BerGenBio ASA (OSE:BGBIO)

DnB Nordic-American Life Science Conf.

BerGenBio

29 November 2018

Richard Godfrey, CEO

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Corporate Snapshot

Focussed on AXL

Leaders in developing selective AXL inhibitors: innovative drugs for aggressive diseases, including immune evasive, drug resistant and metastatic 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

Emerging Phase II data with first-in-class asset

Bemcentinib*: First-in-class highly selective oral AXL inhibitor

Developed as potential cornerstone of cancer therapy.

Well funded

Cash runway through to 2020

Included in the OSEBX index from 1st June 2018

Pipeline with significant milestones in 2018/19

Proof of Concept Phase 2 data with bemcentinib

Phase 1 clinical trial with AXL antibody

Experienced Team

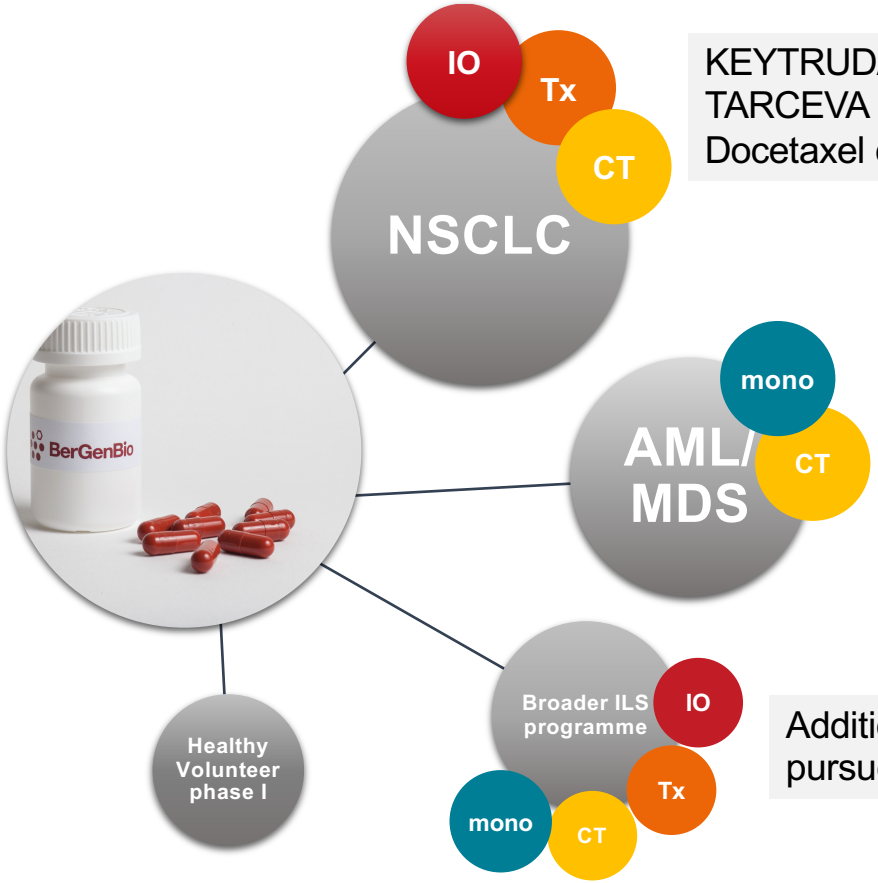
40 staff

Headquarters and research in Bergen, Norway

Clinical Trial Management in Oxford, UK

*formerly referred to as BGB324

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): **>40% ORR in AXL+ patients**

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

Strong biomarker correlation

AXL IHC identifies NSCLC pts with improved outcomes to bemcentinib + KEYTRUDA

Approximately half of previously treated NSCLC patients had AXL positive disease

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

(stage 1, n = 21 pts evaluable for AXL status, of which ca half were AXL positive)

Soluble AXL levels identify R/R AML & MDS pts with improved outcomes to monotherapy

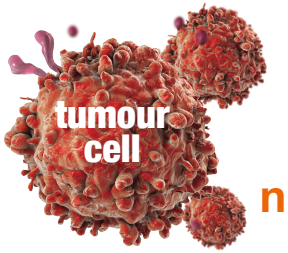
Plasma shed AXL (sAXL) levels are inversely correlated to receptor activity

Biomarker at screen	sAXL low	sAXL high
ORR	46%	0%
CBR	92%	17%

(part A, n = 20 pts evaluable for sAXL status)

Additional predictive soluble and tissue markers identified & under investigation

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

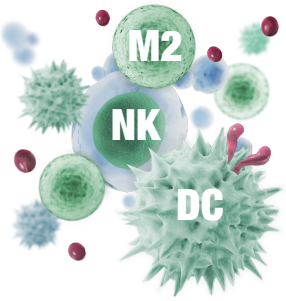


Drives tumour cell plasticity: non-genetic resistance mechanism

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**

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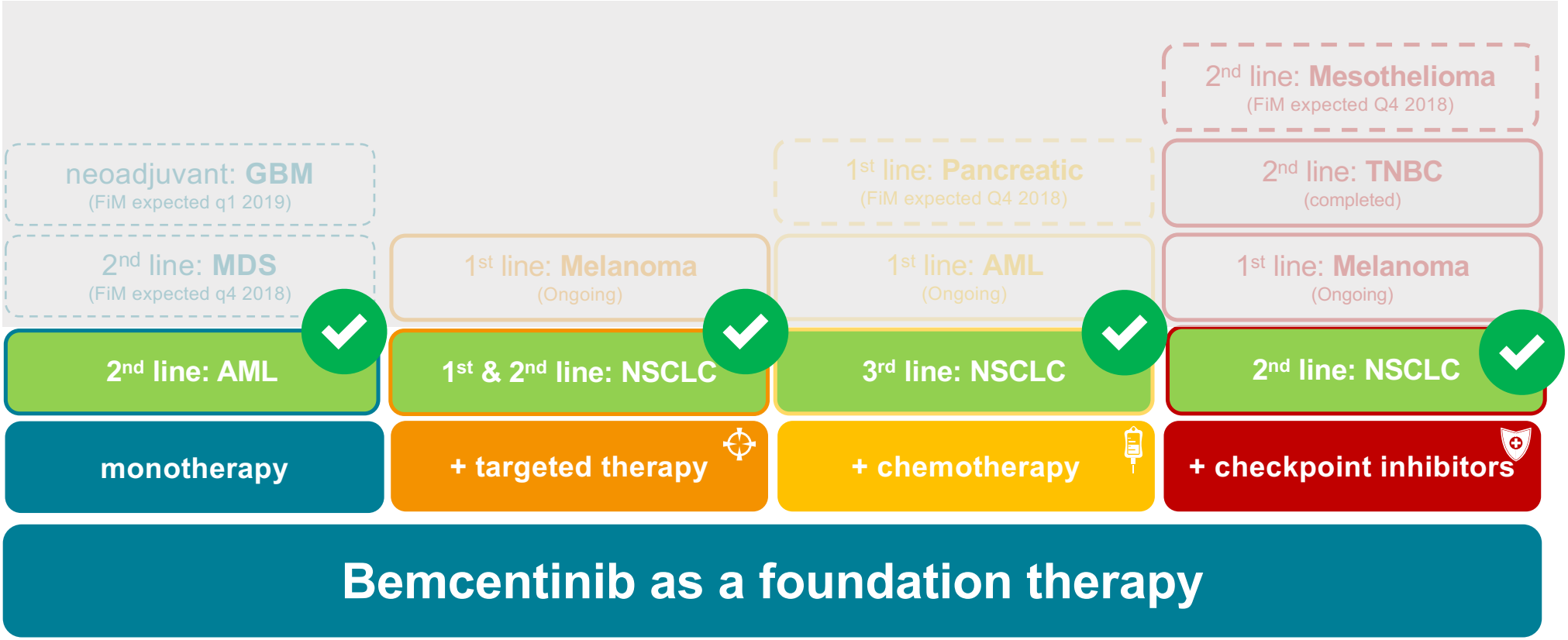
Bemcentinib as cornerstone for cancer therapy: Phase II proof-of-concept development programme



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Q3 2018 results

Efficacy reported in several Phase II trials with bemcentinib

Bemcentinib + KEYTRUDA 2L (BGBC008): Superior PFS & 40% response rate in AXL positive patients

- ✓ Median PFS of 5.9 months reported in AXL positive patients vs 3.3 months in AXL negative (late-breaking abstract at SITC)
- ✓ 40% ORR in AXL positive, predominantly PD-L1 negative/low patients (KEYTRUDA monotherapy effect is limited)
- ✓ Stage 2 is actively recruiting and enrolling patients

Additional advanced NSCLC phII trials: Superior PFS in combo with TARCEVA

- ✓ First line PFS prolonged by adding bemcentinib to TARCEVA, predictive biomarker candidate
- ✓ Encouraging efficacy in combination with docetaxel in later line setting, overall well tolerated

Bemcentinib biomarker programme: Biomarker candidates identified across phase II trial programme

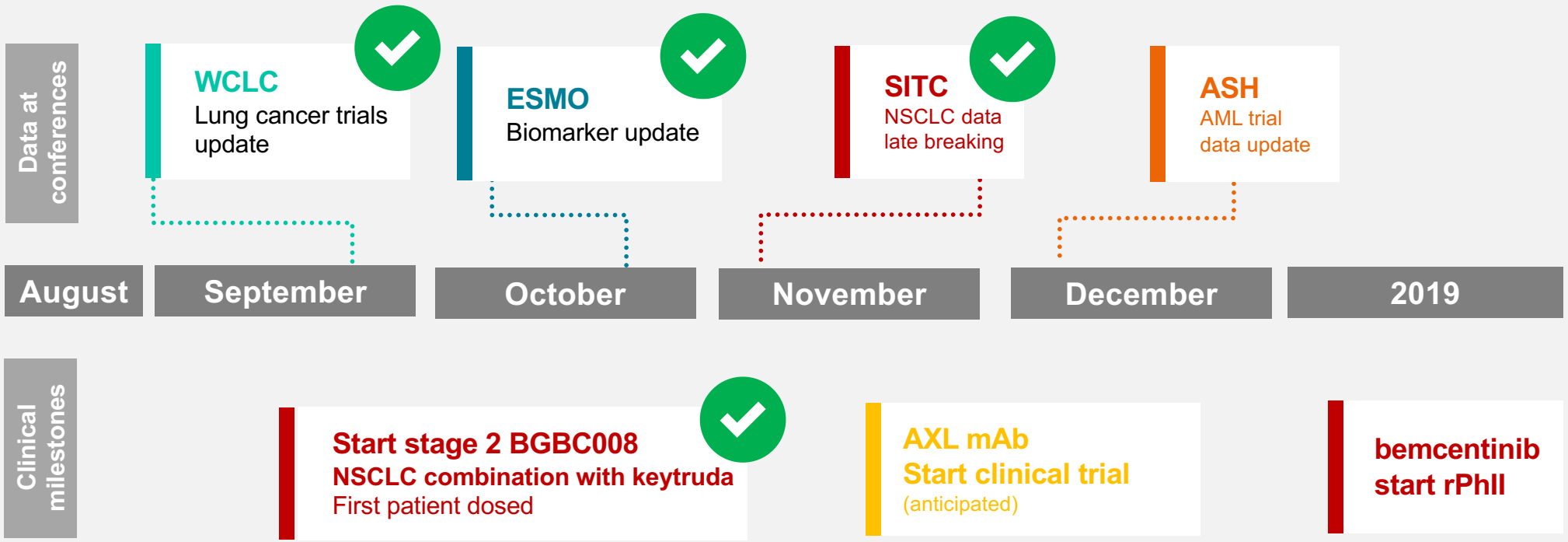
- ✓ Strong correlation with tissue AXL status in NSCLC (bemcentinib + KEYTRUDA)
- ✓ Strong correlation with soluble AXL status in AML/MDS (bemcentinib monotherapy)
- ✓ Additional soluble markers identified across additional indications and drug combinations

Pipeline of innovative AXL inhibitors: AXL function blocking antibody BGB149 on track for FiH trials

- ✓ IND filed, phase I trial to be initiated at the end of Q4

Cash position NOK398m, tight cost control. Cash to complete all ongoing clinical trials.

Upcoming data & clinical milestones



WCLC: World Conference of Lung Cancer, Toronto
ESMO: European Society of Medical Oncology, Munich
SITC: Society for Immunotherapy of Cancer, DC
ASH: American Society for Hematology, San Diego

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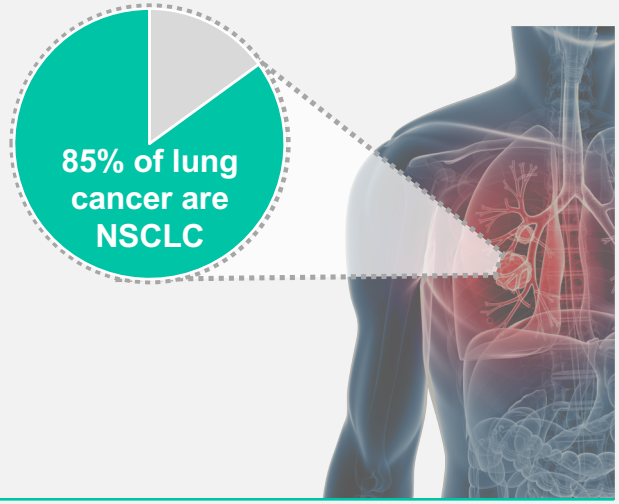
Non-small Cell Lung Cancer (NSCLC)

Bemcentinib is being combined with the major therapy classes to treat advanced NSCLC

Lung Cancer: rapidly evolving standard of care…
- but still lacking effective Chemo free regimens



The largest cancer killer, most patients depend on drug therapy

- **More than 1.76 million lung cancer deaths**/yr worldwide[1]

NSCLC standard of care (SoC)

	No or low PD-L1 expression	High PD-L1 expression	driver mutations*
1L	Anti-PD-1 + chemotherapy	Anti-PD-1	Targeted therapy
2L	Docetaxel increasingly used in 2L - limited by low response rate and high side effects	Pt chemo	Pt chemo

Rapidly emerging SoC creates opportunities for effective, chemo free second line combinations

- **Most patients will start on Anti-PD-1 + chemo in first line**
- **Vacuum in second line,** effective chemo free regimens needed

NSCLC: Non-small cell lung cancer (1) WHO: Globocan 2012 (2) NIH: seer.cancer.gov, accessed August 2018 * driver mutations are known and actionable mutations like EGFR mutations or ALK re-arrangements

POC bemcentinib as cornerstone of treatment for NSCLC by combining with standard of care therapies

- Company anticipates to update the market with proposed rPh2 strategy towards the end of 2018

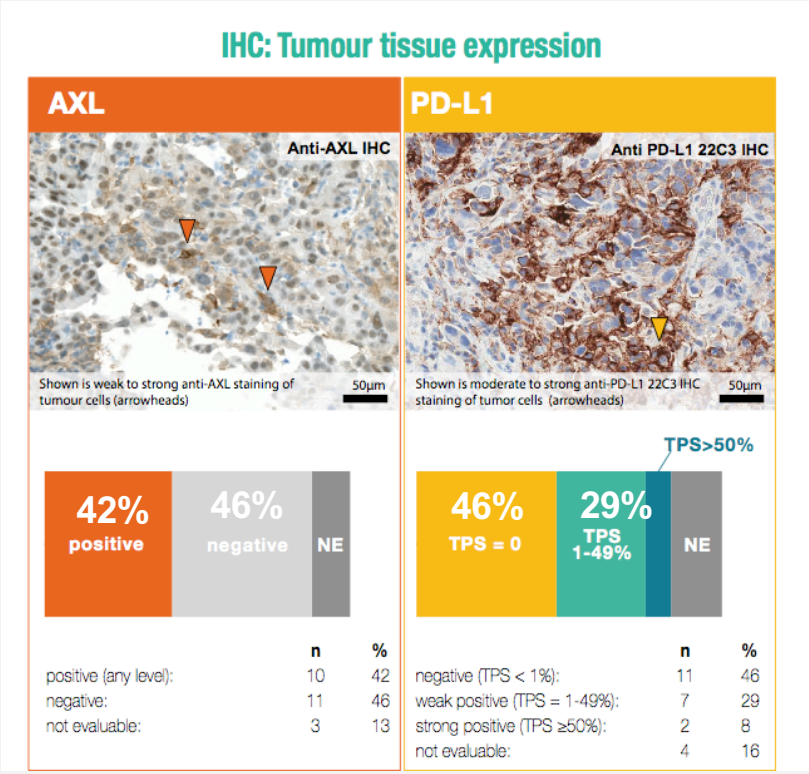
	Targeted therapy	PD-1 blockade	Chemotherapy
Bemcentinib PoC phase II programme			
bemcentinib single arm POC	**BGBC004** Reverse (2L) and prevent resistance (1L) to EGFR targeted therapy (Tx)	**BGBC008** Increase response rate - especially in PD-L1 negative	**BGBIL005** Increase response rate
Strategic considerations for randomised phase II programme based on phase II PoC			
Bemcentinib randomised combos	1L • First line Tx +/- bemcentinib 2L • non-mutation driven resistance to Tx	1L • CT free combo (incl. PD-L1 neg) • Add to Pt CT 2L • Add to IO upon progression	2L • Combo with next generation TKI or Tx at progression

BGBC008: Combination studies with KEYTRUDA

BGBC008 Phase 2 – Adenocarcinoma of the lung

Previously treated, unresectable adenocarcinoma of the lung up to 48 pts any PD-L1 expression any AXL expression no prior IO	**Simon two stage**		**Status Nov 2018**
	Single arm bemcentinib 200mg/d KEYTRUDA 200mg/3w	**ORR**	✓ Stage 1: 24 patients dosed ➢ 1st efficacy endpoint met ➢ 40% ORR in AXL positive patients ➢ 27% ORR in PD-L1 negative patients ➢ Ca. 6 months PFS in AXL positive patients ✓ Stage 2 open and actively recruiting

Biomarker analyses reveal predominantly PD-L1 low/negative patient population, half are AXL positive



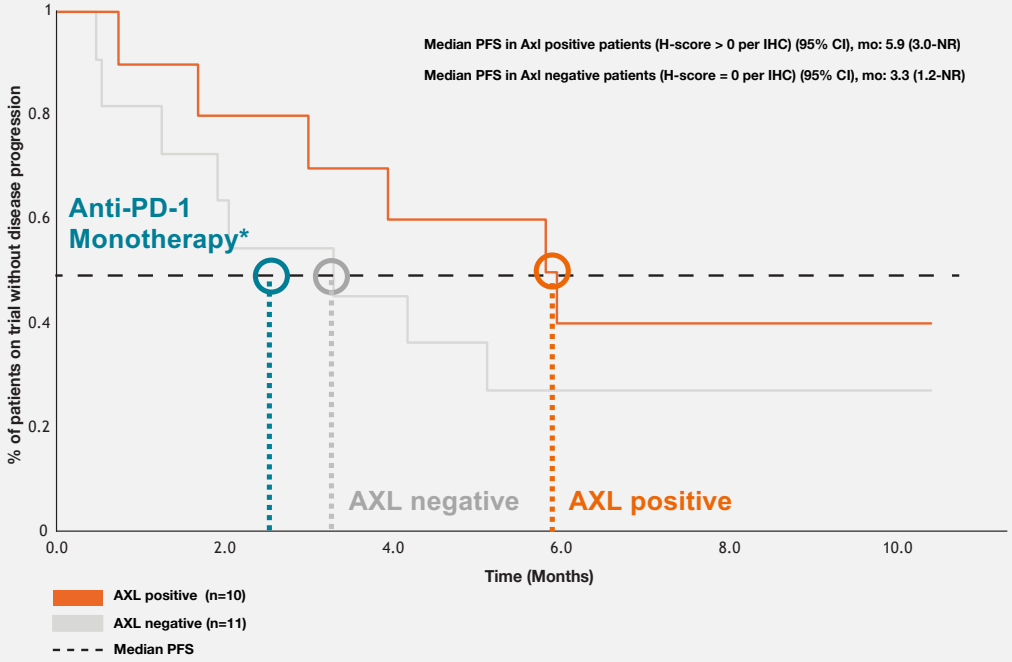
Trial has enrolled

- predominantly **PD-L1 negative and low** positive patients
- in whom **little benefit from anti-PD-1 monotherapy** is expected

Lorens *et al* WCLC 2018

In AXL positive patients, the bemcentinib + KEYTRUDA combination is more efficacious than KEYTRUDA monotherapy*

Progression Free Survival: 5.9 months in AXL positive vs 3.3 in negative patients (ca 80% improvement)



Comparison of bemcentinib combination data (BGBC008) with selected anti-PD-1 monotherapy trial results

Trial	PD-L1 status		ORR (%)	PFS (months)
BGBC008	**Mostly (75% of patients)** 0 – 49%	**AXL+**	**40**	**5.9**
		AXL-	9	3.3
Keynote 001[1]	0 %		9	2.1
	1 – 49 %		14	2.3
CheckMate 057[2]	0 – 100 %		19	2.3

Source: Krebs *et al* SITC 2018 (November 2018); * comparison with historical data (see table) (1) Garon *et al* NEJM 2015 (2) http://www.opdivohcp.com/metastatic-nsclc/efficacy/clinical-trial-results

BGBC004: Phase Ib/II trial in NSCLC of bemcentinib with TARCEVA® (erlotinib)

Stage IIIb or IV disease EGFR mutation positive

Dose escalation & expansion (ongoing)

Phase Ib	**Heavily pre-treated** **Arm A1:** bemcentinib monotherapy **Arm A2:** Dose finding in combination	**Safety & efficacy**
Phase II	**Arm B: 2nd line** *Resistance reversal* **bemcentinib 200mg daily + erlotinib daily**	
Phase II	**Arm C: 1st line** *Resistance prevention* **bemcentinib 200mg daily + erlotinib daily**	

June 2018 Status

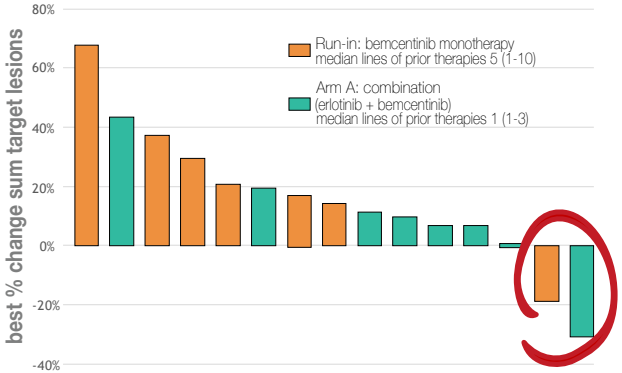
- ✓ **Arm A1 - monotherapy: 25% CBR**
  2 SD including tumour shrinkage (19%) n=8
- ✓ **Arm A2– combination with erlotinib: 50% CBR**
  1 PR and 3 SD n=8. PR ongoing in excess of 2 years
- ✓ **Arm B – 2L / combo w/ erlotinib: 33% CBR**
  First efficacy endpoint met
  1 PR & 2 SD n=9
- ✓ **Arm C – resistance prevention combo w/ erlotinib:**
  PFS has surpassed that of erlotinib (TARCEVA) alone, currently 11.4 months and further maturing

Source: NCT02424617

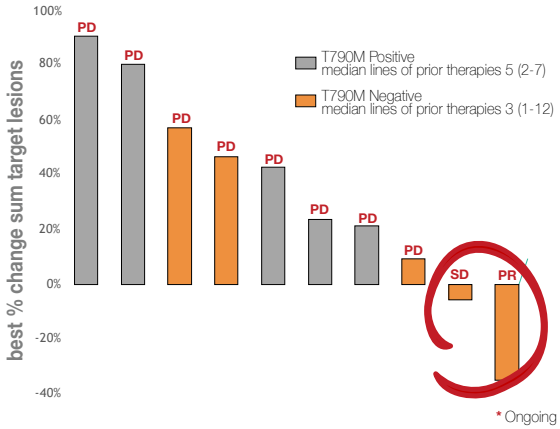
IASLC 19th World Conference on Lung Cancer
September 23–26, 2018 Toronto, Canada

Subset of patients shows benefit when adding bemcentinib to TARCEVA, identifiable by proprietary predictive marker BGBM14

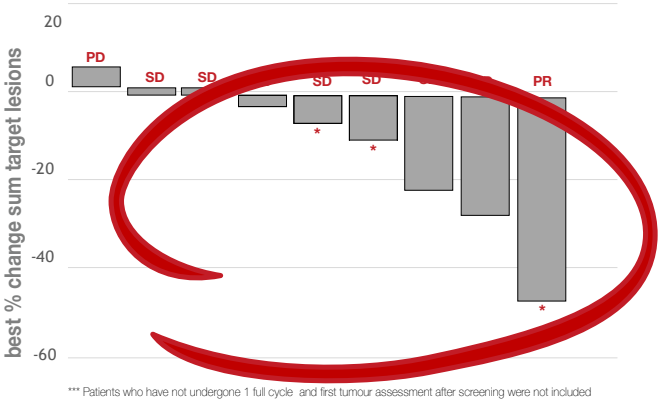
Arm A
Resistance reversal & monotherapy



Arm B
Resistance reversal



Arm C
Resistance prevention



Byers *et al* WCLC 2018 (September 2018)

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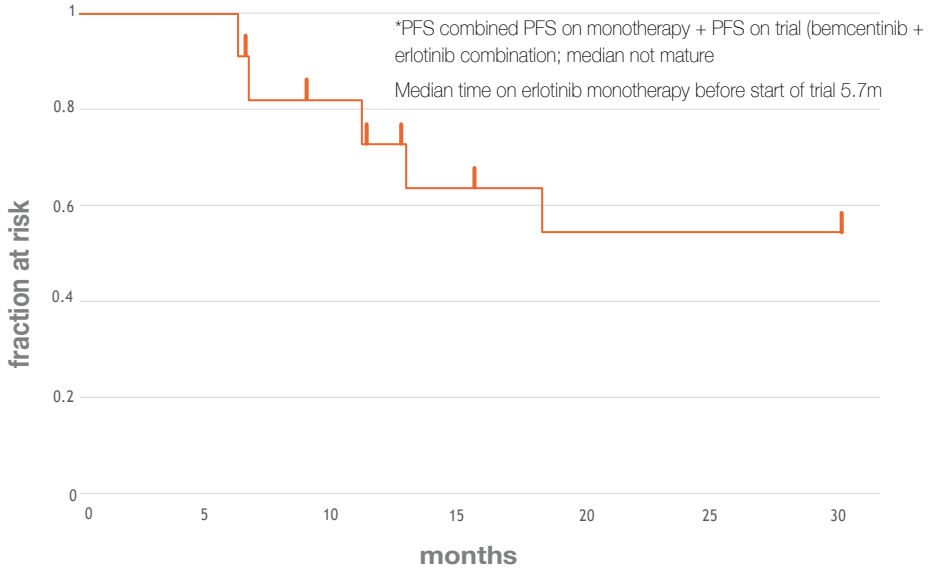
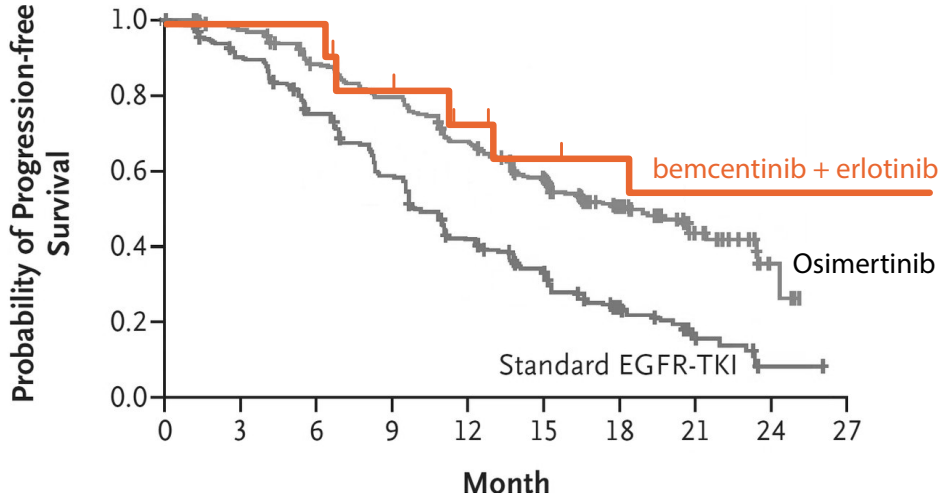
Arm C – resistance prevention
Superior PFS of bemcentinib + erlotinib combination in first line (data still maturing)

PFS in arm C:
bemcentinib + erlotinib first line



PFS in arm C:
Overlay with FLAURA data

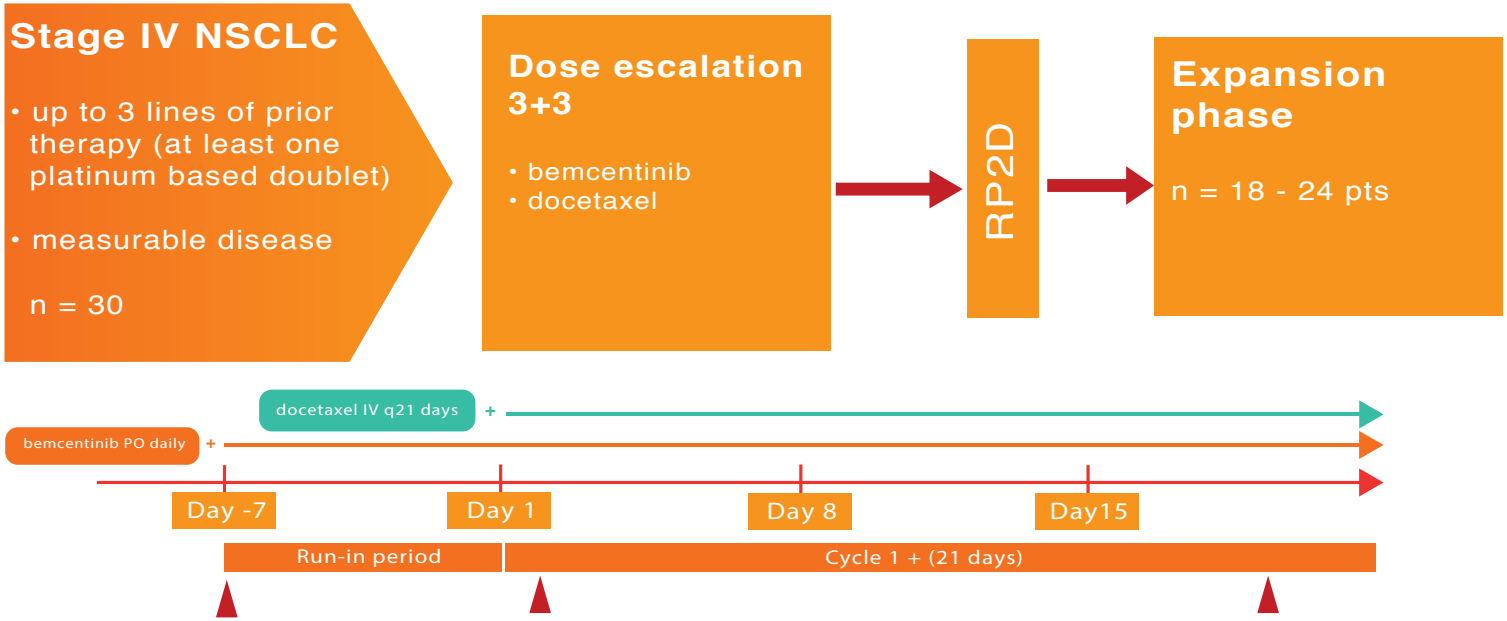


Byers *et al* WCLC 2018 (September 2018)

BGBIL006: Phase Ib/II trial with bemcentinib and docetaxel in NSCLC

Sponsor Investigator: Dr David Gerber, UTSW Dallas

"It is important to remember that most patients with lung cancer will eventually be treated with chemotherapy and for most patients, the benefit from chemotherapy is suboptimal."



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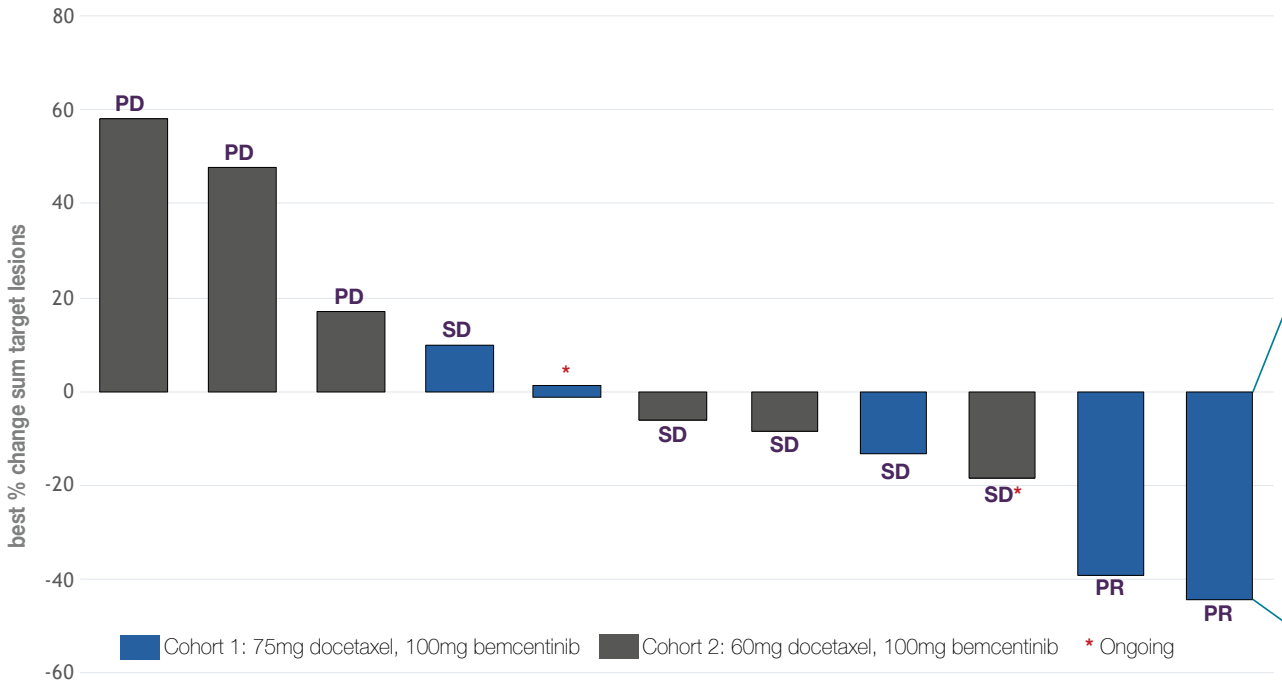
Majority of patients experience benefit, including PRs

Includes patients with primary and acquired resistance to CPIs

Best % Change in Sum of Target Lesions



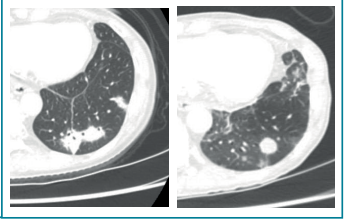
Patient 004

Patient is a 64 year old caucasian female diagnosed with stage IV NSCLC.

EGFR wild type and ALK mutation negative.

Received 3 lines of prior therapy:
- Carboplatin/paclitaxel (SD)
- Carboplatin/pemetrexed (PD)
- Pembrolizumab (PD)

Achieved PR after 2 cycles of combination therapy and re-mained in response for 10 cycles.



Source: Gerber *et al* WCLC 2018 (September 2018)

Strategy to position bemcentinib as cornerstone of treatment for NSCLC by combining with standard of care therapies

- Company anticipates to update the market with proposed rPh2 strategy towards the end of 2018

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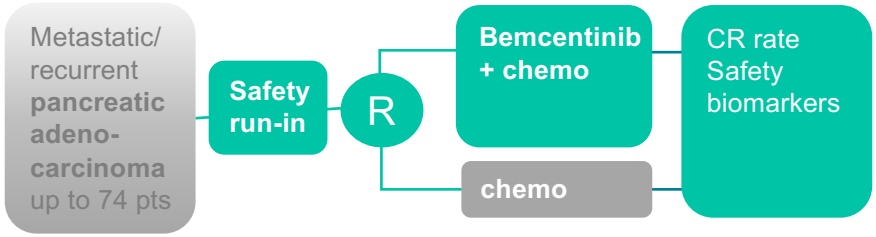
BerGenBio Investigator led programme: explore additional opportunities for bemcentinib

New Investigator Sponsored Trials in start up stage

Randomised phI/II in pancreatic cancer

Randomised trial combining bemcentinib with nab-paclitaxel, gemcitabine and cisplatin chemotherapy combo in advanced pancreatic cancer

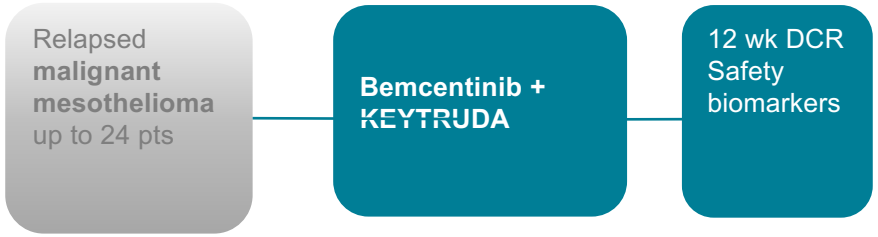


Sponsor: UT Southwestern, Dallas, TX, Dr Muhammad Beg

Supported by: STAND UP TO CANCER

Phase II in mesothelioma

Phase II study combining bemcentinib with KEYTRUDA in malignant mesothelioma



Sponsor: University of Leicester, UK, Prof Dean Fennel

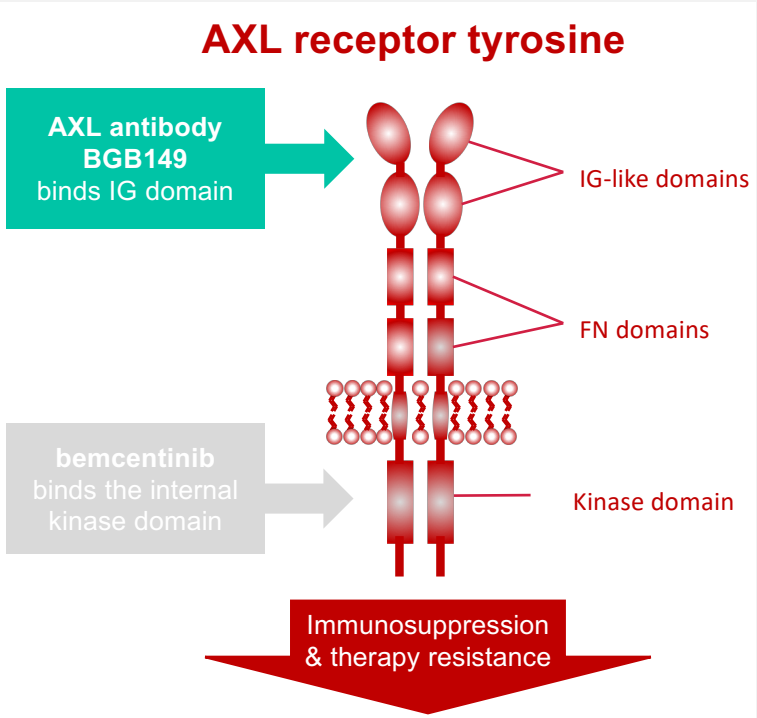
Supported by: MERCK, British Lung Foundation, The Christie NHS FOUNDATION TRUST

ILS: Investigator led study

BGB149

AXL mAb – clinical trials start Dec 2018

BGB149: AXL function blocking antibody programme



AXL functionally blocking human antibody

Highly selective to human AXL

High affinity (K_D: 500pM)

robust, scaleable manufacturing process

good titre and yield

Strong patent position on CDR sequences

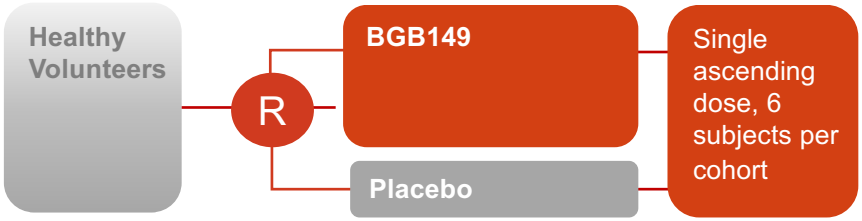
Anti-tumour MoA and efficacy demonstrated (AML, NSCLC, pancreatic)

Robust GMP manufacturing process established and phase I *first-in-man* clinical studies starting in Q4 2018

Robust GMP Manufacturing Route

- **Scale:** current GMP manufacturing scale was 250L (bulk drug substance)
- **Cell banks:** MCB & WCB characterised and laid down
- **Stability:** current drug substance has 18 month stability at <-60 degrees C.
- **Toxicity:** GLP toxicity reported no major concerns
- **CTA** filed

Phase I starting Dec 2018



Projected completion in 3Q 2019

Start of patient trials H2 2019

Financial review: Good financial position and cost control

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CFO

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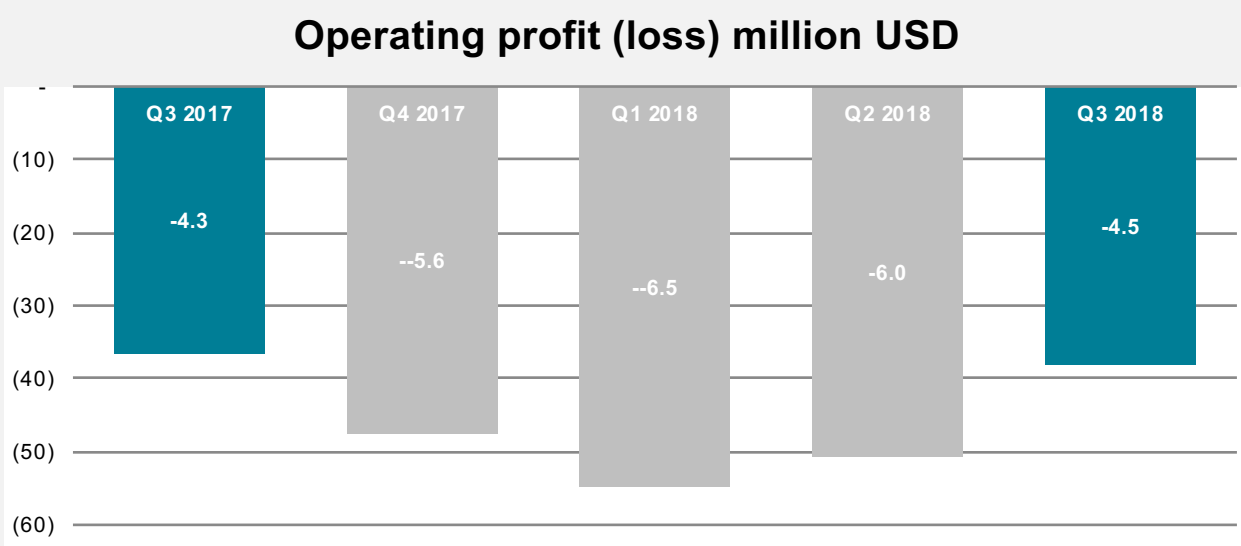
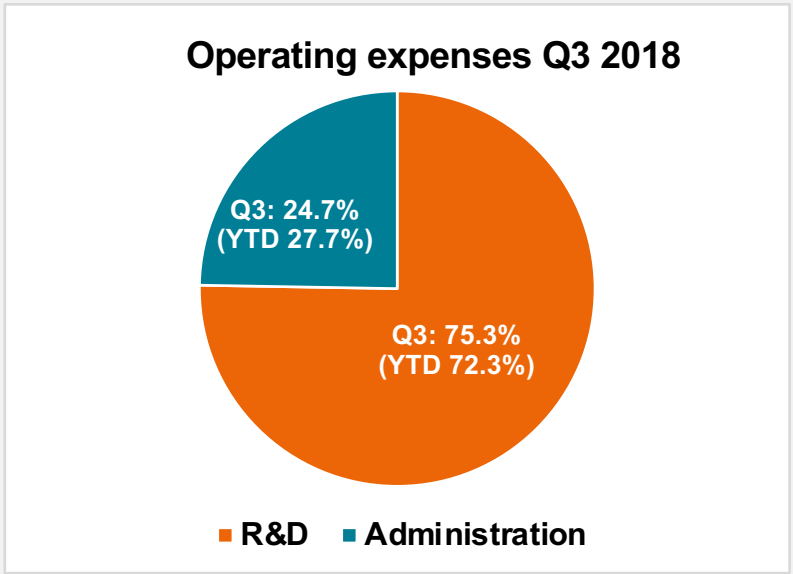
Operating profit (loss)



- Q3'18 decrease in operating loss associated with stage 1 of NSCLC study in combination with Keytruda meeting its clinical efficacy endpoint in Q2, requiring a 12 week safety review and therefore reduced spend in Q3. Stage 2 opened in Q4.
- In addition increased cost reduction by grants:

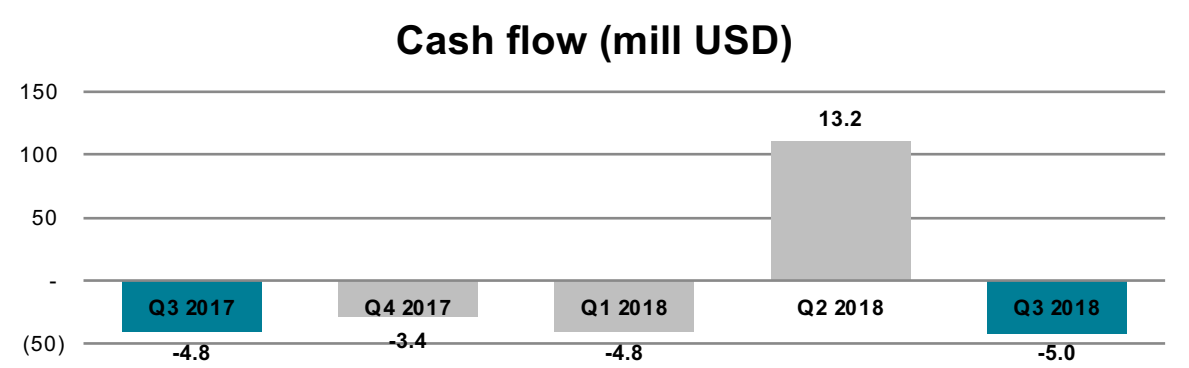
  Approval tax refund (Skatte funn) cost reduction in Q3´18 USD 0.6 mill (Q3´17 USD 0.3 mill)
  Other grants Q3´18 USD 0.4 mill (Q3´17 USD 0.1 mill)



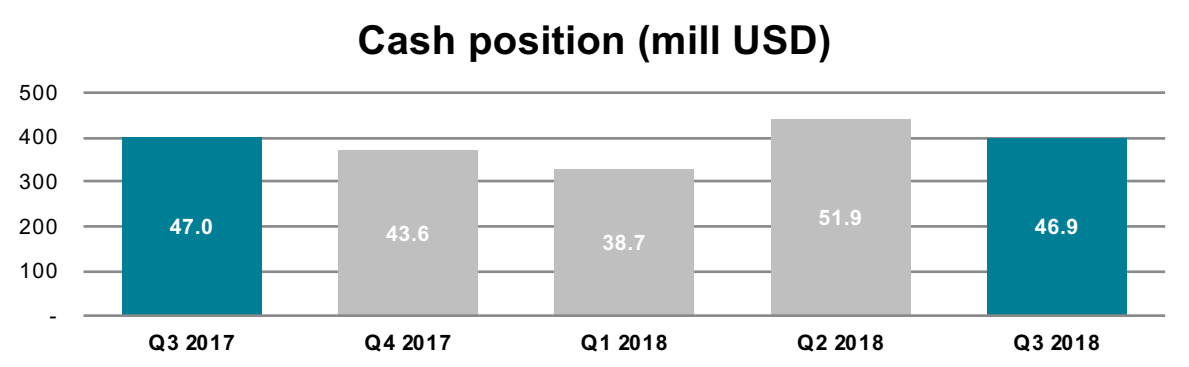
- Effective organisation
- 75.3% (YTD 72.3%) of operating expenses in Q3 2018 attributable to Research & Development activities

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

Cash flow and cash position



- Private placement Q2,18 strengthened cash position - gross funds raised USD 24m
- Quarterly cash burn average at USD 5.3m

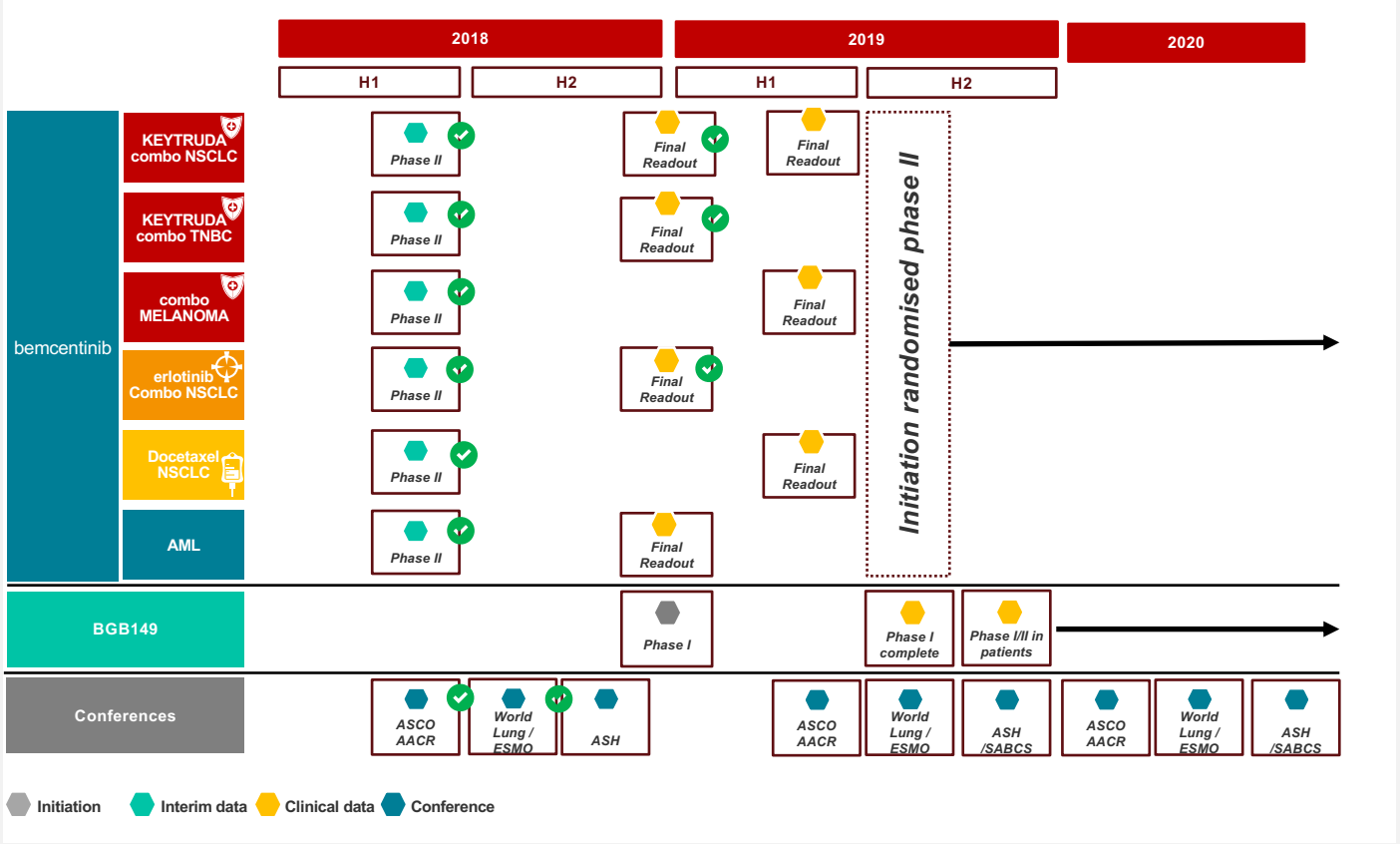


- Cash position gives runway to deliver key clinical read outs from ongoing clinical studies
- Cash runway into 2020 based on current burn rate

Summary & Outlook:
A number of significant milestones expected in H2 2018 and 2019

Richard Godfrey
CEO

Significant milestones expected in 2018 & 2019



Bemcentinib

NSCLC KEYTRUDA combo: presentation of completed stage 1 data and initiate stage 2

BGB149

AXL antibody BGB149: begin phase I clinical trial

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

Summary

Focused on developing innovative drugs for aggressive diseases

Selective AXL inhibitors: a novel cornerstone approach to target immune evasive, drug resistant and metastatic cancers

Promising interim Ph II clinical data in NSCLC and Leukaemia

Selected for high profile presentations at global medical conferences

Significant milestones in the next 12 months

- Additional read-outs from phase II trial PoC programme with bemcentinib in NSCLC, AML/MDS and melanoma
- Start first in man phase I clinical trial with BGB149, anti AXL antibody
- Start randomised phase II programme with bemcentinib in target indications

Anticipated cash runway into 2020 based on current burn rate

Included in the OSEBX index from 1st June

Thank you for your attention

Q&A