



Introduction and Update - Q2 2020

LSX Nordic Life Science Conference

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1-4 September 2020  
Richard Godfrey, CEO

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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

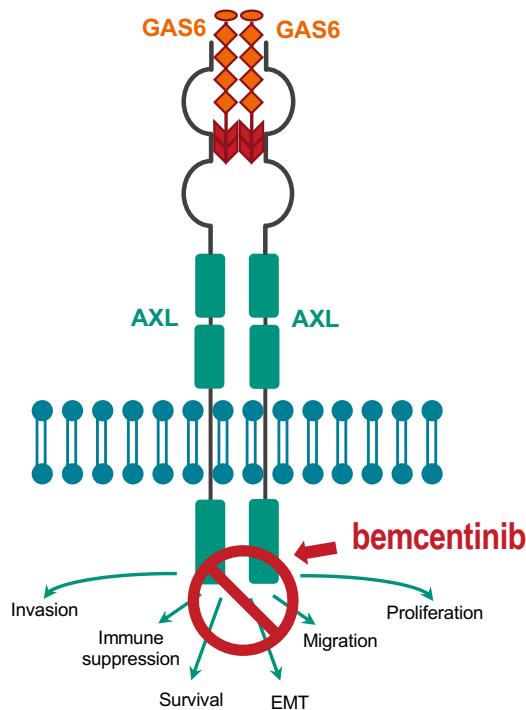
45 staff at two locations:  
HQ & R&D in Bergen, Norway;  
Clinical Development in Oxford, UK

**Cash Q2'20 NOK828m,**



**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>

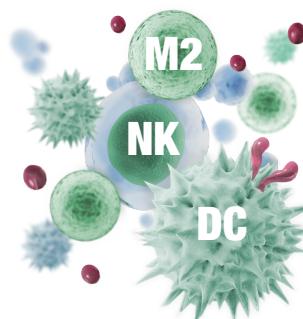
Very low expression under healthy physiological conditions

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

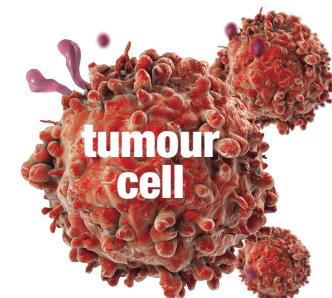
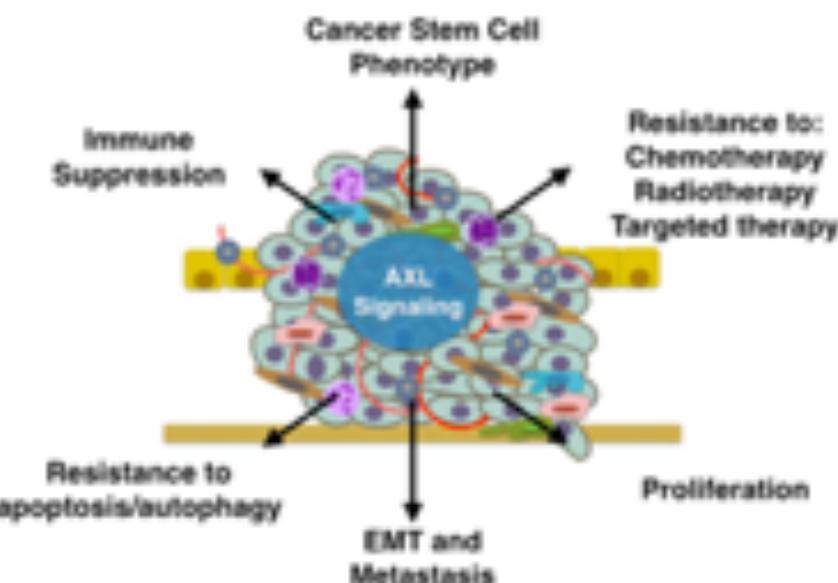


AXL increases on immune cells and suppresses the innate immune response

- 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

DC- dendritic cells Treg – Regulatory T Cell

<sup>6</sup> 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

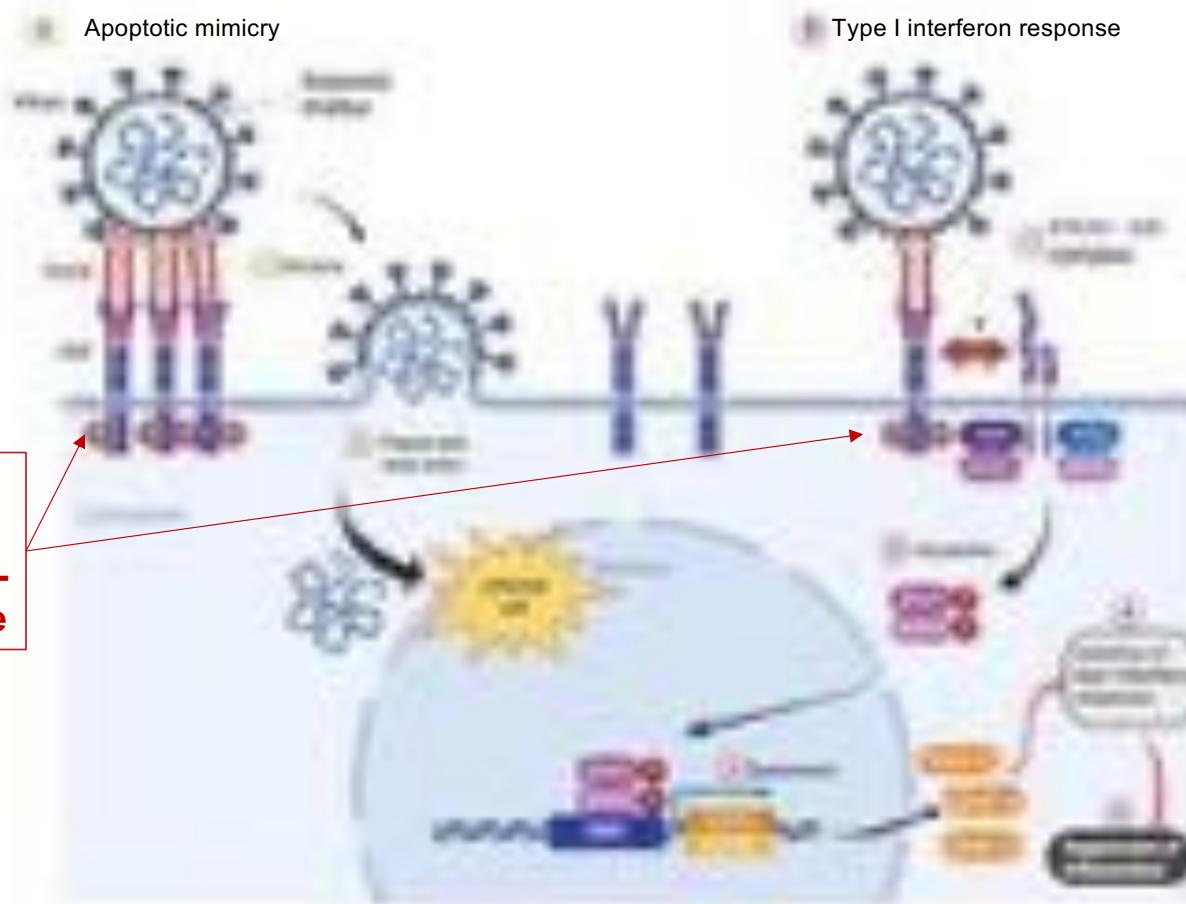


AXL increases on the tumor cell and causes cancer escape and survival

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

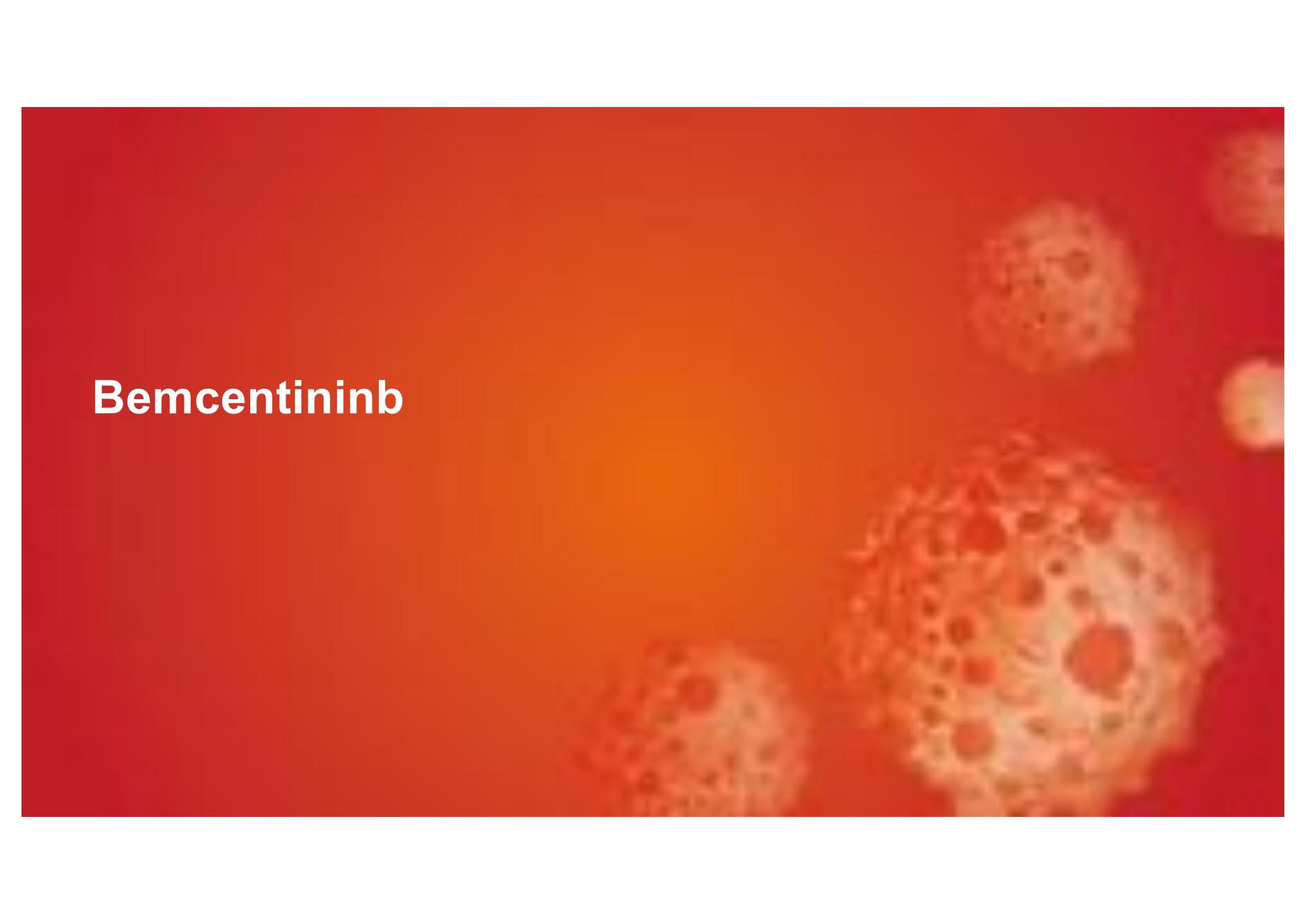
# AXL is targeted by enveloped viruses to enter cells and dampen the viral immune response

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



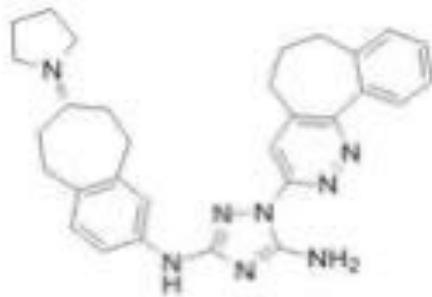
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<sup>1</sup> Maury IOWA unpublished / Meertens L et al. *Cell Host & Microbe* 2012, 12:544 / Chen J et al. *Nat Microbiol* 2018 3:302



**Bemcentinib**

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



- ✓ Nanomolar in vitro potency ( $IC_{50} = 150$  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
  - ✓ >300 patients
- ✓ Safety and tolerability profile supports use in combination with other drugs
- ✓ MOA is synergistic with other therapies, enhancing response

# 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 & MDS			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>
	2L NSCLC chemo refractory			Ph II POC efficacy demonstrated in 50 patient trial, end points met			Fully recruited
Bemcentinib combination with Keytruda	2L NSCLC CPI refractory			Ph II stage 1, 13 pts. met ORR proof of concept end point Expansion 16 pts.			
	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>
Bemcentinib monotherapy	Hospital COVID19 Patients			In set up stage			Q3'20, FPI
Tilvestamab (BGB149)	Phase I		Ph Ia HV SAD complete	Ph Ib MAD in set up			Q4'20 First patient In



\* Increased uncertainty due to COVID crisis

CPI – checkpoint inhibitor

mOS – median overall survival

10

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			Recruitment stop due to low incidence & funding cessation
	European MDS Cooperative Group	2L AML	Monotherapy	open-label, single-arm , phase II study.			Fully recruited.
		2L MDS	Monotherapy	open-label, single-arm , phase II study			Met Primary End Point of Overall Response Rate
	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins	Recurrent Glioblastoma	Monotherapy	Ph I safety study			Full data in Q4'20 (ASH)
	University of Leicester	Relapse Mesothelioma	+ pembrolizumab	Set up			Interim analysis of bemcentinib levels at 5pts. YE'20
	Haukeland University Hospital	1L Metastatic Melanoma	+ pembrolizumab or +Dabrafenib/Trametinib	Randomised Phase II			FPI Q3'20
	UT Southwestern Medical Center	2-4L Stage 4 NSCLC	+ docetaxel	Ph I safety study			Restart pending Biomarker Analysis Q3'20
	UT Southwestern Medical Center	1L metastatic or recurrent PDAC	+ Nab-paclitaxel+ Gemcitabine+ Cisplatin	Ph I safety study			Fully recruited YE'20 Confirm RP2D

11

\* Increased uncertainty due to COVID crisis



# Bemcentinib clinical development in COVID19

To evaluate the efficacy and safety in hospitalized COVID19 patients

*- BGBC020 trial in set up*



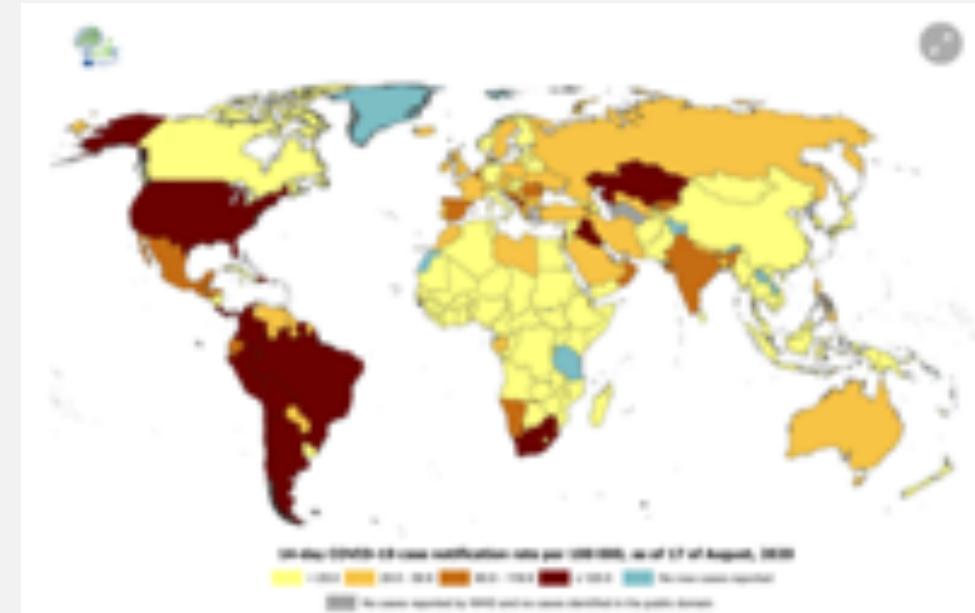
# BGBC020 – BerGenBio sponsored trial in COVID-19 patients

- COVID-19 pandemic remains ongoing – some slow down seen in countries with effective public health measures
  - 21m reported cases and more than 770,000 deaths worldwide
- Currently, no medication is recommended to treat COVID-19, and no cure is available.
- The FDA has granted emergency use authorization for the antiviral drug remdesivir to treat severe COVID-19.
- The U.S. National Institutes of Health recently recommended the corticosteroid dexamethasone for people with severe COVID-19 who require supplemental oxygen or mechanical ventilation.

## BGBC020

- BerGenBio sponsored clinical trial COVID-19 patients
- Will be in a country of high COVID incidence
- Protocol will permit co-administration with remdesivir and dexamethasone
- Anticipate FPI September 2020.

Geographic distribution of 14-day cumulative number of reported COVID-19 cases per 100 000 population, worldwide, as of 17 August 2020



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

Phase I/II open label, multi centre international trials to evaluate safety and efficacy

## BGBC003

- monotherapy in r/r patients AML or MDS 
- combination with low-dose cytarabine (LDAC) in 1L newly diagnosed or r/r patients with AML 
- combination with LDAC in 2L relapsed patients with AML **Expansion On going**

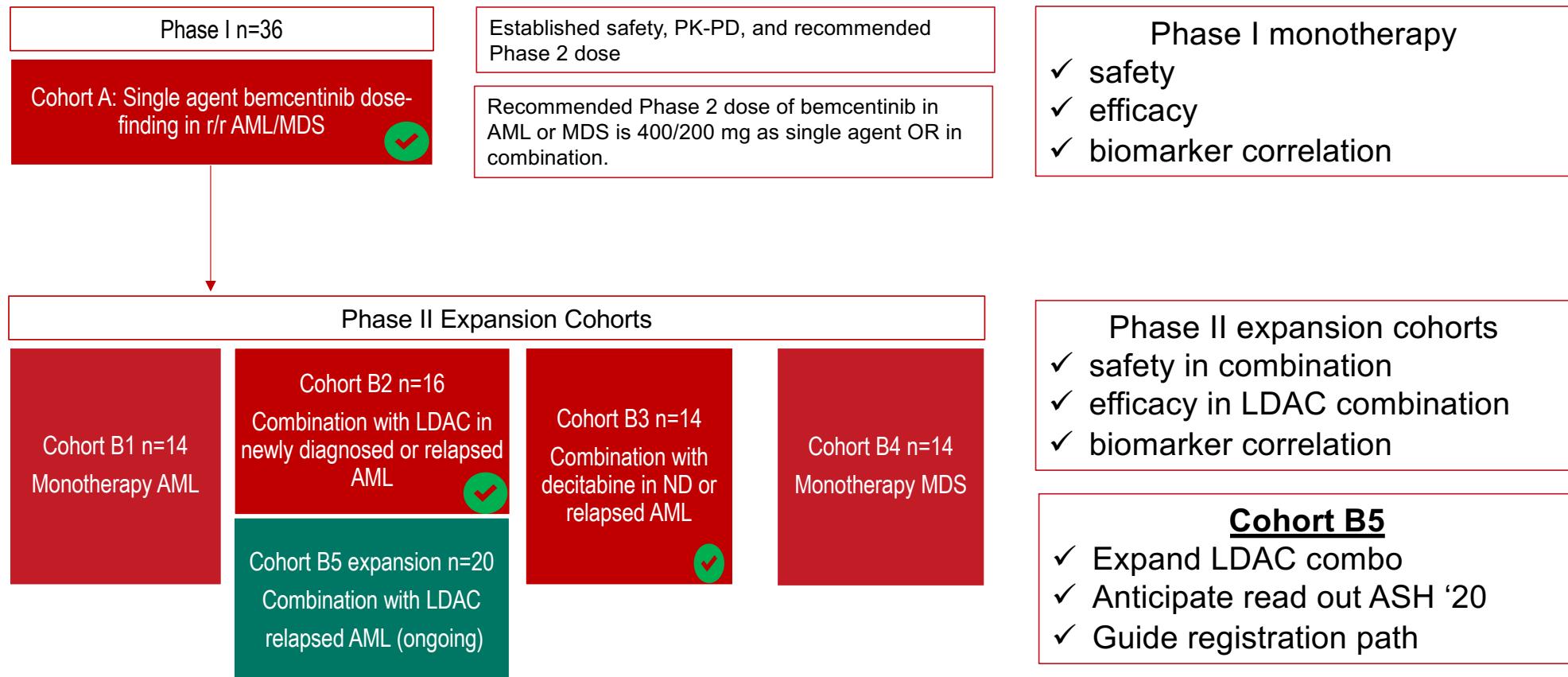
## BGBIL009 – BERGAMO Investigator Sponsored Trial

- Monotherapy in r/r AML or MDS patients 



BGBC003 NCT02488408

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



## BGBIL009 / NCT03824080 (BERGAMO study)

- A phase II study evaluating the efficacy and safety of Bemcentinib in patients with MDS or AML failing standard of care therapy
- MET PRIMARY END POINT

- Investigator Sponsored Trial: EMSCO
- Chief Investigator : Uwe Platzbecker, MD, Leipzig University Hospital, Germany
- Open-label, multi-centre phase II trial of 45 patients with high risk MDS or AML who have failed or are refractory to hypomethylating agent treatment
  - Study Rationale: Poor prognosis / limited treatment options – mOS 5.6m after failing HMA for HR-MDS<sup>1</sup>
  - Bemcentinib monotherapy standard dosing
- End Points:
  - Primary: Overall response rate assessed in week 17 (beginning of cycle 5)
  - Secondary: Toxicity, OS, PFS, TTF, DoR, BOR
  - Exploratory endpoint: Translational project evaluating the role of potential biomarkers, e.g. Axl/Gas6
- Full data to be disclosed at upcoming scientific / medical congress



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



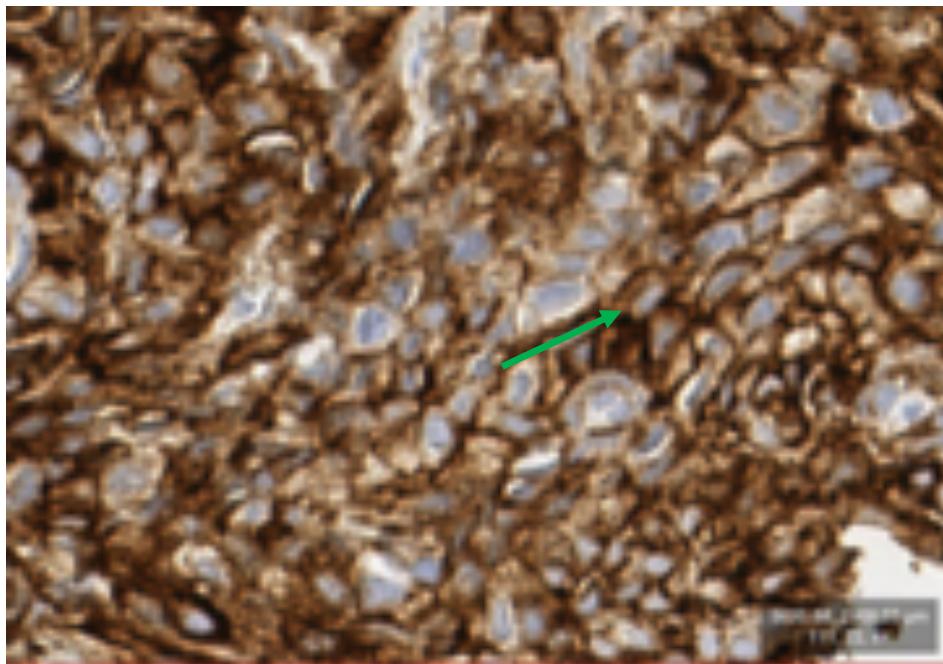
CPI +/- chemotherapy refractory patients **On going**

CPI + Chemotherapy refractory patients **On going**

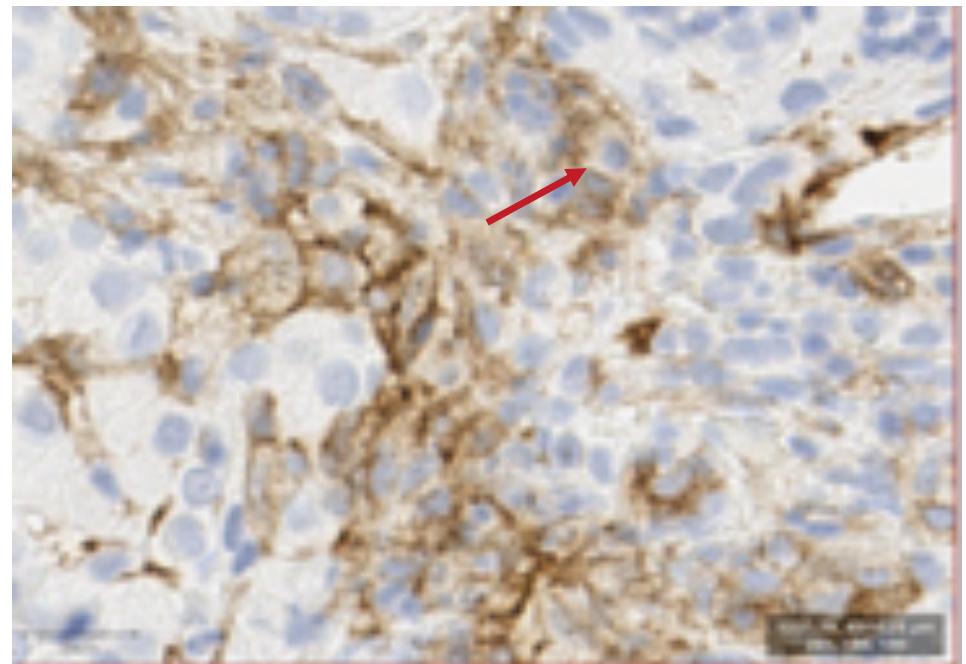


## Composite AXL (cAXL) status defined by presence of AXL on membranes of tumor & immune cells in tumour micro environment

Example of high AXL expression on tumour cells: cAXL status of this patient is positive



Example of tumour with a high number of AXL positive immune cells: cAXL status of this patient is positive



- Arrows directed at examples of positively-stained **tumour** and **immune** cell, respectively
- Both patients experienced significant tumour shrinkage on bemcentinib + pembrolizumab treatment combination

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

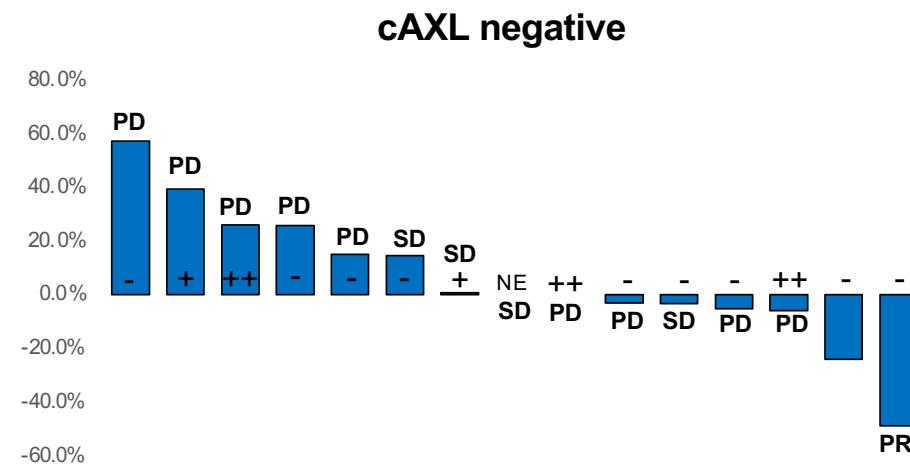
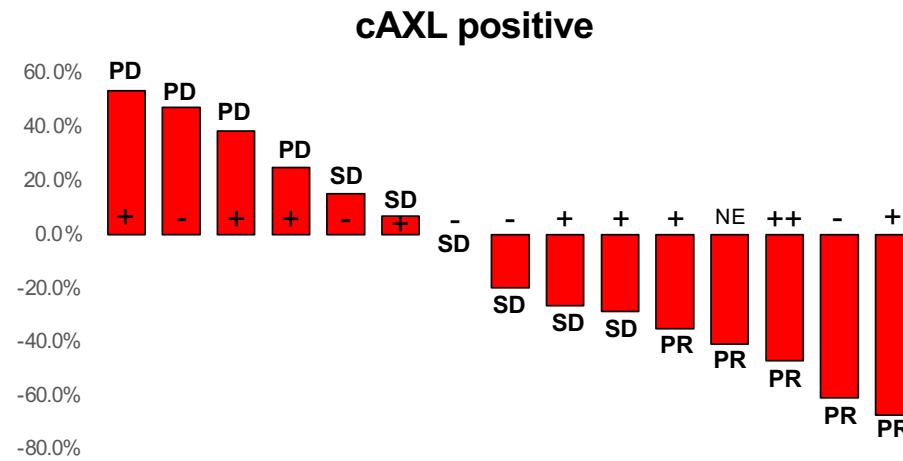
NSCLC patients previously treated with a platinum containing chemotherapy

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

- ✓ - mOS 17.3months : 140% greater in cAXL +ve patients
- ✓ - mPFS: 442% greater in cAXL +ve patients
- ✓ - ORR cAXL +ve patients 5 X cAXL -ve patients
- ✓ - 73% Clinical Benefit Rate in cAXL +ve patients
- ✓ - independent of PD-L1 status

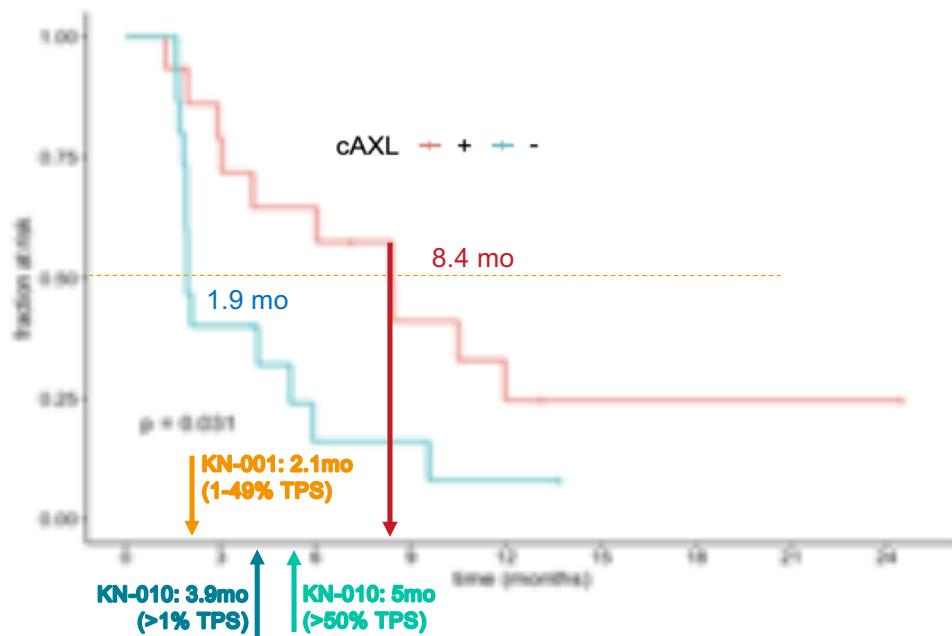
# Change in tumour size from baseline in cAXL-evaluable patients only

Cohort A



# Enhanced survival in cAXL +ve patients with addition of bemcentinib to pembrolizumab

AXL is an adverse prognostic biomarker  
mPFS 8.4 months in cAXL+ patients



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%

\*OS data still maturing, current calculation (cut-off survival: 28-May-2020)

\*\*pts who have been on study treatment for at least 1 cycle (n=42)

- 4-fold improvement in PFS in cAXL +ve vs. cAXL -ve patients.
- 12 mo OS in cAXL positive patients 79% vs 60% in cAXL negative patients
- Clinical benefit reflected in mOS of cAXL +ve patients vs. cAXL -ve
- cAXL -ve patient survival data is comparable to historic controls

Data cut-off: 17-April-2020

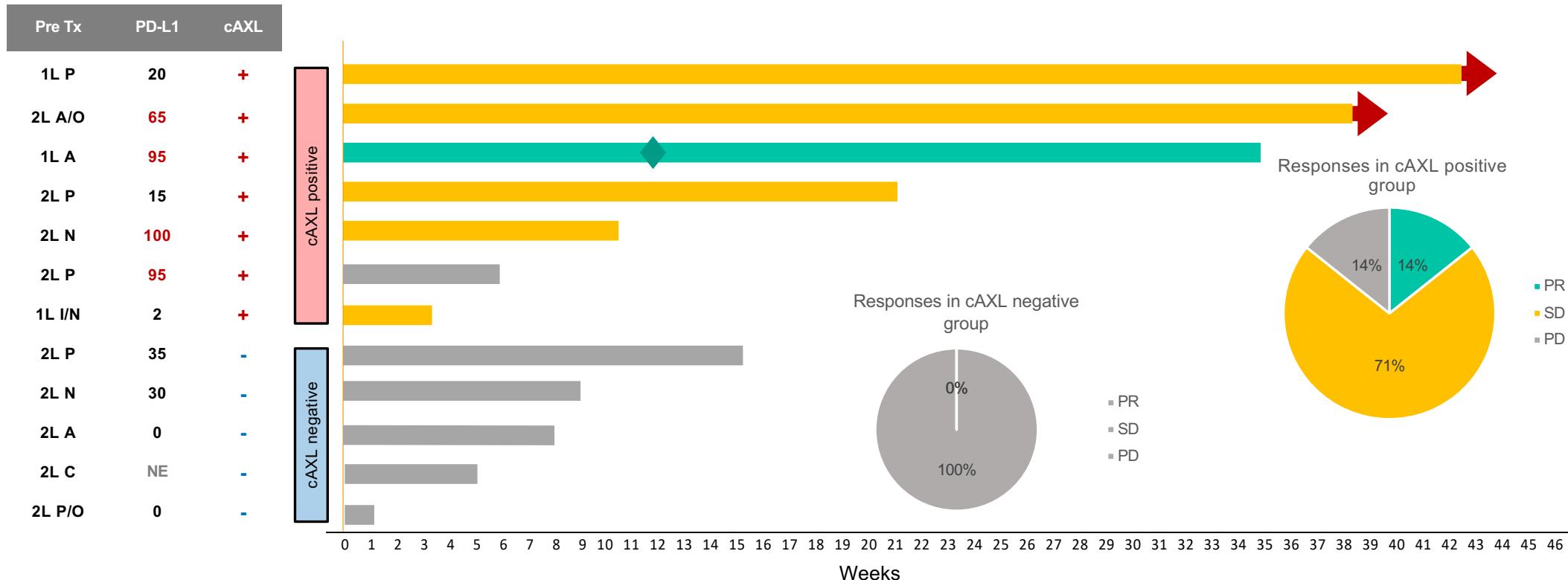
Source: KN-001: Garon et al NEJM 2015; KN-010: Herbst et al, Lancet 2016;

CheckMate-057: Borghaei et al, NEJM 2015

## **Cohort B:**

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

## Time on treatment in patients evaluable for cAXL



Data cut-off: 17-April-2020

+ cAXL positive

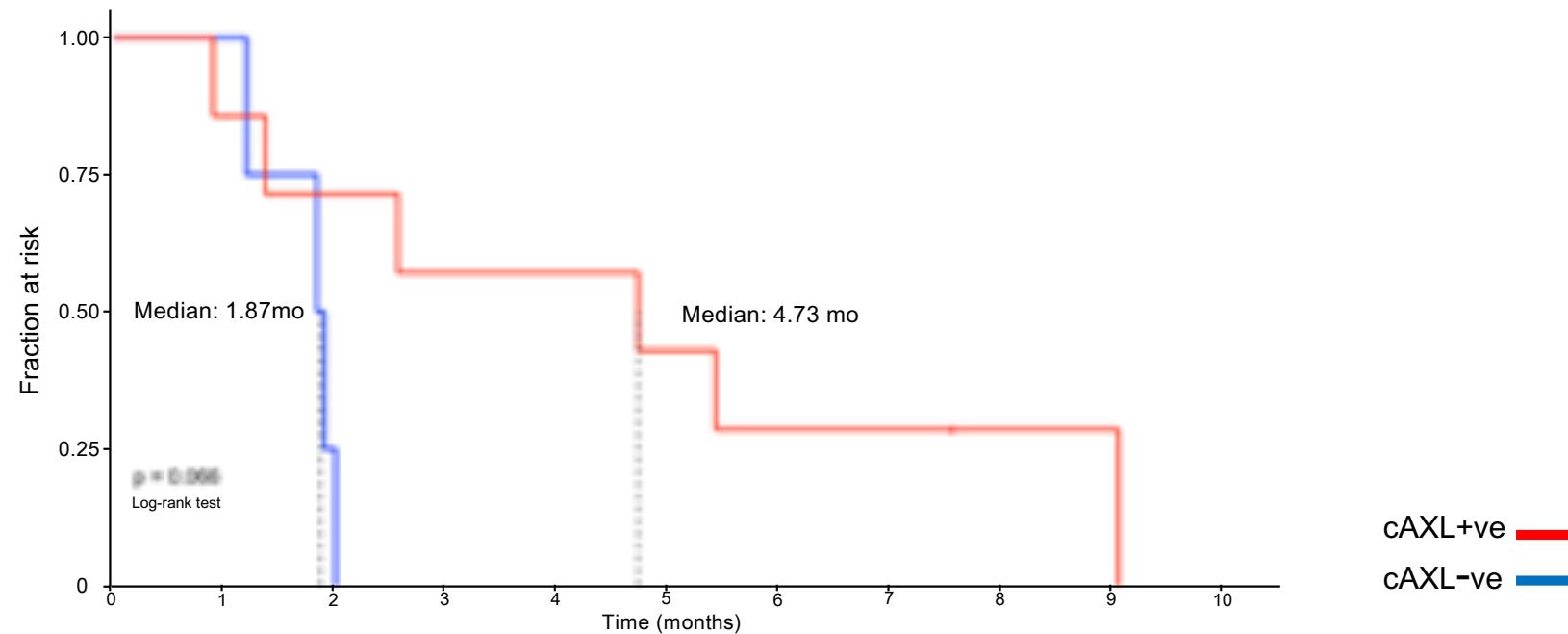
- cAXL negative

### Previous immunotherapy (1 or 2L)

P: pembrolizumab; A: atezolizumab; N: nivolumab; C: cetrelimab; I: ipilimumab; O: other

## mPFS improvement in cAXL +ve patients

Cohort B1



# Finance Report

Q2, 2020

# Key financial figures

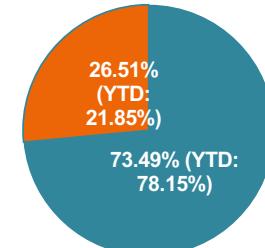
(NOK million)	Q2 2020	Q2 2019	YTD 2020	YTD 2019	FY 2019
Operating revenues	0,0	0,0	0,0	8,7	8,9
Operating expenses	64,7	52,0	121,0	106,5	213,3
Operating profit (-loss)	-64,7	-52,0	-121,0	-97,8	-204,4
Profit (-loss) after tax	-67,3	-52,8	-115,8	-97,1	-199,3
Basic and diluted earnings (loss) per share (NOK)	-0,86	-0,95	-1,59	-1,76	-3,43
Net cash flow in the period	412,3	19,0	571,3	-35,2	-107,2
Cash burn operating activities	-50,0	-53,0	-109,1	-108,6	-186,7
Cash position end of period	828,4	324,4	828,4	324,4	253,6

Operating profit (-loss) million NOK



- NOK 7.5m of the operating loss in Q2 2020 is a P&L non cash option cost (increase in accruals for option and social and security tax on employee share option as a result of a positive development in the company's share price in the quarter). In Q2 2019 the option cost was negative with NOK 2.5 million.

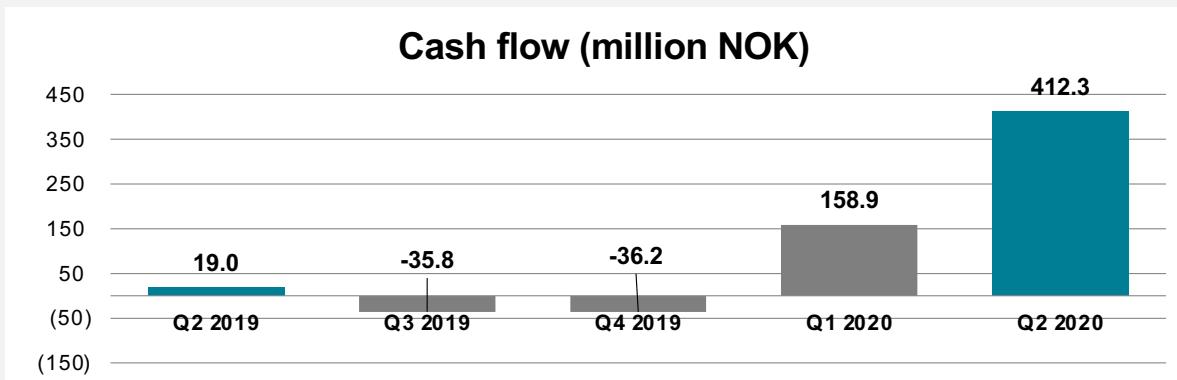
Operating expenses Q2 2020 (YTD)



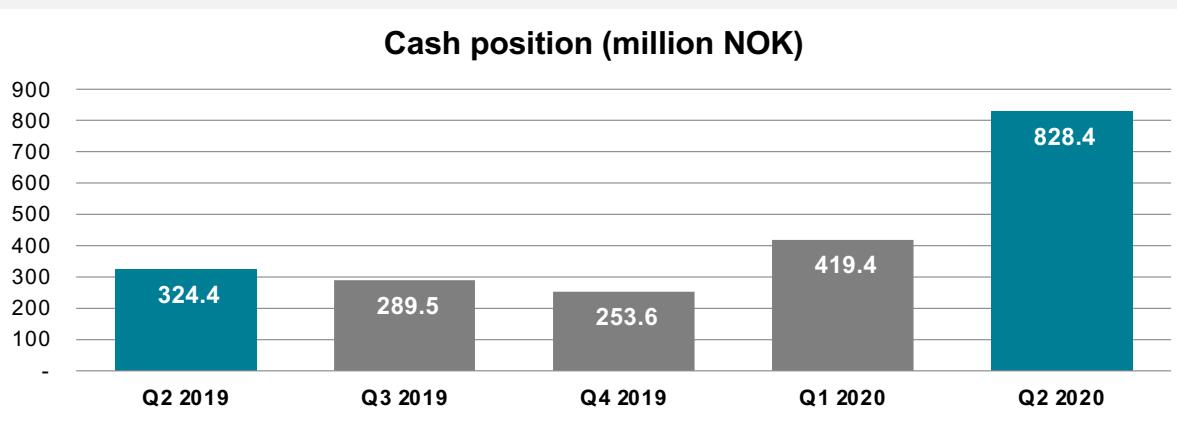
■ R&D ■ Administration

- Well managed overhead costs.
- 73,49 % of operating expenses Q2 2020 (YTD 78,15%) is attributable to Research & Development activities.
- Organisation growth in preparation for late stage development (45 staff)

# Cash flow and cash position



- Cash flow from operating activities NOK -50m.
- Q2 cash flow include proceed from Private Placement in May raising gross NOK 500m.
- Quarterly average cash burn (Q219 – Q220) NOK 48.3m (USD 5.2m)



- Cash position Q2 2020 NOK 828.4 million (USD 85.7m).
- Subsequent repair offering completed July 2020 not included, raising an additional NOK 20m (USD 2.1m).

# Analyst coverage



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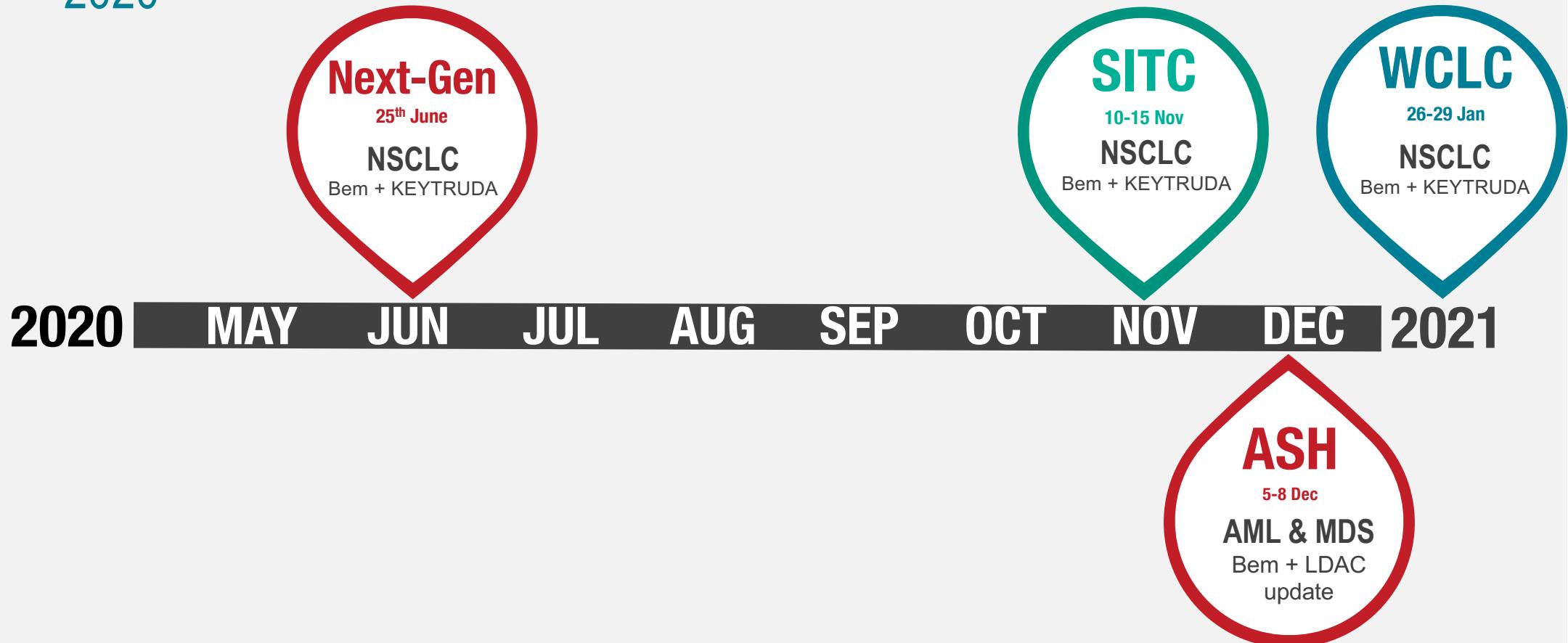
Link to reports from Trinity Delta:

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

# News Flow 2020

# Expected Newsflow\*

2020



\* Conditional on impact of global COVID crisis

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

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

30 SITC – Society of Immunotherapy of Cancer (Nov 10-15)  
WCLC – World Congress of Lung Cancer (Jan 26-29 2021)