

BerGenBio

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

Second Quarter and First Half 2017 presentation August 18th 2017

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Q2 and 1H 2017 Achievements R&D programmes are progressing to plan – solid foundation to build value

Corporate

- Successful IPO (April) raised NOK 400 million to finance development strategy
- Clinical collaboration agreement with Merck & Co (MSD) (March)
 - Two Phase II combination trials with MSD's immune checkpoint inhibitor KEYTRUDA® in patients with advanced lung (NSCLC) and triple negative breast cancer (TNBC)

BGB324

Phase II clinical development program opened and enrolling

- Monotherapy study in AML/MDS enrolling patients
- Combination study with erlotinib opened in lung cancer enrolling first and second line cohorts
- Sites active and patient recruitment ongoing in BGB324/KEYTRUDA study in patients with TNBC,
- Site activation underway for BGB324/KEYTRUDA study in patients with NSCLC
- Investigator-sponsored studies in lung cancer (docetaxel combo) and melanoma (combination with current targeted & I-O therapies) opened and dosed first patients
- Biomarker studies underway in association with clinical studies
- Scientific and clinical presentations made at AACR and ASCO international cancer conferences

Pipeline

- Clinical candidate BGB149 was nominated, a humanised anti-Axl monoclonal antibody
 - Cell line development and antibody manufacturing is underway with a leading biologics CRO

Cash

NOK 440 million at end of Q2 2017

- Cash runway into 2019, and sufficient to deliver key read-outs from four Phase II trials in 2H 2018
- Awarded BIA Grant by NFR and IFU grant from Innovasjon Norge of NOK 24 m

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BerGenBio – First-in-class Axl inhibitors for multiple aggressive cancers

90% of cancer deaths result from tumors spreading, becoming immune evasive and drug resistant

AxI is a key mediator of these traits in a broad range of cancers

BerGenBio is a **world-leader** in AxI biology and is developing an exciting **pipeline** of AxI inhibitors

BGB324 initially addressing an annual market potential of USD 11 Billion

BGB324 - First-in-class, highly selective oral Axl inhibitor

Mode of Action Gas6 **AXL** Cancer cell membrane **BGB324** Kinase domain blocks drug resistance immune evasion survival

metastasis

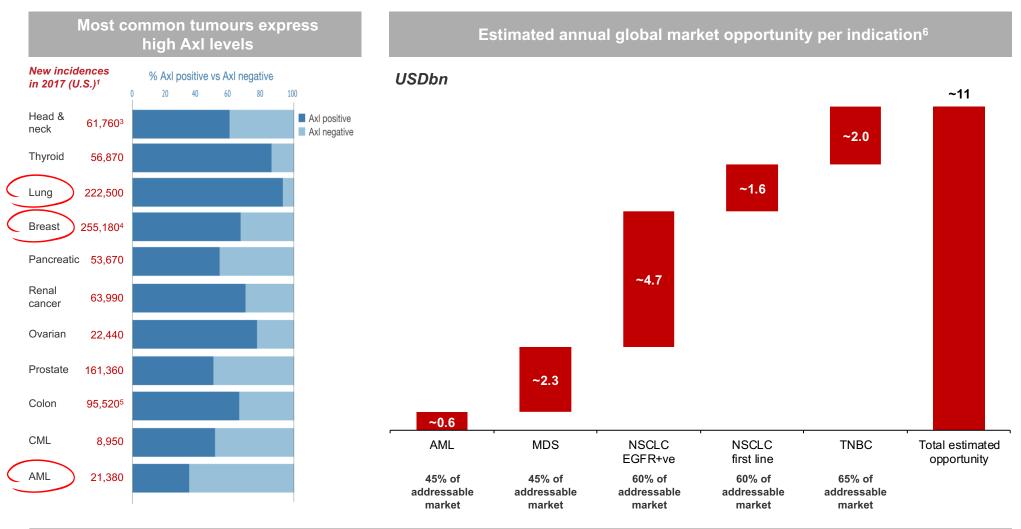
Drug substance

- Highly selective and potent
- Orally bioavailable
- Well tolerated: suitable for long-term therapy
- Wide therapeutic index: suitable for combination with existing drugs
- Orphan status in US for AML
- Licensed from Rigel Inc. 2011

Investigational Medicinal Product

- Patients take medicines home, one-a-day dose
- 100mg capsules, standard pharmaceutical formulation
- 3yr shelf life
- Cost effective treatment

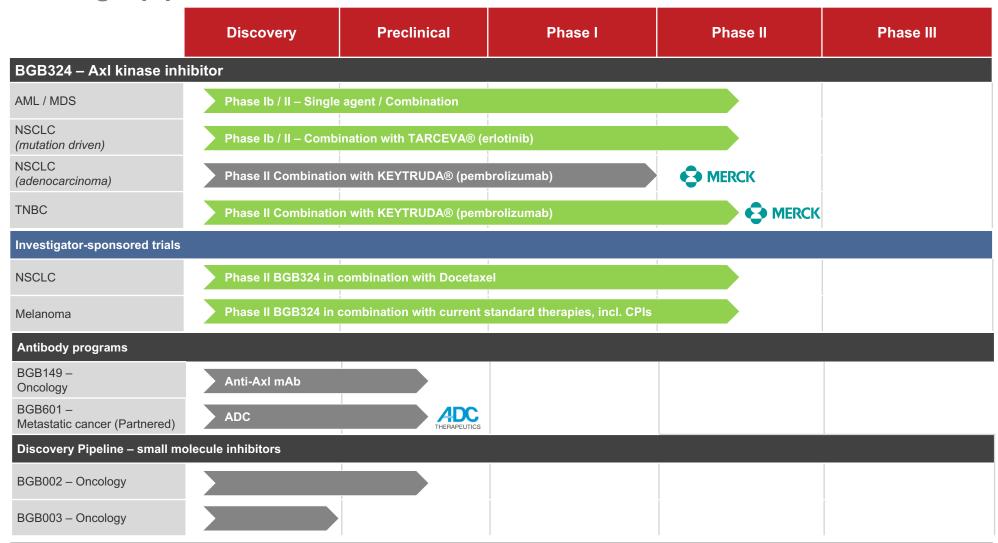
Strategic rationale for target indications Major unmet need, strong scientific basis, large addressable market (~USD11Bn)



¹⁾ SEER Program – National Cancer Institute (National Institute of Health) http://seer.cancer.gov/; 3) Cancer.net; 4) Figure for male and female breast cancer; 5) Excluding rectum; 6) Estimates by Alacrita Consulting

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Strategic pipeline will drive value creation



Compelling Phase Ib clinical data for BGB324

AML/MDS

- Elderly AML/MDS patients
- Relapsed & refractory
 - Heavily pretreated
- Single agent

32% clinical benefit rate

- Correlation with diagnostic
- Well tolerated (up to >15 months)

NSCLC

- Stage IV metastatic patients
- Heavily pretreated
 - Exhausted existing licensed drugs
- Single agent

1 year PFS in 25% of patients

NSCLC

- Stage IV metastatic patients
 - With EGFR mutation
 - Heavily pretreated
- Second line setting
 - Combination with erlotinib

50% clinical benefit rate

- Disease stabilisation > 4 months
- One patient ongoing > 21 months

BGB324 has generated strong efficacy data in patients with no other existing treatment options

Status of BGB324 phase II clinical trials

BerGenBio sponsored clinical trials

AML/MDS

Single agent and combination with cytarabine or decitabine



- 8 sites open in Norway, Germany and USA
- Completion of dose-escalation phase; safety, confirmation of RP2D
- Enrolment open for dose-expansion phase

NSCLC

Combination with TARCEVA (erlotinib)



- 6 sites open in USA
- Phase II arms were opened and patient enrolment started in Q1 2017
 - · First line setting : prevention of acquired resistance to erlotinib
 - · Second line setting : reversal of resistance to erlotinib

NSCLC MERCK

Combination with KEYTRUDA (pembrolizumab)



- · FDA IND approval received
- · EU CTA approvals received in UK, Norway and Spain.
- Site startup ongoing



Combination with KEYTRUDA (pembrolizumab)



- FDA IND approval received
- EU CTA approvals received in UK and Norway, submission made in Spain.
- Sites active and patient recruitment ongoing

Investigator sponsored clinical trials

NSCLC

Combination with docetaxel



- · Open and enrolling patients at 1 site, Dallas TX. Additional sites planned
- Sponsored by Dr. Gerber/UTSW & South Plains Oncology Consortium (SPOC)
- Encouraging results presented at Precision Lung Cancer (July 2017)

Melanoma

Combination with KEYTRUDA or TAFINLAR (dabrafenib) / MEKINIST (trametinib)



- · Randomised Phase II combination trial mimics real-world setting
- · Open and enrolling patients in Bergen, additional sites planned
- Comprehensive programme of explorative biomarkers in collaboration with Massachusetts Institute of Technology and Harvard Medical School

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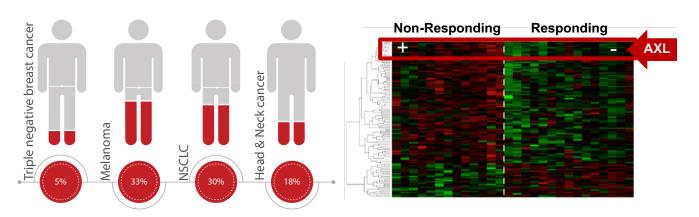
Strong rationale for combining BGB324 with checkpoint inhibitors

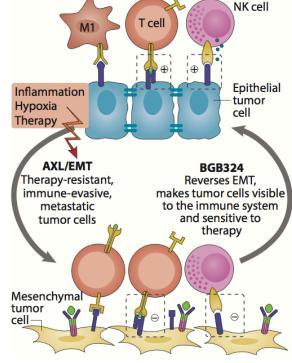
Checkpoint inhibitors do <u>not</u> work for all patients in all cancers

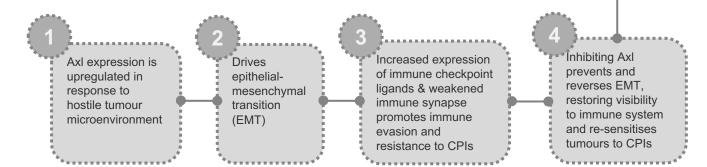
AXL up-regulation is the greatest change in non-responders

AXL drives immune evasion

STABLE TUMOUR







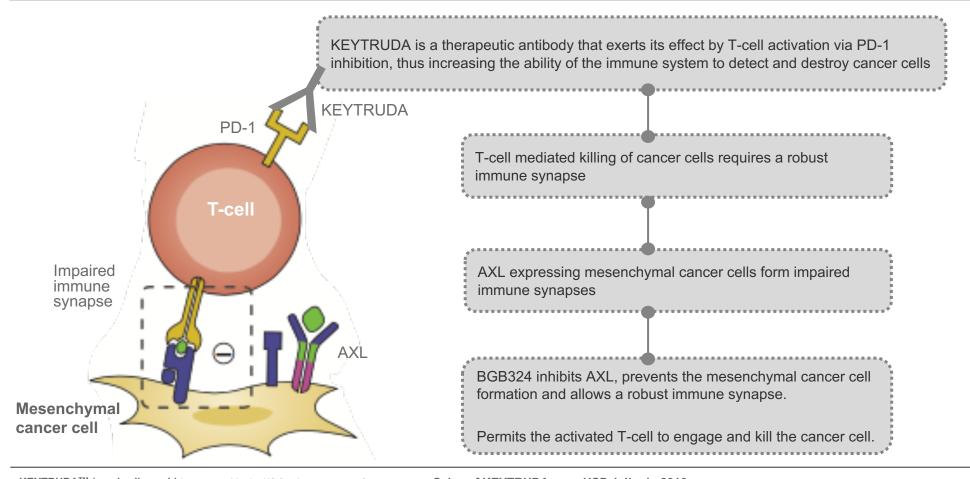
AGGRESSIVE TUMOUR

Y TCR	PAMP	Y AXL	●Gas6
*TLR	PDL-1	₩ AVE	Antigen
₩ PD-1	MHC-I	⊕ Strong/	Lytic
Activating receptor	Stimulatory ligand		granules

Phase II studies of BGB324 in combination with KEYTRUDATM



The ONLY combination study with KEYTRUDA addressing the <u>fundamental</u> mechanism of cancer cell resistance to CPIs



KEYTRUDA™ (pembrolizumab) is approved in the US for the treatment of:

- First-line treatment of metastatic NSCLC high PD-L1 expression
- PDL-1 positive Metastatic NSCLC Unresectable / metastatic melanoma
- Recurrent / metastatic HNSCC
- Microsatellite instability-high (MSI-H) or a mismatch repair deficient (dMMR) solid tumours

Sales of KEYTRUDA were USD 1.4bn in 2016

Merck collaboration studies – BGB324 in combination with KEYTRUDA

BGBC007 Phase II – Triple negative breast cancer

Patient population

- Previously treated unresectable or metastatic triple negative breast cancer
- Measurable disease
- Fresh tissue biopsy

Parameters

28 patients (up to 56)

 Continuous treatment with BGB324 in combination with KEYTRUDA

Biomarker:

- Tissue sample and blood based biomarker collection and processing
- Assay development and qualification
- PD-L1 assay to be performed by Merck

Read out (exp. 2H 2018)

1º Endpoint:

Objective response rate

2º Endpoint:

- Safety
- Duration of response
- Time to progression
- Survival at 12 months
- Response by biomarker expression

Status

- Protocol approved in US, UK & Norway (under review in Spain)
- Patient recruitment ongoing at active sites

BGBC008 Phase II - Adenocarcinoma of the lung

Patient population

- Previously treated unresectable adenocarcinoma of the lung
- Measurable disease
- Fresh tissue biopsy

Parameters

22 patients (up to 48)

Continuous treatment with BGB324 in combination with KEYTRUDA

Biomarker:

- Tissue sample and blood based biomarker collection and processing
- Assay development and qualification
- PD-L1 assay to be performed by Merck

Read out (exp. 2H 2018)

1º Endpoint:

Objective response rate

2º Endpoint:

- Safety
- Duration of response
- Progression free survival
- Survival at 12 months
- Response by biomarker expression

Status

- Protocol approved in US, UK, Norway & Spain
- Site startup ongoing
- First patient dosing imminent

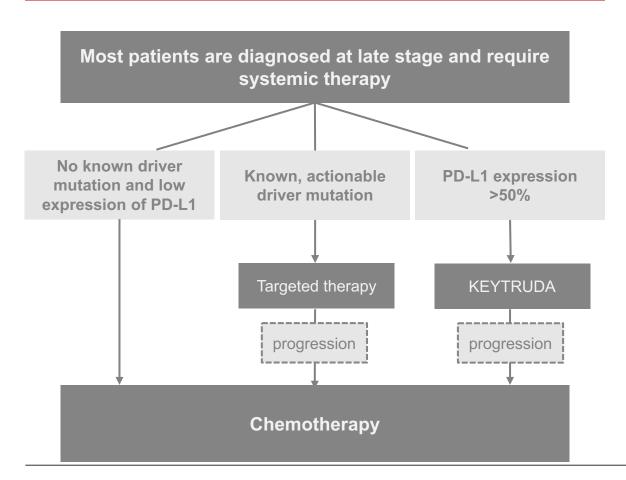


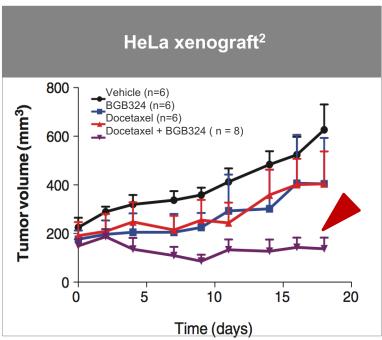
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Rationale for combining BGB324 and docetaxel in NSCLC patients

Chemotherapy still is an important part of the treatment landscape for advanced NSCLC¹

BGB324 enhances the effect of chemotherapy in animal models



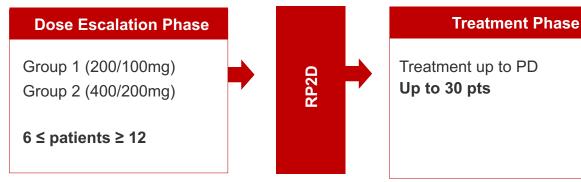


BGB324 + docetaxel is a potential new treatment regime for patients in first and second line setting

(1) As per ASCO guidelines 2017 (2) Wilson et al. Cancer Res (2014) (2) Wilson et al. Cancer Res (2014)

Investigator-sponsored study: Phase I/II trial in NSCLC of BGB324 with docetaxel

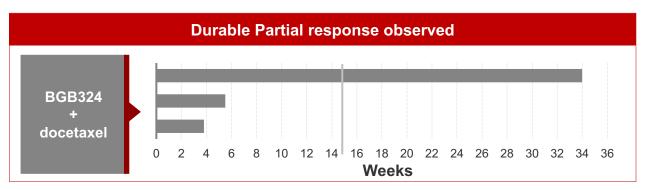
Patient population Patients with previously treated advanced non-small cell lung cancer (NSCLC) – have exhausted all treatment



Overview

options

- One patient on treatment for 13 cycles
- 1 partial response (Recist 1.1)





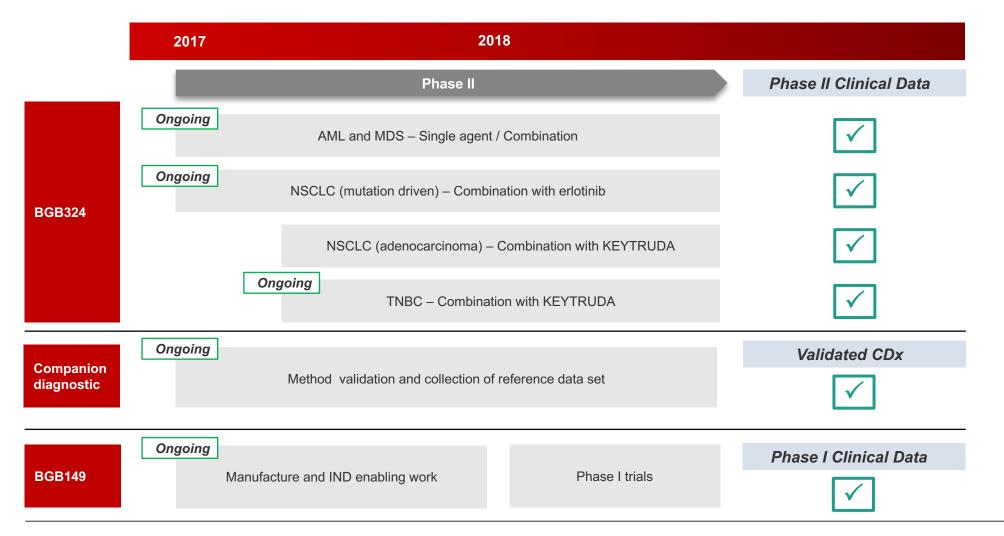
Sponsor Investigator: Dr David Gerber, UTSW Dallas

'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."

UTSouthwestern Medical Center

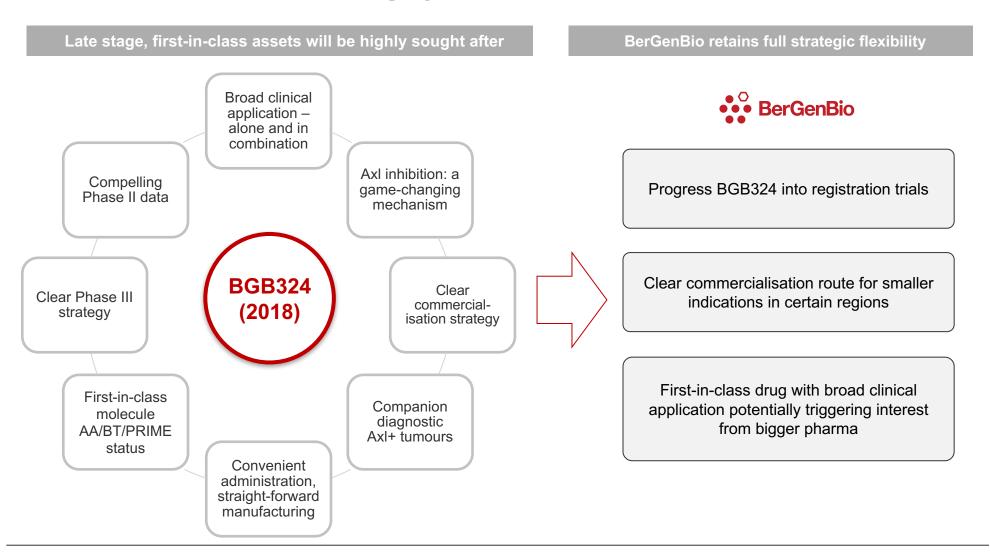
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Summary of BerGenBio's clinical development plan to deliver Phase II data in high-value indications by end 2018



IND: Investigational New Drug - required prior to initiation of clinical trials in the USA

BGB324 – Set to become a highly attractive and valuable asset



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Successful IPO and broadened shareholder base

IPO and listing on OSE

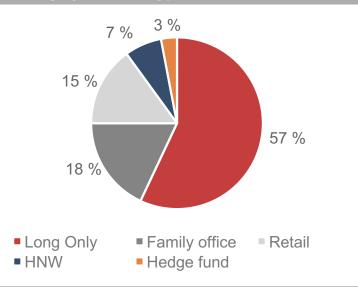
- Completed 7 April 2017, ticker BGBIO
- Raised NOK 400 million in gross proceeds
- New and existing investors participated (approximately 2,000 shareholders)



Share facts *

Currency	NOK
Market	Oslo (NOK)
ISIN code	NO0010650013
Ticker code	BGBIO
Industry	Biotechnology
Market Capitalization	NOK 1.1 bn
Number of Shares	49,757,200
Number of shareholders	1,954

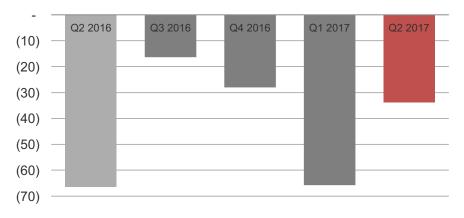
Shareholding by investor type in IPO

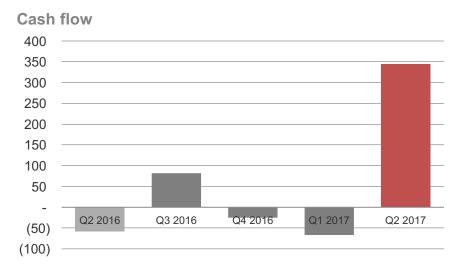


Key financials Q2 and 1H 2017

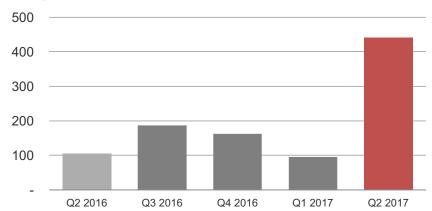
(NOK million)	Q2 '17	Q2 '16	YTD '17	YTD '16	FY '16
Operating revenues	-	-	-	-	-
Operating expenses	33.8	66.5	99.6	87.2	131.6
Operating profit (loss)	(33.8)	(66.5)	(99.6)	(87.2)	(131.6)
Profit (loss) after tax	(34.1)	(66.2)	(99.1)	(86.5)	(129.8)
Basic and diluted earnings (loss) per share (NOK)	(0.70)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

Operating loss





Cash position



- Operating expenses in Q1 2017 impacted by NOK 27.8 million (USD 3.3 million) Phase II milestone payment to Rigel Pharmaceuticals Inc, and Q2 2016 impacted by the first instalment of the Phase II milestone
- Net proceeds from the IPO approximately NOK 375 million received in April

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Key progress and future milestones

Lung cancer (NSCLC) study with BGB324 in combination with TARCEVA opened (first and second line cohorts)	V
IPO – NOK 400m to fund BGB324 Phase II clinical programme, AxI CDx and BGB149 into the clinic	✓
Data presentations at AACR and ASCO	V
Investigator-sponsored Phase II trial opened, first NSCLC patients dosed with BGB324 in combination with docetaxel	✓
Investigator-sponsored Phase II trial opened, first melanoma patients dosed with BGB324 in combination with KEYTRUDA or targeted therapy	V
Phase II initiated in TNBC study with BGB324 in combination with KEYTRUDA - Sites active and patient recruitment ongoing	✓
Phase II initiated in NSCLC study with BGB324 in combination with KEYTRUDA - First patient dosed	2H 2017
Presentation of interim data from Phase II study of BGB324 in AML/MDS	2H 2017
Presentation of Interim data from Phase II study of BGB324 in EGFR+ NSCLC	2H 2017
Initiation of Phase I for BGB149	2H 2018
Phase II Clinical proof-of-concept data from BGB324 studies	
- AML/MDS – single agent/combination	
- NSCLC (EGFR+) – combination with TARCEVA	2H 2018
- NSCLC (adenocarcinoma) – combination with KEYTRUDA	
- TNBC – combination with KEYTRUDA	

Summary and outlook

- First-in-class drugs targeting aggressive cancers with large unmet need
- Universal mechanism of action confers broad clinical potential across many tumour types
- \$11bn addressable market from ongoing sponsored studies

Multiple Phase II programmes with BGB324 in significant cancer indications are open and recruiting

• Recent IPO provides funding for clinical and pipeline development through high-value inflection points

- Clear strategy to develop and commercialise assets
 - High value, first-in-class drug candidates are attractive targets for partnering and M&A
 - Go-to market possibilities in enriched patient populations
 - High visibility with strong news flow and multiple value driving inflection points though 2018



Thank you.

For further information please visit www.bergenbio.com

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

Glossary

AA	Accelerated approval	FDA	US Food and Drug Administration
ADC	Antibody drug conjugate	GLP	Good Laboratory Practice
ALK	Alkaline phosphatase	IHC	Immunohistochemistry
AML	Acute myeloid leukemia	mAb	Monoclonal antibody
BLA	Biologic license application	MDS	Myeloid dysplastic syndrome
ВТ	Breakthrough therapy	NDA	New drug application
CAB	Clinical advisory board	NSCLC	Non-small cell lung cancer
CBR	Clinical benefit rate	pAxl	Phosphorylated AxI (activated AxI)
CDx	Companion diagnostic	PD	Progressive disease
CLIA	Clinical Laboratory Improvement Amendments	PR	Partial response
CLL	Chronic lymphocytic leukemia	RCC	Renal carcinoma
CPI	Checkpoint inhibitor	RP2D	Recommended Phase II Dose
CR	Complete response	RTK	Receptor tyrosine kinase
CTL	Cytotoxic T-lymphocytes	TAM	Tyro, Axl, Mer (family of kinases)
ECG	Electrocardiogram	TNBC	Triple negative breast cancer
EGFR	Epidermal growth factor receptor	sAxI	Soluble AxI
ELISA	Enzyme-linked immunosorbent assay	SD	Stable disease
EMT	Epithelial-to-mesenchymal transition	SoC	Standard of Care
EU5	France, Germany, Italy, Spain, United Kingdom	QTcF	QT inverval, a measure of time in the heart's electrical cycle