BerGenBio ASA

Biotech Showcase

8th January 2019

BerGenBio

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$BGBIO - Investment Highlights

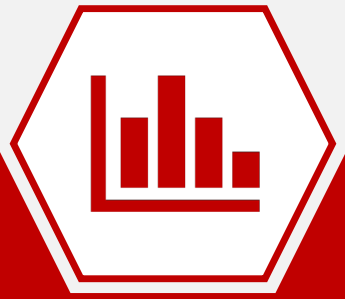
Clinical portfolio of first-in-class AXL therapeutics

Leaders in developing selective AXL inhibitors

Two clinical assets: bemcentinib (Ph2), AXL-antibody BGB149 (Ph1)

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

Pipeline opportunities in multiple cancers and fibrosis



Ph2 data in NSCLC & AML with selective AXL inhibitor bemcentinib

Monotherapy and combinations with immune-, targeted and chemotherapies

Biomarker correlation across programme, parallel CDx development

AXL positive patients:
40% ORR in 2L NSCLC (KEYTRUDA combo)
43% ORR in R/R AML/MDS (monotherapy)

Randomised programme to start H2 2019

Resourced to deliver significant milestones

Clinical trial collaborations with Merck and leading academic centres

AXL ADC out licensed to ADC Therapeutics SA

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

Cash (USD50m, Sep 30 '18) to milestones: Ph2 bemcentinib, Ph1 BGB149

Experienced management team with international experience

RICHARD GODFREY
MRPharmS, MBA
Chief Executive Officer

Lilly · aenova · Catalent · Reckitt Benckiser · DCC

ALAN BARGE, MD
MD
Chief Medical Officer (interim)

AstraZeneca · AMGEN · Carrick therapeutics · ASLAN PHARMACEUTICALS

RUNE SKEIE
Chief Financial Officer

EY Building a better working world · REMA

ANTHONY BROWN
PHD, MBA
Chief Scientific Officer

British Biotech · (osi) pharmaceuticals · Piramed Limited, acquired by Roche · CANCER RESEARCH UK · CellCentric unlocking epigenetics

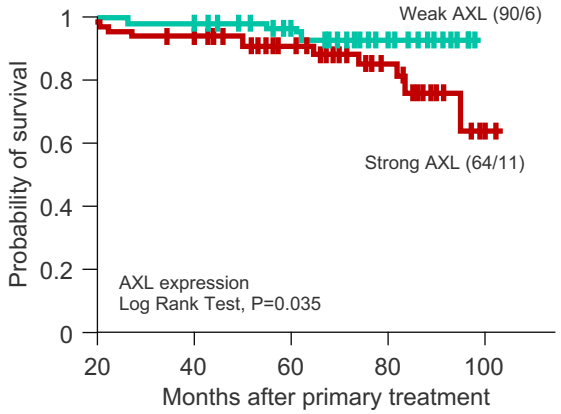
PROF JAMES LORENS
PHD
Co-founder, senior scientific advisor

rigel · Stanford University · UNIVERSITY OF BERGEN

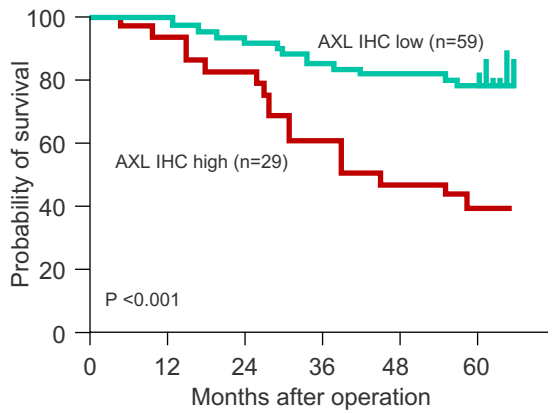
AXL is independent negative prognostic factor in most cancers

Strong AXL expression correlates with poor survival rate

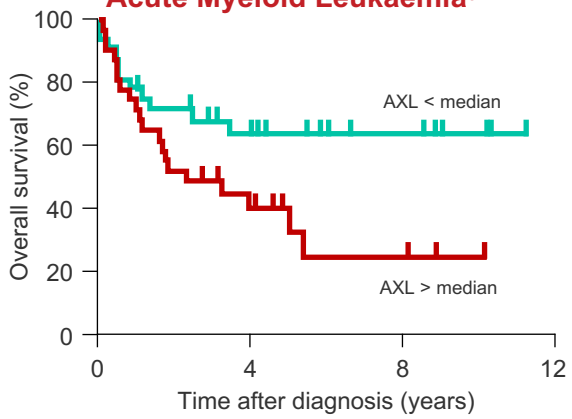
Breast carcinoma[1]



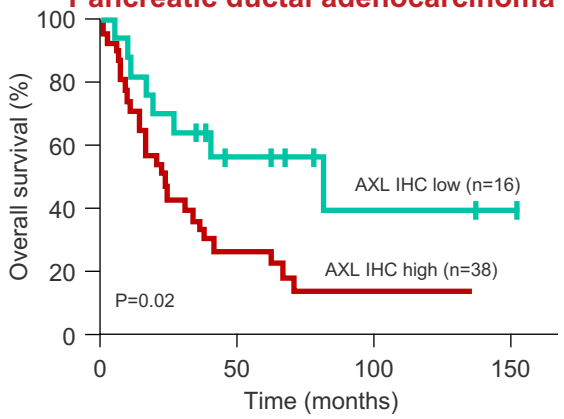
Lung adenocarcinoma (NSCLC)[2]



Acute Myeloid Leukaemia[3]



Pancreatic ductal adenocarcinoma[4]

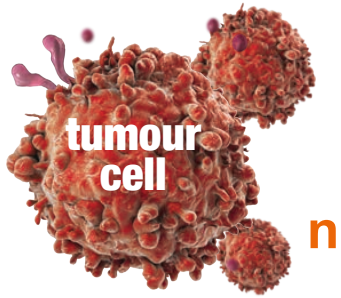


Broad evidence of AXL linked with poor prognosis[5]

Astrocytic brain tumours	Melanoma
Breast cancer	Mesothelioma
Gallbladder cancer	NSCLC
GI	Pancreatic cancer
• Colon cancer	Sarcomas
• Oesophageal cancer	• Ewing Sarcoma
• Gastric cancer	• Kaposis sarcoma
Gynaecological	• Liposarcoma
• Ovarian cancer	• Osteosarcoma
• Uterine cancer	Skin SCC
HCC	Thyroid cancer
HNC	Urological
Haematological	• Bladder cancer
• AML	• Prostate cancer
• CLL	• RCC
• CML	

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

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

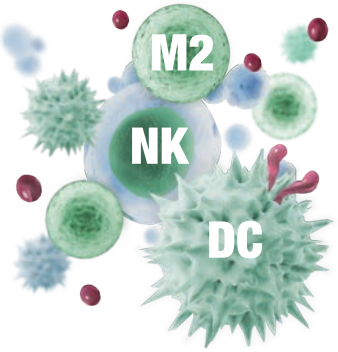


Drives tumour cell plasticity: non-genetic resistance mechanism

AXL drives features of aggressive cancer:

- Acquired therapy resistance
- Immune escape
- Metastasis

Key suppressor of innate immune response



AXL is an innate immune checkpoint:

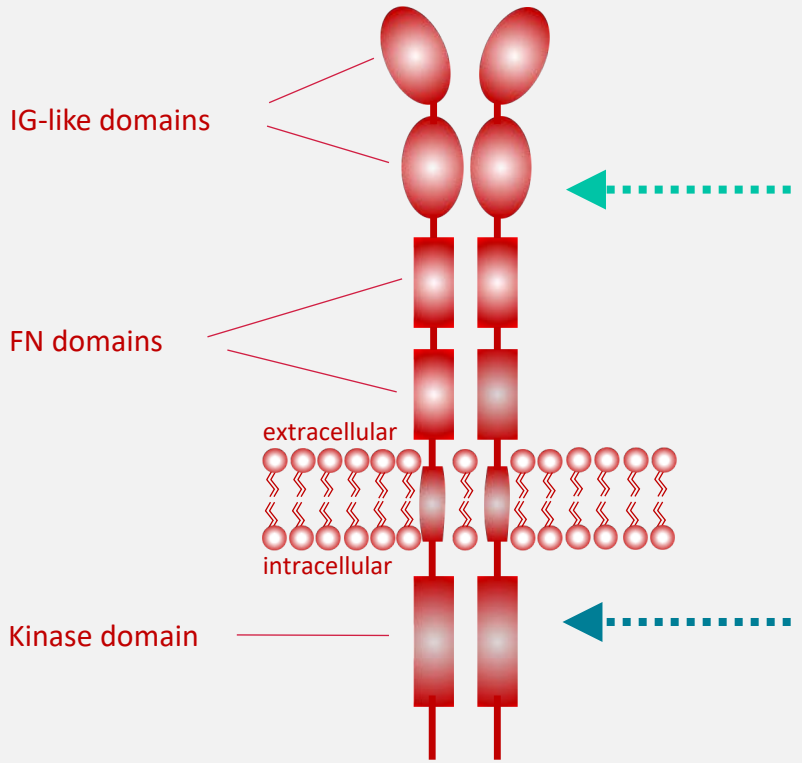
- M1 to M2 macrophage polarisation
- Decreased antigen presentation by DCs
- Immunosuppressive cytokine profile

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**

Two first-in-class selective AXL inhibitors



BGB149

- AXL function blocking antibody
- Highly selective to human AXL
- Robust, scalable manufacturing process

Bemcentinib (BGB324)

- Orally bioavailable small molecule TKI
- Highly selective for AXL
- Straight forward CMC

Clinical development programmes of AXL inhibitors

> 350 patients at 50 sites across Europe and US

	Preclinical	Phase I	Phase II	Phase III	Status
Selective AXL kinase inhibitors					
Bemcentinib: selective oral small molecule AXL inhibitor					
NSCLC + KEYTRUDA (2L, IO naïve)		previously treated advanced adenocarcinoma of the lung		MERCK (1)	Stage 1 complete, 40% ORR in AXL+; stage 2 ongoing
NSCLC + TARCEVA (1L & 2L)		advanced NSCLC with activating mutation of EGFR			Fully recruited, 1st efficacy endpoint met
NSCLC + docetaxel (later line) (2)		previously treated advanced NSCLC			IIT, ongoing – latest update WCLC 2018
AML single agent + low dose chemo (1L & 2L)		AML or previously treated MDS unfit for intensive chemo			Ph1b complete, 43% ORR in AXL+ R/R AML/MDS; Ph2 ongoing
IIT programme in additional oncology indications (2)		Melanoma, mesothelioma, pancreatic, glioblastoma, MDS			IIT, ongoing & in set-up
Fibrosis - *preclinical*		IPF, NASH			Pre-clinical work published throughout 2018
BGB149: anti-AXL mAb					
Healthy volunteers – phase 1a dose escalation		Healthy volunteer SAD			
BGB601: AXL ADC *outlicensed*					
Metastatic cancers		Pre-IND (ADC THERAPEUTICS)			
Companion Diagnostics Pipeline	**Biomarker Discovery**	**Biomarker Verification**		**Validation**	
Tissue AXL **Soluble AXL** **Additional soluble markers**		Correlation with benefit from monotherapy, combo with targeted and immunotherapy			**Correlation with efficacy reported**

(1): Clinical trial collaboration, no preferential rights (2) Investigator initiated trial (IIT)

Near term goals

Bemcentinib – selective AXL inhibitor

Complete PoC phase IIa programme in NSCLC & AML/MDS	H1 2019
Start randomised potentially pivotal programme	H2 2019
Complete randomised potentially pivotal programme	H2 2020

BGB149 – AXL function blocking antibody

Complete First-in-Man clinical trial	H1 2019
Advance BGB149 into disease indications	H2 2019

Clinical data in 2018 & 2019

2019

ASCO*
NSCLC: Bem + KEYTRUDA
2nd stage ORR
OS 1st stage

EHA*
AML: Bem + low dose chemo
Efficacy
Biomarker update

WCLC*
NSCLC: Bem + KEYTRUDA
2nd stage PFS
First stage survival update

SITC*
Other indications: Bem + KEYTRUDA
IIT programme

ASH*
AML: Bem + low dose chemo
Survival

Q1
- 1L/2L AML chemo combo top line data
- Complete recruitment stage 2 bem + KEYTRUDA (NSCLC)

Q2/Q3
- **Initiate randomised potentially pivotal programme**
- Complete Phase 1 BGB149

Q4
- Initiate first-in-patient trials BGB149

* expected

January | February | March | April | May | June | July | August | September | October | November | December

2018

ASCO-SITC
Lung cancer, TNBC and AML trial update
- ✓ KEYTRUDA combo well tolerated
- ✓ Bemcentinib induces diversification of T-cell receptor repertoire (AML)

AACR
Preclinical Update
Bemcentinib increases efficacy of checkpoint inhibitors

ASCO
NSCLC, AML, Melanoma and biomarker update
Bemcentinib enhances responses to
- ✓ IO,
- ✓ chemo,
- ✓ targeted therapies
- ✓ and has monotherapy efficacy

EHA
AML trial update
Responses to bemcentinib monotherapy correlated with AXL biomarker

WCLC
Lung cancer trials update
- ✓ 40% ORR in AXL+ pts in combo w/ KEYTRUDA
- ✓ Improved PFS in combo with erlotinib and chemo

ESMO
Biomarker update
- ✓ AXL biomarkers identified
- ✓ Melanoma clinical update
- ✓ AXL's role in low-risk MDS (pre-clinical)

SITC
NSCLC data late breaking
Late-breaking abstract: 5.9m PFS in AXL+ previously treated NSCL in combo w/ KEYTRUDA (c80% improvement in AXL+ pts vs AXL-)

ASH
AML trial data update
43% CR/Cri/CRp rate in AXL biomarker positive pts

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

Bemcentinib:
First-in-class highly selective AXL inhibitor in Phase II

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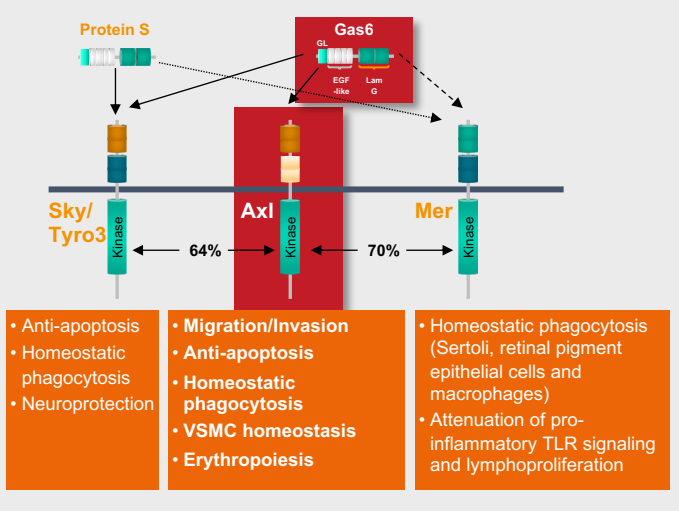
Bemcentinib: uniquely selective for AXL, excellent clinical safety profile

AXL is the only TAM member that drives aggressive cancer

- TAM family members Tyro and Mer have homeostatic roles[1]
- TAM kinase domains are highly homologous
- TAM ligands promiscuous

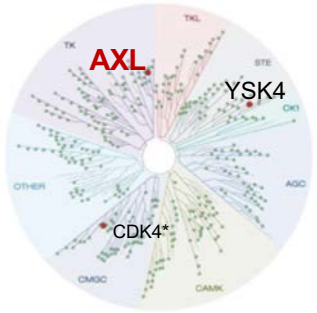


Bemcentinib was discovered by cell-based counterscreen and as a result is highly selective for AXL

- Bemcentinib is highly potent and selective, particularly over other TAM receptors
- Not spectrum-selective: no activity against Met, Flt3, Ron

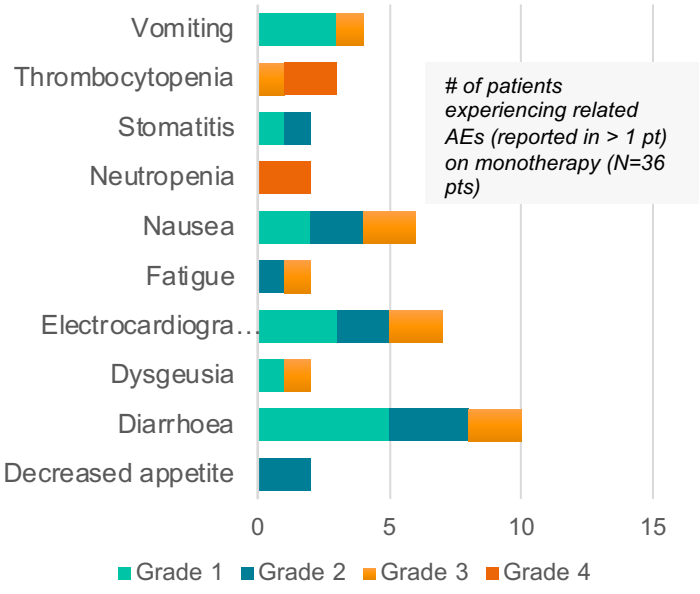
Cell based selectivity assay: EC50 (μM)[2]		
	AXL	0.014
	Mer	49.49
	Tyro	>160

KinomeScan at 4nM bemcentinib (biochemical selectivity assay)



Bemcentinib has excellent clinical safety profile

- Combo did not lead to new findings
- HV SAD study: 50mg – 1.5g, MTD not reached



(1) Mer -/-, Tyro -/- or TAM -/- mice exhibit broad spectrum autoimmune diseases, defective NK cell differentiation, impaired erythropoiesis, male sterility, blindness and seizures. AXL -/- mice are phenotypically normal. (2) Independently verified: Kimani, *Cell Communication and Signaling* 2016 *The observed CDK4 inhibition was not dose dependent and is thus not believed to be a real effect

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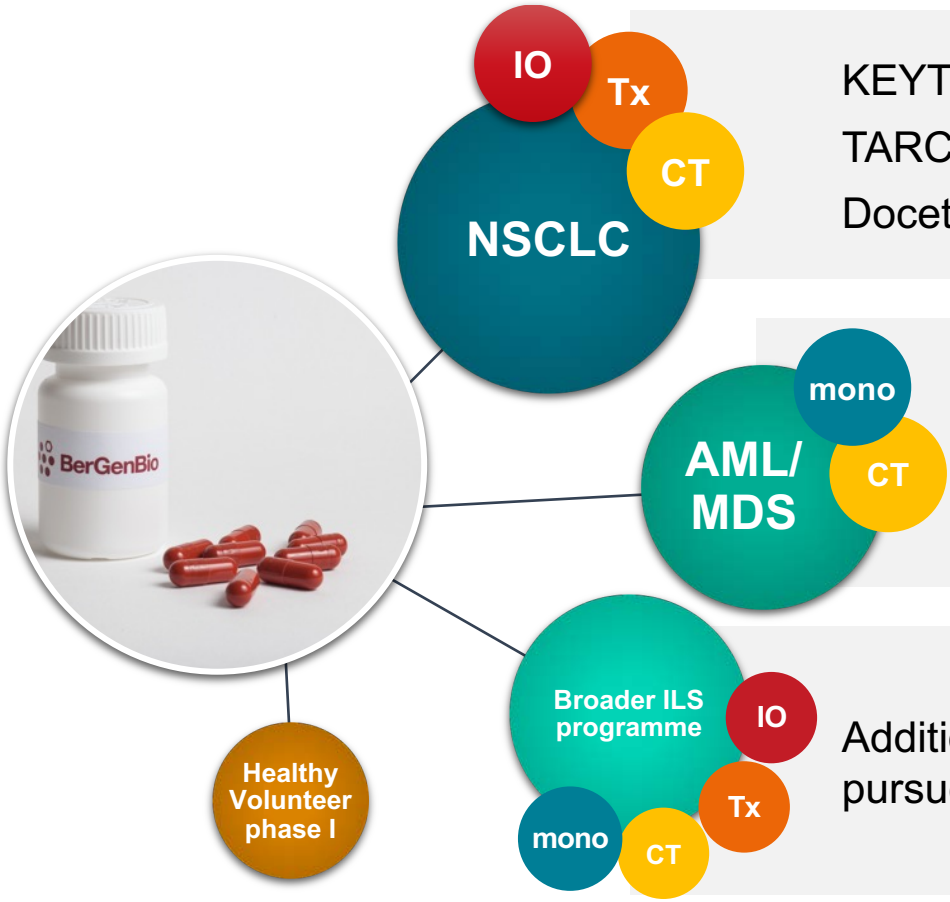
Phase II PoC data
- Focus on NSCLC & leukaemia



KEYTRUDA combo (2L): **40% ORR and ca. 6m median PFS in AXL+ disease**

TARCEVA combo (1L): **Extended PFS**

Docetaxel combo (later line): **Clinical benefit in 8/11 pts, incl. 2 PRs**

Monotherapy (2L): **43% ORR in AXL+ patients**

Additional indications with strong rationale and KOL endorsement are being pursued through active support of broad ILS programme

Bemcentinib PoC data summary: Monotherapy and combinations

Associate Professor Dr David Gerber, UTSW Dallas, TC, lead PI BGBIL005

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Source: Loges *et al* ASH 2018; Byers *et al* ENA 2016 and WCLC 2018

Monotherapy efficacy with biomarker correlation

Relapsed / refractory AML & MDS, unfit for intensive chemo (BGBC003)

All comers

Daily bemcentinib single agent

Dose escalation ASH 2018

N = 27*

(complete)

Expansion

N = up to 14 each

IIT

N = up to 43

(ongoing)

	Overall (n=27)		sAXL low (n=14)		sAXL high (n=11)	
	n	%	n	%	n	%
CR/CRi/CRp	6	22%	6	43%	0	0%
SD	8	30%	3	21%	5	45%
PD*	13	48%	5	36%	6	55%
ORR	**6**	**22%**	**6**	**43%**	**0**	**0%**

Median age of all patients: 74.5
Responses included poor risk and secondary disease
mDoR = 3.4 months

43% ORR in patients with +sAXL biomarker

Later line NSCLC, EGFR wt and mutant (BGBC004, trial complete)

All comers

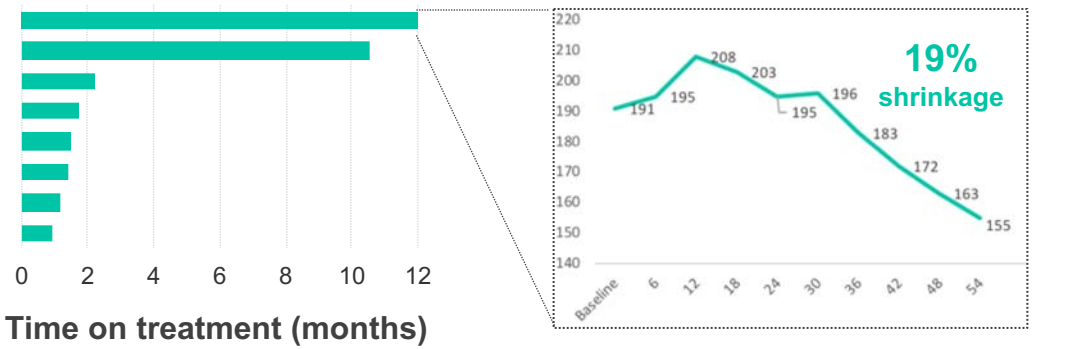
Daily bemcentinib single agent

Phase I ENA 2016

N = 8

(complete)

RP2D confirmed for combination studies



25% DCR for ca 1 year, including 1 minor response

*27 evaluable pts: Patients who had completed at least one cycle of treatment and who had been relapsed or refractory to previous treatment. sAXL status was available for 25 of 27 evaluable patients.

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Source: Krebs *et al* SITC 2018; Schuster *et al* ESMO 2018

KEYTRUDA efficacy increased in combination and correlated with tumour AXL

Advanced NSCLC, 1 prior line of Pt, IO-naïve (BGBC008)

All comers

Bemcentinib 200 mg daily + 200 mg **KEYTRUDA** q3w

Stage 1 SITC 2018

N = 24*

(complete)

≥4 PR

Stage 2 ASCO 2019

N = 48 total

(ongoing)

Biomarker at screen	AXL pos	AXL neg
ORR	40%	9%
CBR	70%	45%
mPFS	5.9 months	3.3 months

40% ORR and 5.9 mth mPFS in AXL+ patients

Newly diagnosed advanced melanoma (BGBIL006)

BRAFwt / BRAFm w/ low tumour burden

Bemcentinib 200 mg daily + 200 mg **KEYTRUDA** q3w

R

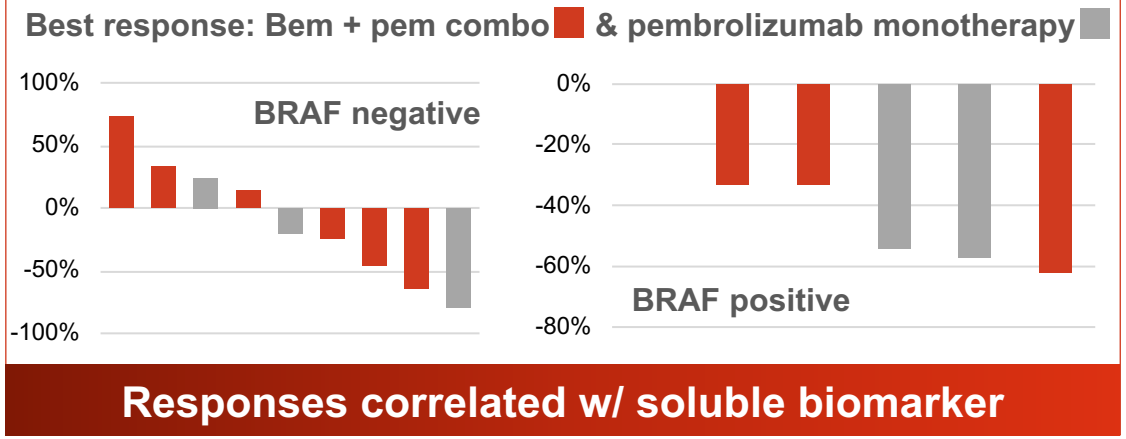
Bemcentinib + KEYTRUDA

KEYTRUDA

Phase II ESMO 2018

N = ca 40

(ongoing)



Responses correlated w/ soluble biomarker

*Intention to treat analysis

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Source: Byers *et al* WCLC 2018; Schuster *et al* ESMO 2018

Prevention and reversal of resistance to targeted therapy

Advanced NSCLC, first and second line (BGBC004, trial complete)

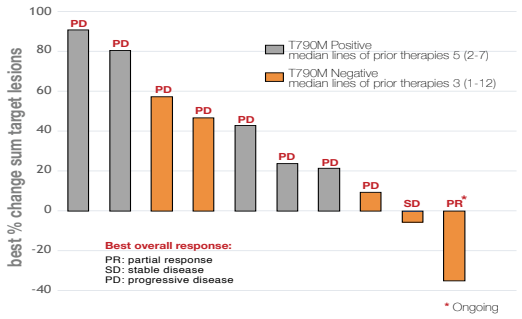
All comers

Bemcentinib 200 mg daily + 150 mg **TARCEVA** daily

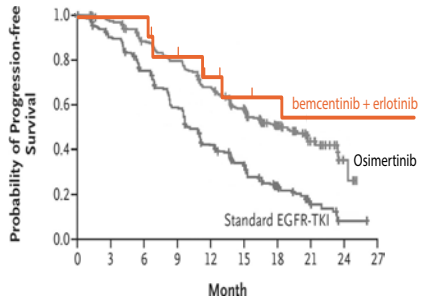
Arm B: reversal of resistance to TARCEVA
WCLC 2018
N = 14

Arm C: prevention of resistance to TARCEVA
N = 14

resistance reversal in T790 neg pts



1L combo, PFS extended



Extended PFS in 1L, 40% CBR in 2L, T790M neg pts

Newly diagnosed advanced melanoma (BGBIL006)

BRAFm w/ high tumour burden

Bemcentinib 200 mg daily + **BRAF/MEKi** daily

R

Bemcentinib + BRAF/MEKi

BRAF/MEKi

Phase II (ongoing) ESMO 2018

N = ca 40 total

Best response: Bem + BRAF/MEKi combo & BRAF/MEKi mono

Responses correlated w/ soluble biomarker

Soluble predictive markers identified

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Source: Gerber *et al* WCLC 2018

Prevention and reversal of resistance to chemotherapy

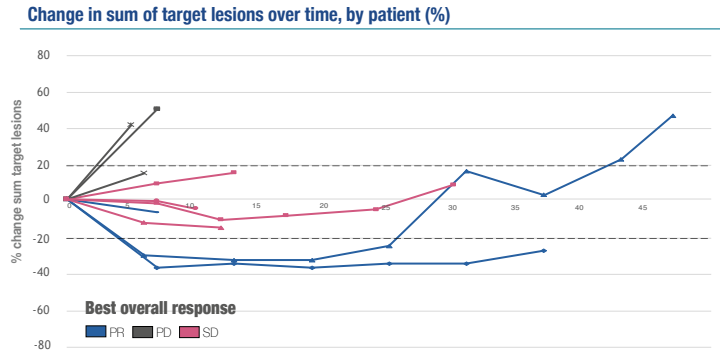
Later line NSCLC, includes CPI failures (BGBIL005)

All comers

Daily bemcentinib + docetaxel q3w
Dose escalation & expansion

Phase I/II (ongoing)
WCLC 2018

N = up to 30



PRs & SDs included patients who previously failed CPI

73% CBR (8 of 11 evaluable pts) incl. 2 PRs, PFS ca 7m

Additional indications to read out in 2019 (BGBC003, IIT programme)

- **AML low dose chemo combo**
- Pancreatic, randomised combo of bemcentinib with gemcitabine, nab-paclitaxel & cisplatin

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Clinical Development opportunities for bemcentinib

Monotherapy opportunities
Selected, biomarker directed, indications

Chemotherapy combos
Improve responses in hard to treat settings

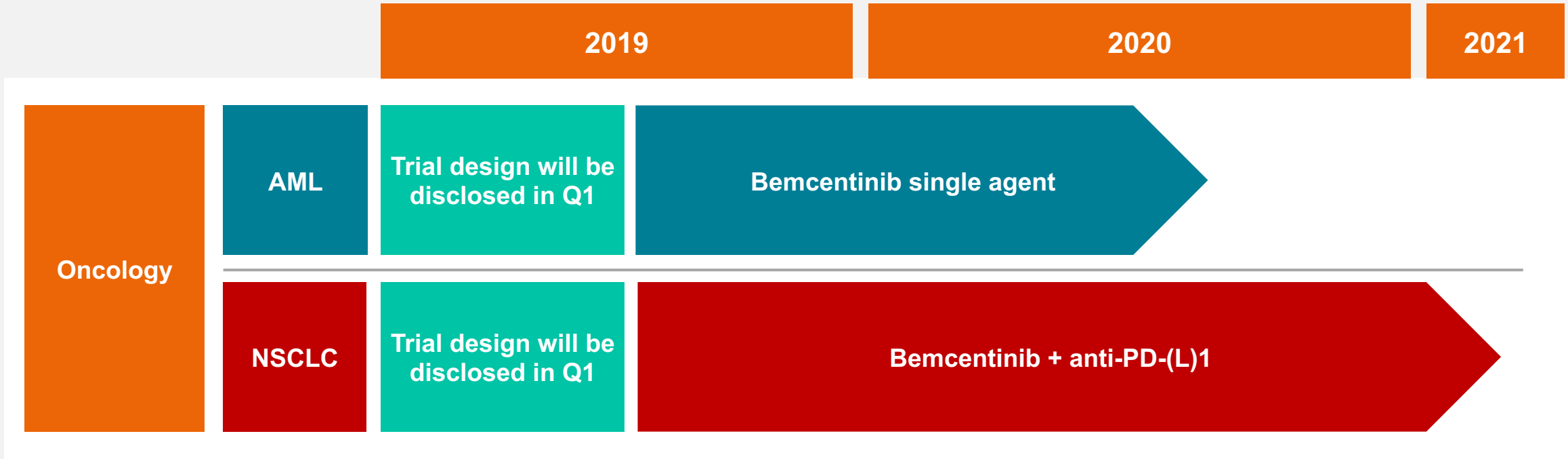
Immunotherapy combos
Target resistance, enlarge addressable pt population

Targeted therapy combos
Target resistance, enlarge addressable pt population

Earlier line opportunities
Radiotherapy and maintenance opportunities

Phase IIa	Phase IIb/III
AML / MDS (complete) → **Glioblastoma** (ongoing, IIT) **EMT signature selected** (potential)	
AML / MDS + LDCT ----------→ Pending read-out, expected in H1 2019 **Pancreatic,** (IIT in set-up) **NSCLC** (ongoing, IIT)	
NSCLC (PD-L1 all comers) → • **IO naïve** (ongoing, stage 1 complete) **Melanoma,** (ongoing, IIT) **Mesothelioma** (IIT in set-up) **Bladder ++, CAR-T combos** (under consideration)	
NSCLC + EGFRi (complete) --------→ **Melanoma,** (ongoing, IIT) **PARPi combos ++** (under consideration)	
Multitude of maintenance opportunities given very favourable safety profile	

Data generated provides strong rationale for randomised, potentially pivotal programme to start in 2019



Bemcentinib: First-in-class highly selective AXL inhibitor in phII

Strong biological rationale: AXL widely recognised as driver of aggressive cancers and innate immune checkpoint

Excellent clinical safety profile: successfully combines with major classes of cancer drugs with no insignificant added tox

Strong biomarker correlation: blood and tissue based predictive and response biomarkers identified across complete clinical programme

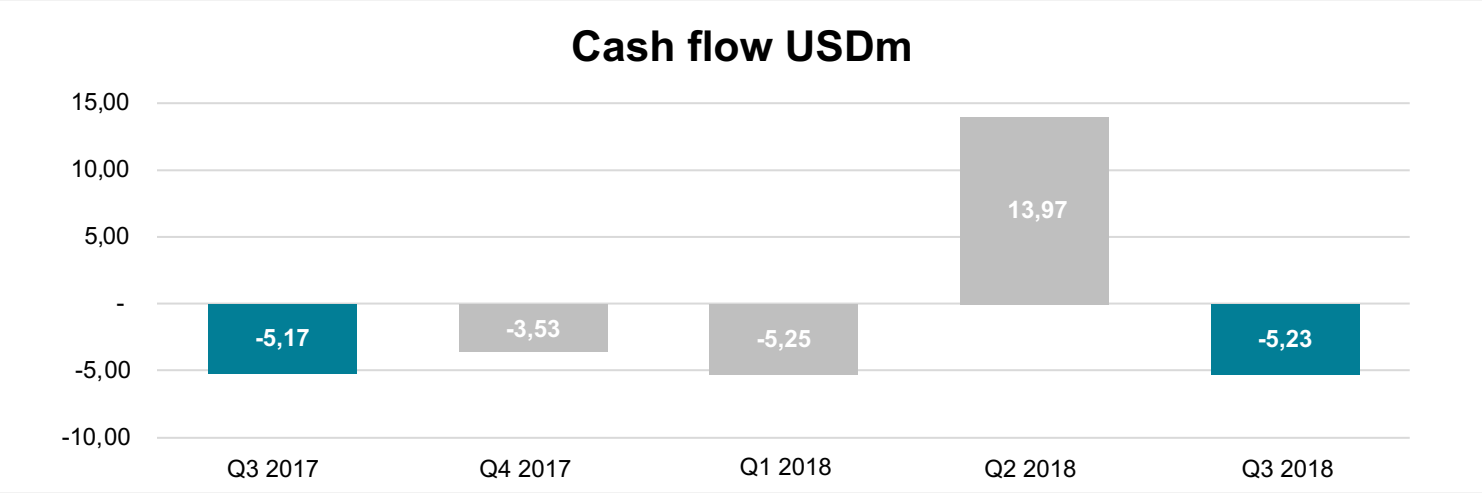
PoC in AML and NSCLC: 43% ORR in AXL+ r/r AML as **monotherapy** and 40% ORR & 6m PFS in AXL+ NSCLC in **combo w/ KEYTRUDA**

Randomised studies with the potential to be pivotal starting 2019

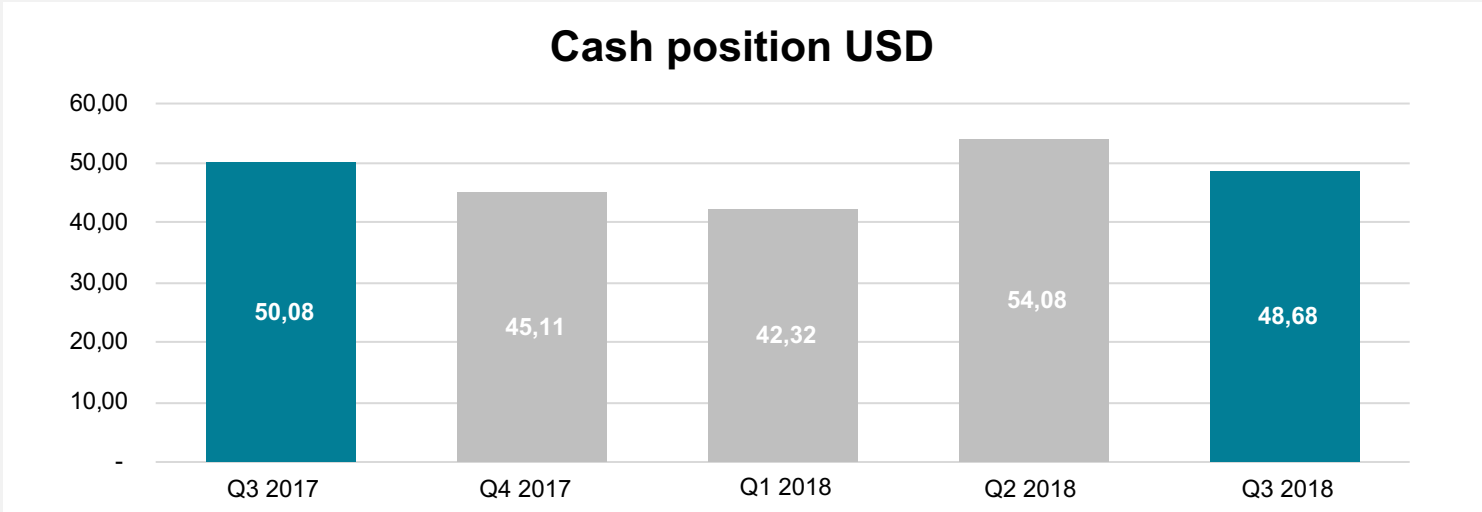
Additional indications: Broad programme of IITs exploring additional oncology indications, strong pre-clinical rationale in fibrosis

Key financial figures

Cash flow and cash position



- Private placement Q2,18 strengthened cash position - gross funds raised USDm 24.0
- Quarterly cash burn average at USDm 5.5



- Cash position gives runway to deliver key clinical read outs from ongoing clinical studies
- Cash runway into 2020 based on current burn rate

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Summary

Two first-in-class highly selective, potent, AXL inhibitors

Bemcentinib Proof-of-concept Phase II clinical data

Bemcentinib clinical development programme to focus on Lung Cancer and Leukaemia

Anticipated cash runway into 2020, with significant milestones in the next 12 months