First-in-class medicines to treat aggressive cancers

DNB Nordic Healthcare day 2017

14th December 2017

Richard Godfrey, CEO

BerGenBio

Disclaimer

Certain statements contained in this presentation constitute forward-looking statements. Forward-looking statements are statements that are not historical facts and they can be identified by the use of forward-looking terminology, including the words "anticipate", "believe", "intend", "estimate", "expect", "will", "may", "should" and words of similar meaning. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. Accordingly, no assurance is given that such forward-looking statements will prove to have been correct. They speak only as at the date of the presentation and no representation or warranty, expressed or implied, is made by BerGenBio ASA or its affiliates ("BerGenBio"), or by any of their respective members, directors, officers or employees that any of these forward-looking statements or forecasts will come to pass or that any forecast result will be achieved and you are cautioned not to place any undue influence on any forward-looking statement. BerGenBio is making no representation or warranty, expressed or implied, as to the accuracy, reliability or completeness of this presentation, and neither BerGenBio nor any of its directors, officers or employees will have any liability to you or any other person resulting from the use of this presentation.

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 NOK400m in IPO on OSE in April ’17

NOK1,000m market cap (Dec13th 2017)

Corporate

35 staff

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

BerGenBio is developing AXL inhibitor drugs to treat aggressive cancers

BGB324 Phase II clinical trials
AXL inhibition as cornerstone for cancer therapy

BGBC008: **NSCLC**			
BGBC007: **TNBC**	BGBIL006: **Melanoma**	BGBIL005: **NSCLC**	
BGBIL006: **Melanoma**	BGBC004: **NSCLC**	BGBC003: **AML**	BGBC003: **AML/MDS**
+ checkpoint inhibitors	+ targeted therapy	+ chemotherapy	monotherapy

BGB324 foundation therapy

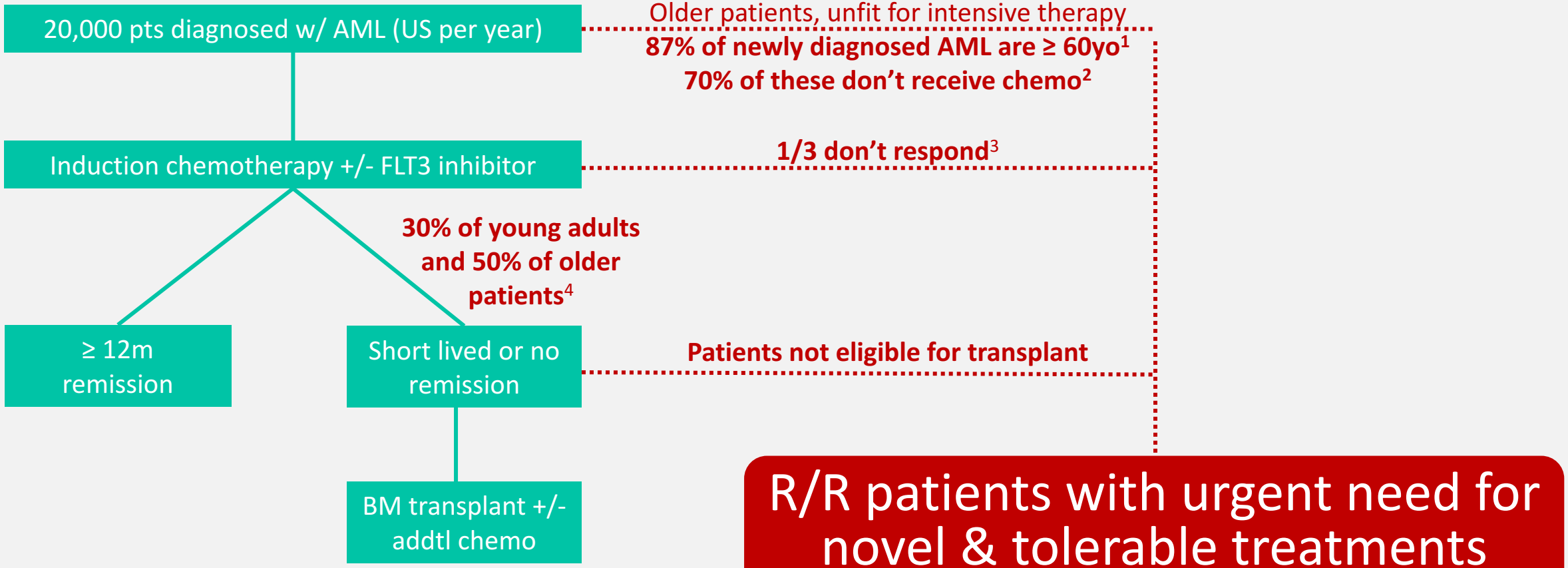
Recent highlights from clinical studies:

- BGBC003 – Leukaemia
- BGBC004 & BGBIL005 – Lung cancer

BGBC003

Relapsed & refractory AML and high risk MDS

Relapsed/refractory AML & MDS – Blood cancer, difficult to treat malignancies, predominantly elderly frail patient population.



MDS: Myelodysplastic syndrome

Source: (1) Juliusson, Blood (2009) (2) Erba, Leukemia Research (2015) (3) cancer.org (4) uotodate.com

Clinical Trial data for R/R AML patients from ASH December 2017

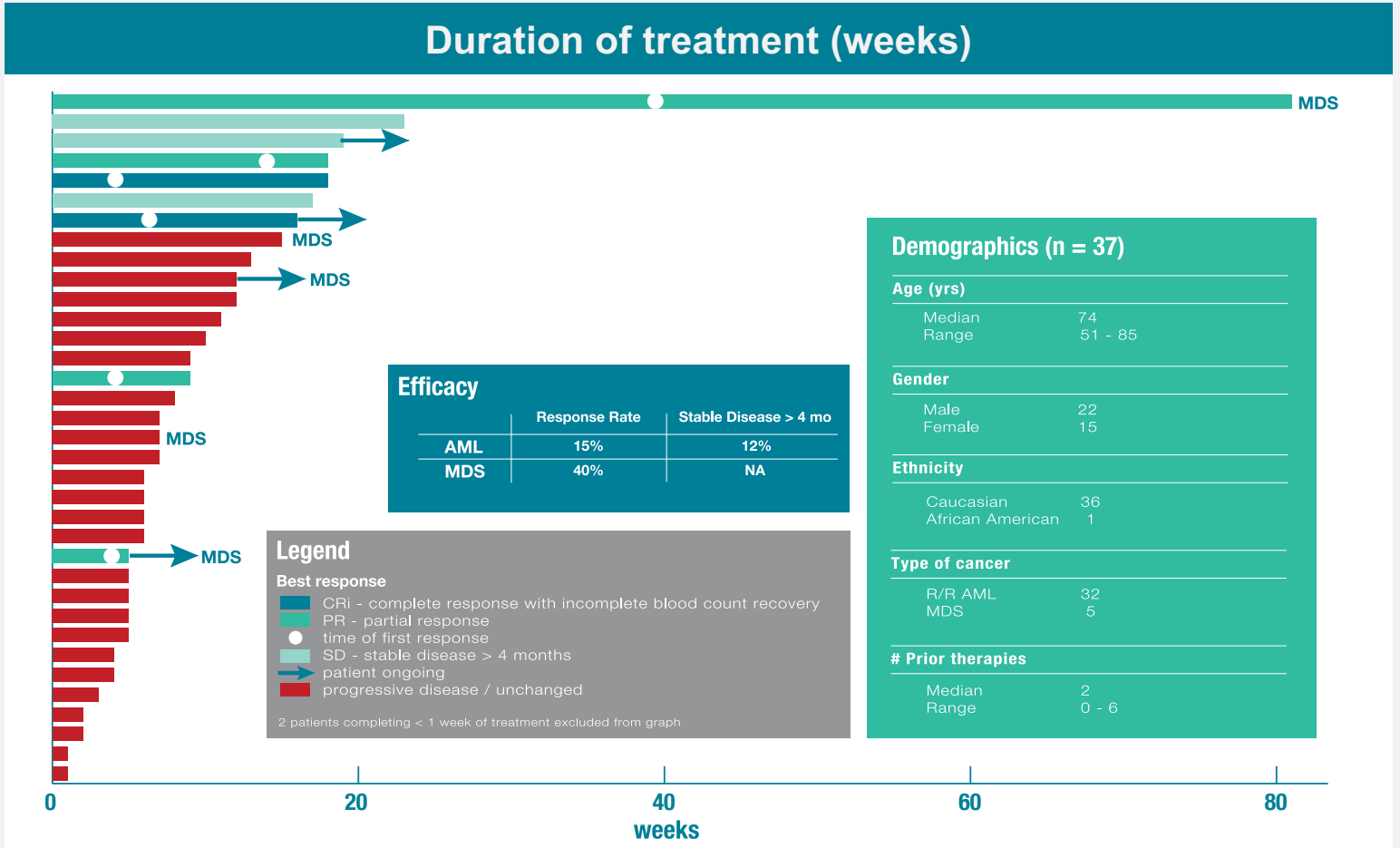
American Society of Hematology
Helping hematologists conquer blood diseases worldwide

	Study	Intervention	ORR
Single agent	***BerGenBio*** *37 patients*	*BGB324* *all comers, elderly R/R patients*	***19%***
	Pratz *et al*[1] 31 patients	TAK-659 investigational FLT-3 and SYK inhibitor	**9%**
	Daver *et al*[4] 51 patients	FLX925 Dual FLT3 and CDK4/6	**0%**
	Dawson et al[6] 46 patients	GSK525762 BET inhibitor	**11%**
	DiNardo *et al*[5] 258 patients – ***selected for mIDH1 mutation***	Ivosidenib (AG-120) mutant IDH1 (mIDH1) inhibitor	**30%**
Combination	Goldberg *et al*[2] 24 patients	Venetoclax* + hypomethylating agent (HMA) or low dose cytarabine (LDAC)	**28%**
	Rausch *et al*[3] 27 patients	Venetoclax + HMA or LDAC	**22%**

***Venetoclax + LDAC received breakthrough designation in 1st line AML (July 2017)**

(1) ASH 2017 abstract 2622 (2) ASH 2017 abstract 1353 (3) ASH 2017 abstract 1356 (4) ASH 2017 abstract 1343 (5) ASH 2017 abstract 725 (6) ASH 2017 abstract 1377

Superior early monotherapy efficacy with favourable safety in R/R AML & high risk MDS reported at ASH 2017



19% Response Rate (CRi + PR)

- 2 CRi
- 5 PRs

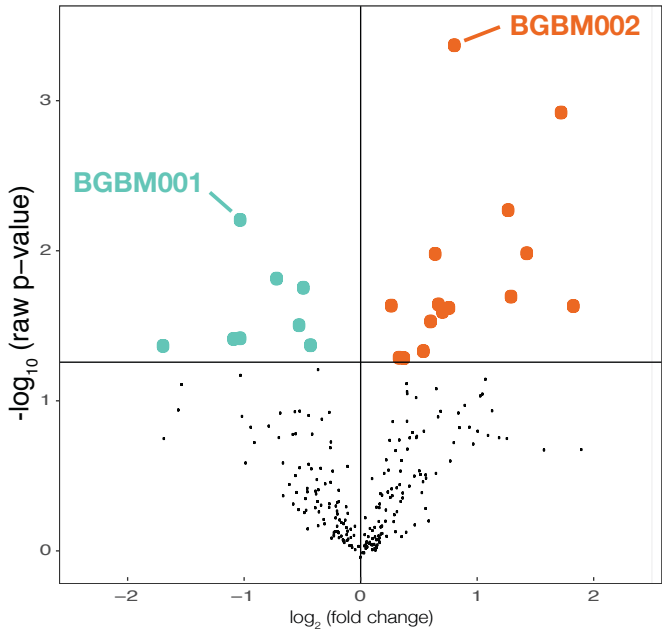
An additional 7 patients were stable > 4 months

Well tolerated

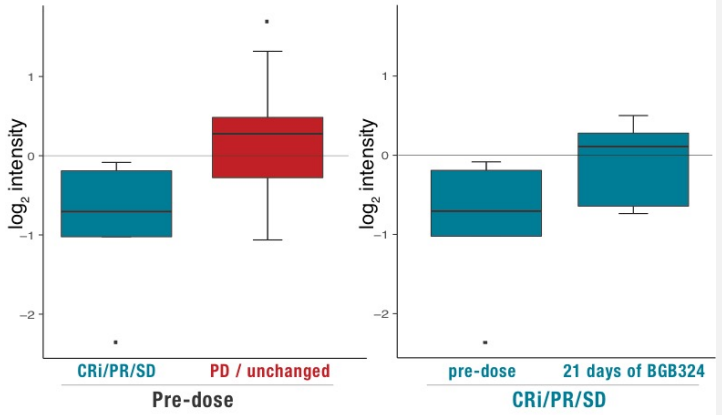
Correlation with predictive biomarker candidates

BerGenBio AML blood based biomarkers predict patients benefitting from BGB324 therapy

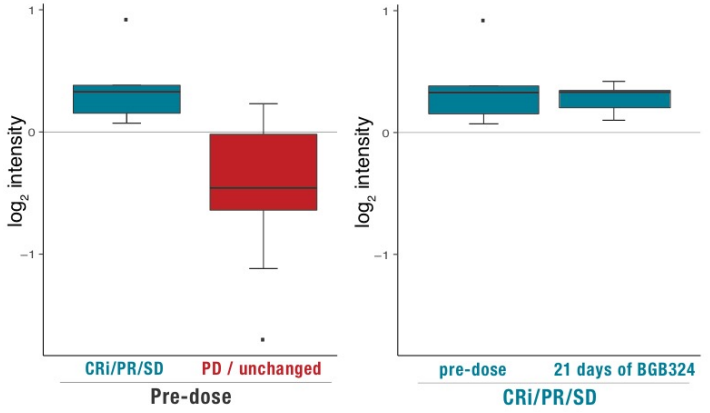
Liquid biopsy in blood plasma: BGBM001 & BGBM002



BGBM001 in blood plasma



BGBM002 in blood plasma



BerGenBio

BGBC003: Phase II trial in AML and MDS – remains ongoing.

BGBC003 Phase II – AML/high risk MDS as monotherapy and in combination with decitabine or azacitidine

Relapsed/refractory AML & high-risk MDS

up to 75 pts

Dose escalation (completed)

AML

2nd line monotherapy

1st line combo
BGB324 + decitabine or azacitidine

MDS

2nd line monotherapy

Safety & efficacy

PK, biomarkers

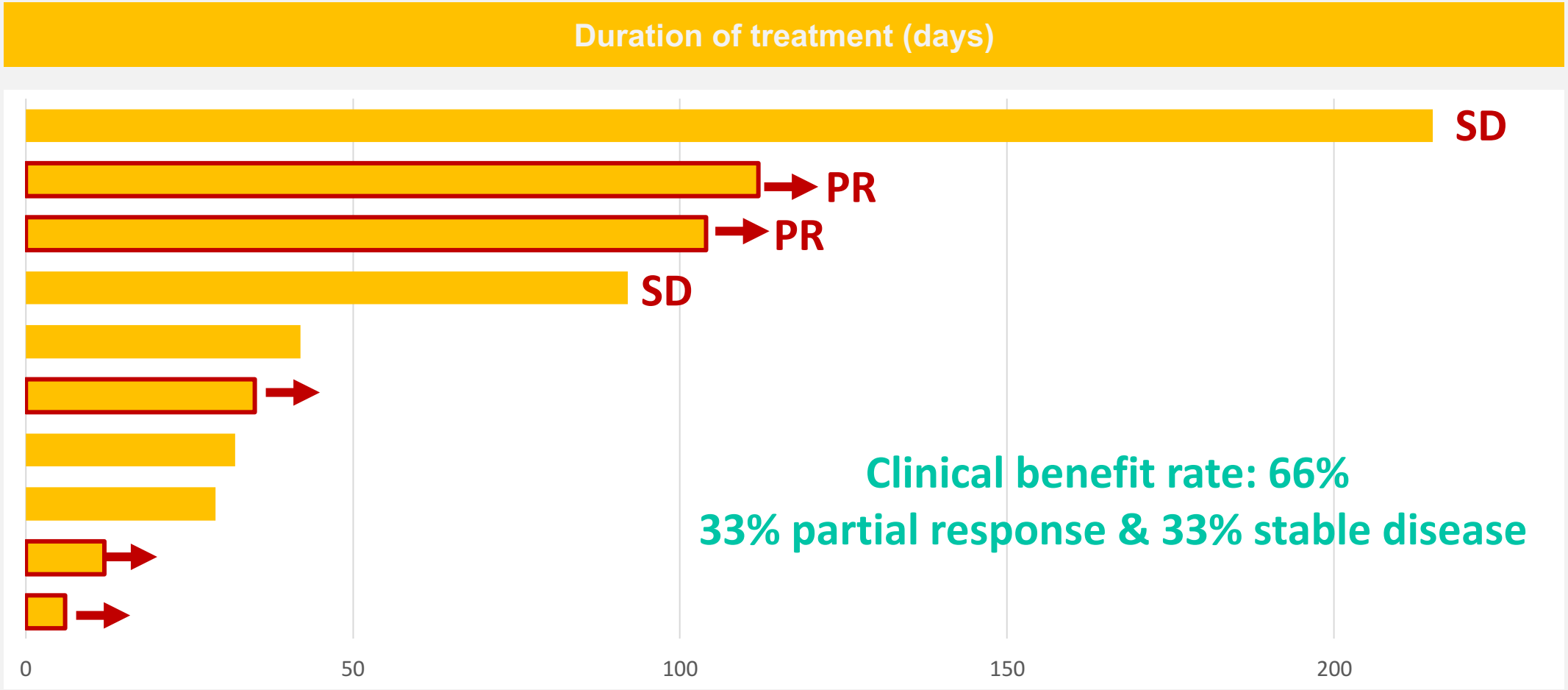
Expected readout

Initial read-out expected 2H 2018

BGBC005

NSCLC patients, last line setting
BGB324 + chemo (docetaxel)

BGB324 + docetaxel in NSCLC patients (last line setting)



BerGenBio

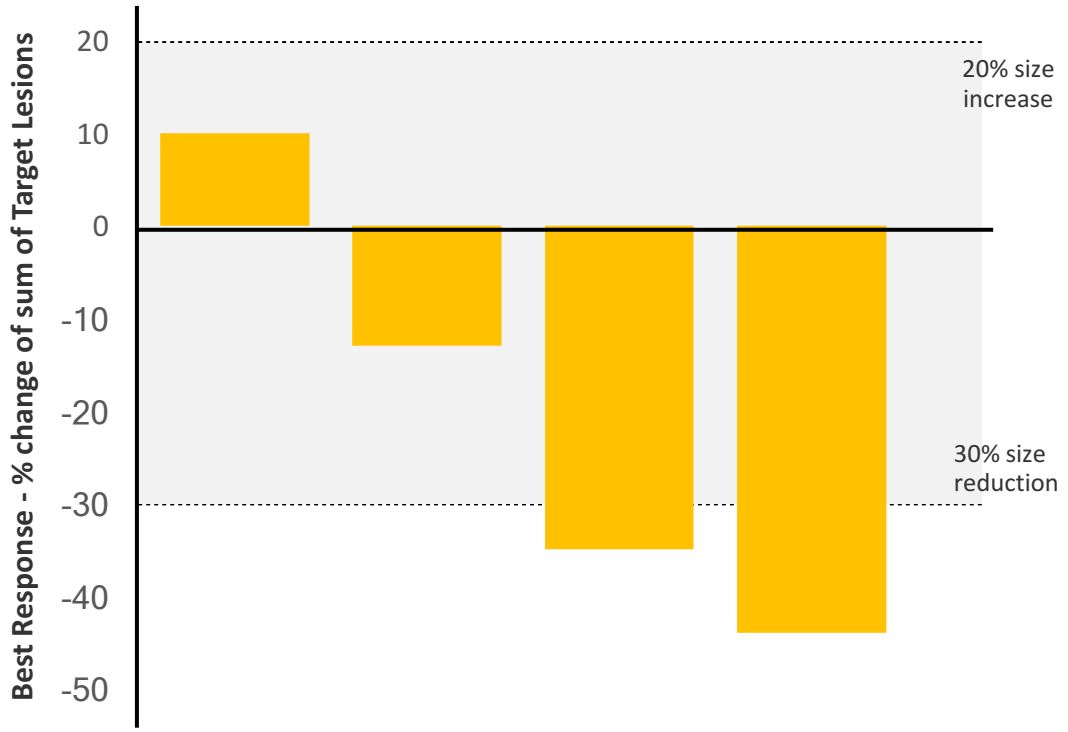
NSCLC Patients
Mostly diagnosed at late stage, 70% mortality within 1y

BGBIL005 – patient population

Heavily pre-treated patient population:

- All failed at least 1 line of chemo
- Most received prior immunotherapy without sustained benefit
- Most patients are metastatic
- No more treatment options remain

Best response (CT scan every 6 weeks)



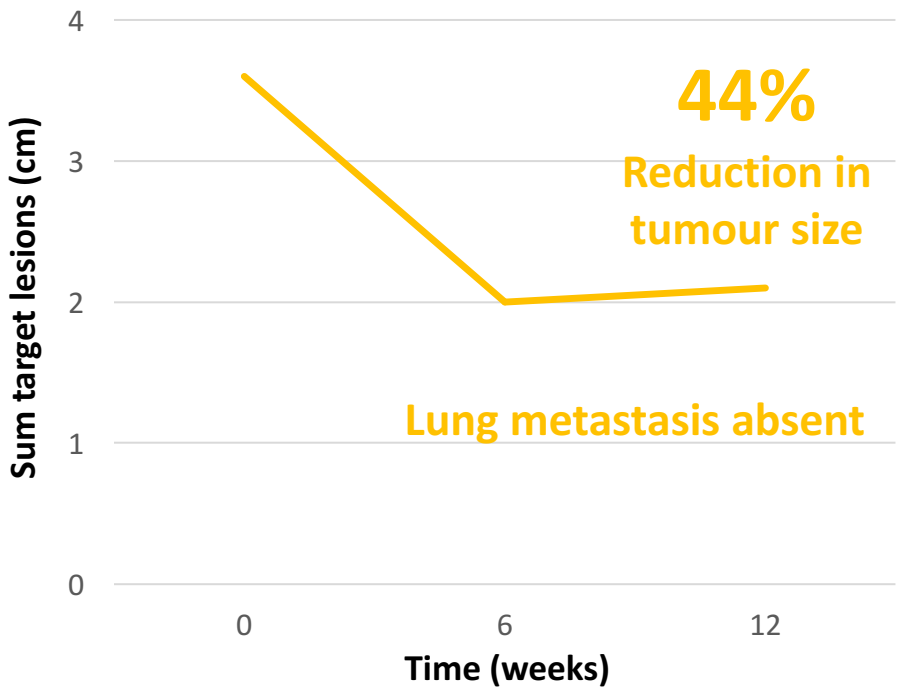
BerGenBio

BGBIL005, Patient case # 004:
PR on BGB324 + docetaxel after failure on chemo and IO

Pt 004 characteristics

Age, ethnicity & sex	63 year old Caucasian female
Histologic diagnosis	NSCLC
Stage	IV
Sites	Lung, lymph, lung metastasis
Mutations	None (EGFR wt, ALK negative)
Previous lines of therapy	CARBOPLATIN/PACLITAXEL CARBOPLATIN/PEMETREXED PEMBROLIZUMAB
Current status	Ongoing, C5

Pt 311-210 response assessment (weeks)



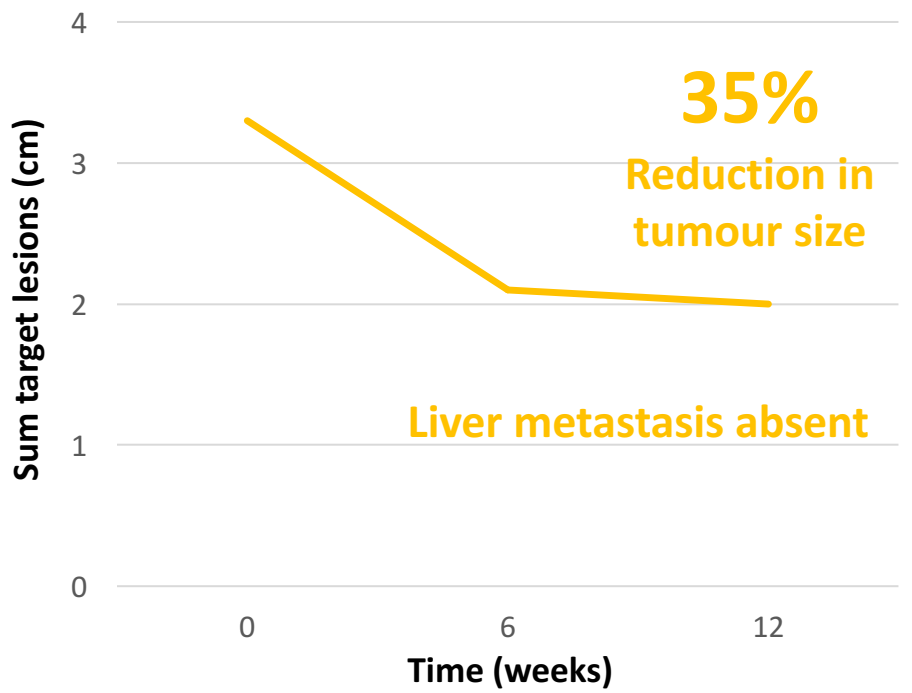
BerGenBio

BGBIL005, Patient case # 006:
PR on BGB324 + docetaxel after failure on chemo and IO

Pt 006 characteristics

Age, ethnicity & sex	53 year old Asian male
Histologic diagnosis	NSCLC
Stage	IV
Sites	Lung, lymph, liver, brain
Mutations	None (EGFR wt, ALK negative)
Previous lines of therapy	CISPLATIN/PEMETREXED CISPLATIN VINORELBINE NIVOLUMAB
Current status	Ongoing, C5

Pt 311-210 response assessment (weeks)



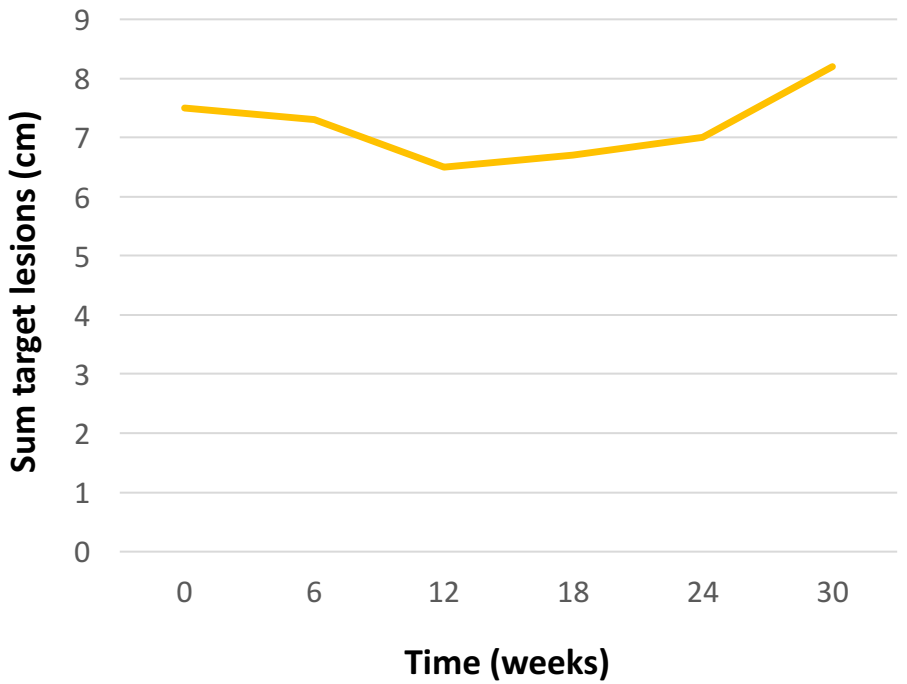
BerGenBio

BGBIL005, Patient case # 002:
SD on BGB324 + docetaxel after failure on chemo and IO

Pt 002 characteristics

Age, ethnicity & sex	75 year old Caucasian male
Histologic diagnosis	NSCLC
Stage	IV
Sites	Lung, lymph
Mutations	CAM5.2, MIB-1
Previous lines of therapy	CARBOPLATIN/PACLITAXEL/BEVACIZUMAB PEMETREXED NIVOLUMAB
Current status	Off study, alive

Pt 311-210 response assessment (weeks)



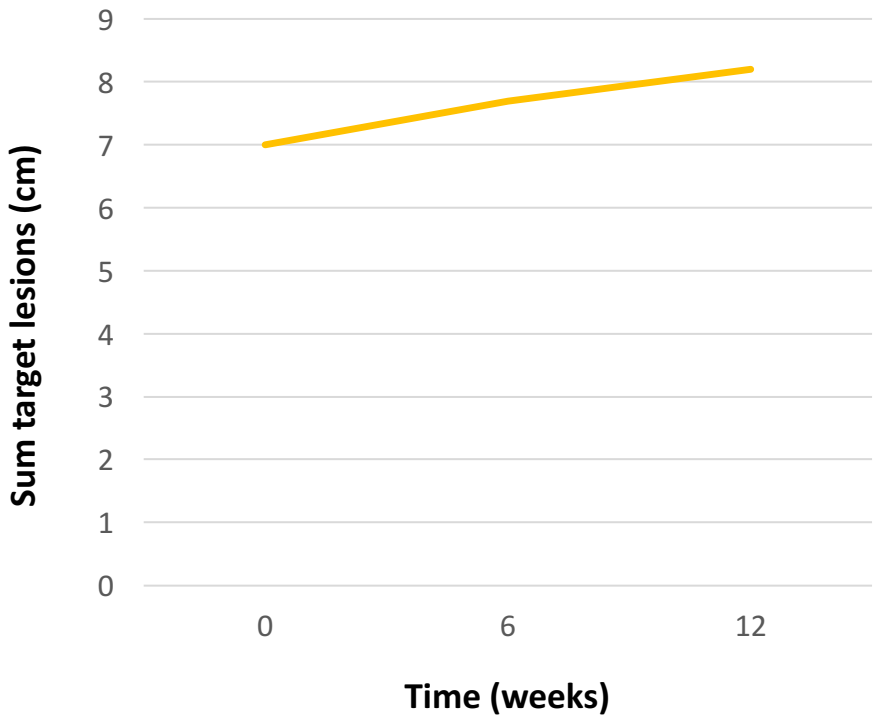
BerGenBio

BGBIL005, Patient case # 005:
SD on BGB324 + docetaxel after failure on chemo and IO

Pt 005 characteristics

Age, ethnicity & sex	63 year old Hispanic male
Histologic diagnosis	NSCLC
Stage	IV
Sites	Lung
Mutations	None (EGFR wt, ALK negative)
Previous lines of therapy	NIVOLUMAB/IPILIMUMAB NIVOLUMAB CARBOPLATIN/PEMETREXED
Current status	Off study, alive

Pt 311-210 response assessment (weeks)



BerGenBio

UTSouthwestern Medical Center

BGBIL005: Phase I/II trial in NSCLC, BGB324 with docetaxel – remains ongoing.

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

Advanced NSCLC, exhausted all treatment options

up to 30 pts
any prior treatment

3+3 dose escalation & expansion

Single arm

BGB324 100 mg/d
Docetaxel 60 mg/m^2

Safety

ORR, PFS, OS, PK, biomarker assessments

Expected readout

Initial read-out expected 2H 2018

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: NCT02922777

BGB324 is an AXL inhibitor to target aggressive cancers…

50%

of people will get a form of cancer in their lifetime

90%

of cancer deaths due to aggressive cancer

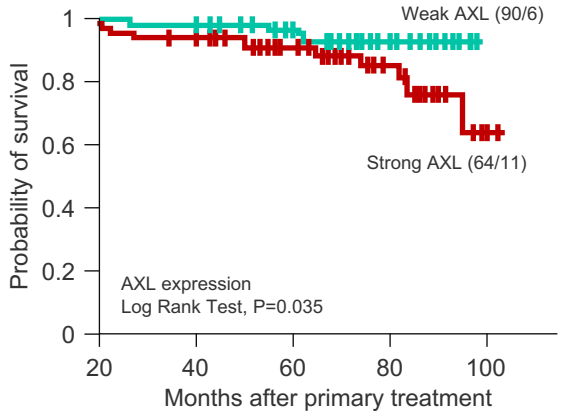
Treat. Reverse. Stop.

BerGenBio

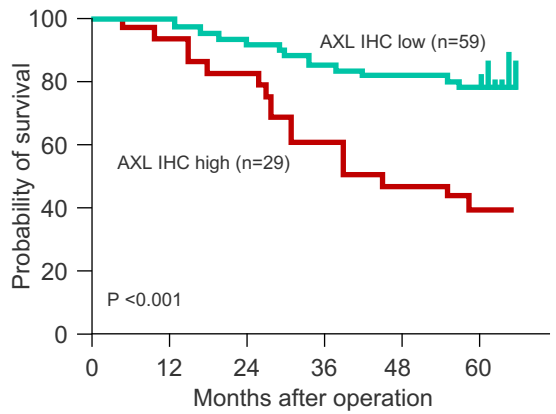
Aggressive cancers

Strong AXL expression correlates with poor survival rate

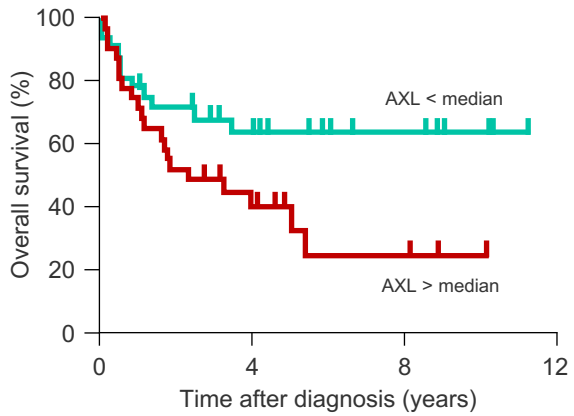
Breast carcinoma[1]



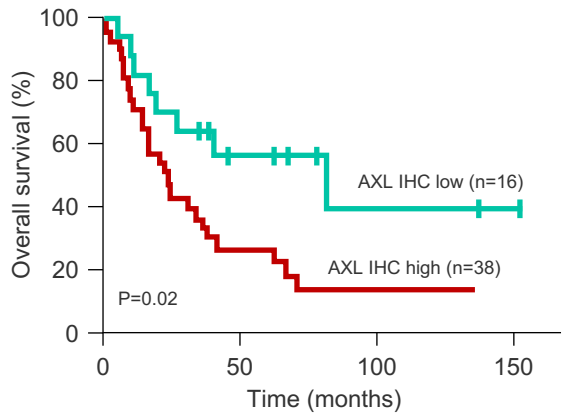
Lung adenocarcinoma (NSCLC)[2]



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

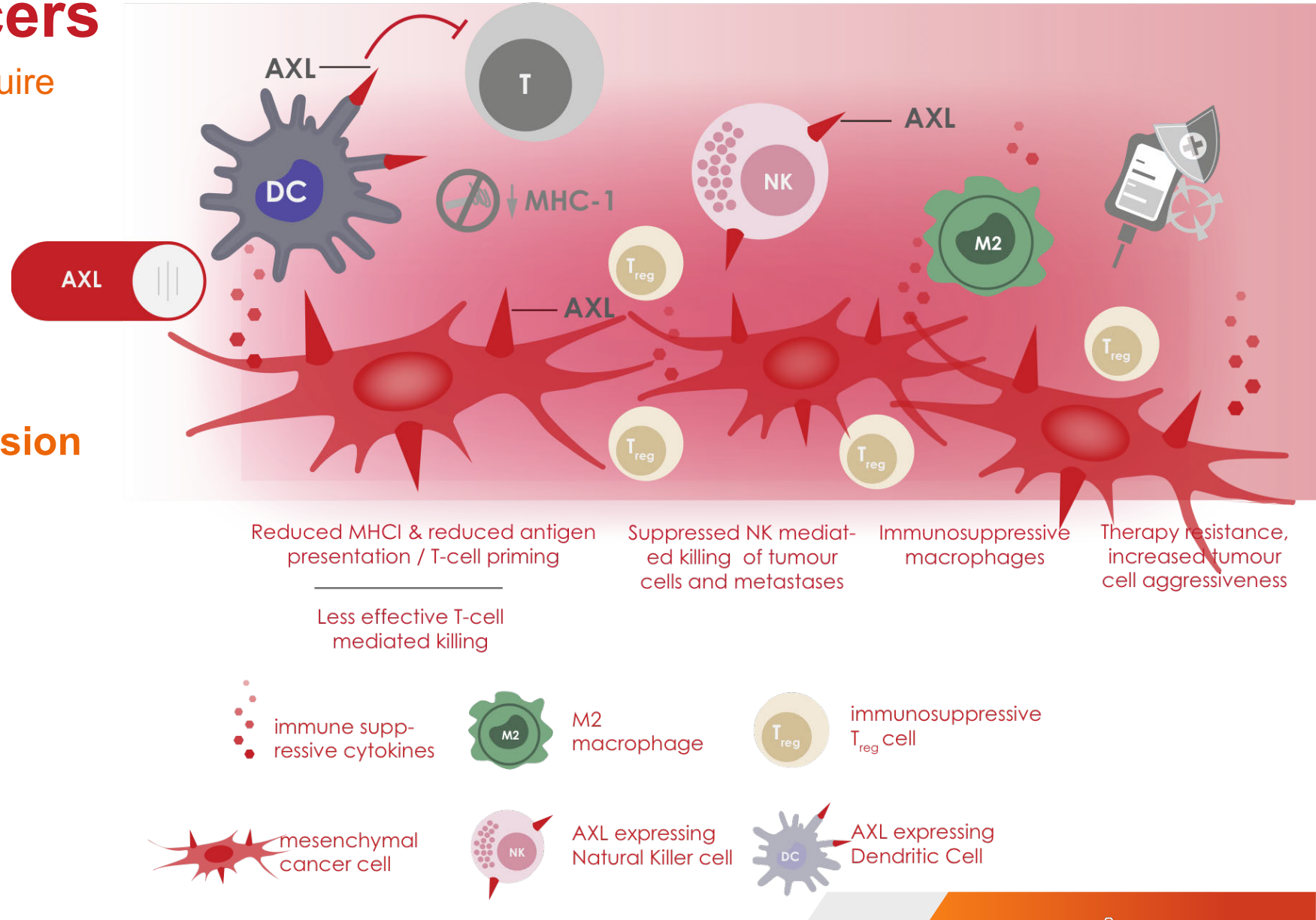
1 Gjerdrum, 2010; 2 Ishikawa, 2012; 3 Ben-Battala, 2013; 4 Song, 2010, 5 supported by > 100 publications

Aggressive cancers

evade the immune system, acquire drug resistance and spread

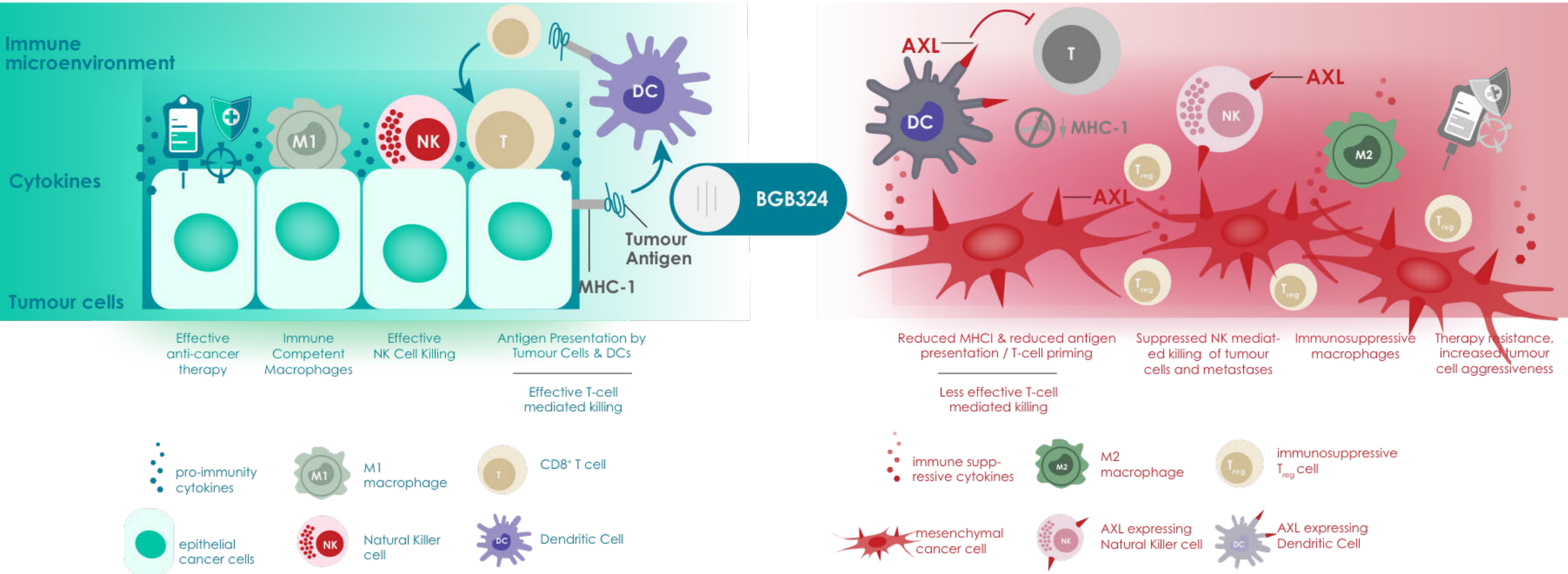
AXL is a key regulator of aggressive cancers driving:

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



BerGenBio

BGB324: selective AXL inhibitor, restores sensitivity to immune cell attack and therapy, prevents spread

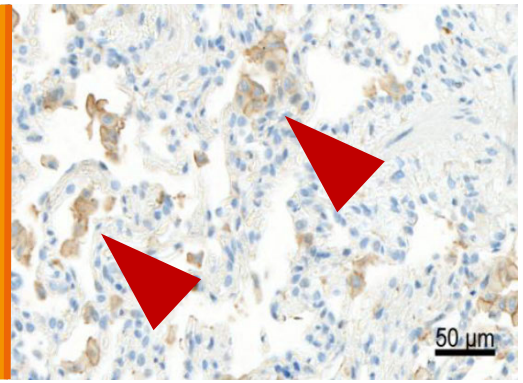


BerGenBio

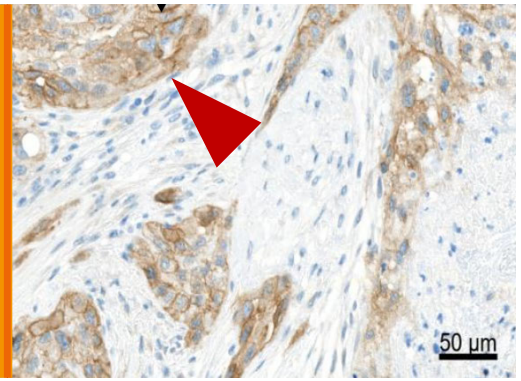
BGB324 targets immunosuppression and therapy resistance

Lung cancer patient samples

Axl is expressed on immune cells in the tumour*

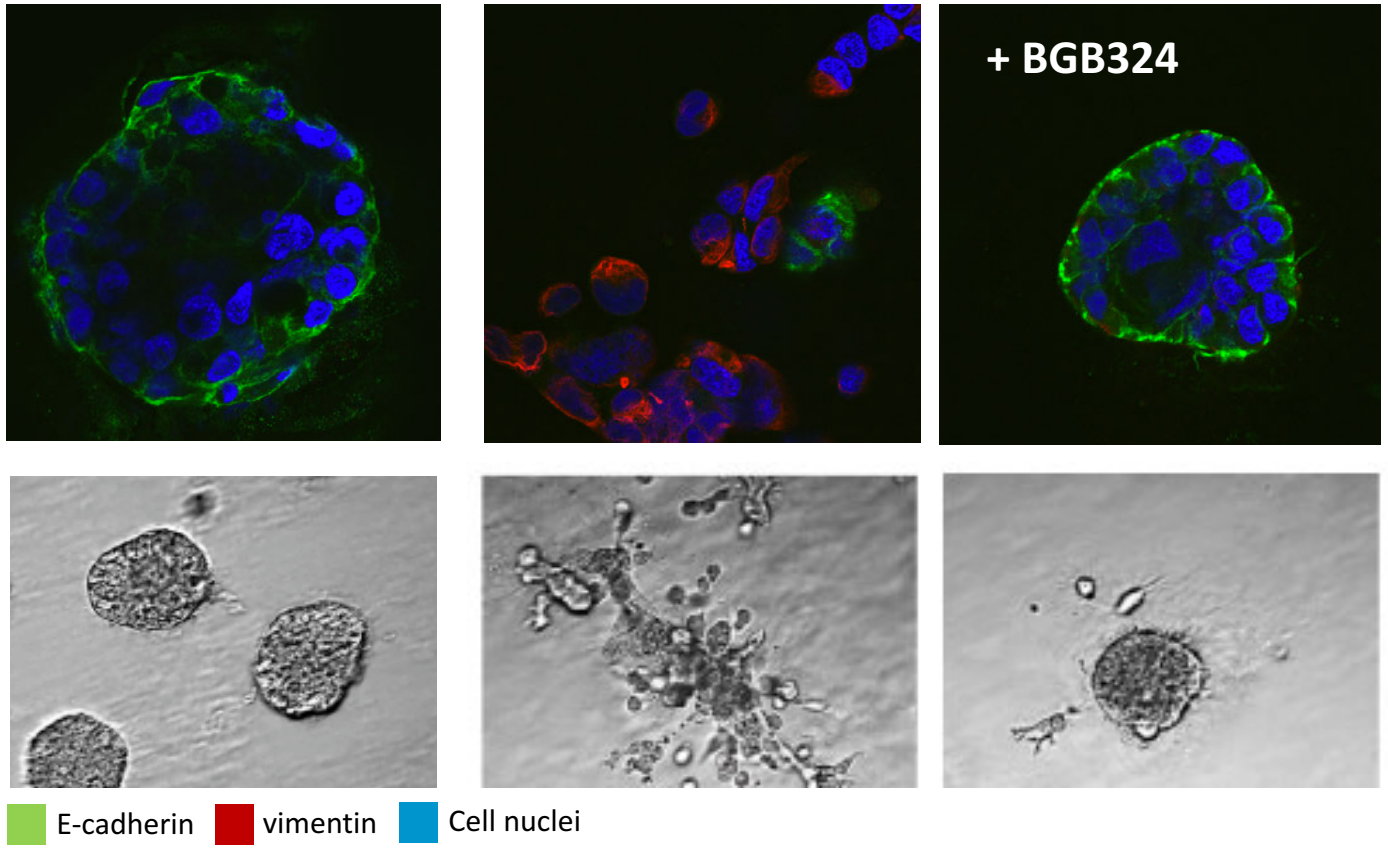


Axl is expressed on tumour cells*



Non aggressive

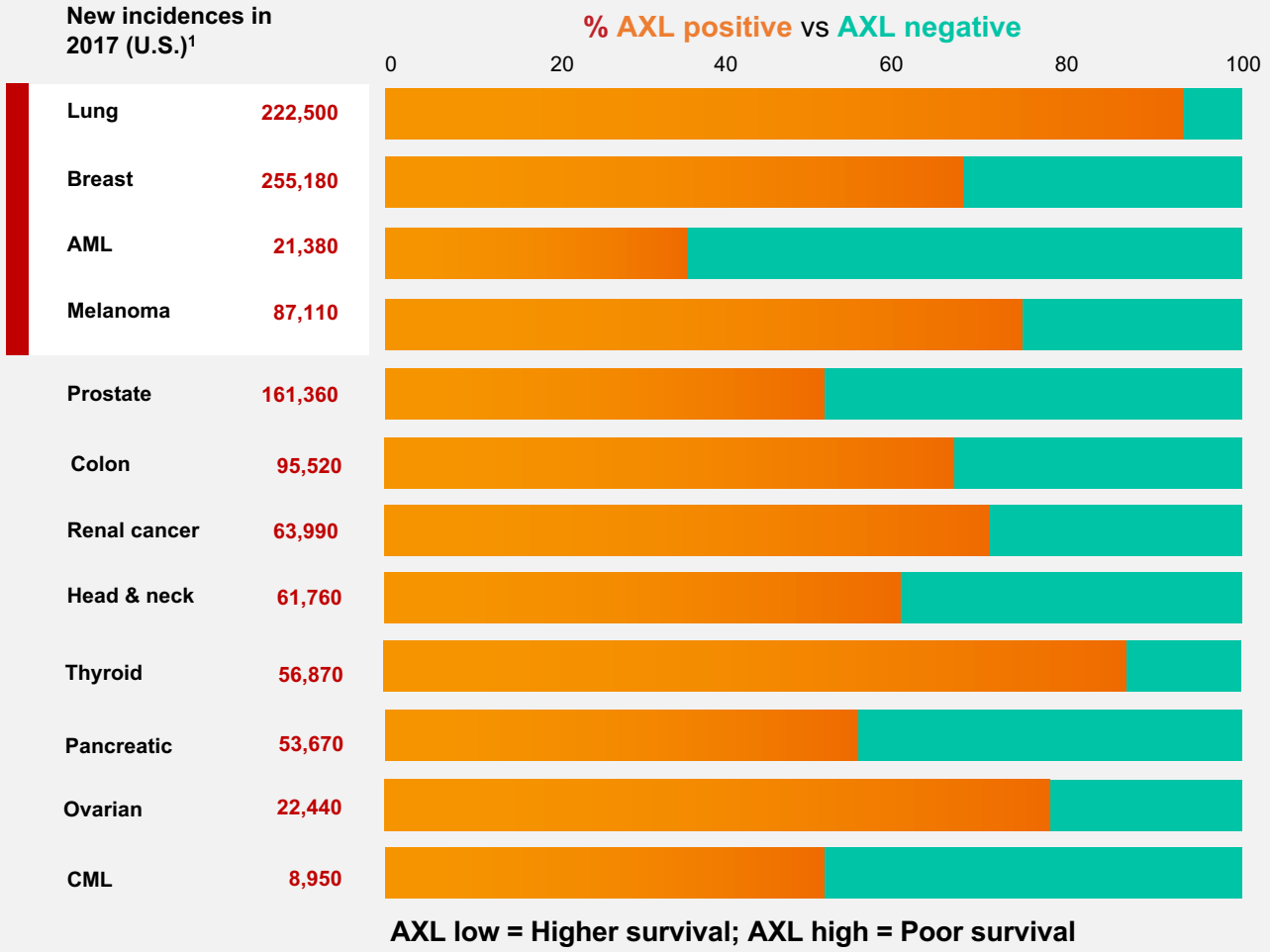
AXL programme induced



BerGenBio

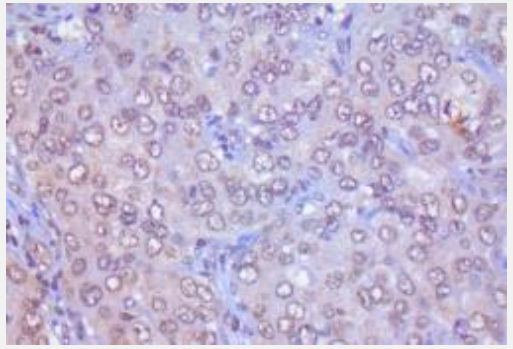
Which cancers are we targeting

Most common tumours express high AXL levels

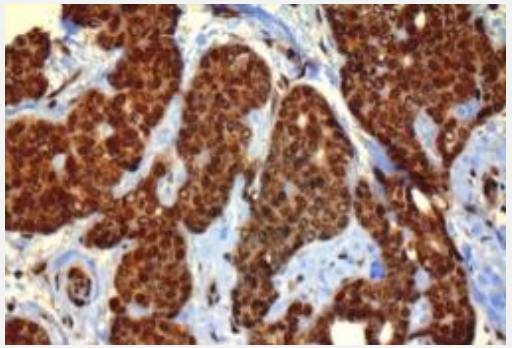


AXL low = Higher survival; AXL high = Poor survival

Low Axl expression[2]



High Axl expression[2]



Companion diagnostic in development to identify AXL positive patients

(1) SEER (2) Gjerdrum 2010

Advancing a broad clinical development pipeline

		Discovery	Preclinical	Phase I	Phase II	Phase III
BGB324 – Axl kinase inhibitor						
NSCLC	*adenocarcinoma*				Phase II Combination with KEYTRUDA® (pembrolizumab)	MERCK
	mutation driven				Phase Ib / II – Combination with TARCEVA® (erlotinib)	
	*all comers**				Phase II BGB324 in combination with Docetaxel	
TNBC					Phase II Combination with KEYTRUDA® (pembrolizumab)	MERCK
Melanoma*					Phase II BGB324 in combination with current standard therapies, incl. CPIs	
AML / MDS					Phase Ib / II – Single agent / Combination	
Antibody programs						
BGB149	*Oncology*			Anti-Axl mAb		
BGB601 (Partnered)	*Metastatic cancer*			ADC	ADC THERAPEUTICS	
Discovery Pipeline – small molecule inhibitors						
BGB002/ BGB003	*Oncology*			Small molecule		

Patients:

>350

Key read-outs:

2018

50

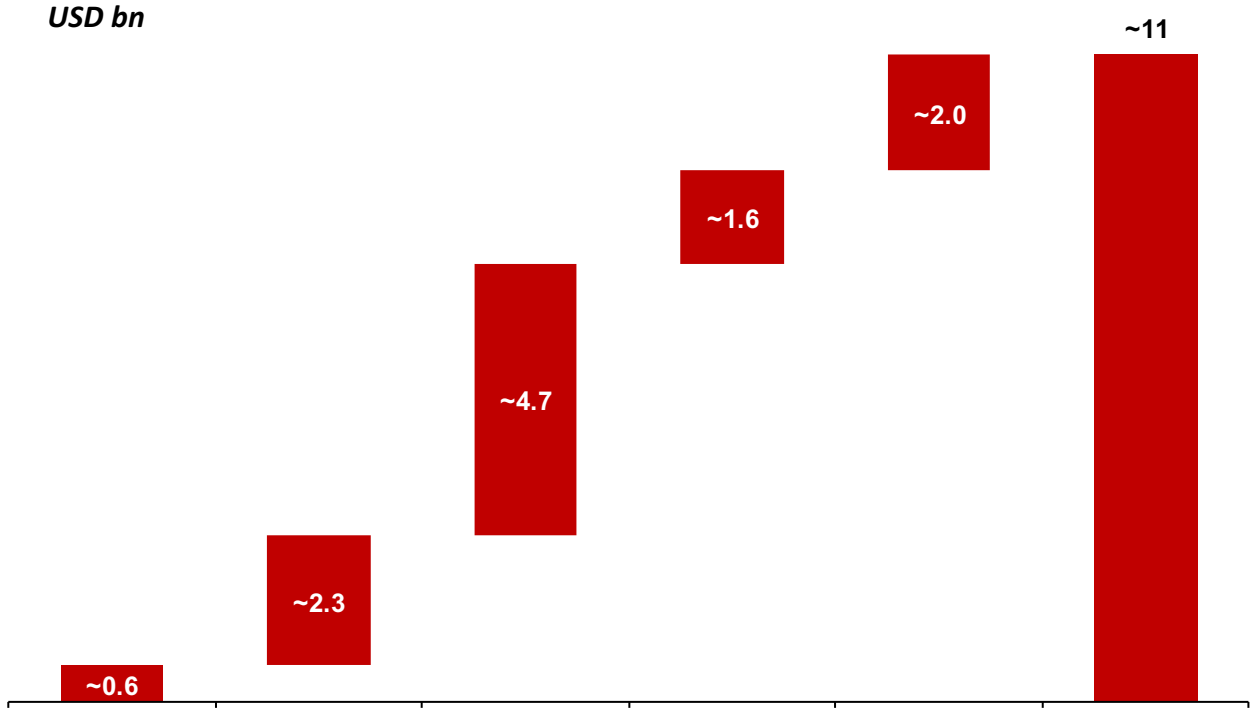
sites in Europe and North America.

*Investigator-sponsored trials

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

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

BGB324 clinical development strategy: AXL inhibition as cornerstone for cancer therapy

Last line, heavily pre-treated

R/R AML
19% RR
11% SD > 4mo

High risk MDS
40% RR

NSCLC
25% 1-year PFS

+ checkpoint inhibitors

+ targeted therapy

+ chemotherapy

monotherapy

BGB324 foundation therapy

BGB324 clinical development strategy: AXL inhibition as cornerstone for cancer therapy

Last line, stage IV metastatic NSCLC, heavily pre-treated:

- 66% CBR
- 2 Partial Responses
- Durable response (> 10 cycles)
- Favourable safety

+ checkpoint inhibitors

+ targeted therapy

+ chemotherapy

monotherapy

BGB324 foundation therapy

BGB324 clinical development strategy: AXL inhibition as cornerstone for cancer therapy

Last line, stage IV metastatic NSCLC, EGFR+, heavily pre-treated:

- 50% CBR
- Including 1 PR
- One patient ongoing > 21 months

+ checkpoint inhibitors

+ targeted therapy

+ chemotherapy

monotherapy

BGB324 foundation therapy

BGB324 clinical development strategy: AXL inhibition as cornerstone for cancer therapy

First line metastatic melanoma:

- Favourable safety

+ checkpoint inhibitors

+ targeted therapy

+ chemotherapy

monotherapy

BGB324 foundation therapy

BGB324 ongoing clinical trials
Reporting interim response & safety data on a regular basis

BGBC008: NSCLC
OPEN & RECRUITING

BGBC007: TNBC
OPEN & RECRUITING

BGBIL006: Melanoma
OPEN & RECRUITING
WORLD MELANOMA '17

+ checkpoint inhibitors 

BGBIL006: Melanoma
OPEN & RECRUITING
WORLD MELANOMA '17

BGBC004: NSCLC
OPEN & RECRUITING
WORLD LUNG '17

+ targeted therapy 

BGBIL005: NSCLC
OPEN & RECRUITING
WORLD LUNG '17

BGBC003: AML
OPEN & RECRUITING

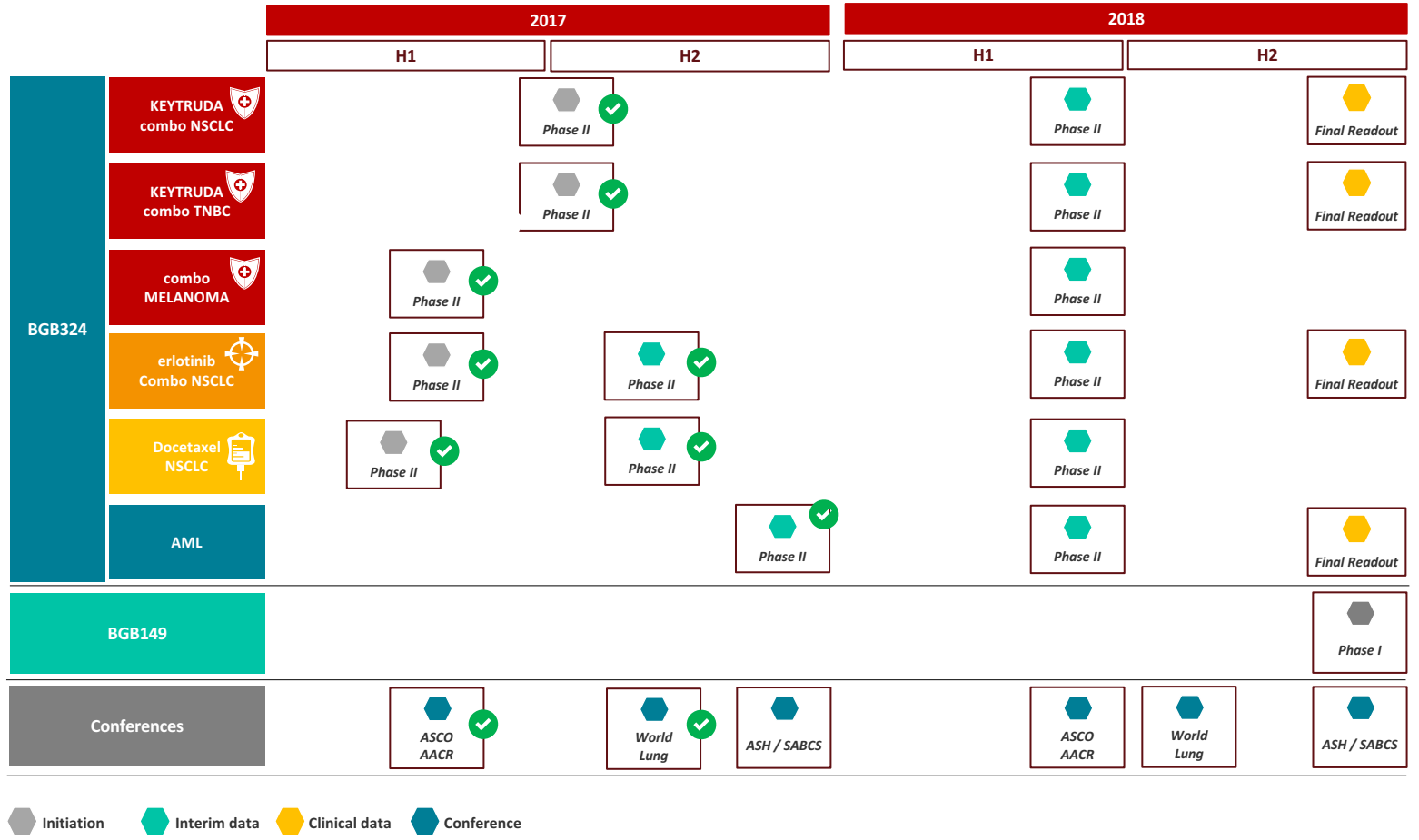
+ chemotherapy 

BGBC003:
AML/MDS
ASH '17

monotherapy

BGB324 foundation therapy

Milestones 2017 & 2018



Significant value drivers expected over the next 12 months:

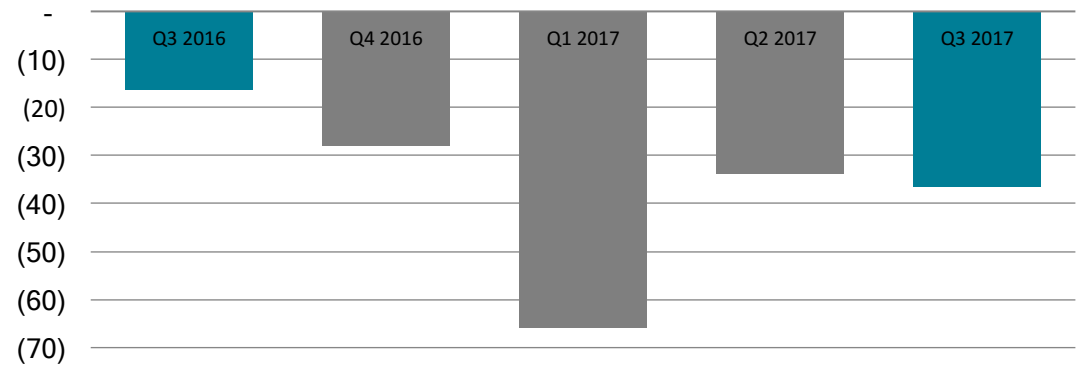
- ✓**Interim clinical data** from 6 ph2 trials **H1'18**
- ✓**Final readout** from 4 phase 2 trials **in H2**
- ✓**Initiation of AXL antibody** BGB149 clinical trials **in H2**

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

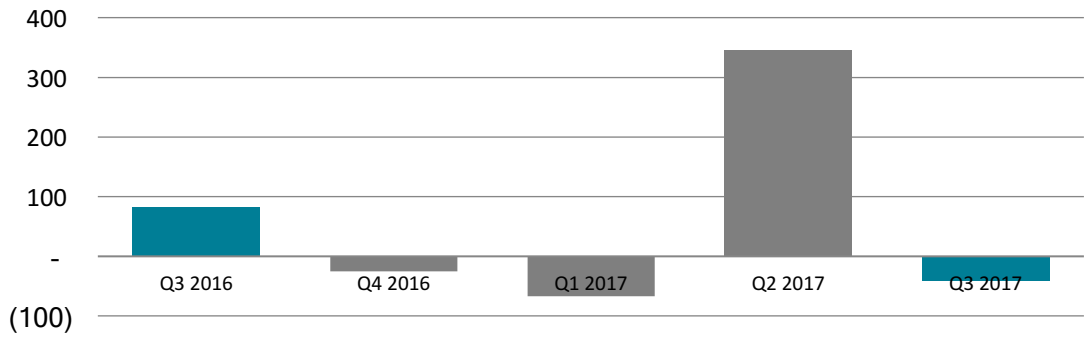
Key financials

Key Figures (NOK million)	Q3 2017	Q3 2016	YTD2017	YTD2016	FY 2016
Operating revenues	-	-	-	-	-
Operating expenses	36.6	16.3	136.2	103.5	131.6
Operating profit (loss)	-36.6	-16.3	-136.2	-103.5	-131.6
Profit (loss) after tax	-35.4	-15.4	-134.6	-101.9	-129.8
Basic and diluted earnings (loss) per share (NOK)	-0.71	-45.64	-3.06	-339.63	-419.68
Net cash flow in the period	-41.1	82.1	237.3	113.2	87.8
Cash position end of period	399.2	187.2	399.2	187.2	161.8

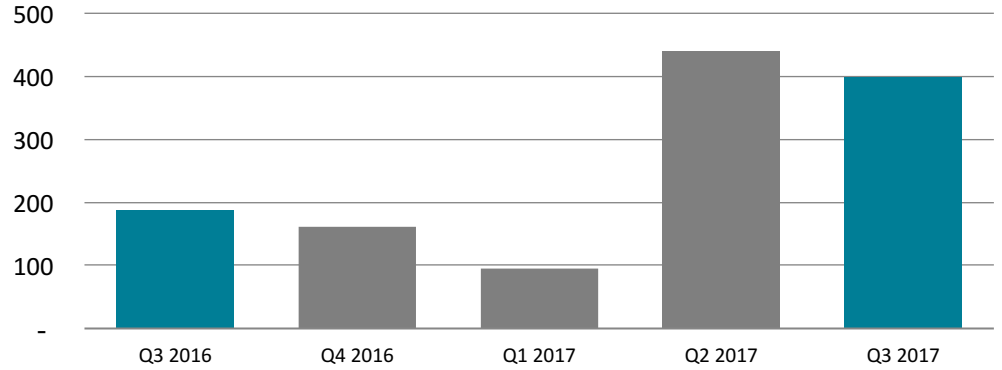
Operating loss



Cash flow



Cash position



- OPEX sequentially increased by 8% in Q317 over Q217 as recruitment to our clinical studies is ramping up
- Robust cash position gives runway to deliver key clinical read outs on our ongoing clinical studies.

Source: BerGenBio ASA Third Quarter Results

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