BerGenBio

Q1 2019 highlights and financial report

8th May 2019

Richard Godfrey , CEO

Rune Skeie, CFO

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Q1 2019 highlights

bemcentinib meets efficacy endpoint in combination with chemotherapy in AML patients
Bemcentinib in combination with low dose cytarabine is efficacious and well tolerated in elderly AML patients.

Phase II trial of bemcentinib and KEYTRUDA® in NSCLC expanded
Additional cohort B initiated to include 2L IO relapsed patient population

Commenced Phase I trial evaluating first-in class anti-AXL antibody BGB149
Phase I study will investigate safety and pharmacokinetics in healthy volunteers

Commenced phase I trial evaluating ADCT-601, a novel anti-AXL antibody drug conjugate (ADC), in patients with advanced solid tumours (partnered program*)
Phase I dose escalation and expansion trial will evaluate ADCT-601 in upto 75 cancer patients

Commencement of Phase II Investigator-Initiated Trial Evaluating Selective AXL Inhibitor Bemcentinib monotherapy in high-risk MDS
Will enrol up to 43 patients at leading MDS centres across Europe

Key appointments to executive team and Board to prepare organisation for next phase of development
Board of Directors strengthened, two new members added to the leadership team

* Partnered to ADCT

3 selective AXL inhibitors in clinical development

Multiple attractive opportunities in many cancers

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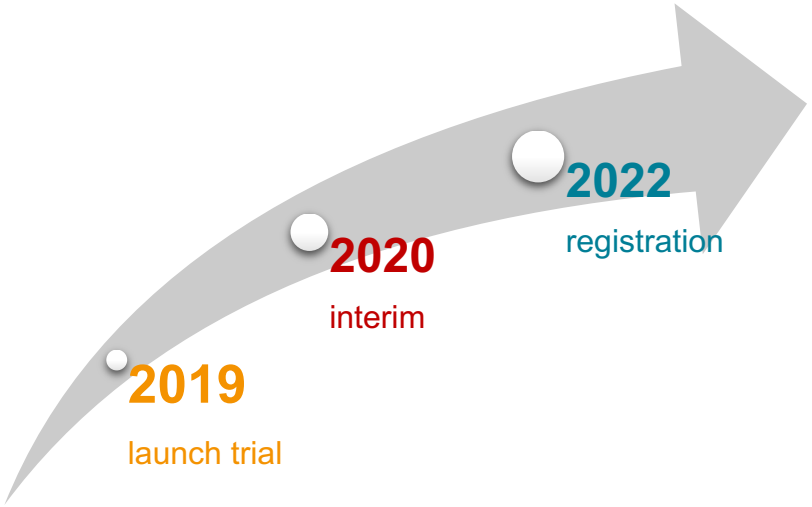
Two significant late stage development opportunities

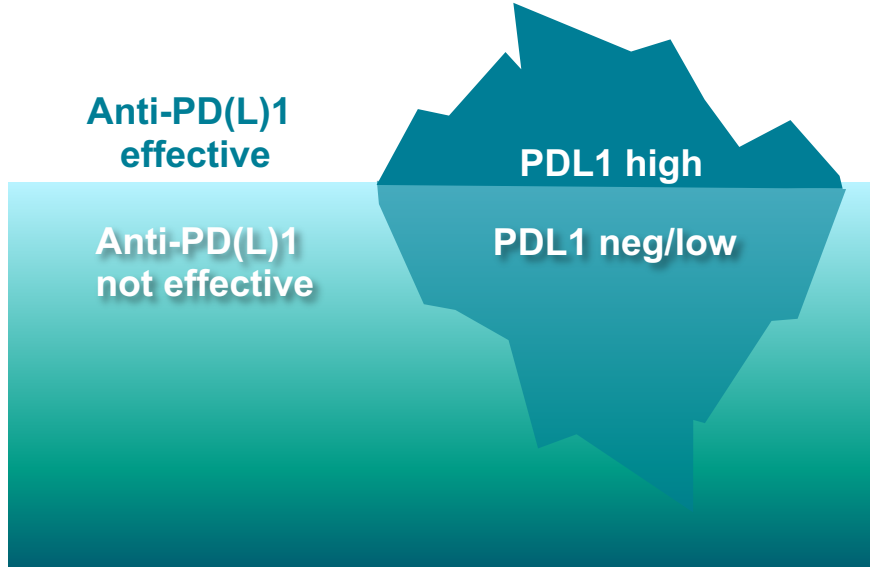
2L AML monotherapy



Defined patient population, potential first & accelerated path to registration

Effective and well tolerated monotherapy treatment option for elderly patient population

NSCLC + anti-PD(L)1 inhibitor



Potential to significantly increase addressable patient population

Unlock promise of IO combo through effective biomarker

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Ref. BGBC003 / NCT02488408

Acute Myeloid Leukaemia (AML)

Bemcentinib is being evaluated as a monotherapy and in combination with standard of care to treat AML and high-risk MDS

- ***43% ORR in AXL +ve R/R AML and MDS patients***
- ***chemo combos in 1L ongoing***

Acute Myeloid Leukaemia (AML)

Most common type of acute leukaemia in adults[1]

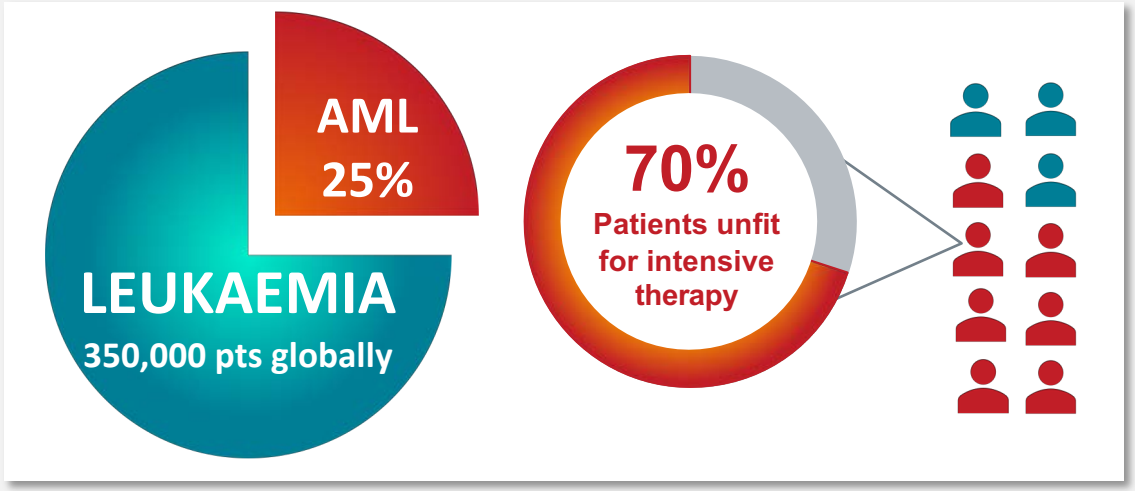
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

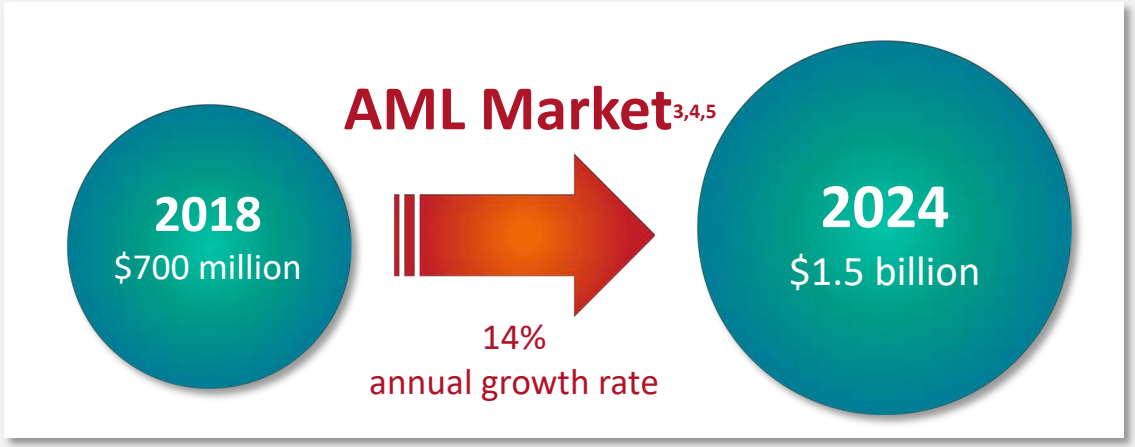
~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018[2]

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 years [6]

5 year survival rates of 3-8% in patients over 60 years old [7]





(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/

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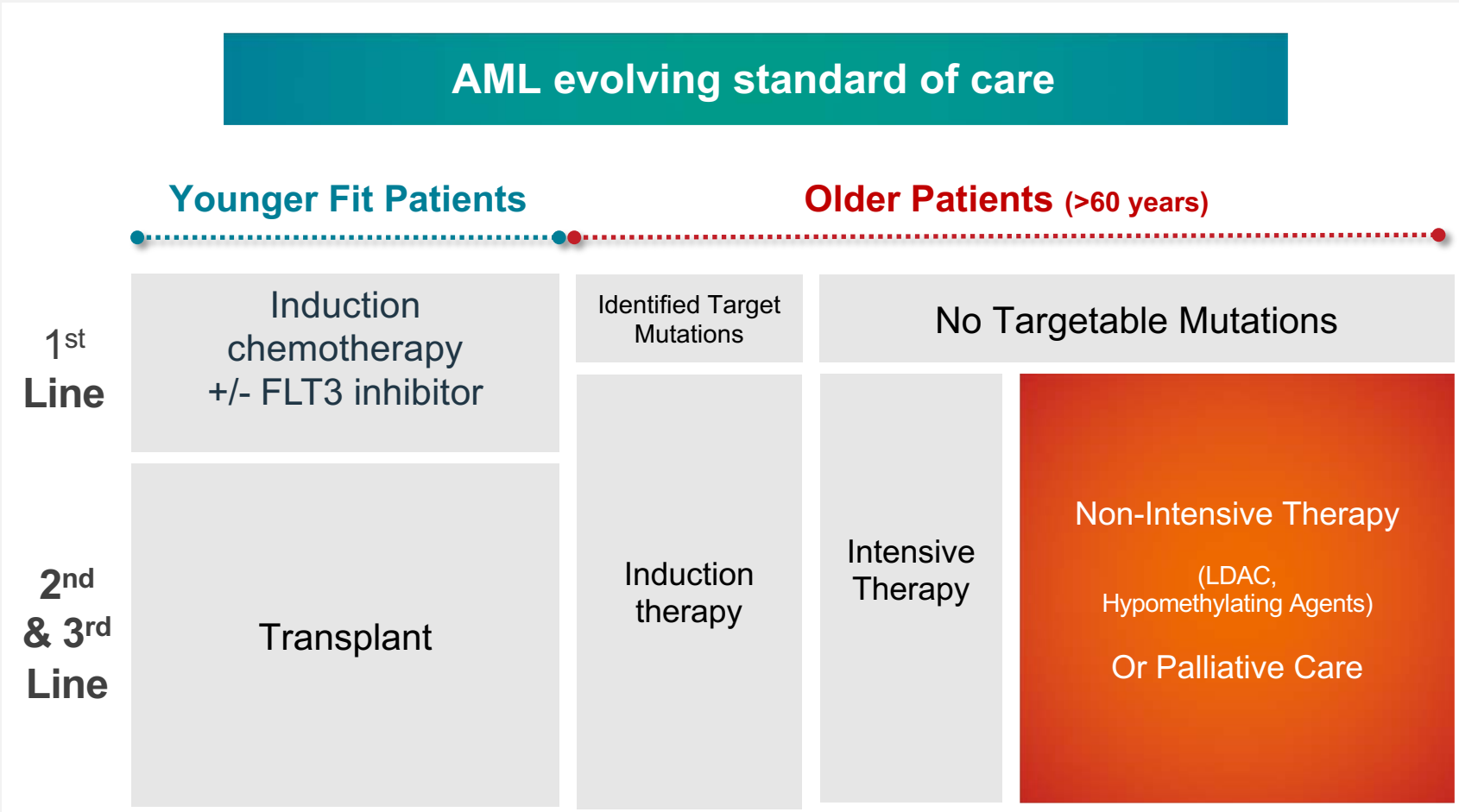
Large unmet need in AML

New therapies needed for patients unfit for intensive therapy



Opportunity in Refractory AML

- New therapies needed for patient's w/o targetable mutations
- Treatment options beyond chemotherapy still limited

1L bemcentinib +chemo combo opportunity

2L (R/R) mono opportunity

- Manageable safety profile
- Well tolerated, low grade adverse event profile

Ref. BGBC003 / NCT02488408

Bemcentinib in AML

Monotherapy & in combination with low-dose chemotherapy

Relapsed/ refractory AML & high-risk MDS

up to 90 pts

2L Monotherapy (completed)

2 L R/R AML & MDS
N = 36 pts

43%* CR/Cri/CRp

* Ca. half of patients found to be AXL positive

Immune activation and clonal stabilisation observed

Combination Therapy (fully recruited)

Decitabine combo
AML, N = 14 pts

Low-dose cytarabine (LDAC) combo
AML, N = 14 pts

Ongoing

- **Efficacy endpoint met in LDAC group:**
  - ✓ **3 CR/CRis among first 10 pts evaluated**
- **Data further maturing**

Endpoints

Primary
safety / ORR
Secondary
RFS
OS
biomarkers

*LDCT: approved low dose chemotherapy regimens

Bemcentinib in AML

April 2019 Update

Bemcentinib Monotherapy (n=27) **ASH Dec 2018**

AXL +ve patients*	*CR/Cri/CRp*	*Stable Disease*
14/27	*6/14*	*3/14*
52%	***43%***	***21%***

Longest duration of Treatment for Responder

>15 Months

Bemcentinib + Low Dose Cytarabine LDAC (n=10) **Q1 2019**

CR/Cri/CRp
3/10
30%

Responses occurred early, improved over time and included poor risk, previously treated patients

Safety Summary (across all bemcentinib programmes)

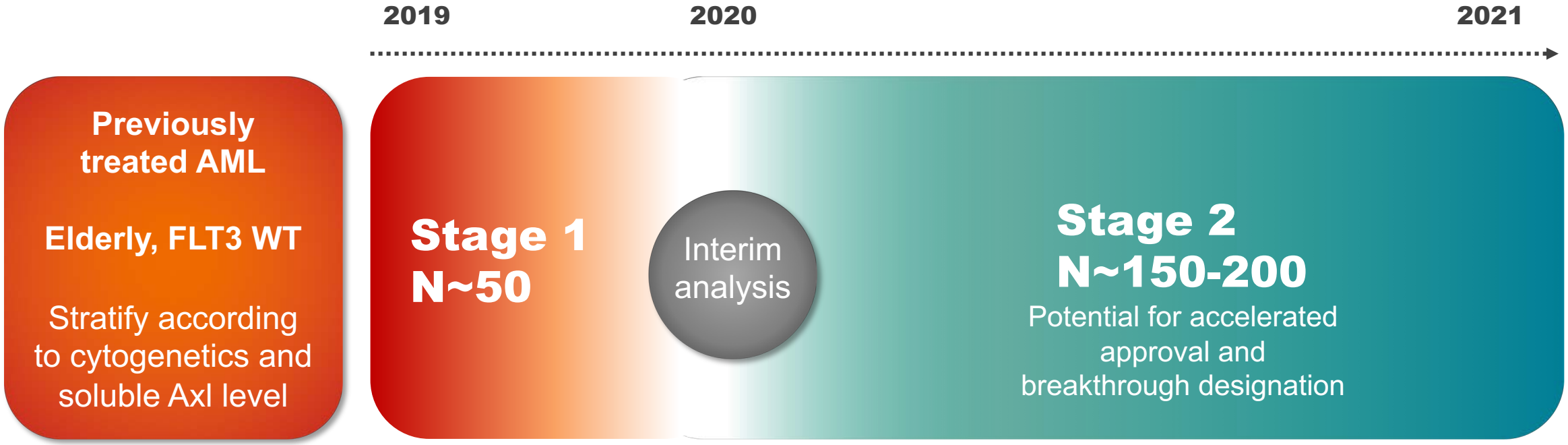
- Treatment related adverse events were generally considered to be less problematic than for other TKIs
- Grade <3 diarrhoea (6%), Grade <3 LFTs abnormalities (6%), and Grade < 3 QTc prolongation (4%)
- Fatigue: any grade: 15% of patients and Grade 3: 3% of patients (no higher grade events)

*Cut-off in development

Bemcentinib targeting 2L AML*

bemcentinib monotherapy in previously treated elderly AML patients

Goal: Prolong PFS in patients who relapse or respond poorly to current first-line treatment options



* Trial in planning and set up stage

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Ref. BGBC008 / NCT03184571

Bemcentinib in NSCLC: Combination with anti-PD(L)1

PoC data in combo with KEYTRUDA, previously treated, IO naïve NSCLC*:*

- ***27% ORR in PD-L1 –ve patients***
- ***40% ORR in AXL+ve patients***

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

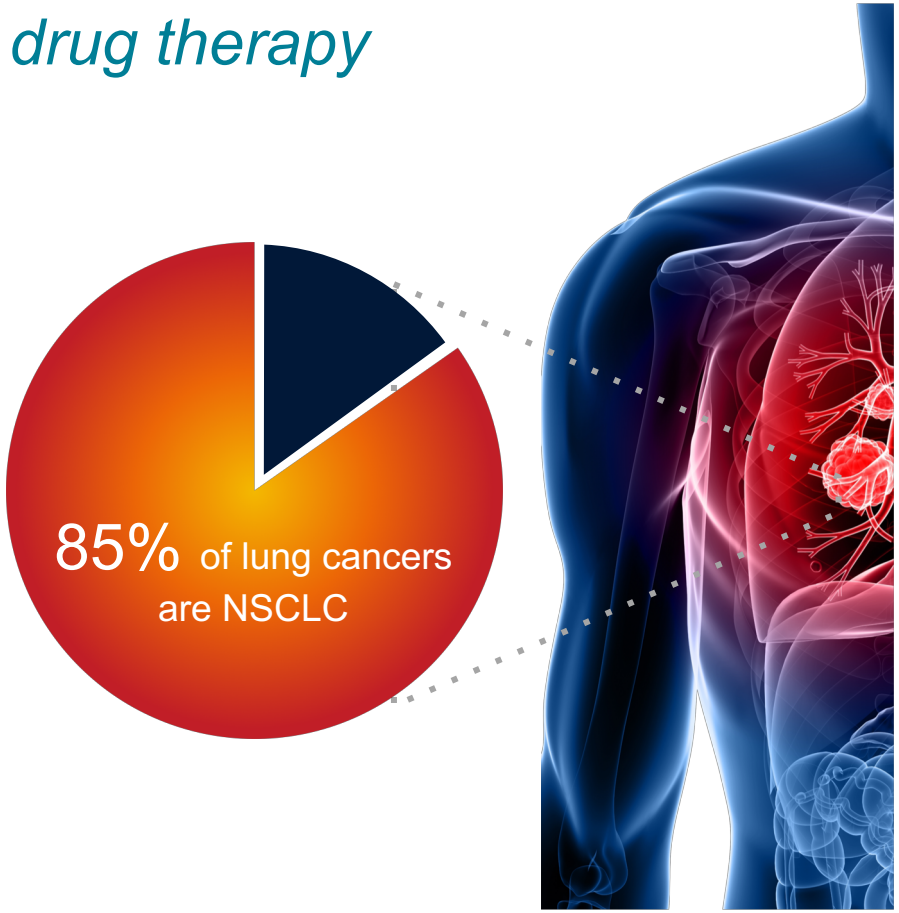
The largest cancer killer, most patients depend on drug therapy

The most common type of cancer

2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases[1]

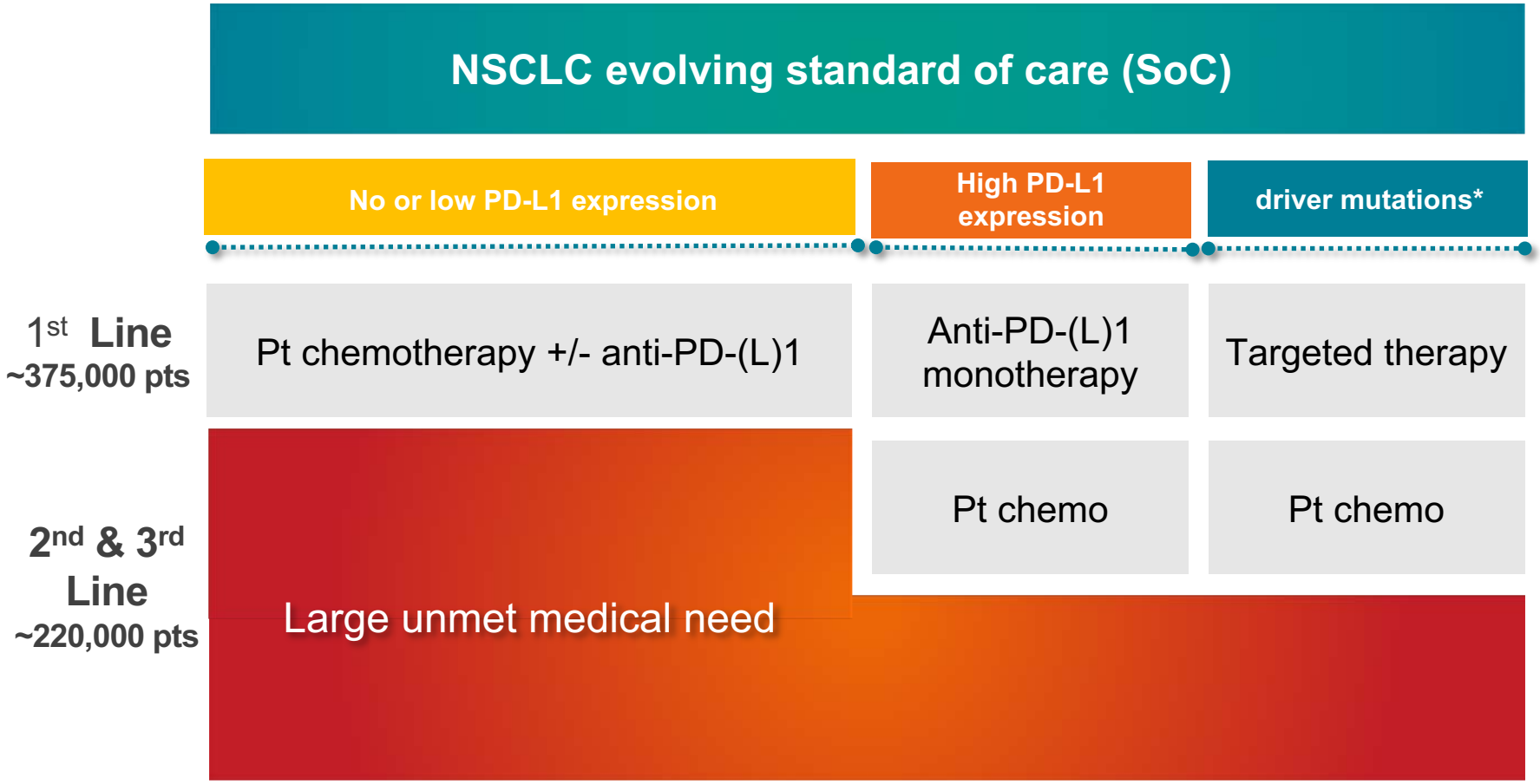
1.76 million lung cancer deaths/yr worldwide[1]

In the U.S, 5-year survival rate is approximately 18.6%, and **4.7%** in patients with distant metastases[2]



(1) Globocan 2018 (2) SEER

Rapidly emerging SoC creates opportunities for novel effective, chemo free regimens



Opportunity in Chemotherapy Refractory NSCLC

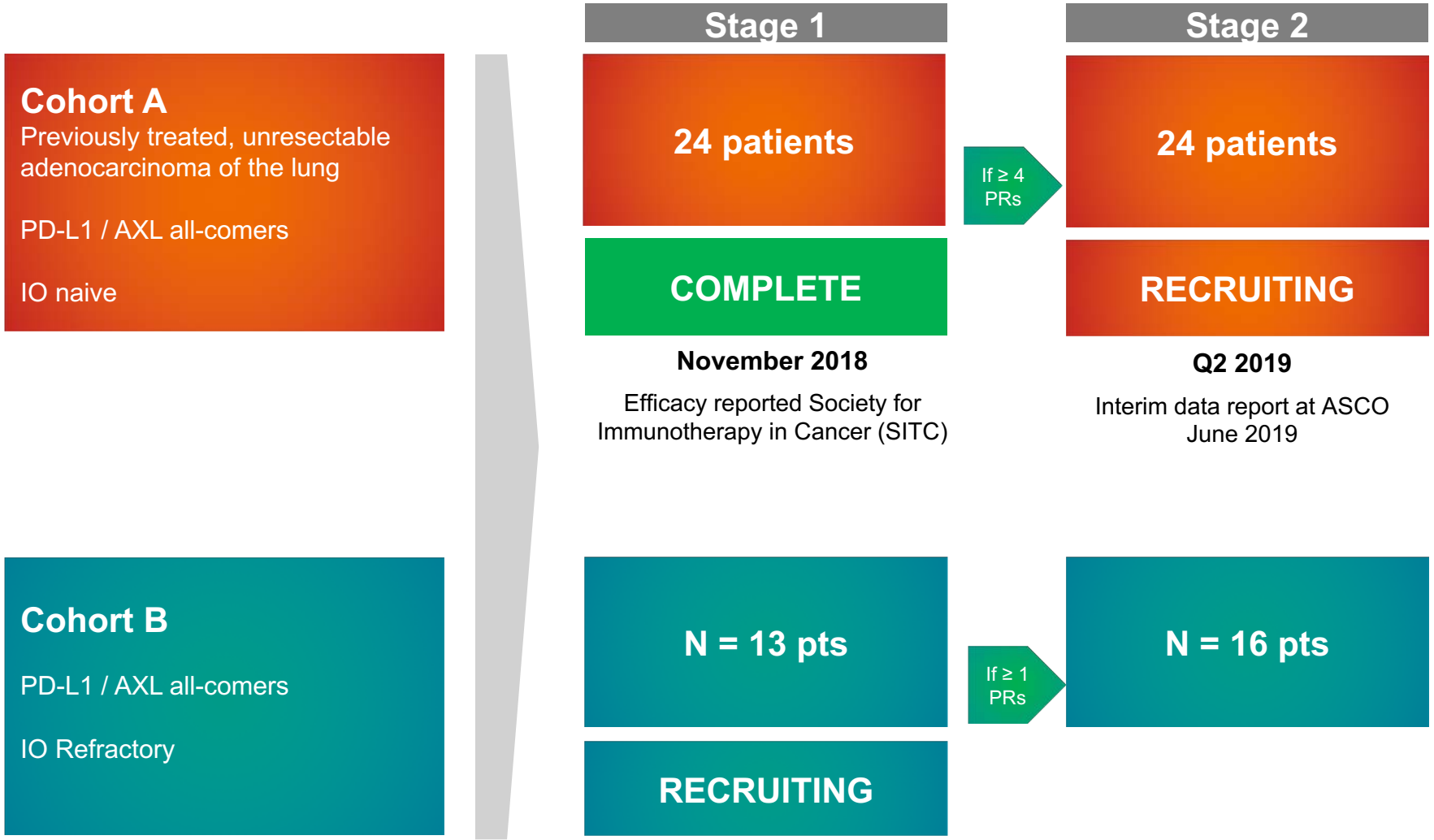
- Deepening 1st Line response, particularly in PD-L1 negative/low patients
- Effective and well-tolerated 2nd Line therapy

* Mutations / rearrangements with available targeted therapies such as EGFR and ALK

Ref. BGBC008 / NCT03184571 – clinical trial collaboration with Merck & Co.

Bemcentinib + KEYTRUDA in Refractory NSCLC

Phase 2 Study Design



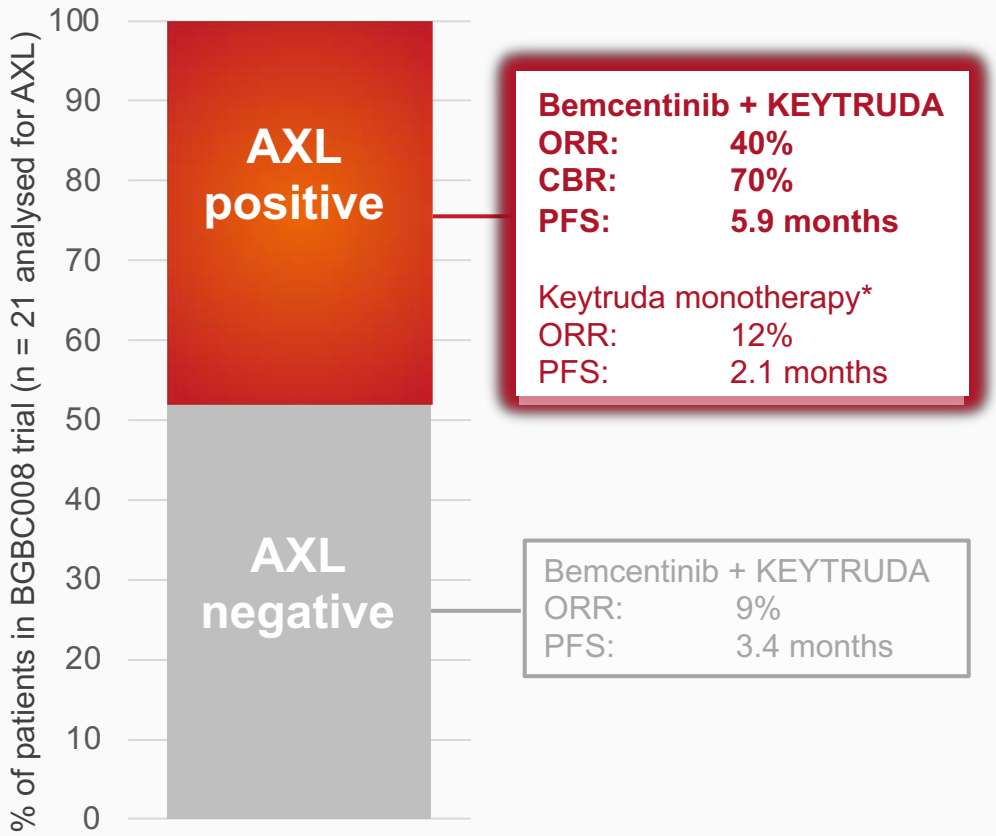
Key objectives

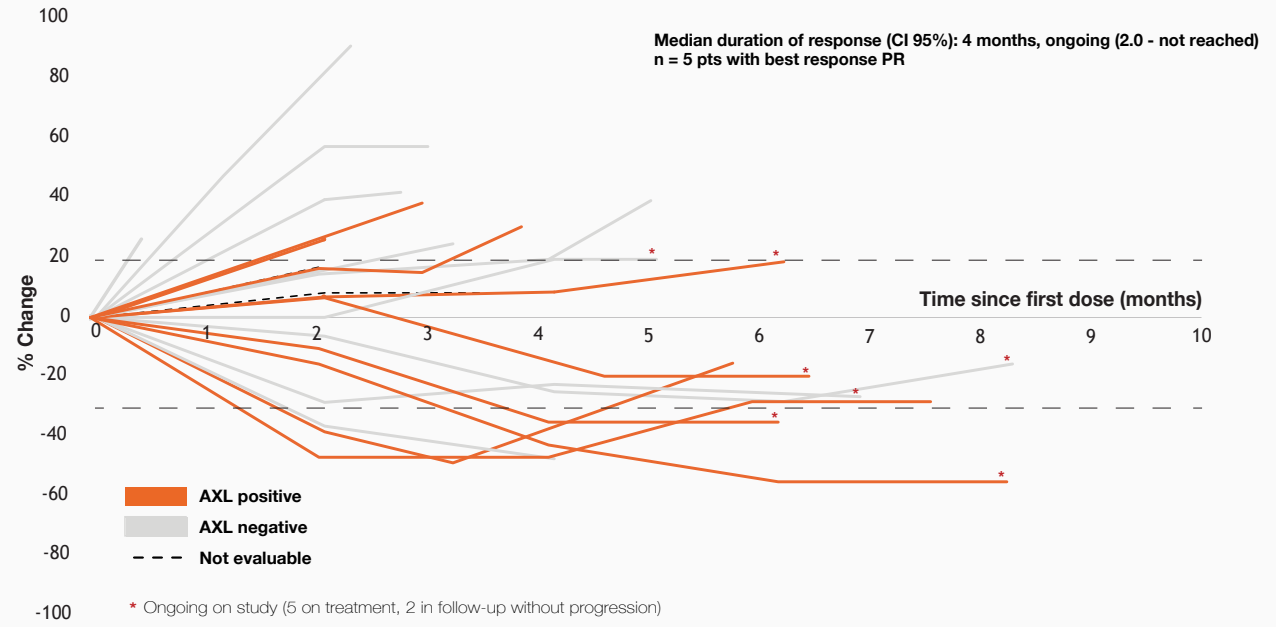
- Evaluate safety of the combination and response to treatment with the combination
- Characterise patients by PD-L1 and AXL status
- Evaluate efficacy of patients by biomarker status, and assess predictive qualities of biomarkers
- Assess survival measures in patients by biomarker status

Ref. BGBC008 / NCT03184571

2nd Line Proof of Concept (PoC) data

bemcentinib + KEYTRUDA: Superior efficacy in AXLpositive pts; Previously treated NSCLC, IO naive





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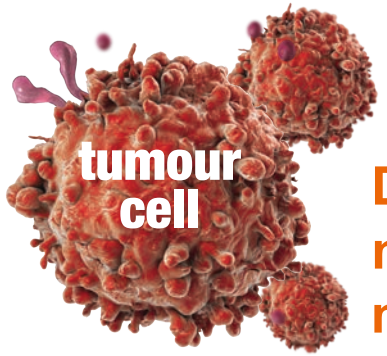
AXL Biology & BerGenBio's Selective AXL Inhibitors

AXL receptor tyrosine kinase drives aggressive disease including therapy resistant, immune-evasive tumours

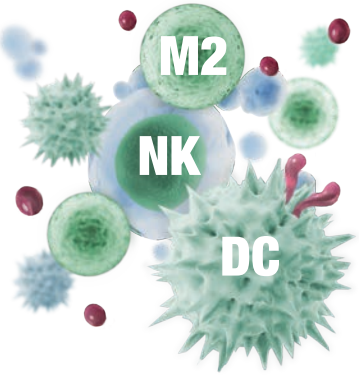


Drives tumour cell plasticity: non-genetic resistance mechanism

AXL drives features of aggressive cancer:

- Acquired therapy resistance
- Immune escape
- Metastasis

Key suppressor of innate immune response



AXL is an innate immune checkpoint:

- M1 to M2 macrophage polarisation
- Decreased antigen presentation by DCs
- Immunosuppressive cytokine profile

very **low** expression under healthy **physiological conditions** (ko mouse phenotypically normal)

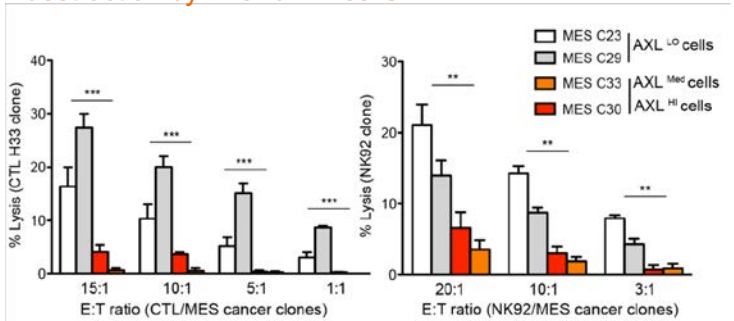
overexpressed in response to **hypoxia, immune reaction, cellular stress** / therapy

overexpression correlates with **worse prognosis in most cancers**

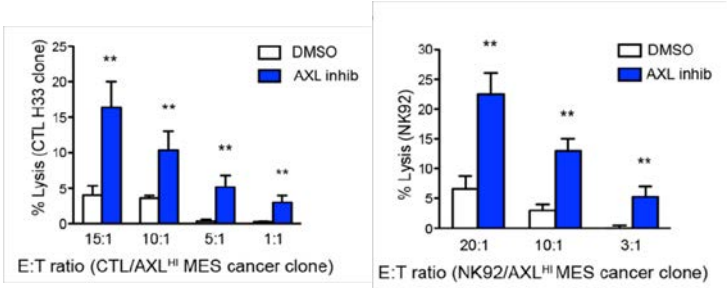
Preclinical data at AACR reinforces bemcentinib's potential to reverse tumour immunosuppression and therapy resistance

Chouaib *et al*

NSCLC cells high in AXL are less susceptible to destruction by T- and NK cells



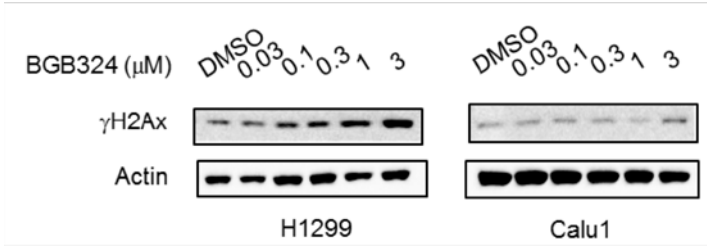
Bemcentinib treatment of the tumour cells with high AXL expression reverses this effect



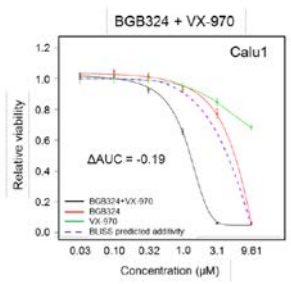
Key pre-clinical data supporting the rationale of combining bemcentinib with IO / bemcentinib's IO MoA

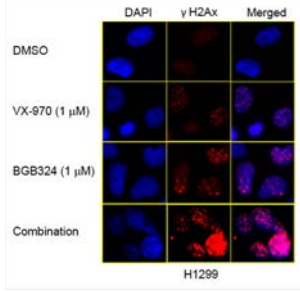
Ramkumar, Byers *et al*

Bemcentinib dose-dependently induces DNA damage in NSCLC cells (γH2Ax is a marker of DNA damage



Bemcentinib has synergistic effect when given in combination with DNA damage targeting agents (VX-970)

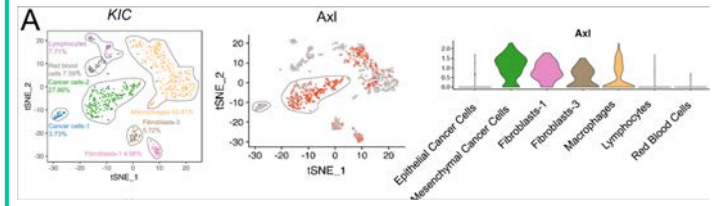




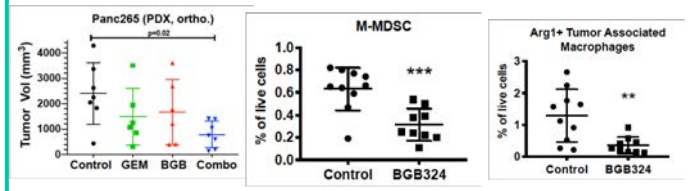
Supports the rationale of combining bemcentinib with chemo and DNA damaging agents

Du, Brekken *et al*

AXL highly expressed in pacreatic tumour models, particularly in cancer cells, fibroblasts & macrophages



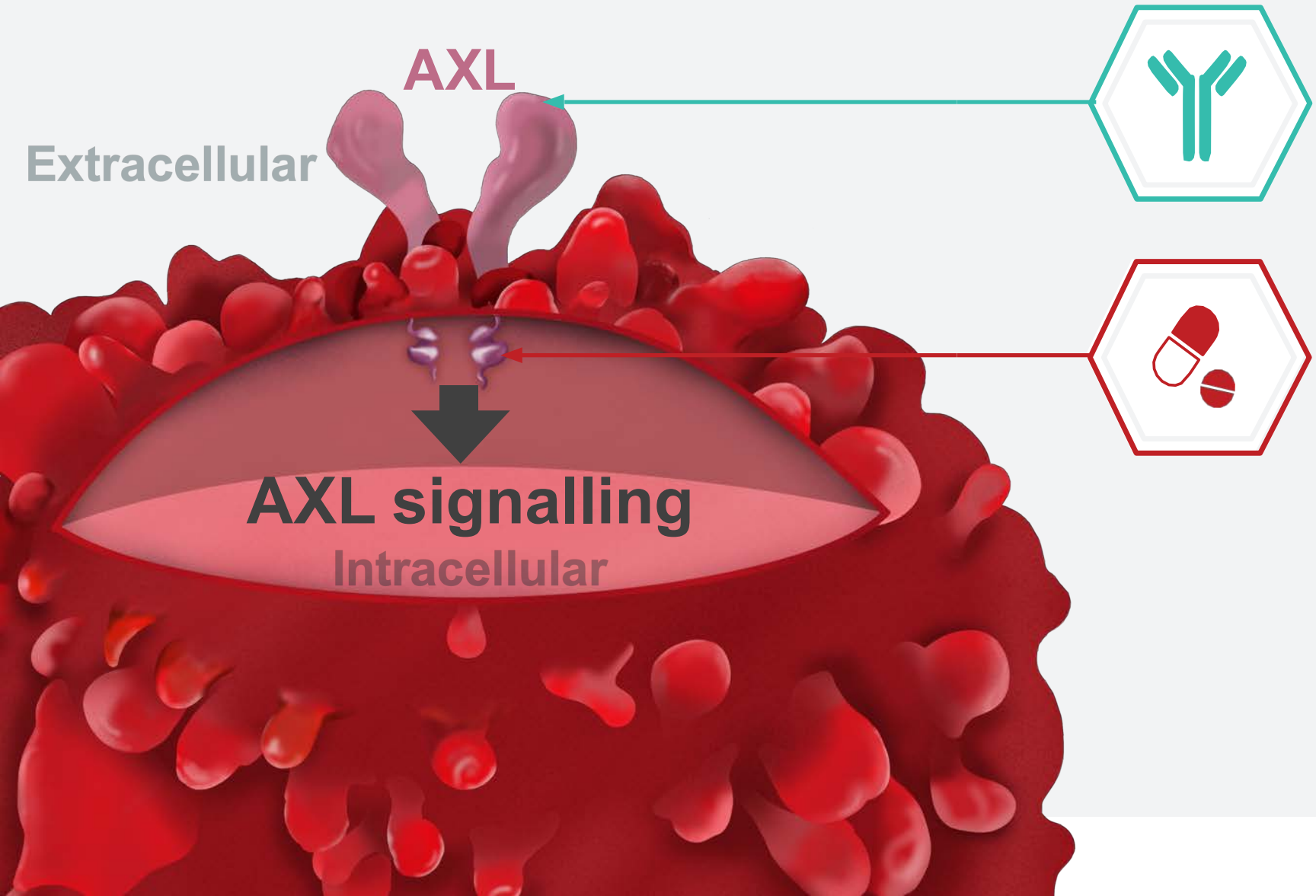
Bemcentinib has synergistic effect when given in combination with chemo, reverses immunosuppression



Supports the rationale of combining bemcentinib with chemotherapy & bemcentinib's IO MoA

BerGenBio provided drug and in some instances part funding for the work

Two AXL targeting candidates in clinical trials



BGB149

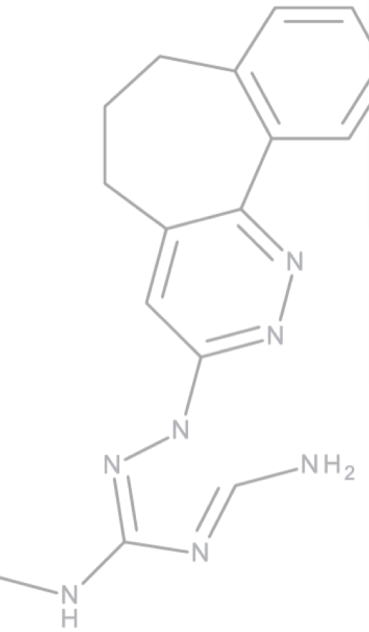
- Wholly owned anti-AXL antibody
- Highly selective to human AXL
- Robust, scalable manufacturing process

Bemcentinib (BGB324)

- Orally bioavailable small molecule
- Administered once a day
- Highly selective for AXL
- Straightforward CMC
- Excellent clinical safety profile

Bemcentinib

AXL selective kinase inhibitor



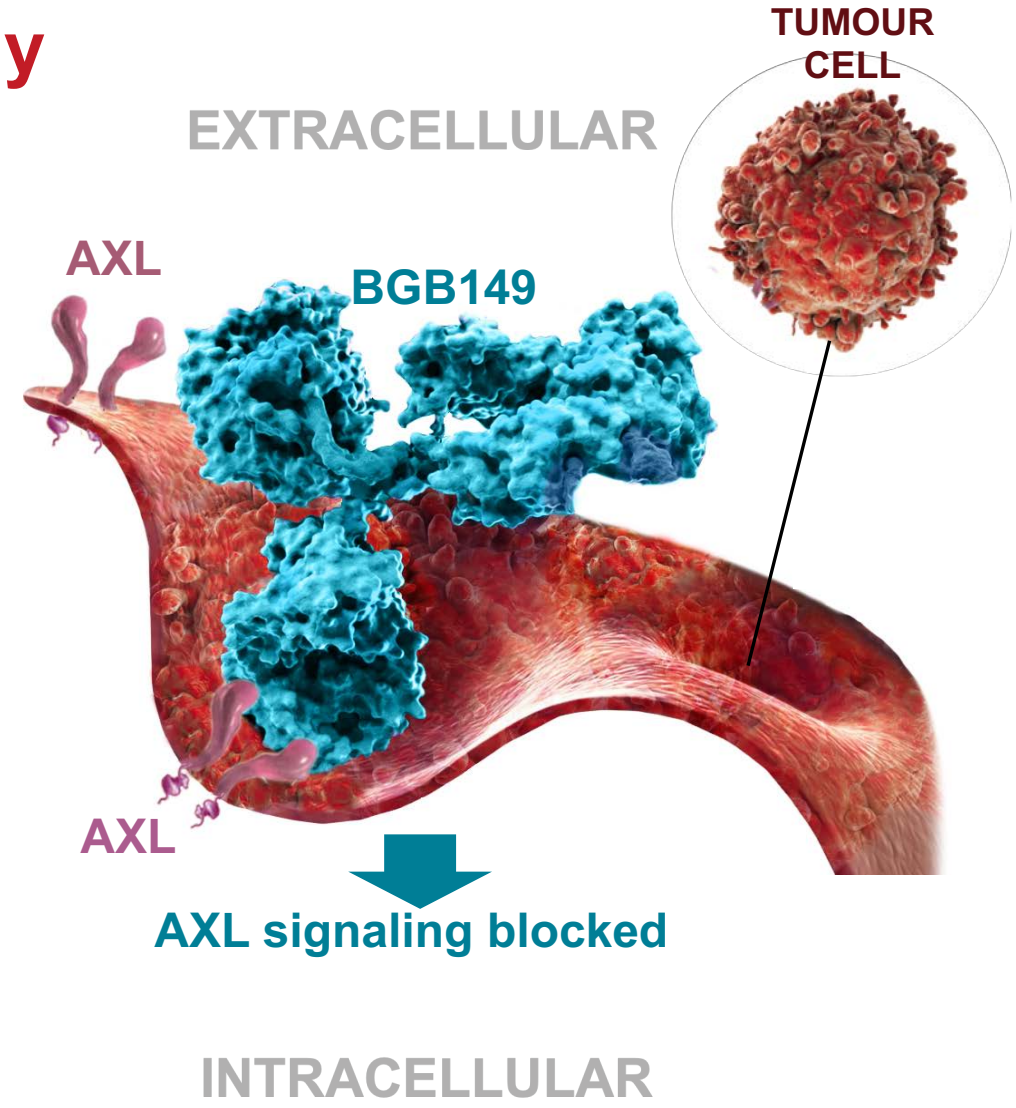
- **Once a day, orally administered**
- **Potent and highly selective**
- **Blocks AXL signalling, reverses aggressive tumour traits & inhibits immune escape**
- **Correlation of clinical efficacy with AXL biomarkers observed**
- **Managable safety profile: >250 subjects dosed**

Ref. BGB149-101 / NCT03795142

BGB149: Anti-AXL monoclonal antibody

Phase I clinical trial ongoing

- **Functional blocking humanised monoclonal antibody**
- **Binds human AXL, blocks AXL signalling**
- High affinity (KD: 500pM),
  Anti-tumour efficacy demonstrated *in vivo*
- Robust manufacturing process established, 18 months stability
- First-in-human healthy volunteer Phase I study initiated
  Up to 36 subjects, Safety, PK/PD
- First-in-patient trial expected in H2 2019



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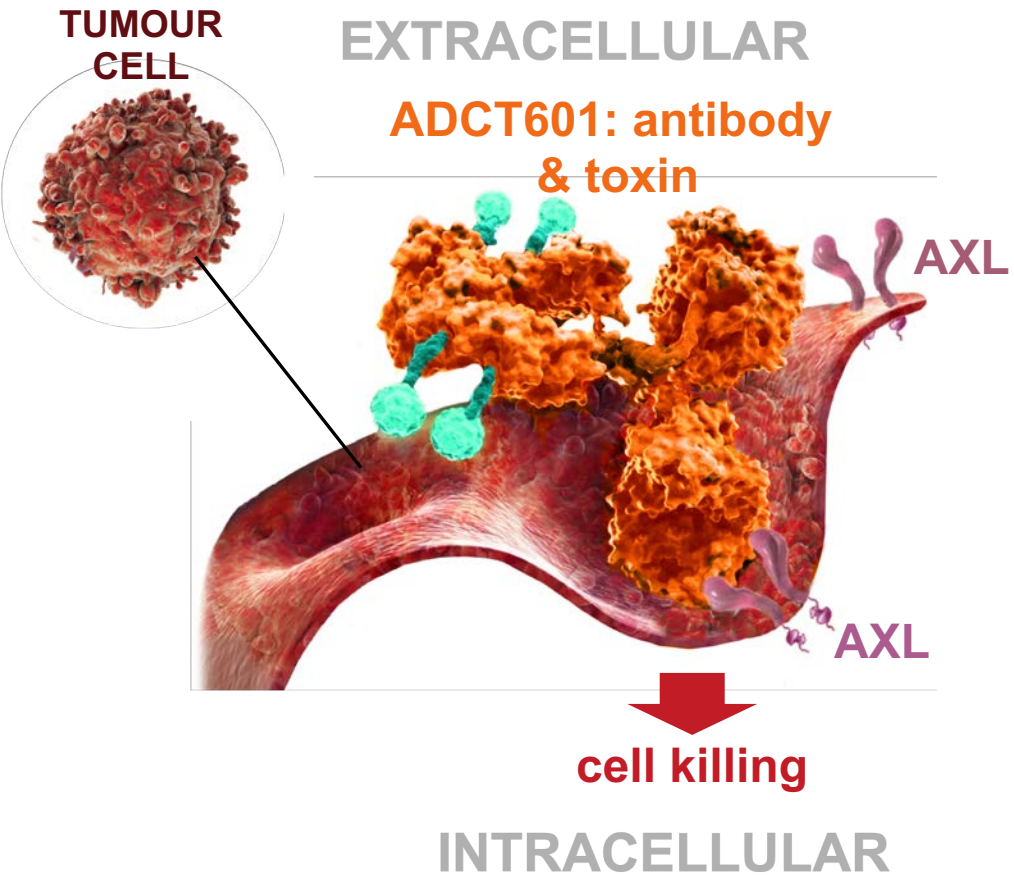
Ref. NCT03700294

BGB601/ADCT-601: Anti-AXL ADC
Phase 1 in solid tumours ongoing

Out-licensed to ADC Therapeutics (ADCT)



Antibody Drug Conjugate (ADC)

Targets human tumour AXL, induces cell death when internalised

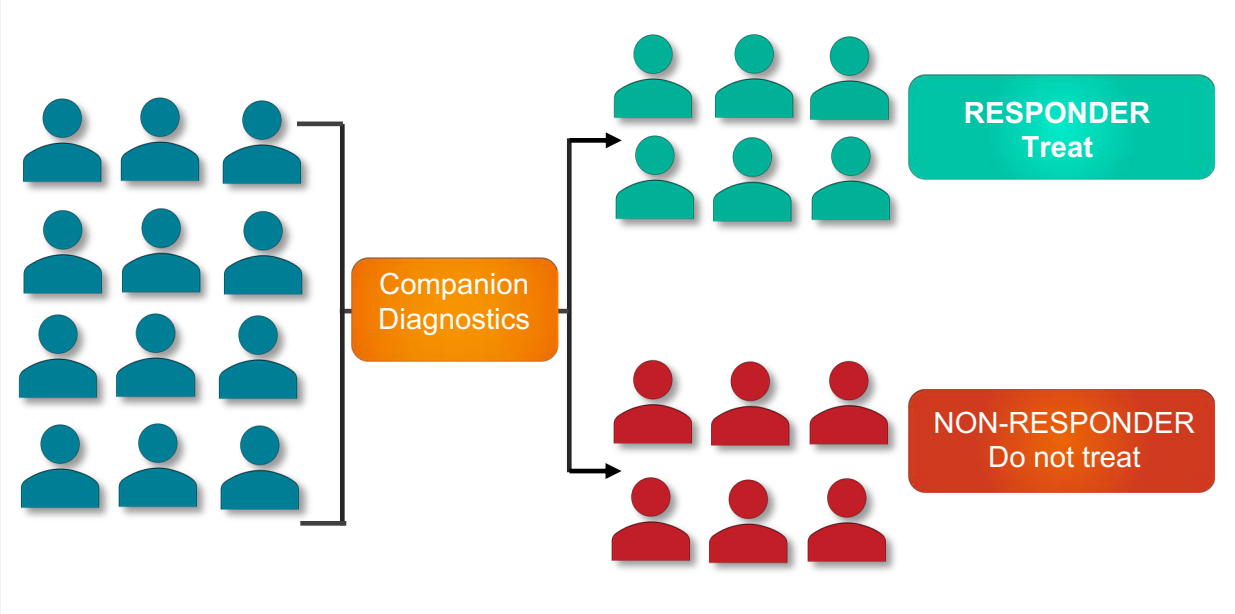
Potent and specific anti-tumour activity demonstrated preclinically[1]

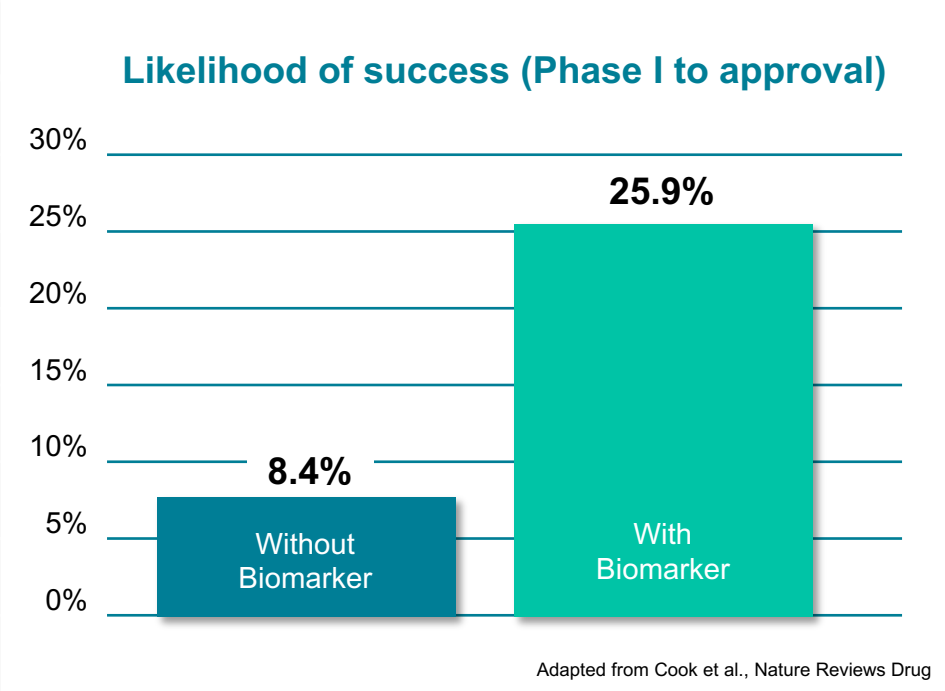
First-in-human Phase I study initiated in Jan 2019
- Solid tumours
- Up to 75 patients
- Safety, PK/PD, preliminary efficacy

Based on anti-AXL antibody BGB601 licensed from BerGenBio

(1) AACR 2018

Companion Diagnostics Programme (CDx)





Adapted from Cook et al., Nature Reviews Drug

CDx Development Programme

Liquid Biopsy

- Soluble AXL (sAXL) - Predictive Biomarker for AML/MDS
- Relapsed/Refractory AML/MDS patients with lower plasma levels of sAXL have shown greater response to bemcentinib monotherapy

Tissue Biopsy

- AXL IHC - Predictive Biomarker for NSCLC
- NSCLC patients with elevated levels of AXL tissue expression have shown improved ORR and PFS when treated with bemcentinib + KEYTRUDA*

* independent of PDL1, BGBC008 trial in 2L, IO naive NSCLC, all comers

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Operational Highlights

Strengthening management team

DOMINIC SMETHURST, MD
Chief Medical Officer

- A physician with two decades of experience in clinical development and leadership roles within the biopharma industry
- AstraZeneca, Amgen, Prescient Life Sciences, ICON & Tusk Therapeutics Ltd.

JAMES BARNES, PHD
Director Regulatory Affairs & Programme Management

- 14 years' experience in regulatory strategy, regulatory policy and project management
- Oncology & innovative breakthrough product experience from pharmaceutical and consultancy sector.

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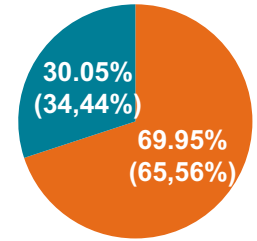
Financial Review

Rune Skeie
CFO

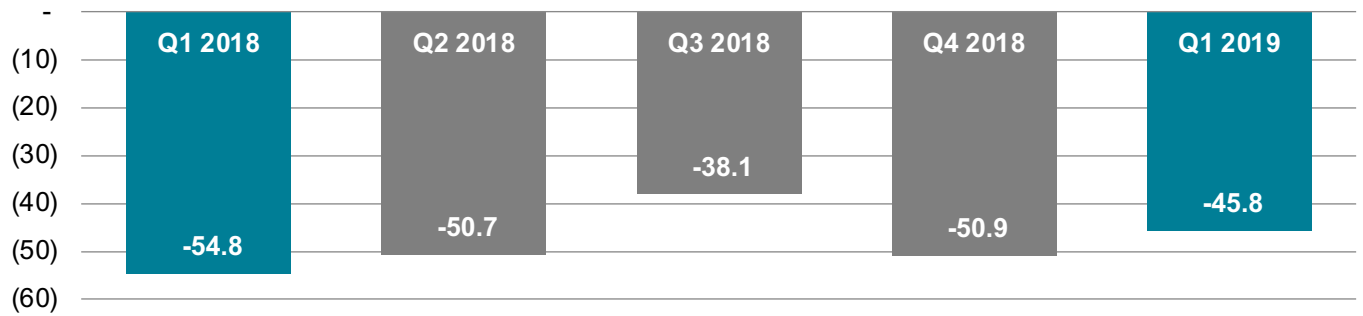
Key financial figures

(NOK million)	Q1 2019	Q1 2018	FY 2018
Operating revenues	8,7	0	2,3
Operating expenses	54,5	54,8	196,9
Operating profit (-loss)	-45,8	-54,8	-194,5
Profit (-loss) after tax	-44,3	-53,8	-191,7
Basic and diluted earnings (loss) per share (NOK)	-0,81	-1,08	-3,60
Net cash flow in the period	-53,7	-41,1	-9,9
Cash position end of period	306,7	329,2	360,4



Operating expenses Q1 2019 (Q1 2018)

R&D Administration



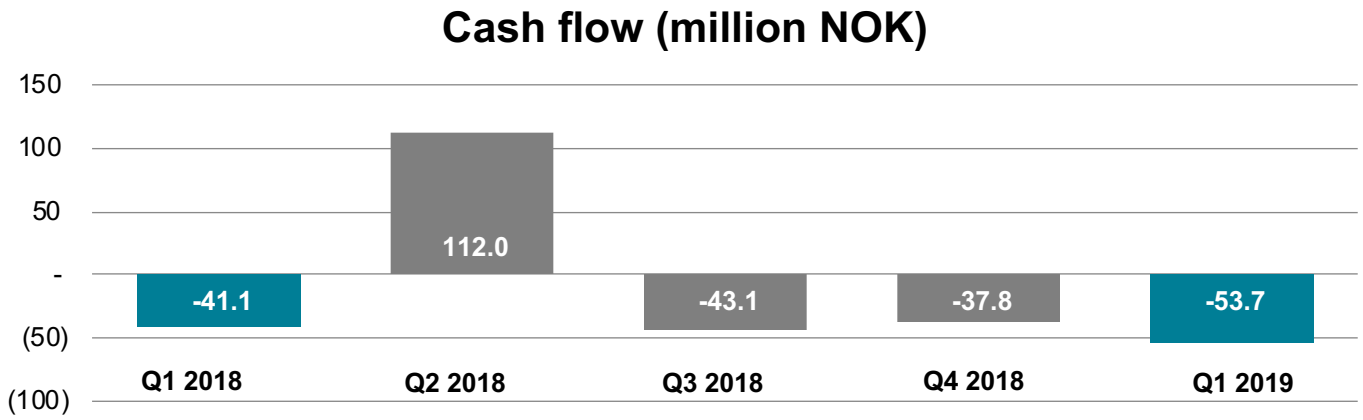
Operating profit (-loss) million NOK

- Effective organisation
- 69.95% of operating expenses in Q1 2019 (Q1 2018: 65,56%) attributable to Research & Development activities

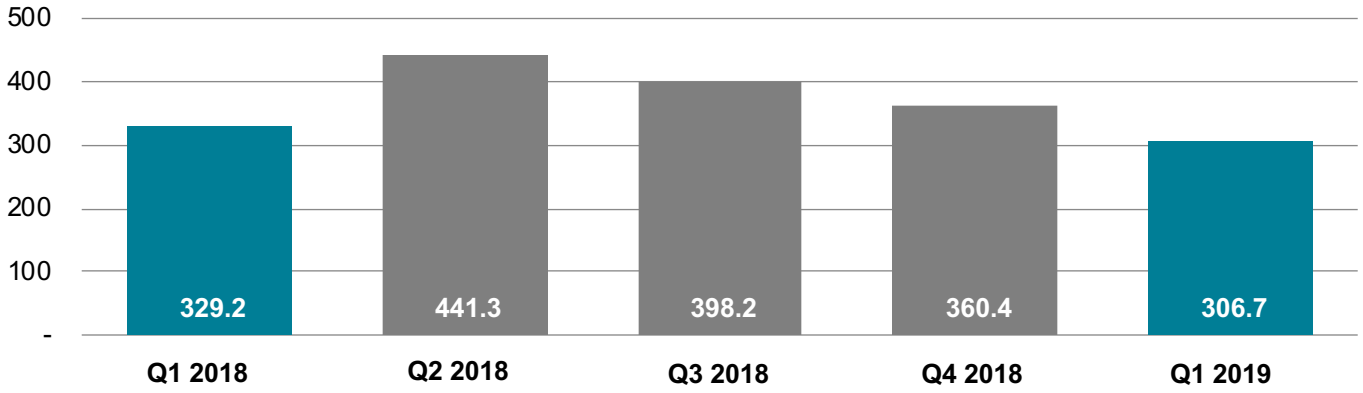
- Revenue NOK 8.7 million, licence revenue triggered by clinical milestone (ADCT-601)

http://www.bergenbio.com/investors/reports/quarterly-reports/

Cash flow and cash position



- Private placement Q2 18 strengthened cash position - gross funds raised NOK 187 million (USD 24 million)
- Quarterly cash burn average (Q118 – Q119) NOK 48.4 million (USD 5.9 million)



- Cash position Q1 2019 NOK 306.7 million (USD 35.7 million) - gives runway to deliver key clinical read outs from ongoing clinical studies
- Cash runway into 2020 based on current burn rate

Financial calendar

2019

13 March 2019	Annual General Meeting
8 May 2019	Quarterly Report – Q1 2019
20 August 2019	Half-year and Q2 report 2019
19 November 2019	Quarterly Report – Q3 2019

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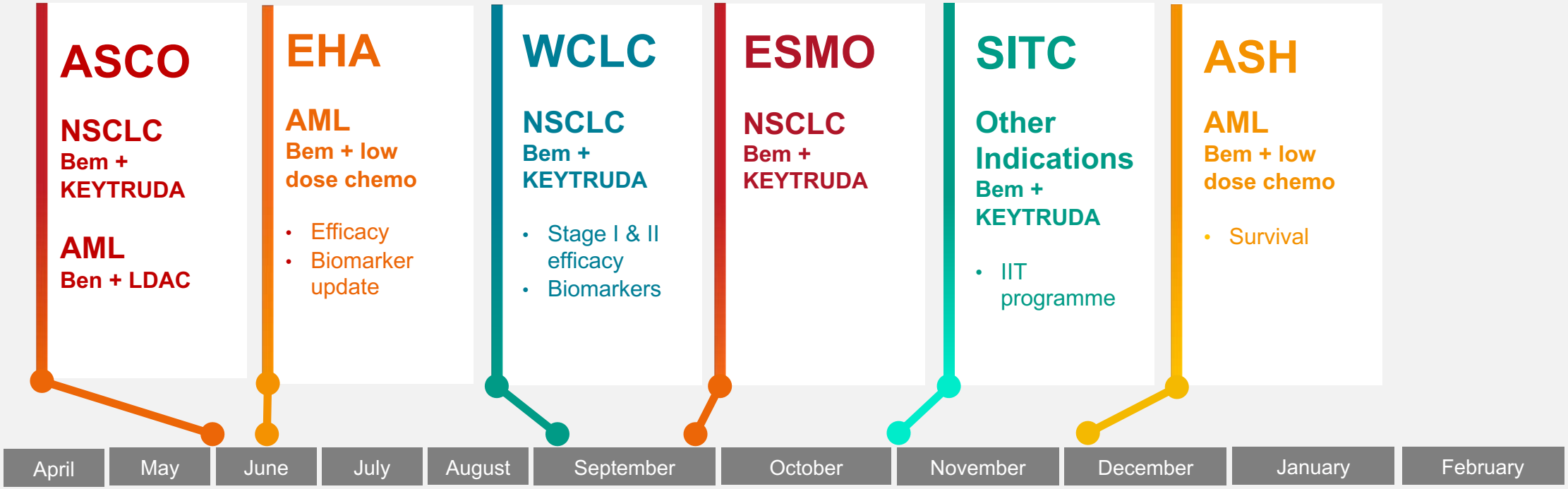
Near term goals and milestones

Expected Newsflow

2019



H2
- **Initiate late stage programme**
- Complete Phase 1 BGB149

Q4
- Initiate first-in-patient trials BGB149

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

Value creating catalysts

Strategic priority		Goals	
Late stage clinical trials with bemcentinib	H2 2018	Clinical PoC monotherapy AML	✓
	H2 2018	Clinical PoC combo in NSCLC	✓
	H1 2019	Clinical PoC combo in AML	✓
	H2 2019	Start late stage clinical programme	
	H2 2020	Interim read-out late stage clinical programme	
Develop Companion Diagnostics	H2 2018	Identify candidates that correlate with efficacy	✓
	H2 2020	Validate candidates in late stage clinical programme	
	H2 2021	Clinical assay developed	
BGB149 anti-AXL antibody programme	H2 2018	Initiate first-in-man phase I trial	✓
	H2 2019	Initiate first-in-patient phase Ib trial	
	H2 2020	Interim readout	
Maximise value for bemcentinib	H1 2019	Initiate pipeline opportunities for bemcentinib via IITs	✓

IIT: Investigator initiated Trials

BGBIO – Investment Highlights

World leaders in understanding AXL biology

AXL is a novel oncology target to overcome immune evasion, therapy resistance & spread

AXL upregulates PDL1 on dendritic cells and blocks T-cell immunity

AXL inhibitors – potential cornerstone of cancer therapy

Pipeline opportunities in multiple cancers and fibrosis

3 selective AXL inhibitors in clinical development

Bemcentinib (Ph2), AXL-antibody BGB149 (Ph1), AXL ADCT601* (Ph1)

Monotherapy and combinations with immune-, targeted and chemotherapies

Biomarker correlation across programme, parallel CDx development

Phase II Proof of Concept

43% ORR in R/R AML/MDS (monotherapy)

40% ORR in 2L NSCLC (KEYTRUDA combo)

Resourced to deliver significant milestones

Clinical trial collaborations with Merck and leading academic centres

*AXL antibody out licensed to ADC Therapeutics SA

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

Cash NOK 306.7m

BerGenBio

Questions