AXL inhibition to prolong life

First-in-class medicines to treat aggressive cancers

Jefferies London Healthcare Conference – November 15-16th 2017

Richard Godfrey, CEO

BerGenBio

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Corporate snapshot

Background

Leaders in developing therapeutics that target AXL, a protein that makes cancers and their environment highly aggressive and which is associated with poorer outcomes across many cancers

Diversified pipeline, lead drug is tested in several indications of high unmet medical need and large market potential

Promising efficacy with sustained treatment benefit and confirmed favourable safety

Companion diagnostic supported by biomarker tests

BGB324

First-in-class highly selective small molecule AXL inhibitor

Broad phase II clinical programme in NSCLC, TNBC, AML/MDS, melanoma

Pipeline

BGB324

AXL antibody

AXL ADC (partnered)

Immunomodulatory small molecules

OSE:BGBIO

Raised USD 50m in IPO on OSE in April '17

USD 120m market cap (Nov 13th 2017)

Corporate

35 staff

Headquarters and research in Bergen, Norway; Clinical Trial Management in Oxford, UK

Developing AXL inhibitors to target aggressive cancers

50%

of people will get a form of cancer in their lifetime

90%

of cancer deaths due to aggressive cancer

Treat. Reverse. Stop.

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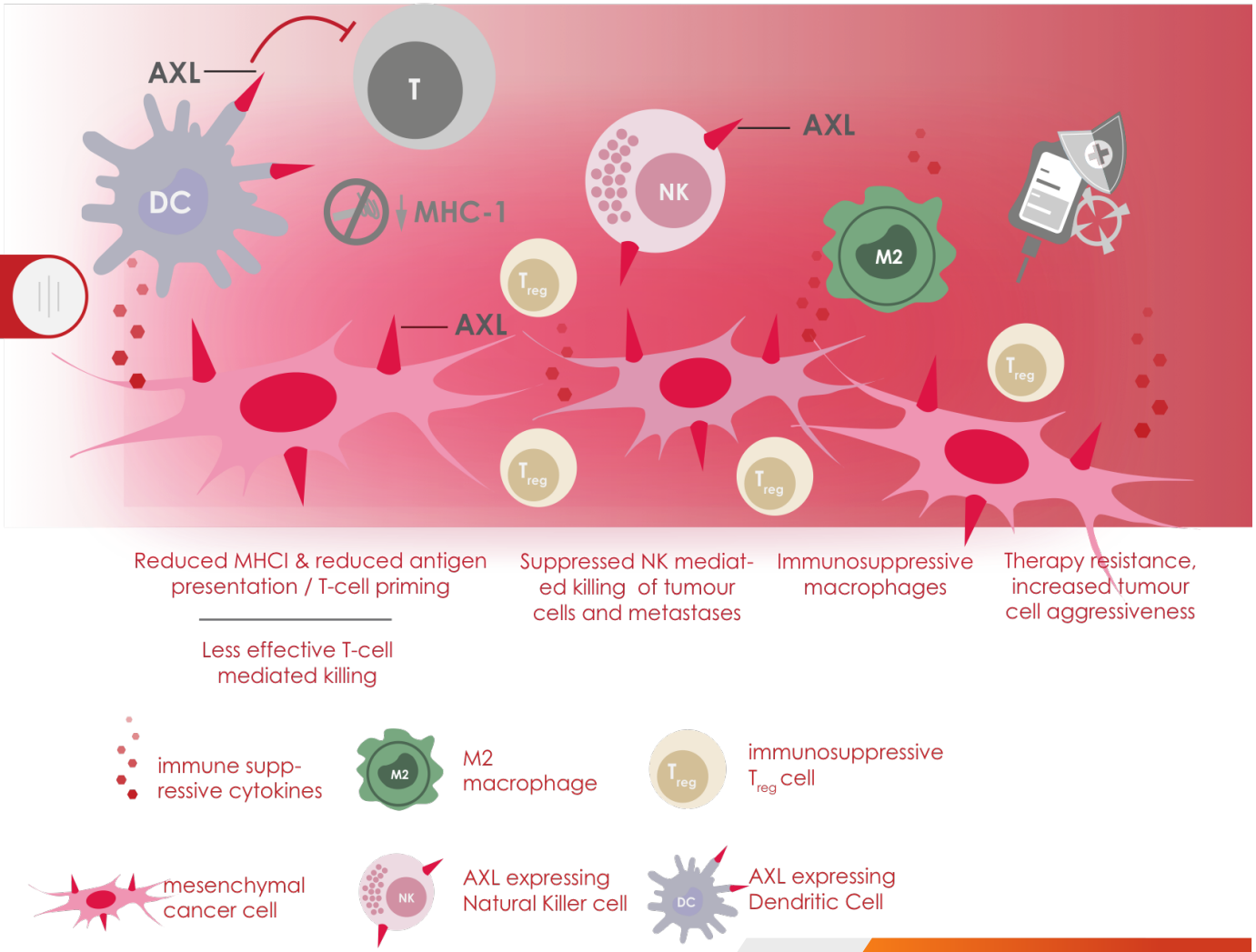
Aggressive cancers

evade the immune system, acquire drug resistance and spread

AXL is a key regulator of aggressive cancers driving:

- **Innate immune suppression**
- **Therapy resistance**
- **Cancer spread**



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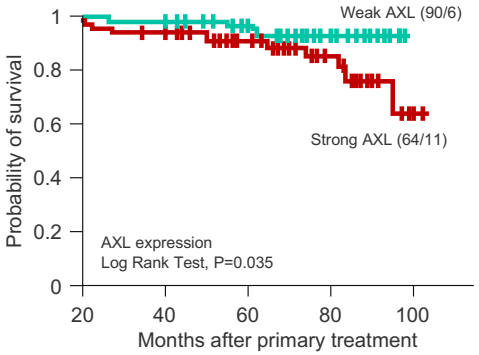
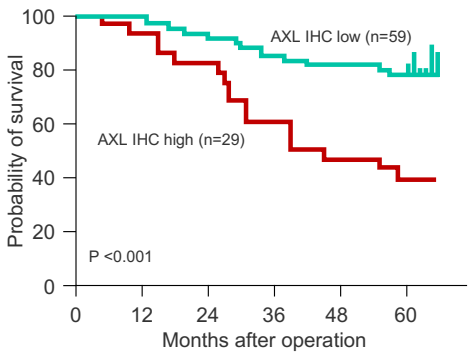
AXL correlates with poor prognosis

Strong AXL expression correlates with poor survival rate

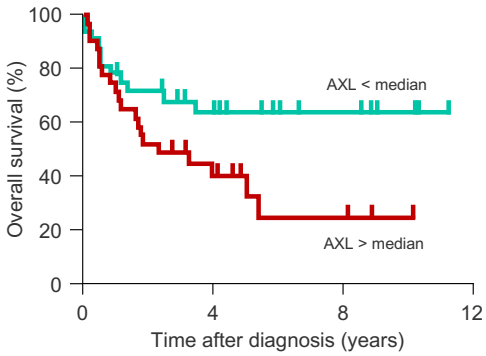
Breast carcinoma[1]



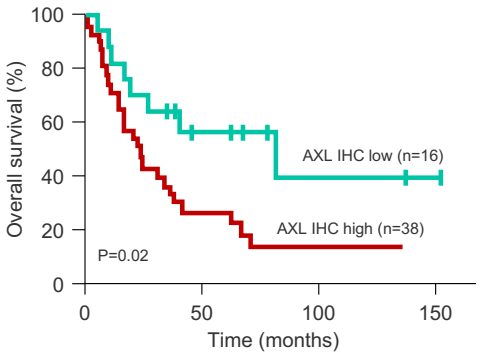
Lung adenocarcinoma (NSCLC)[2]



Acute Myeloid Leukaemia[3]



Pancreatic ductal adenocarcinoma[4]



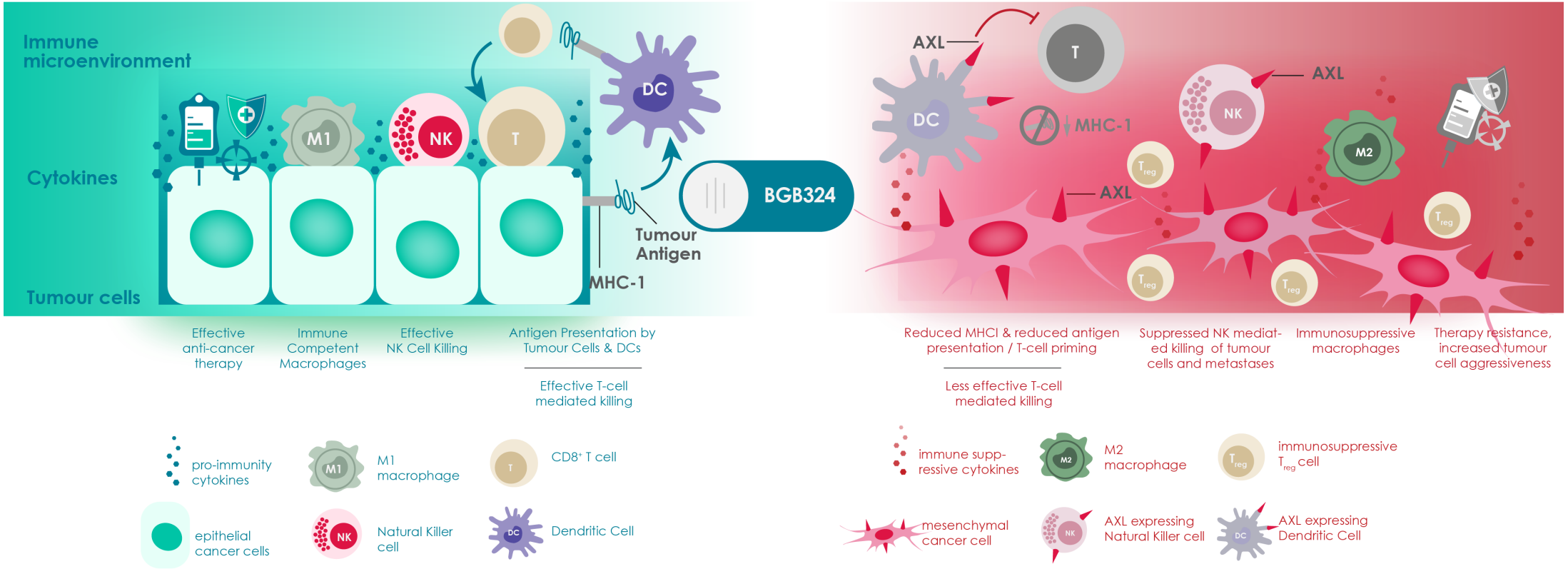
Broad evidence of AXL linked with poor prognosis[5]

Astrocytic brain tumors
Breast cancer
Gallbladder cancer
GI
• Colon cancer
• Esophageal cancer
• Gastric cancer
Gynaecological
• Ovarian cancer
• Uterine cancer
HCC
HNC
Haematological
• AML
• CLL
• CML

Melanoma
Mesothelioma
NSCLC
Pancreatic cancer
Sarcomas
• Ewing Sarcoma
• Kaposis sarcoma
• Liposarcoma
• Osteosarcoma
Skin SCC
Thyroid cancer
Urological
• Bladder cancer
• Prostate cancer
• RCC

1 Gjerdrum, 2010; 2 Ishikawa, 2012; 3 Ben-Battala, 2013; 4 Song, 2010, 5 supported by > 100 publications

BGB324 restores sensitivity to immune cell attack, therapy, and prevents spread



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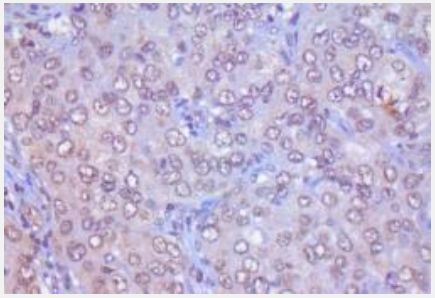
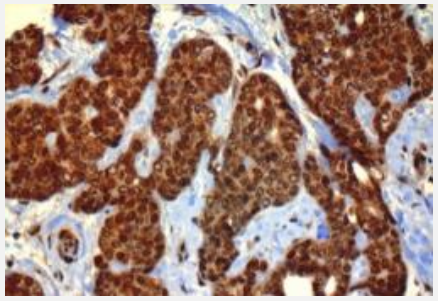
Which cancers are we targeting

Most common tumours express high AXL levels

Low Axl expression[2]



High Axl expression[2]



Companion diagnostic in development to identify AXL positive patients

(1) SEER (2) Gjerdrum 2010

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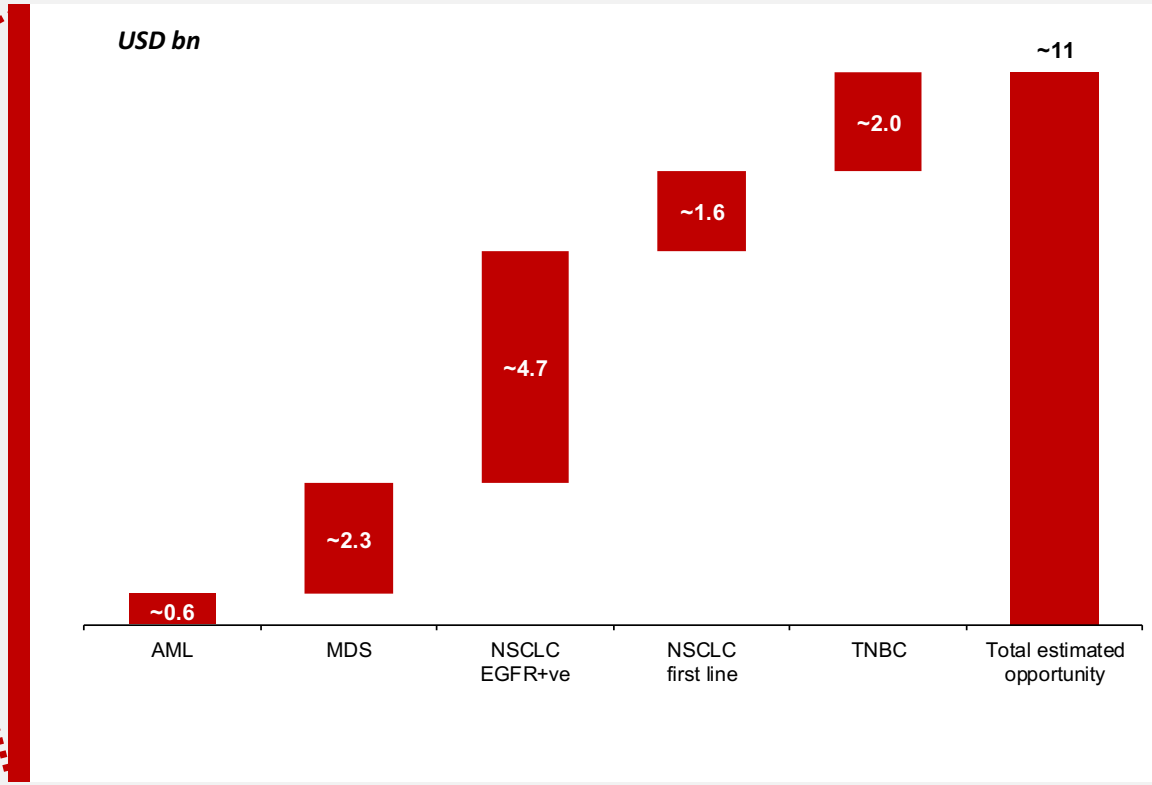
Targeting cancers with an addressable market of USD 11bn

Most common tumours express high AXL levels

New incidences in 2017 (U.S.)[1]	
Lung	222,500
Breast	255,180
AML	21,380
Melanoma	87,110
Prostate	161,360
Colon	95,520
Renal cancer	63,990
Head & neck	61,760
Thyroid	56,870
Pancreatic	53,670
Ovarian	22,440
CML	8,950



Strategy

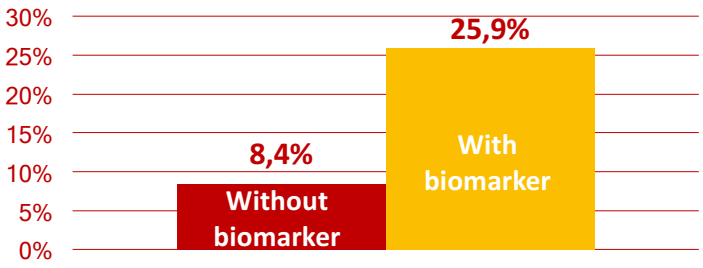
- Major unmet need
- Strong scientific basis
- Blockbuster potential

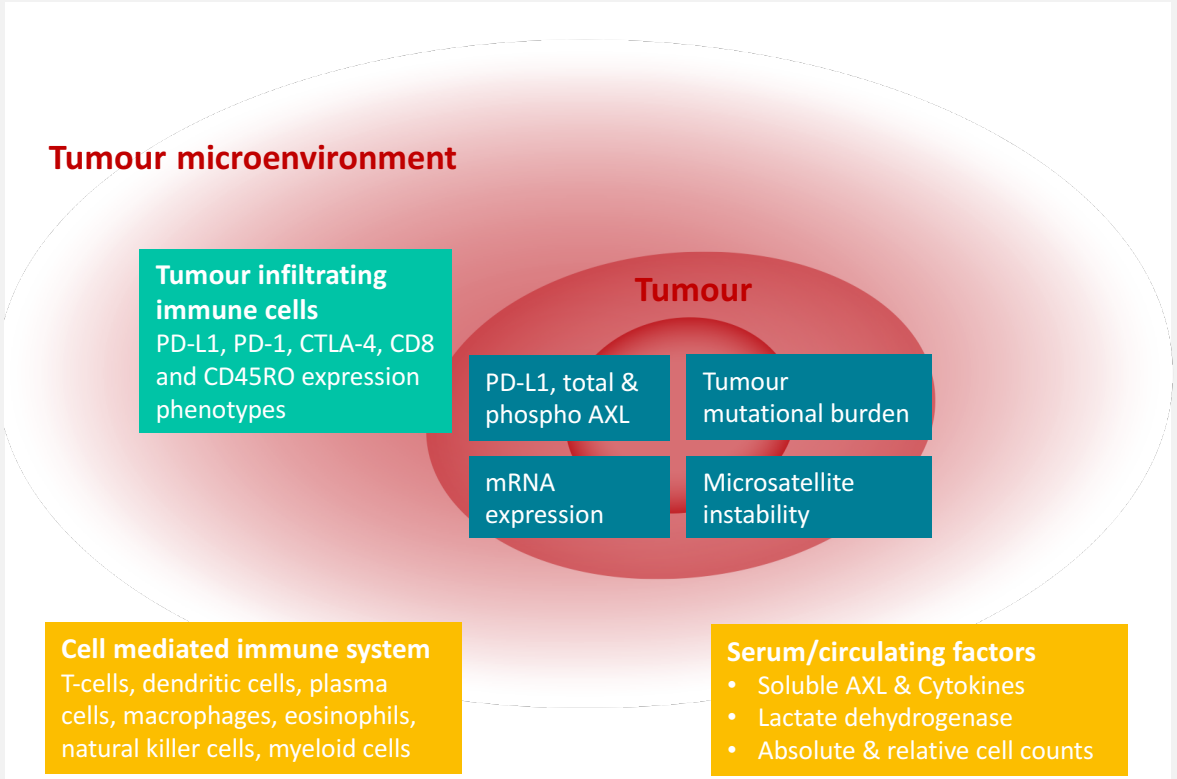
(1) SEER

Companion diagnostic for personalised medicine

- Selecting patients most likely to benefit from treatment
- Improving probability of approval
- Increase reimbursement rate

Likelihood of success (phase I to approval)





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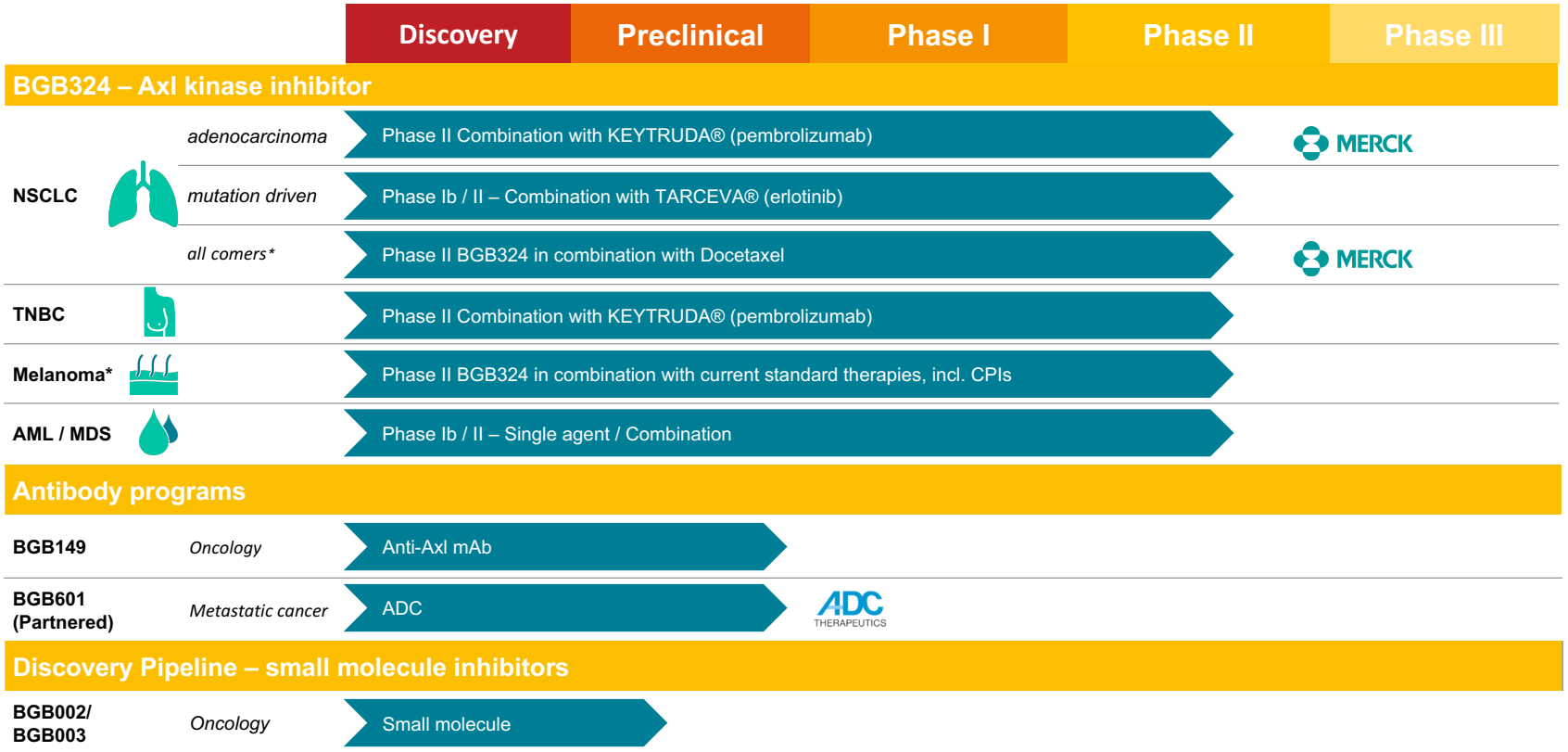
Broad development pipeline



*Investigator-sponsored trials

Patients:

>350

Key read-outs:

2018

50

sites in Europe and North America.

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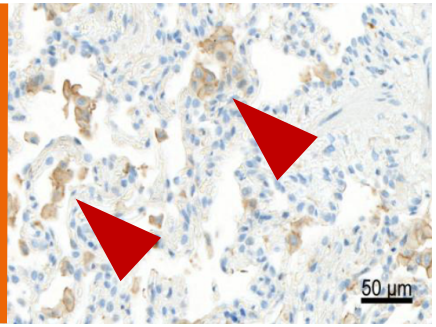
BGB324 is a selective, first-in-class orally bioavailable inhibitor of AXL

Targeting aggressive cancer cells & immunosuppressive tumour microenvironment

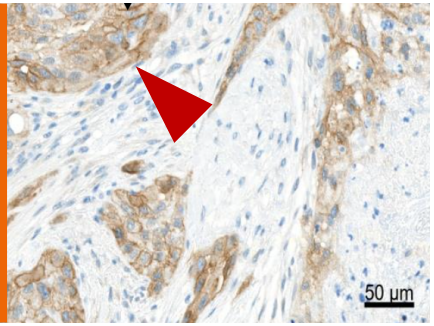
BGB324 targets immunosuppression and therapy resistance

Lung cancer patient samples

Axl is expressed on immune cells in the tumour*

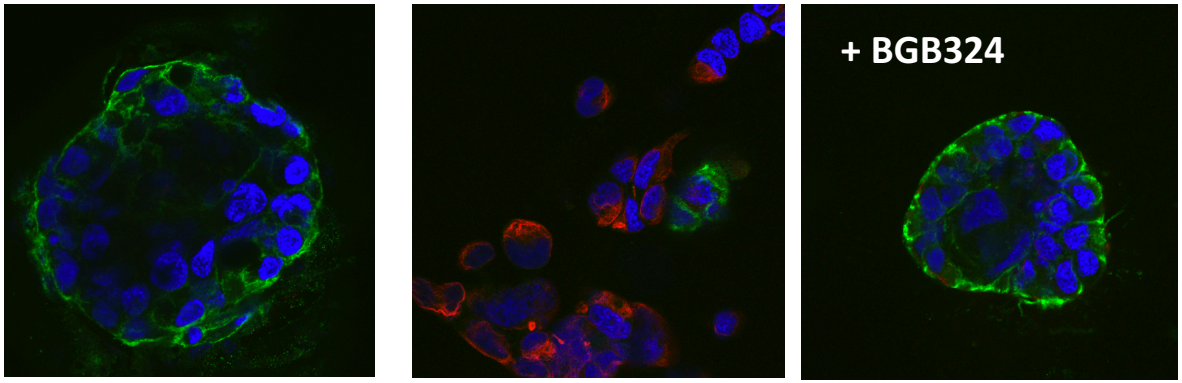


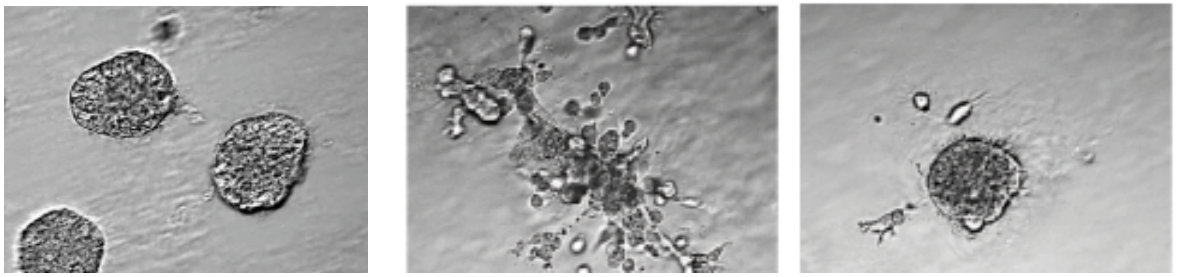
Axl is expressed on tumour cells*



Non aggressive

AXL programme induced





E-cadherin vimentin Cell nuclei

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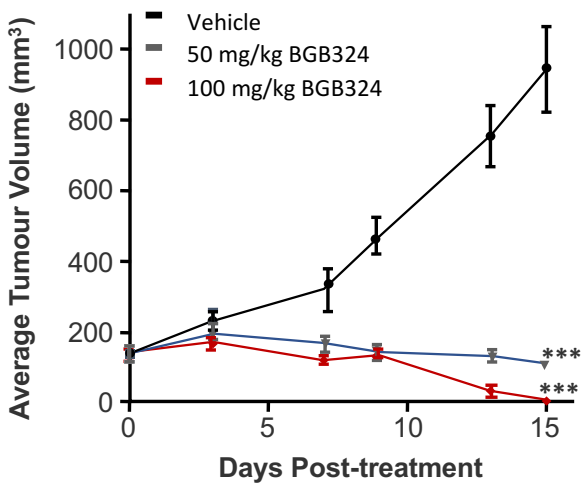
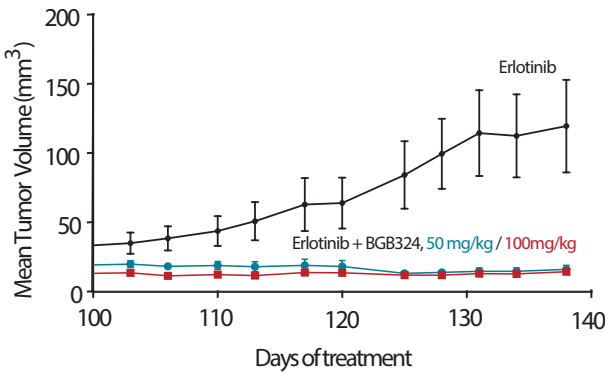
Compelling pre-clinical data highlights BGB324's broad clinical utility

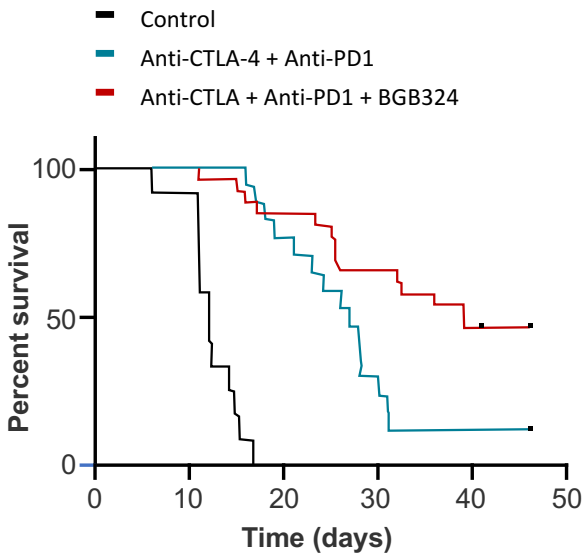
Single agent activity in AML



Combination w/ targeted therapy



Combination w/ CPIs



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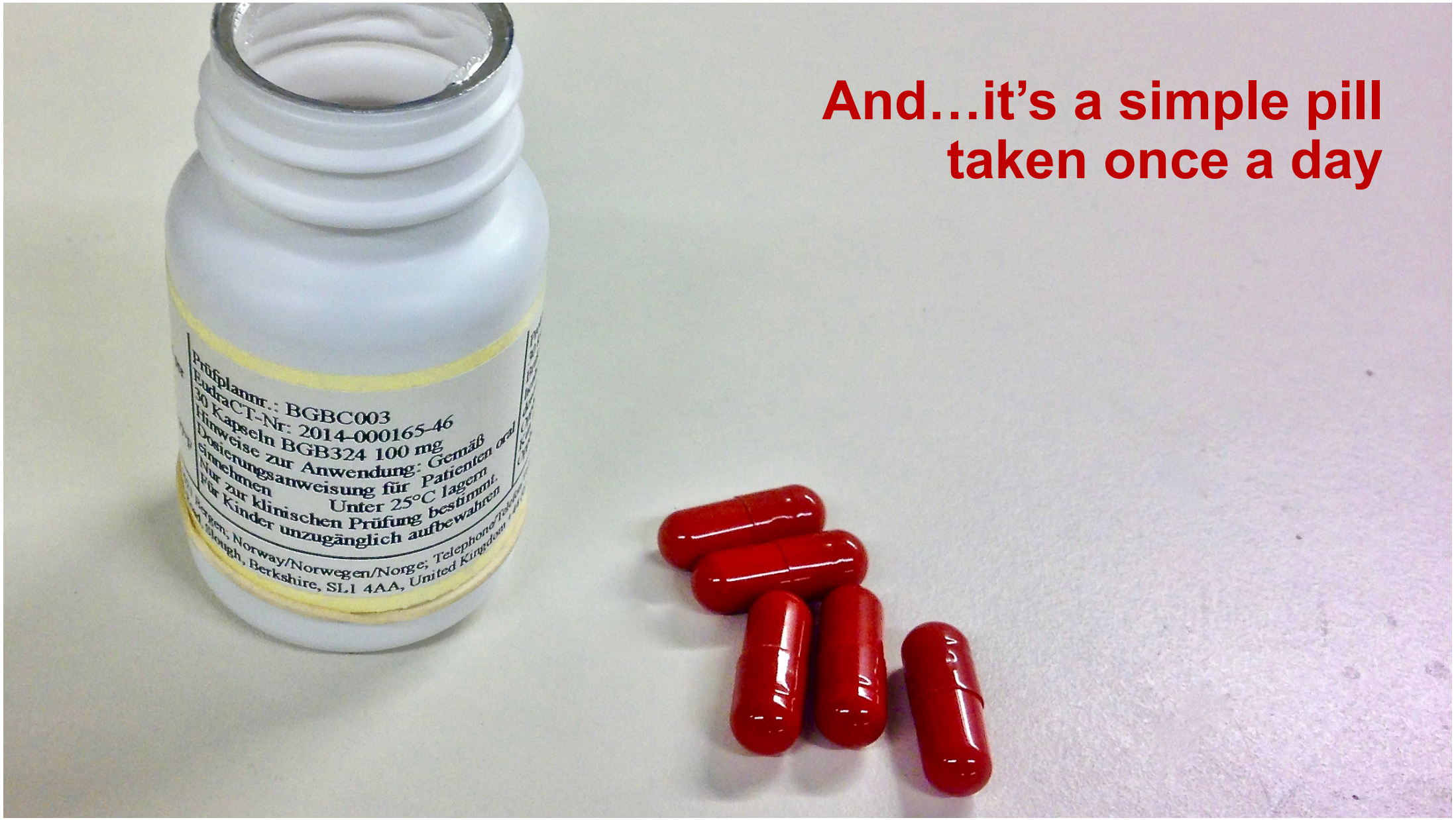


And…it's a simple pill taken once a day

BGB324 clinical development: AXL inhibition as cornerstone for cancer therapy

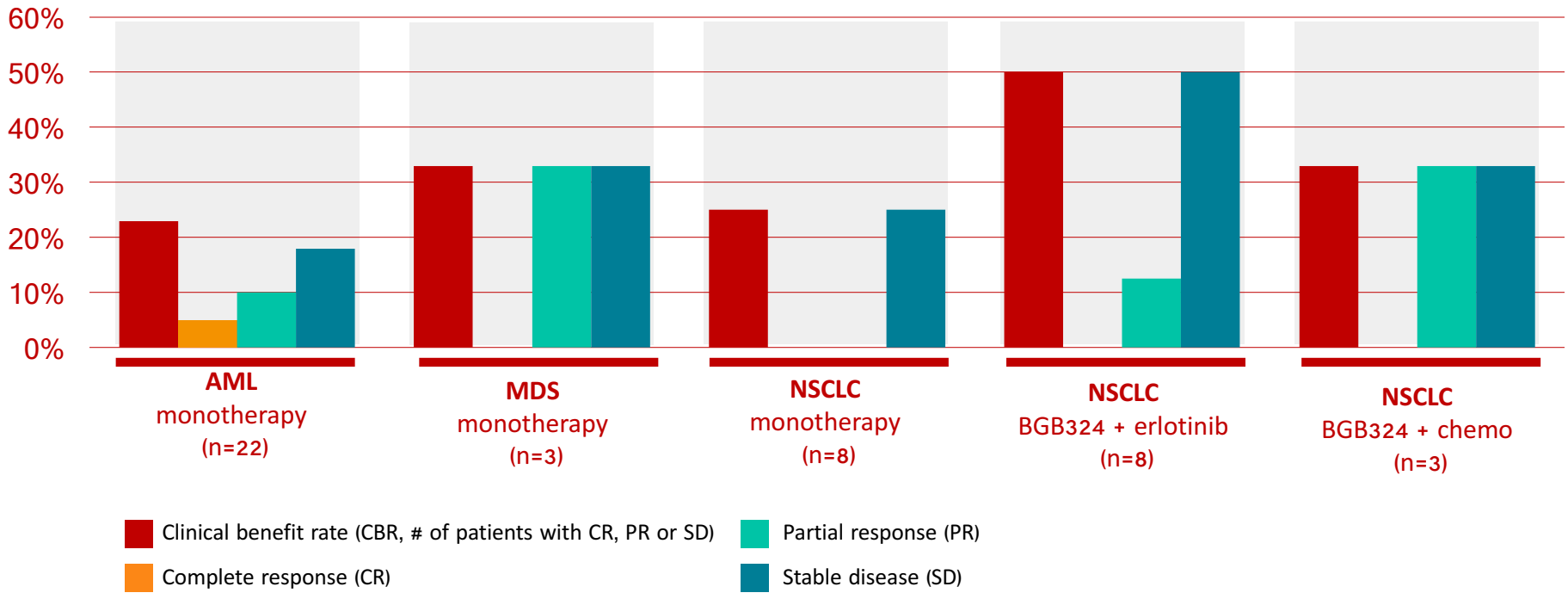
Aiming at patient selection based on proprietary biomarkers

Broad clinical development for BGB324 – 6 trials in phII

Indication	Patient population	Combination	Collaboration	Trial details
NSCLC	*adenocarcinoma*	KEYTRUDA®	MERCK	up to 48 pts
	mutation driven	Tarceva® erlotinib		up to 66 pts
	*all comers**	**docetaxel**	UTSouthwestern Medical Center	up to 30 pts
TNBC		KEYTRUDA®	MERCK	up to 56 pts
Melanoma*		KEYTRUDA® + Tafinlar® (dabrafenib) + Mekinist® (trametinib)	HELSE BERGEN Haukeland universitetssjukehus	up to 92 pts
AML / MDS		DACOGEN® decitabine for injection **single agent, cytarabine**		up to 75 pts

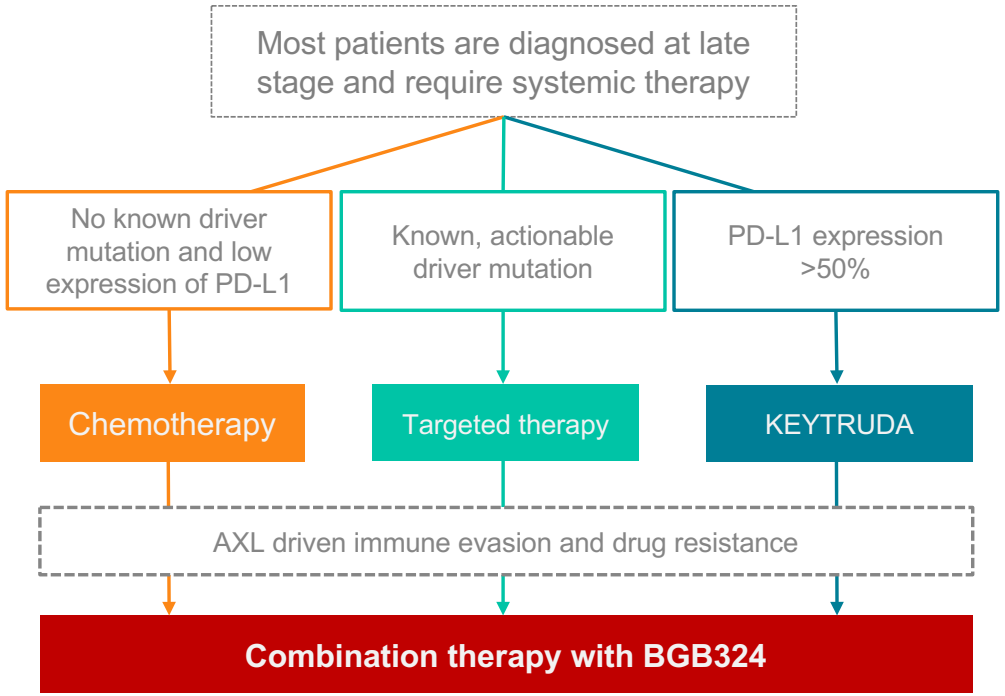
*Investigator-sponsored trials

Summary of responses reported in phase Ib
Heavily pre-treated relapsed and refractory patients



As reported at ASH 2016 and World Conference of Lung 2017

Potential for BGB324 to become a cornerstone therapy for NSCLC



- Lung cancer is the most frequent cause of cancer-related death in developed countries
- Strategy to position BGB324 as the cornerstone of treatment for NSCLC by combining with standard of care therapies

Phase I/II trial in NSCLC of BGB324 with docetaxel

UT Southwestern Medical Center

BGBIL005 Phase I/II – NSCLC (2nd line – progressed/treatment-refractory disease) – *Investigator-sponsored study*

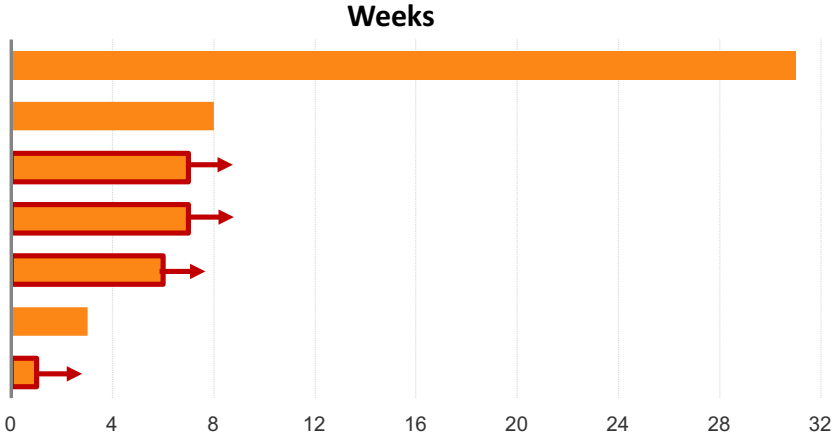
Vast majority of NSCLC patients will receive chemotherapy in 1st or 2nd line settings

BGB324 enhances the effect of chemotherapy in animal models

Trial involves patients with previously treated advanced NSCLC who have exhausted all treatment options

One patient on treatment for 10 months

One partial response (Recist 1.1) with tumour shrinkage



Sponsor Investigator: Dr David Gerber, UTSW Dallas

"The vast majority of my lung cancer patients progress onto chemotherapy, combining this with BGB324 may significantly improve the performance of the chemo and could lead to meaningful disease modification in some patients."

Source: Gerber *et al* World Conference on Lung Cancer (October 2017)

Phase II trial in NSCLC of BGB324 with TARCEVA (erlotinib) - Resistance reversal

BGBC004 Phase II – NSCLC EGFR-mutation driven

Phase Ib/II trial in up to 66 patients with advanced NSCLC patients in 1st and 2nd line settings (to prevent and reverse erlotinib resistance, respectively)

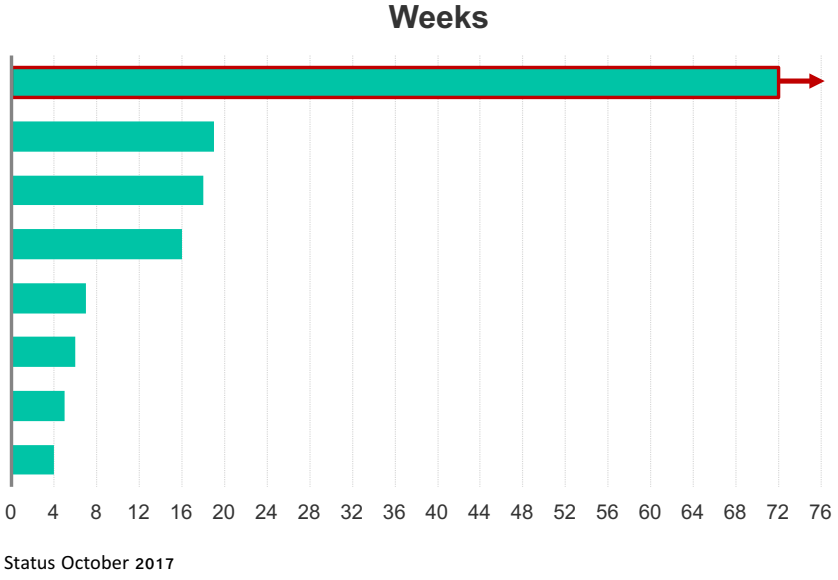
Patients classed as Stage IIIb or IV disease driven EGFR mutation (accounts for approx. 18% of NSCLC patients)

AXL-mediated resistance to erlotinib is common

Biomarker studies underway in parallel

50% CBR:

3 SD > 4 months + 1 stable disease with partial response



Status October 2017

Source: Byers *et al* World Conference on Lung Cancer (October 2017)

Phase II trial in NSCLC of BGB324 in combination with KEYTRUDA

BGBC008 Phase 2 – NSCLC Adenocarcinoma of the lung

Up to 48 patients with previously treated unresectable adenocarcinoma of the lung

Biomarker studies (tissue sample and blood based) ongoing in parallel; PD-L1 assay to be performed by Merck

Patient recruitment ongoing in Norway, UK, Spain, US

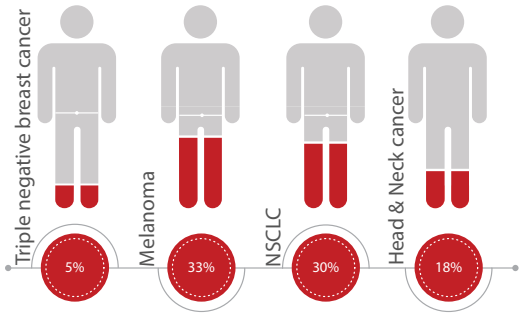
Primary endpoint: Objective response rate

Others endpoints: Safety, duration of response, time to progression, survival at 12 months, response by biomarker expression

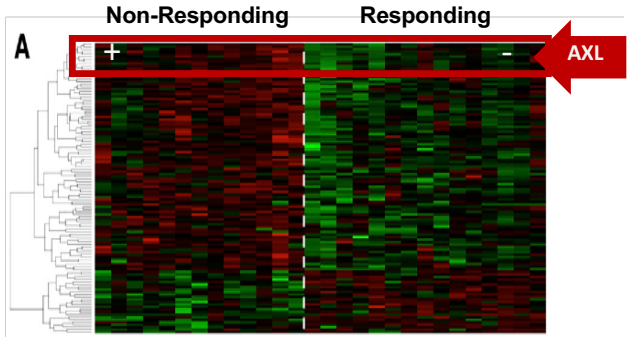
Initial read-out expected 2H 2018

Strong rationale for combining BGB324 with checkpoint inhibitors

Checkpoint inhibitors do not work for all patients in all cancers



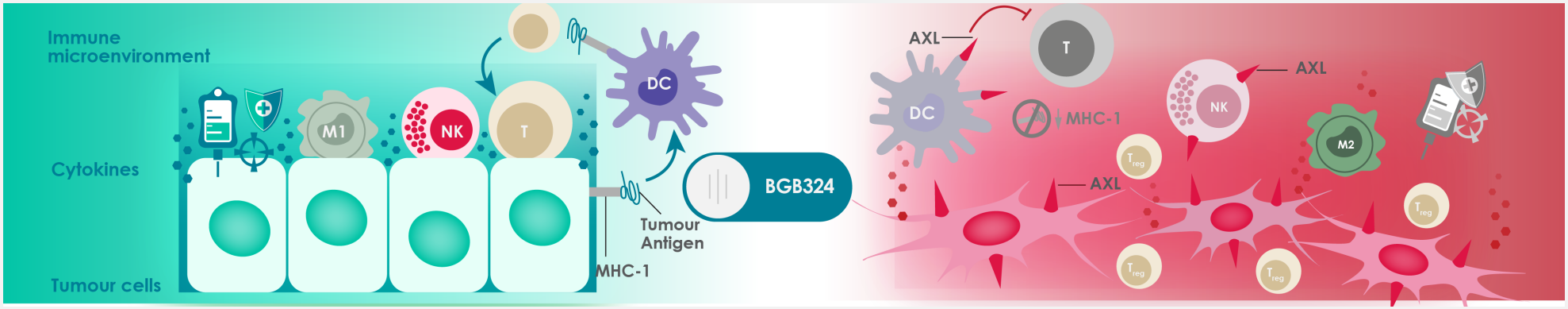
AXL up-regulation is the greatest change in non-responders



Combine BGB324 + CPI to increase response rate

BGB324
+
KEYTRUDA®
=

ONLY combination study addressing the fundamental mechanism of tumour resistance to CPIs



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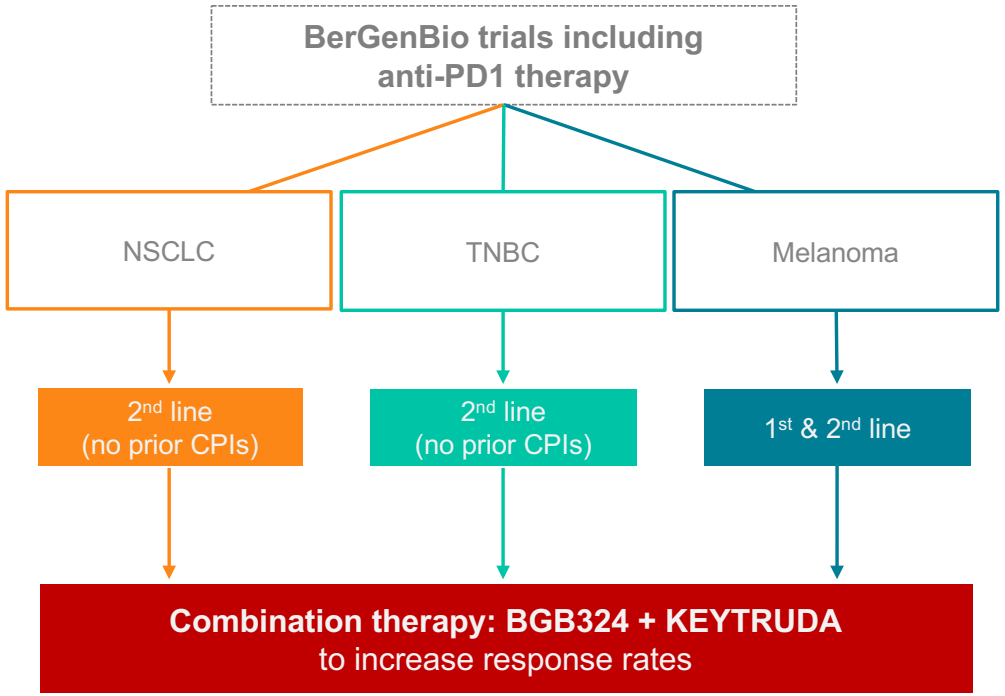
Combination with BGB324 to increase efficacy of anti-PD1 therapy



- A significant proportion of patients do not respond to checkpoint inhibitor therapy
- Non-responders to checkpoint therapy have been shown to express AXL at higher rates
- Inhibiting AXL may increase the number of patients responding to checkpoint therapy
- Comprehensive biomarker programme analysing AXL, PD-L1 and immune signature

Source: Gay *et al* British Journal of Cancer (2017)

Phase II trial in TNBC of BGB324 in combination with KEYTRUDA

MERCK

BGBC007 Phase 2 – Triple negative breast cancer (TNBC)

Up to 56 patients with previously treated, unresectable or metastatic TNBC

Biomarker studies (tissue sample and blood based) ongoing in parallel; PD-L1 assay to be performed by Merck

Patient recruitment ongoing in Norway, UK, Spain, US

Primary endpoint: Objective response rate

Others endpoints: Safety, duration of response, time to progression, survival at 12 months, response by biomarker expression

Initial read-out expected 2H 2018

Randomised Phase II trial of BGB324 in combination with targeted and I/O therapies in Melanoma

BGBIL006 Phase II – Melanoma – *Investigator-sponsored trial*

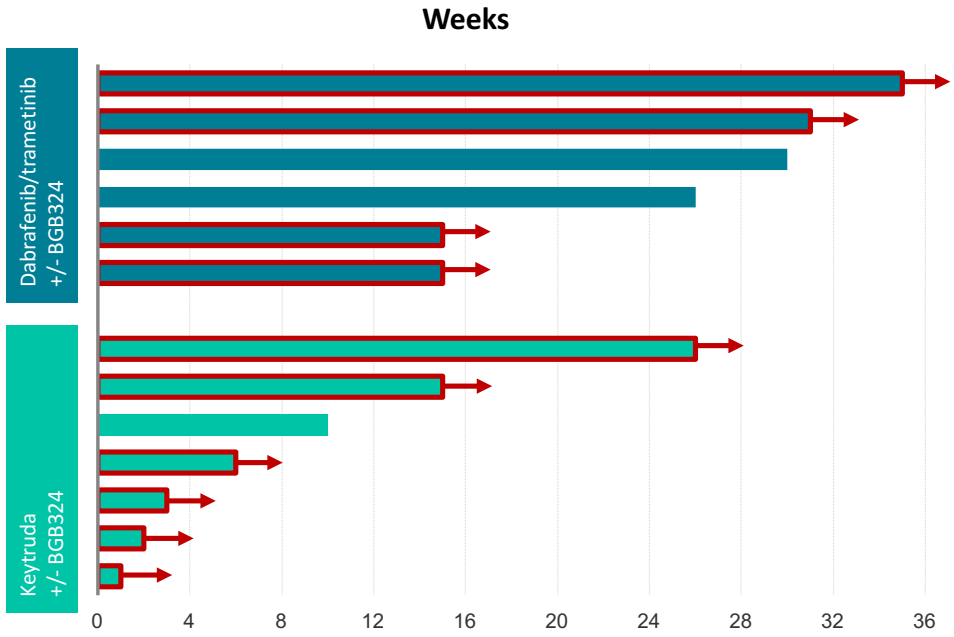
'Real world study' Randomised Phase II – first line

Arm 1: BGB324 + pembrolizumab
Arm 2: BGB324 + dabrafenib and trametinib

Primary outcomes: Safety, objective response rate
Secondary outcomes: PFS, DoR, overall survival

Biomarker programme ongoing in parallel with collaborators at Massachusetts Institute of Technology (MIT) and Harvard Medical School

Sponsor Investigator: Dr Oddbjørn Straume, Haukeland University Hospital and University of Bergen Center for Cancer Biomarkers



Haukeland University Hospital

Massachusetts Institute of Technology

HARVARD MEDICAL SCHOOL

UNIVERSITAS BERGENSIS

Source: Straume *et al* World Conference on Melanoma (October 2017)

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Our strategy – re-thinking cancer treatment

AXL mediates aggressive cancers by driving

- Immune evasion
- Drug resistance
- Metastasis

Patient selection

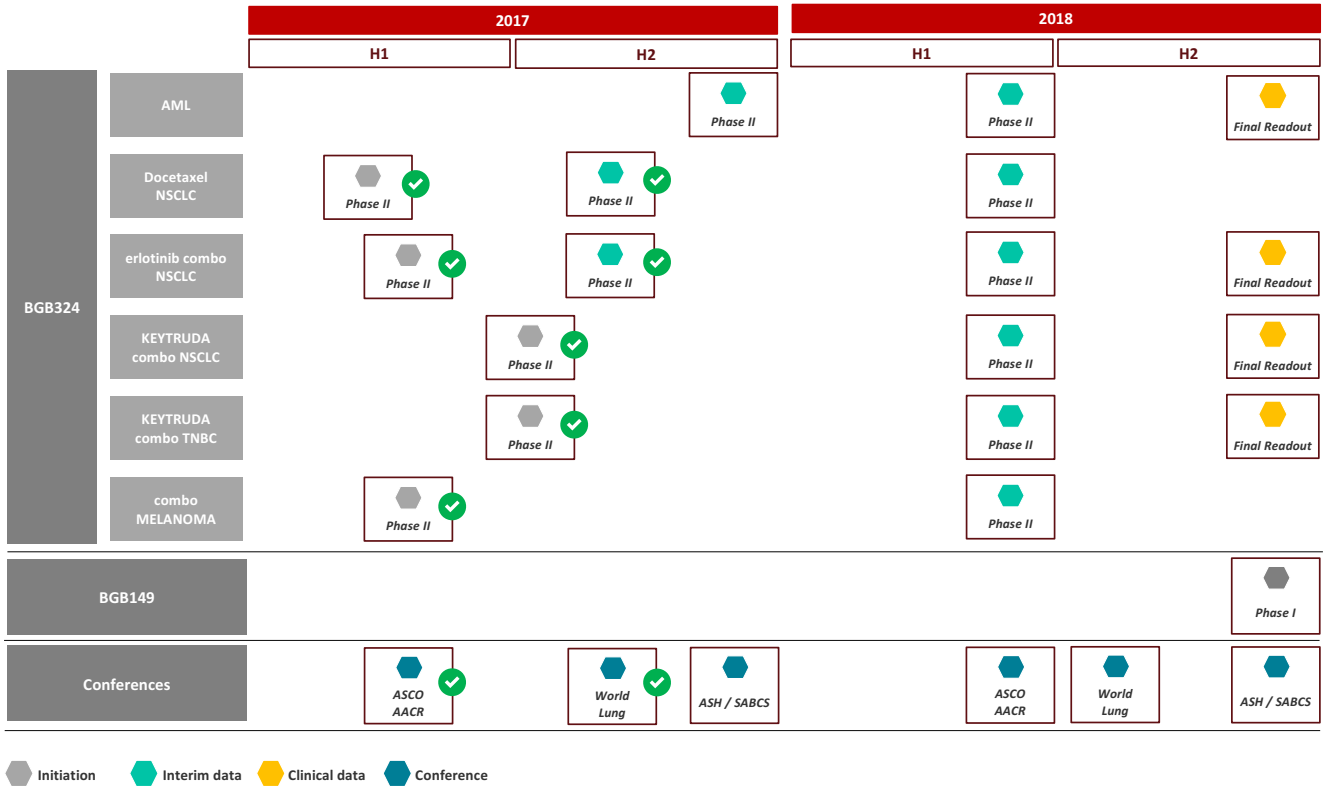
- Proprietary biomarkers
- Companion diagnostics development

Clinical position:

BGB324 in combination with:

- SoC chemotherapy
- SoC immunotherapy
- SoC targeted therapy

Milestones 2017 & 2018



1) Progression of ongoing and start-up of new clinical trials are subject to customary regulatory reviews and approvals

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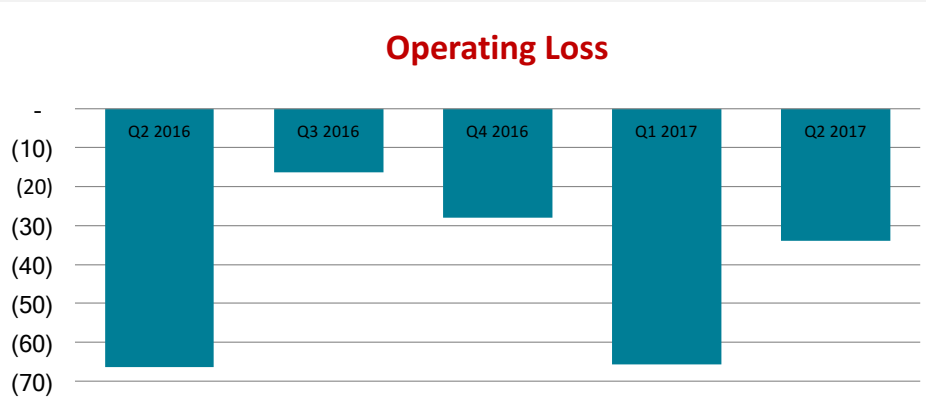
Key partners and collaborators

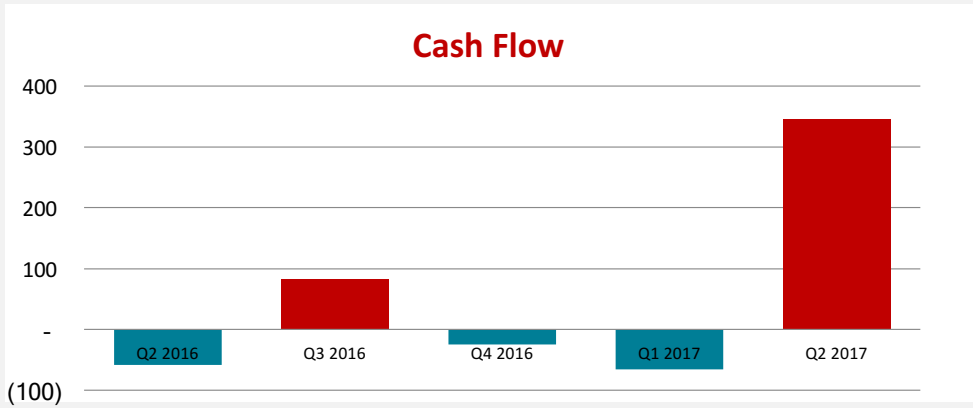
Sponsor Investigator: Dr David Gerber, UTSW Dallas

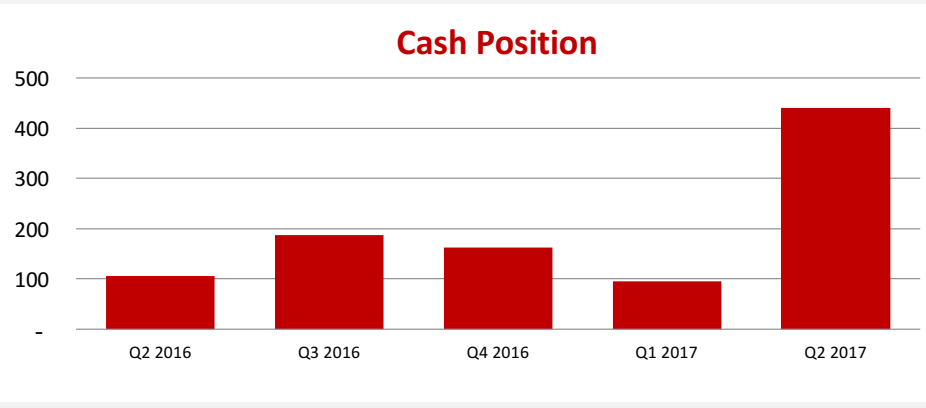
''The vast majority of my lung cancer patients progress onto chemotherapy, combining this with BGB324 may significantly improve the performance of the chemo and could lead to meaningful disease modification in some patients.''

Key financials (NOK million)

Key Figures (NOK million)	Q2 '17	Q2 '16	YTD '17	YTD '16	FY '16
Operating revenues	-	-	-	-	-
Operating expenses	33.8	66.5	99.6	87.2	131.6
Operating profit (loss)	(33.8)	(66.5)	(99.6)	(87.2)	(131.6)
Profit (loss) after tax	**(34.1)**	**(66.2)**	**(99.1)**	**(86.5)**	**(129.8)**
Basic and diluted earnings (loss) per share (NOK)	(0.70)	(225.83)	(2.41)	(307.27)	(419.68)
Cash position end of period	440.3	105.2	440.3	105.2	161.8







Ref: BerGenBio 2Q 2017 report

Summary and outlook / Investment case

- First-in-class AXL inhibitors for aggressive cancers with addressable market in excess of $11bn
- BGB324 in multiple Phase II programmes with interim data readout @ ASCO 2018
- Well resourced & experienced organisation to deliver pipeline and milestones
- Clear strategy to develop and commercialise assets

Thank you.

For further information please visit
www.bergenbio.com

Developing first-in-class Axl inhibitors to treat aggressive cancer

BerGenBio