung Cancer, Toronto
ESMO: European Society of Medical Oncology, Munich
AACR: American Association for Cancer Research, Chicago
EHA: European Hematology Association, Stockholm
SITC: Society for Immunotherapy of Cancer, DC
ASH: American Society for Hematology, San Diego

Thank you.

Questions

