

BerGenBio ASA (OSE:BG BIO) Results Third Quarter 2018

13 November 2018

Richard Godfrey, CEO

Rune Skeie, CFO



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Agenda

1. Introduction and recent highlights
2. Advanced Lung Cancer (NSCLC):
 - Extended progression-free-survival in AXL positive patients on phase II trial with bemcentinib + KEYTRUDA (anti-PD-1 therapy)
 - Extended progression-free-survival in patients on phase II trial with bemcentinib + TARCEVA (anti-EGFR therapy)
 - Encouraging efficacy in combination with docetaxel
3. Investigator initiated trial programme will explore additional opportunities for bemcentinib
4. BGB149 anti-AXL antibody will enter first in human clinical trials in Dec 2018
5. Finance
6. Outlook

Introduction & recent highlights



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.

Pipeline with significant milestones in 2018/19



Proof of Concept Phase 2 data with bemcentinib

Phase 1 clinical trial with AXL antibody

Well funded



Cash runway through to 2020

Included in the OSEBX index from 1st June 2018

Experienced Team



38 staff

Headquarters and research in Bergen, Norway

Clinical Trial Management in Oxford, UK

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

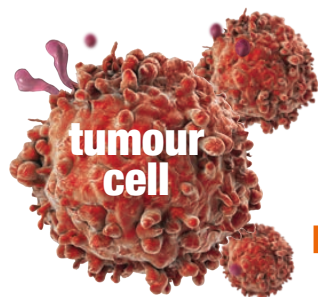
- ✓ Strong correlation with tissue AXL status in NSCLC (bemcentinib + KEYTRUDA)
- ✓ Strong correlation with soluble AXL status in AML/MDS (bemcentinib monotherapy)
- ✓ Additional soluble markers identified across additional indications and drug combinations

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.

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

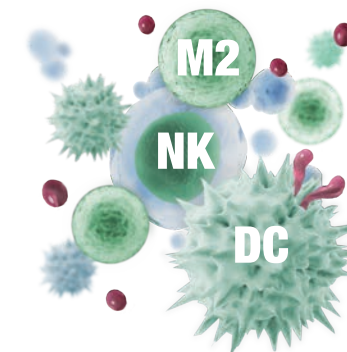


**Drives tumour cell plasticity:
non-genetic resistance mechanism**

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

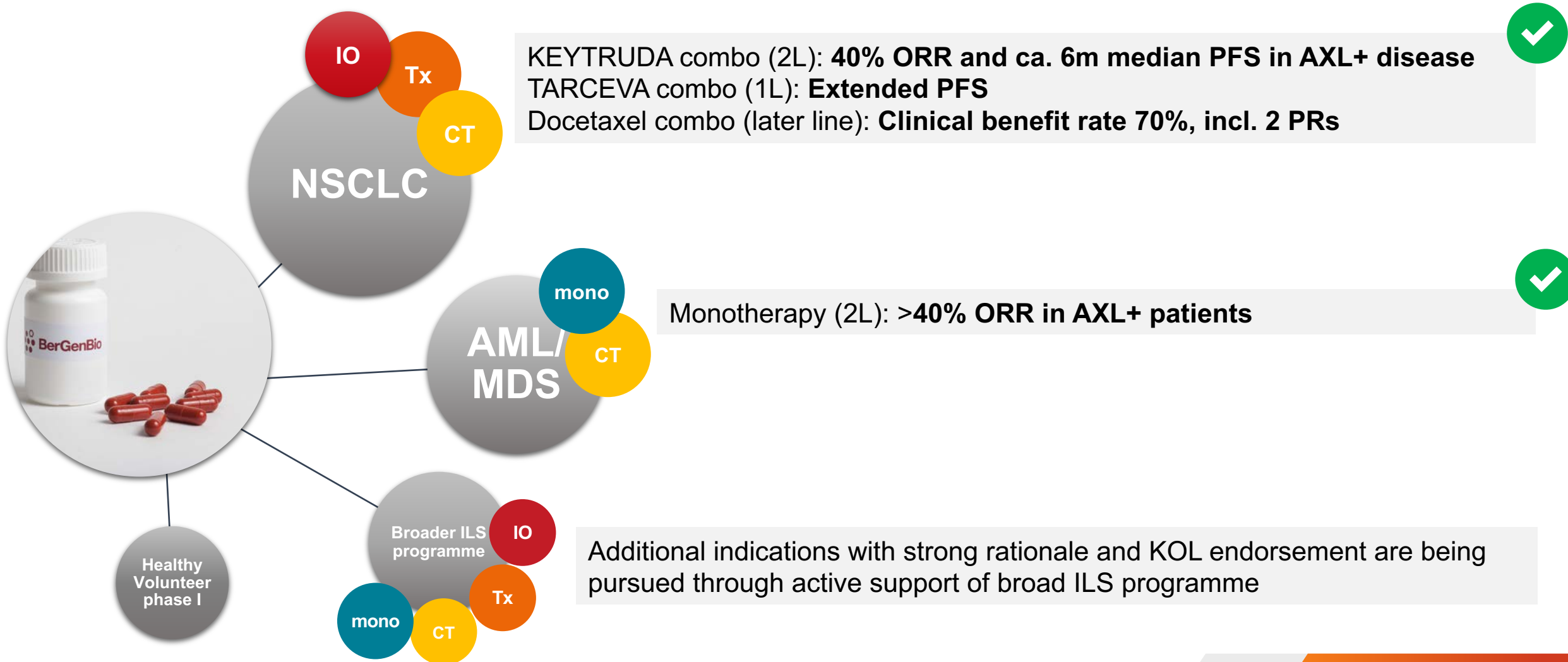
very **low** expression under healthy
physiological conditions (ko
mouse phenotypically normal)

overexpressed in response to
hypoxia, immune reaction,
cellular stress / therapy

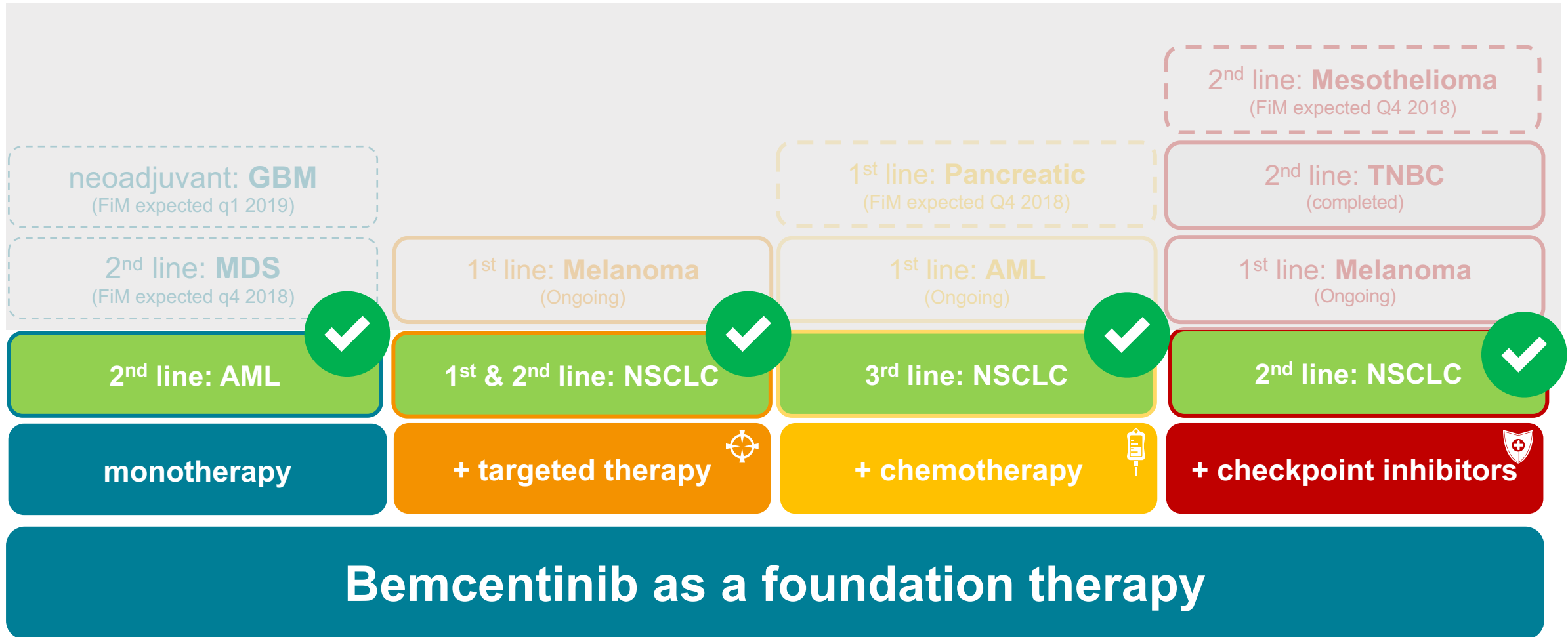
overexpression correlates with
worse prognosis in most
cancers

Phase II Proof of Concept data

- Focus on NSCLC & leukaemia



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

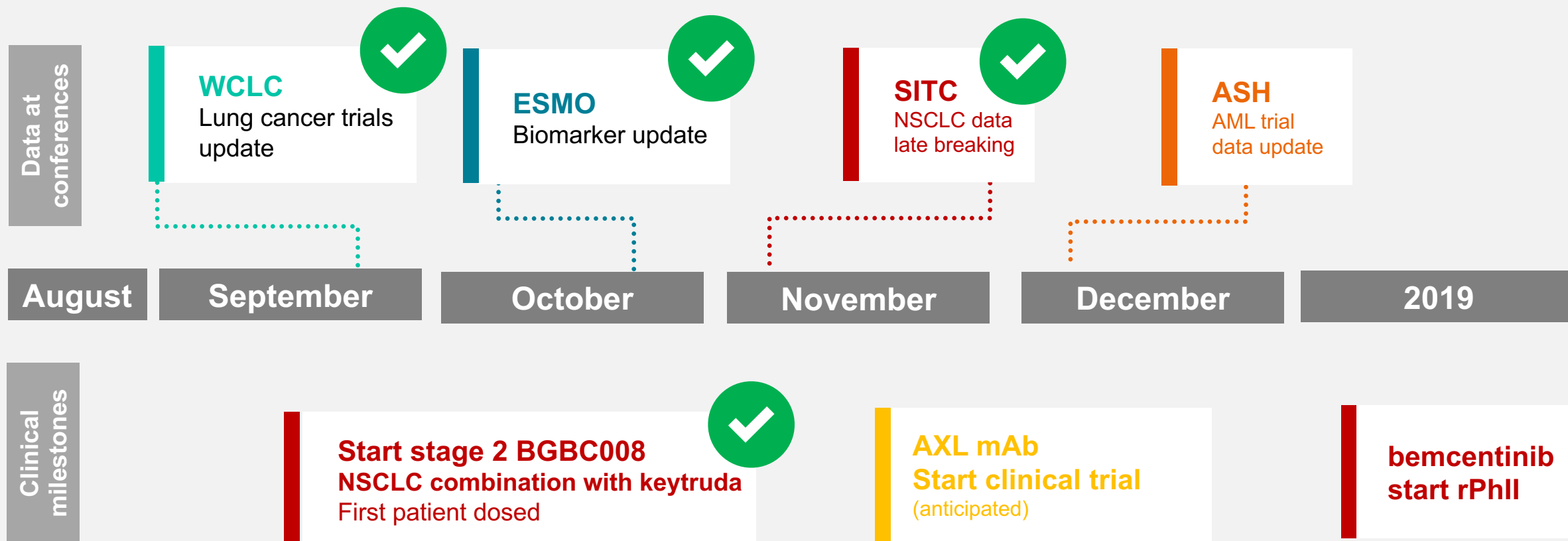
Plasma shed AXL (sAXL) levels are inversely
correlated to receptor activity

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

Upcoming data & clinical milestones

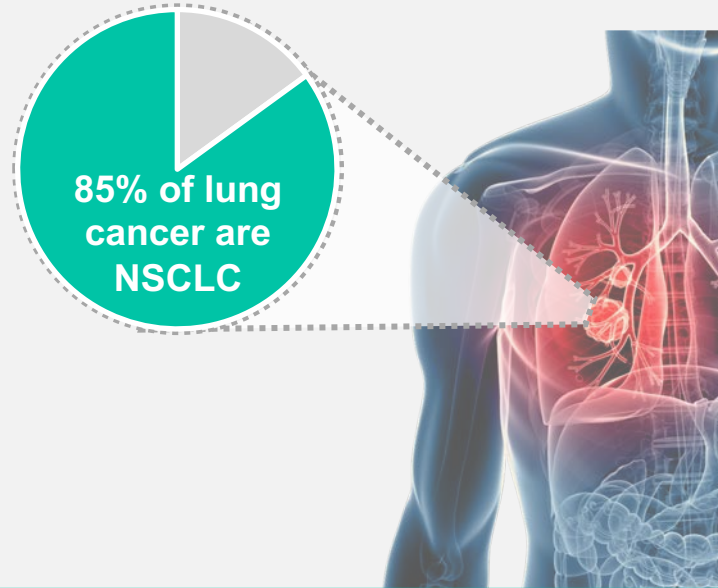


Non-small Cell Lung Cancer (NSCLC)

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



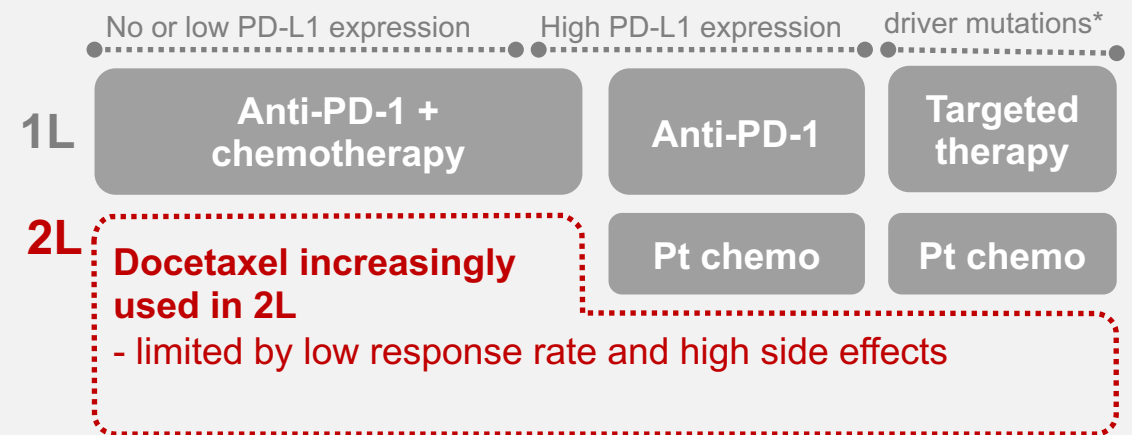
Lung Cancer: rapidly evolving standard of care... - but still lacking effective chemo free regimens



The largest cancer killer, most patients depend on drug therapy

- More than 1.76 million lung cancer deaths/yr worldwide¹

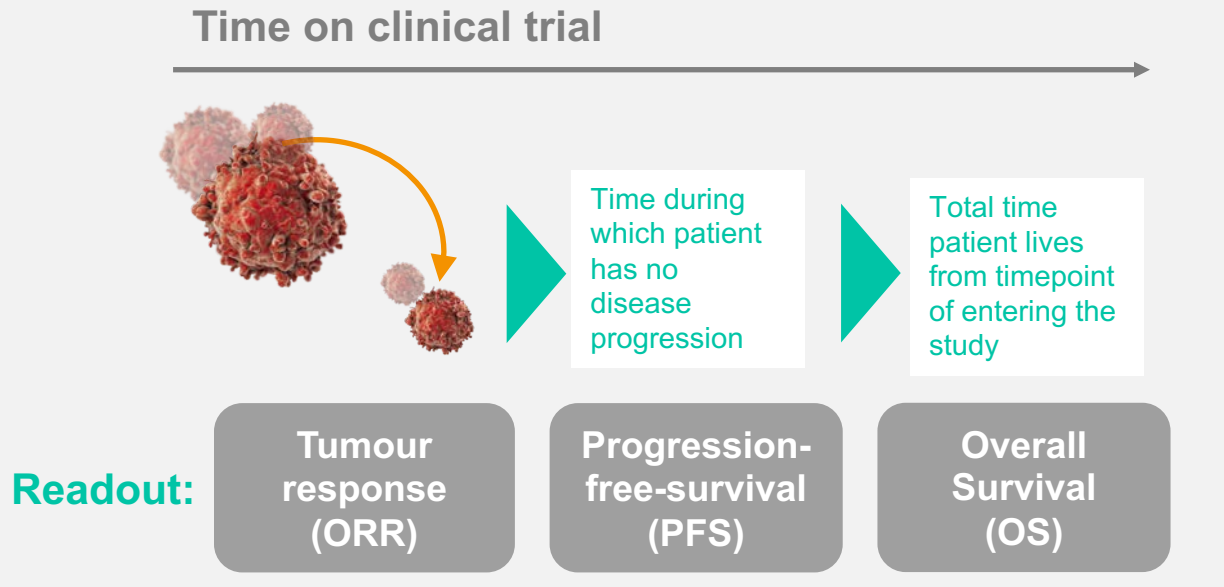
NSCLC standard of care (SoC)



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

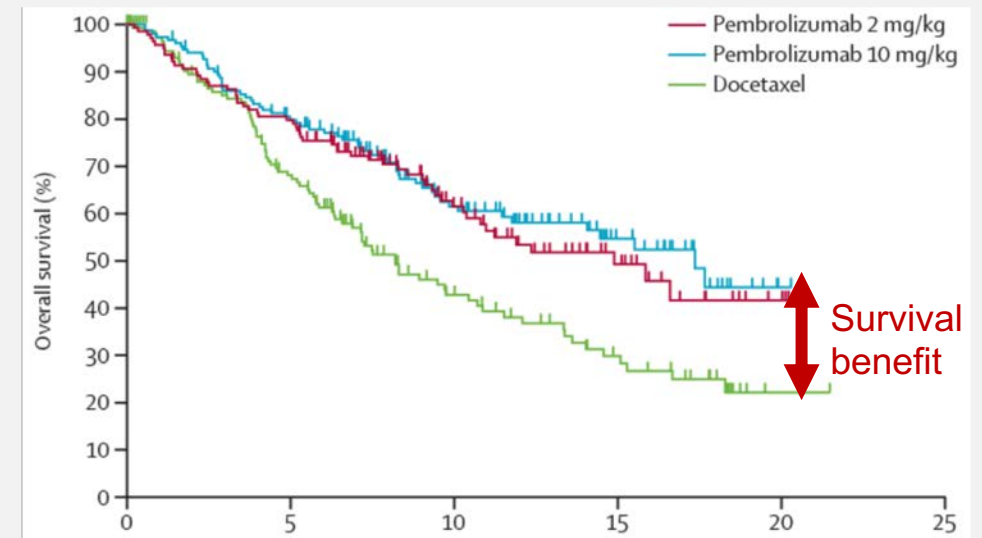
- Most patients will start on Anti-PD-1 + chemo in first line
- Vacuum in second line, effective chemo free regimens needed

(Immuno)therapies are measured by their ability to prolong life



To help patients live longer, therapies need to both initially limit tumour growth and this benefit should be sustained over time

- ORR determines initial control of the tumour
- Patients with objective response and those with stable disease are equally likely to become long term survivors



Only the new immunotherapies lead to a lasting benefit: need to evaluate survival data

- Although initial responses are similar, only immunotherapy leads to improved survival
- **Need for therapies that counteract resistance**

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

Single arm

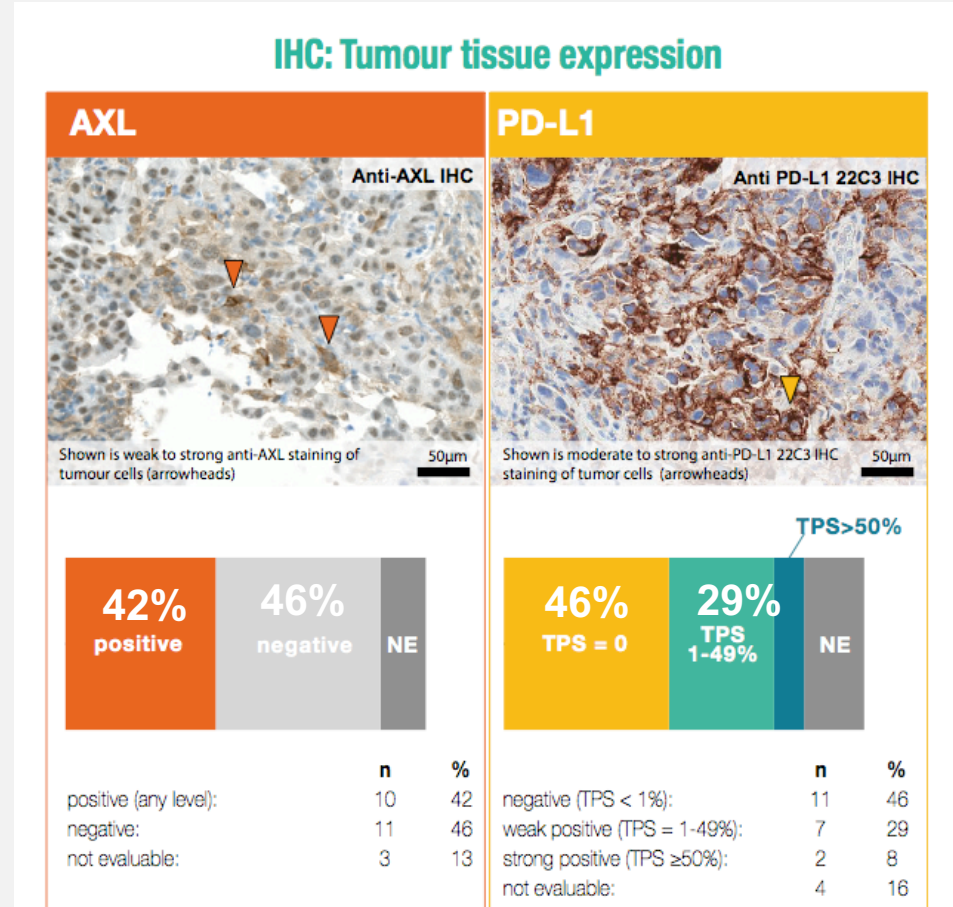
bemcentinib 200mg/d
KEYTRUDA
200mg/3w

ORR

Status Nov 2018

- ✓ 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

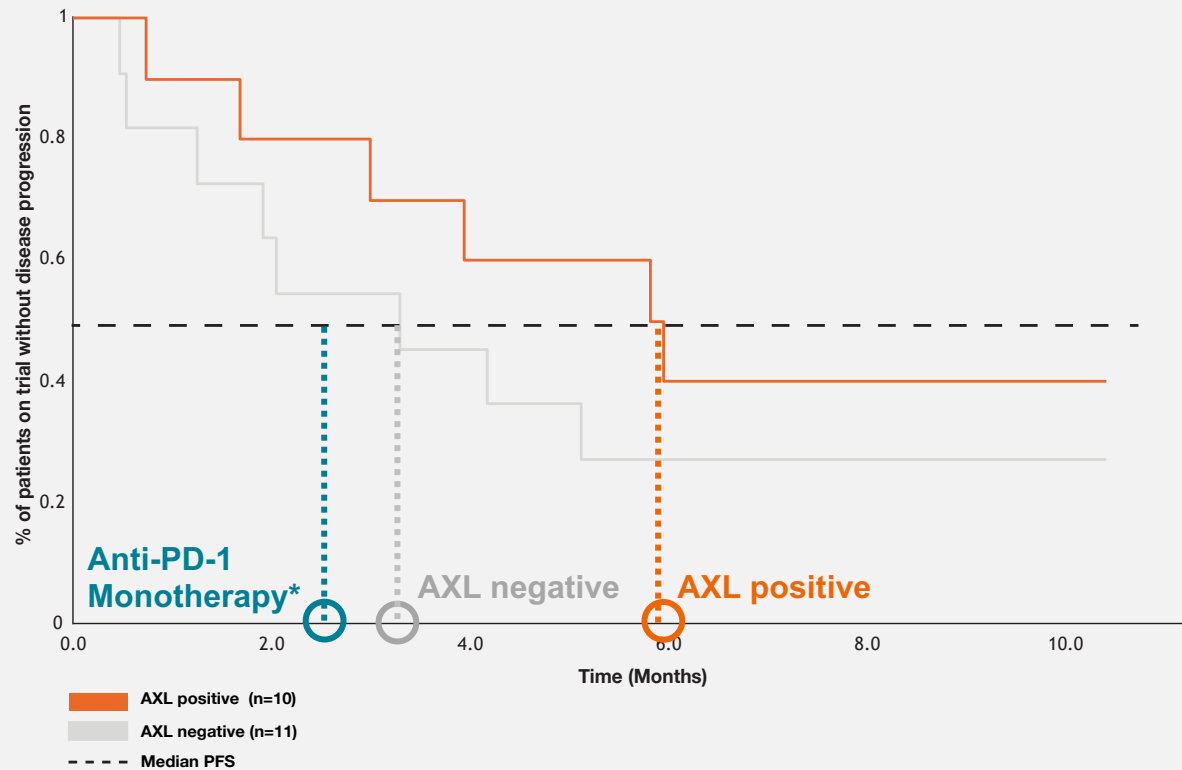


Trial has enrolled

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

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

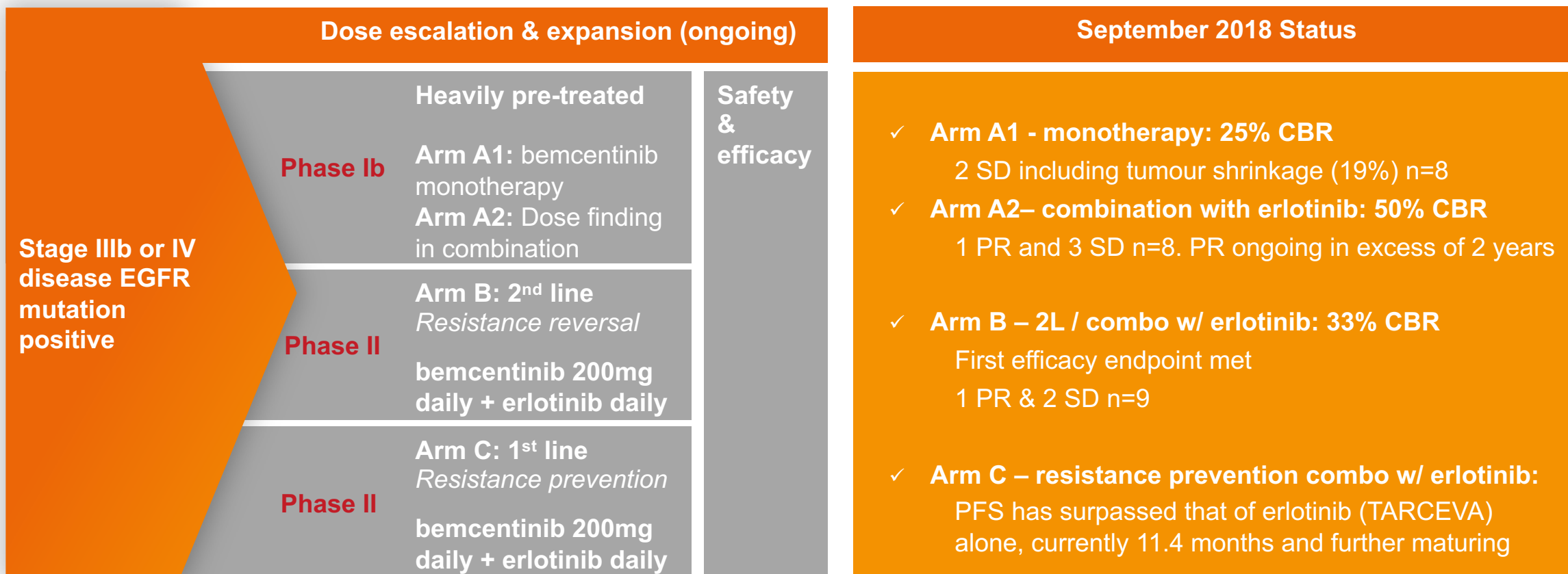
Progression Free Survival: 5.9 months in AXL positive vs 3.3 in negative patients (ca 80% improvement)



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

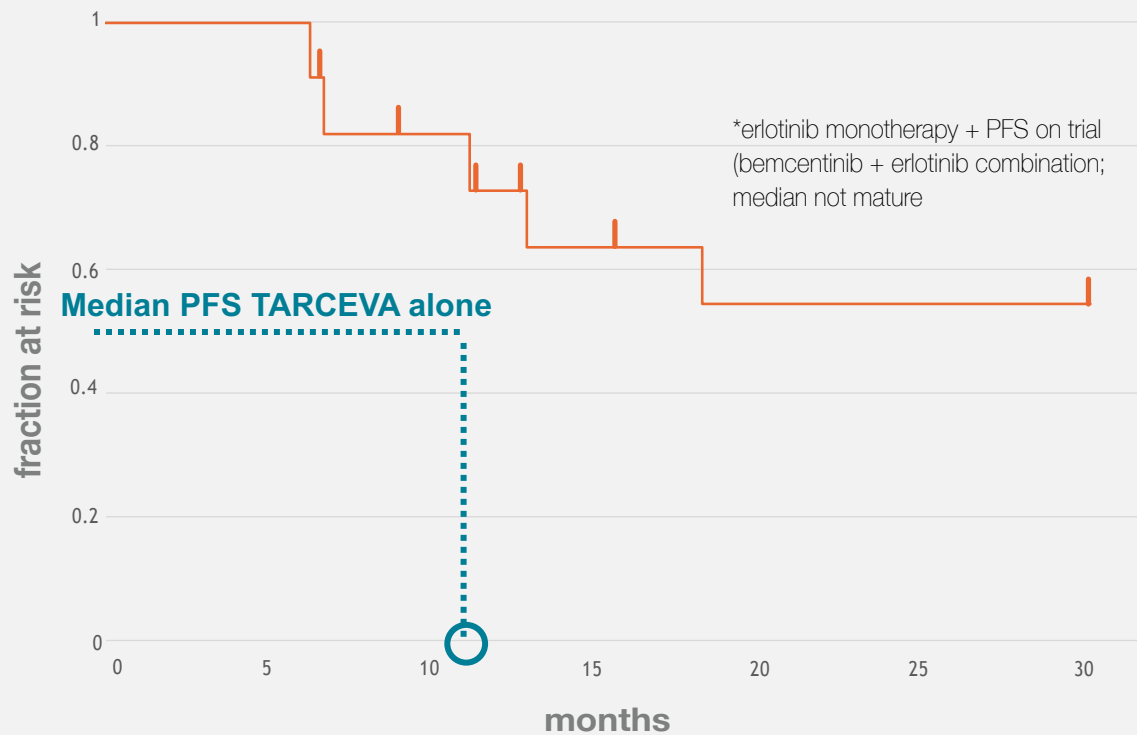
Trial	PD-L1 status		ORR (%)	PFS (months)
BGBC008	Mostly (75% of patients) 0 – 49%	AXL+	40	5.9
		AXL-	9	3.3
Keynote 001 ¹	0 %		9	2.1
	1 – 49 %		14	2.3
CheckMate 057 ²	0 – 100 %		19	2.3

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



Bemcentinib and TARCEVA combination extended PFS compared to TARCEVA monotherapy (historical data)

Progression Free Survival



Comparison of bemcentinib combination data (BGBC004) with TARCEVA alone

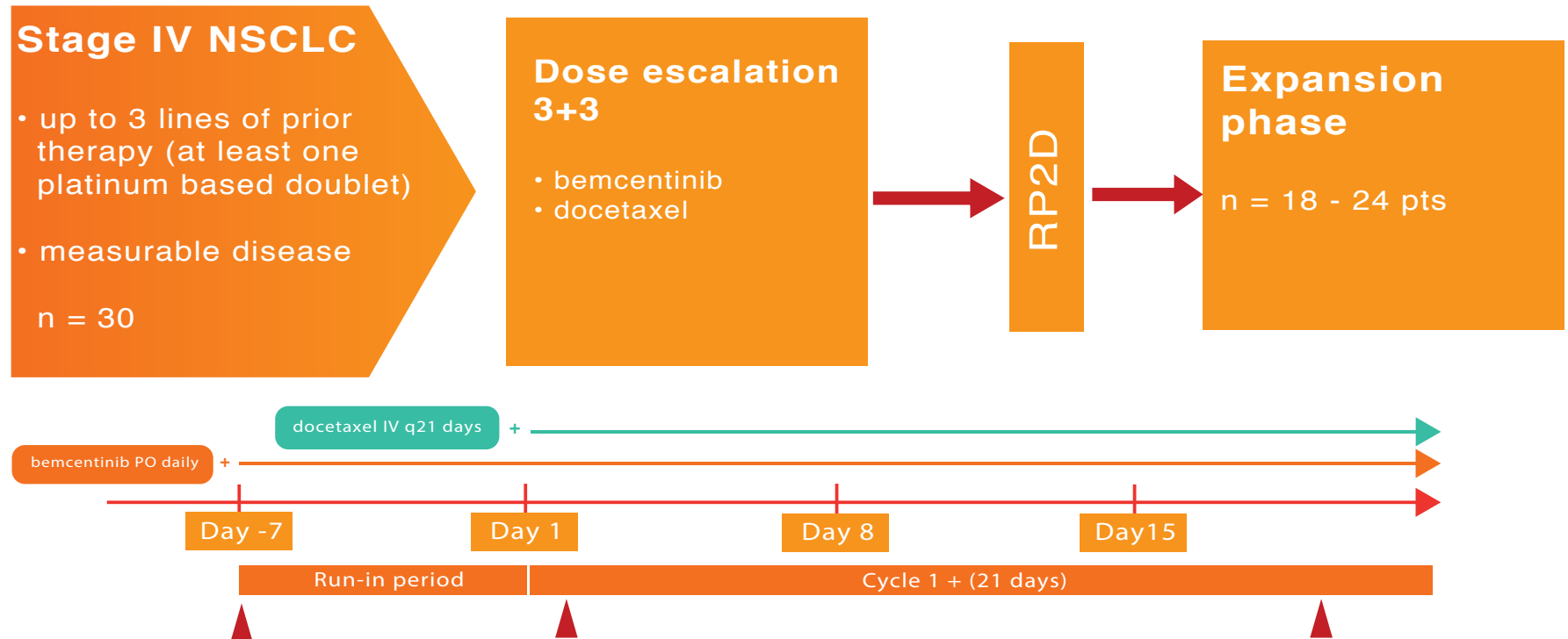
Trial	PFS (months)
BGBC004	11.4 (further maturing)
TARCEVA	10.4 ¹

BGBIL005: Phase Ib/II trial with bemcentinib and docetaxel in NSCLC



Sponsor Investigator:
Dr David Gerber, UTSW Dallas

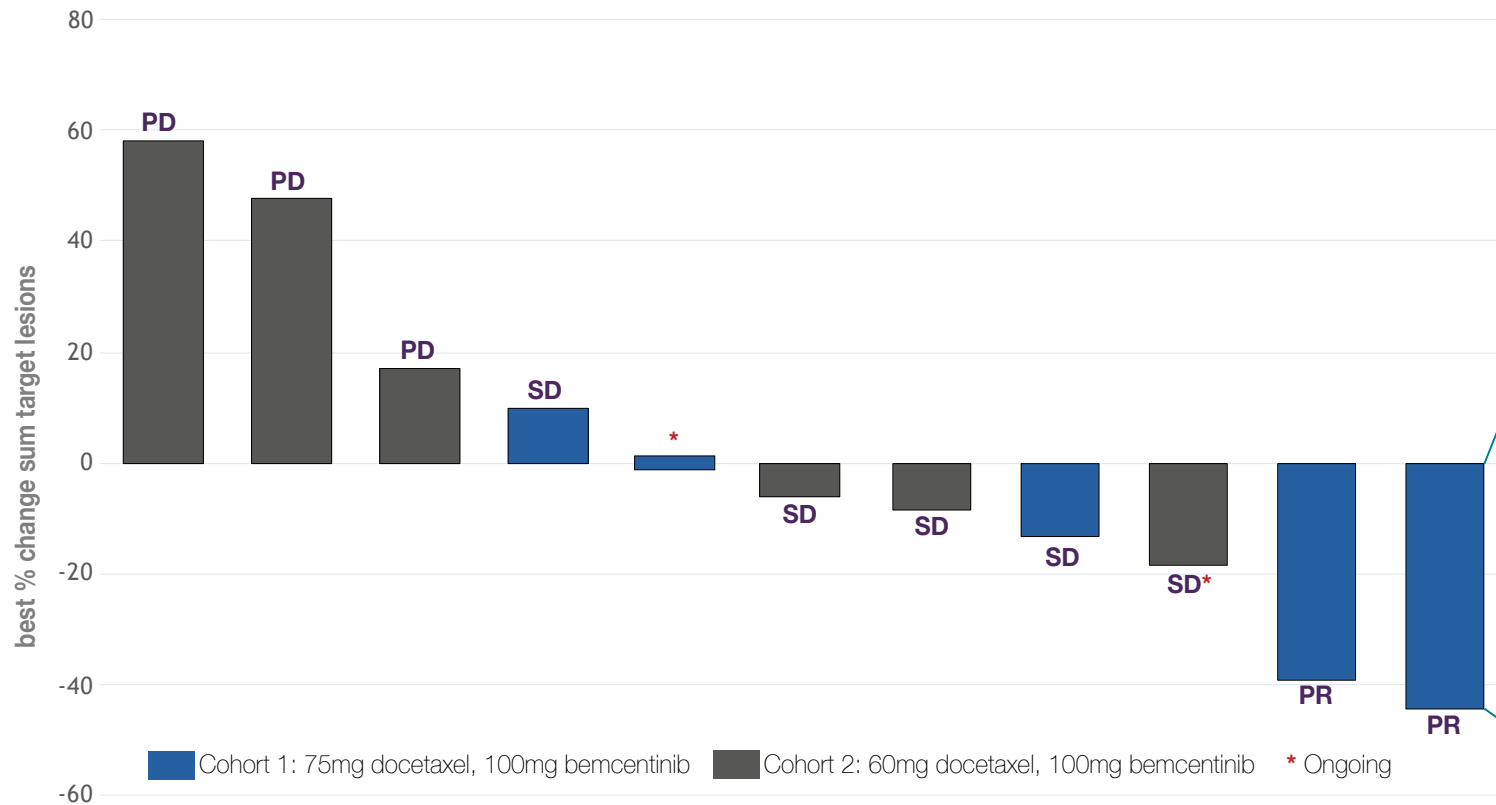
“It is important to remember that most patients with lung cancer will eventually be treated with chemotherapy and for most patients, the benefit from chemotherapy is suboptimal.”



Majority of patients experience benefit, including PRs

Includes patients with primary and acquired resistance to CPIs

Best % Change in Sum of Target Lesions



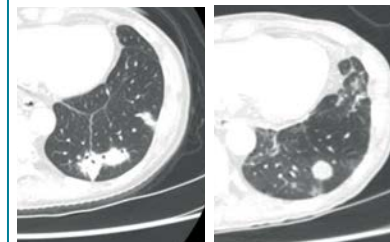
Patient 004

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 remained in response for 10 cycles.





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

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 <ul style="list-style-type: none">First line Tx +/- bemcentinib 2L <ul style="list-style-type: none">non-mutation driven resistance to Tx	1L <ul style="list-style-type: none">CT free combo (incl. PD-L1 neg)Add to Pt CT 2L <ul style="list-style-type: none">Add to IO upon progression	2L <ul style="list-style-type: none">Combo with docetaxel in IO / Pt CT / Tx progressors

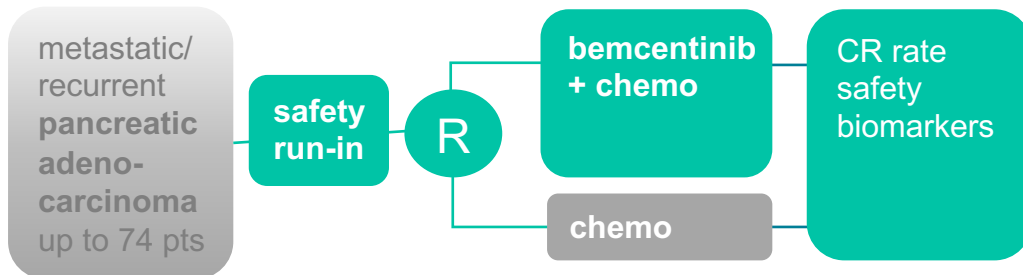
**BerGenBio Investigator led
programme:** explore additional
opportunities for bemcentinib



New Investigator Sponsored Trials in start up stage

Randomised ph/II in pancreatic cancer

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

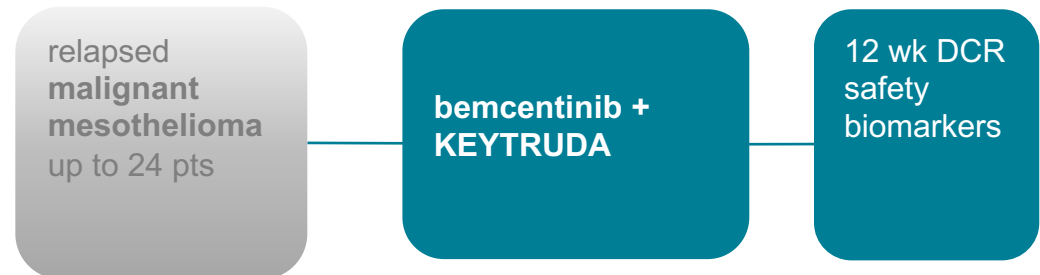


Sponsor: UT Southwestern, Dallas, TX, Dr Muhammad Beg

Supported by: 

Phase II in mesothelioma

Phase II study combining bemcentinib with KEYTRUDA in malignant mesothelioma



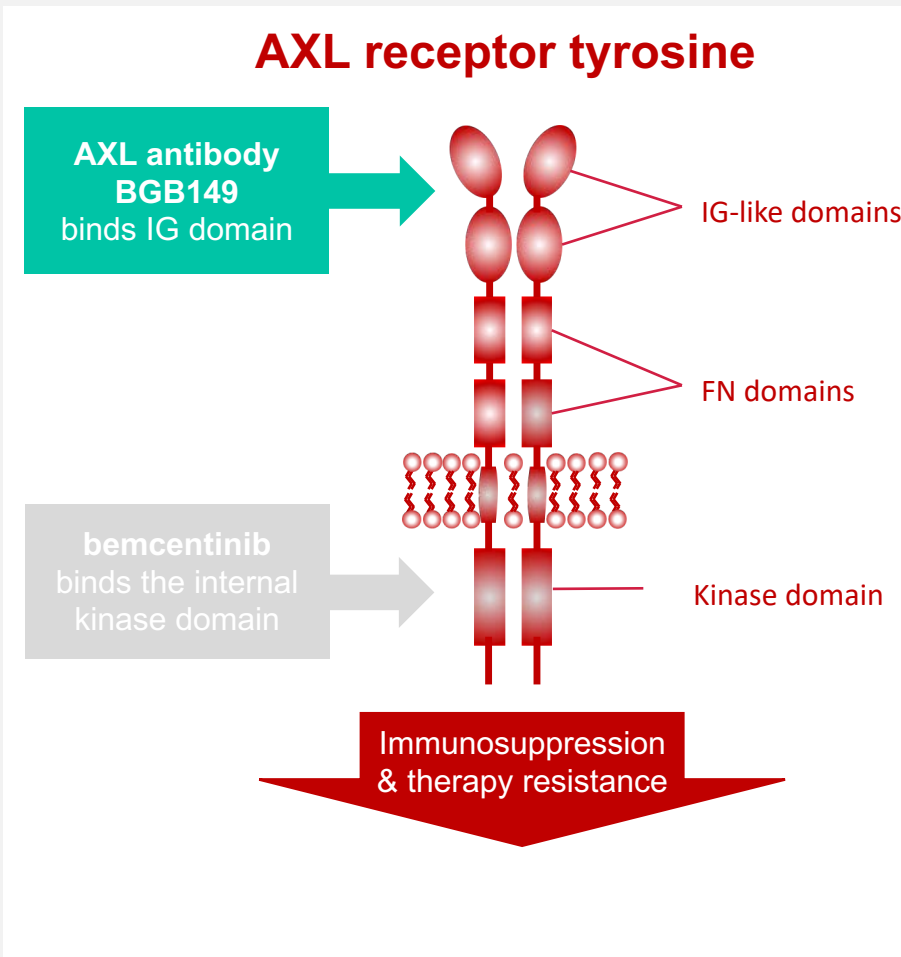
Sponsor: University of Leicester, UK, Prof Dean Fennel

Supported by:   

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, scalable manufacturing process
good titre and yield

Strong patent position on CDR sequences

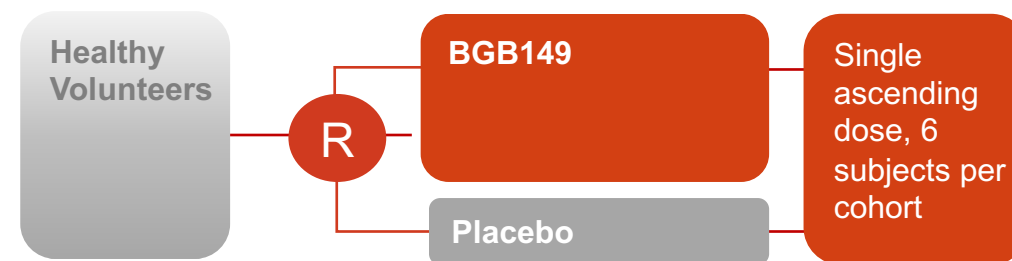
Anti-tumour MoA and efficacy demonstrated (AML, NSCLC, pancreatic)

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

Corporate update: Building the organisation – to prepare for the next stage



Leadership team strengthened with key appointments

- **Mike Rogers** **HR Director**
 - 20 years strategic HR in biotech and biopharma, economist from Edinburgh University
- **Sonia Rodrigues PhD** **Director of Regulatory Affairs**
 - 10 years regulatory affairs with AbbVie, Takeda, Amgen, Merck Serono
- **Tone Bjaaland PhD** **Director of Clinical Operations**
 - 25 years clinical operations with Eisai, Takeda, Shire

Arbitration to Rigel Pharmaceuticals, Inc – in-license partner

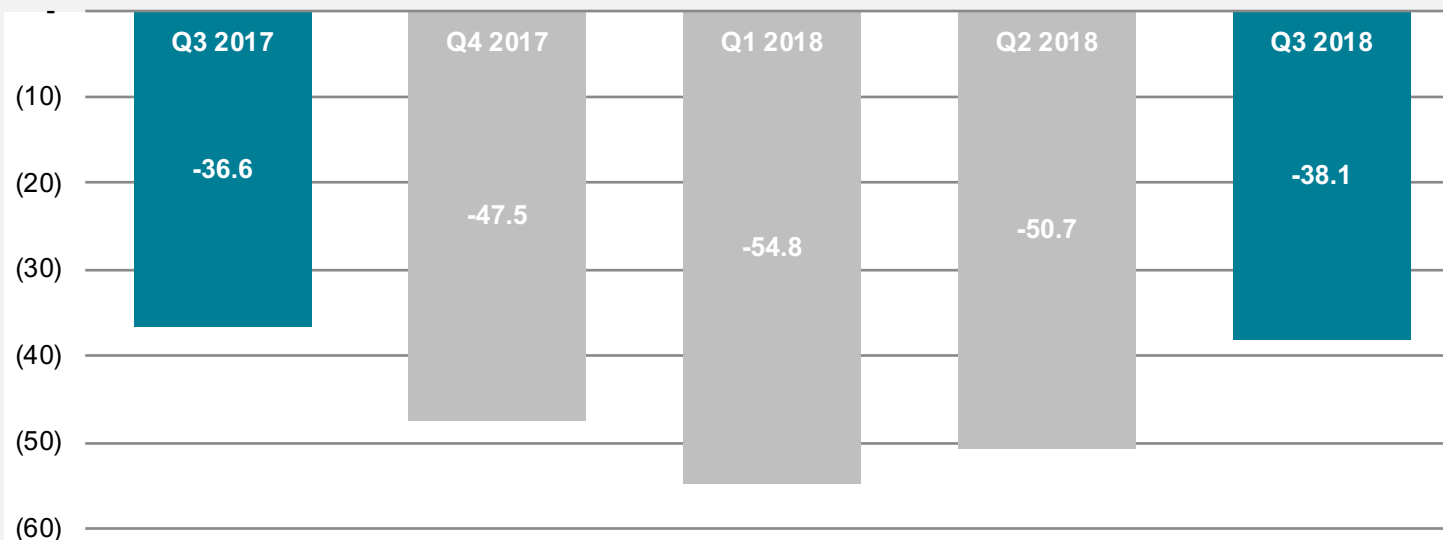
- Sep 13 2018: BerGenBio served Notice of Arbitration to Rigel pursuant to a License Agreement for bemcentinib made and entered into as of 29 June 2011
- A dispute has arisen between the two companies with respect to the interpretation and application of certain provisions of the Agreement, particularly as they relate to the rights and obligations of the parties in the event of the licensing or sale of a Product(s) by BerGenBio and/or the sale of BerGenBio to a third party
- Parties agreed to a binding arbitration to be completed within 180 days of commencement

Financial review: Good financial position and cost control

Rune Skeie
CFO

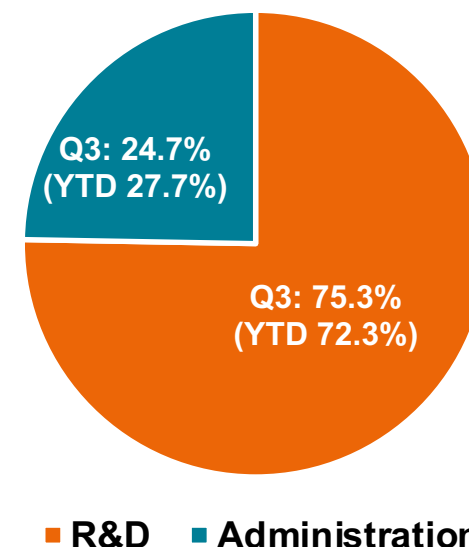
Operating profit (loss)

Operating profit (loss) million NOK



- 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 NOK 5.1 mill (Q3'17 NOK 2.3 mill)
Other grants Q3'18 NOK 3.3 mill (Q3'17 NOK 0.5 mill)

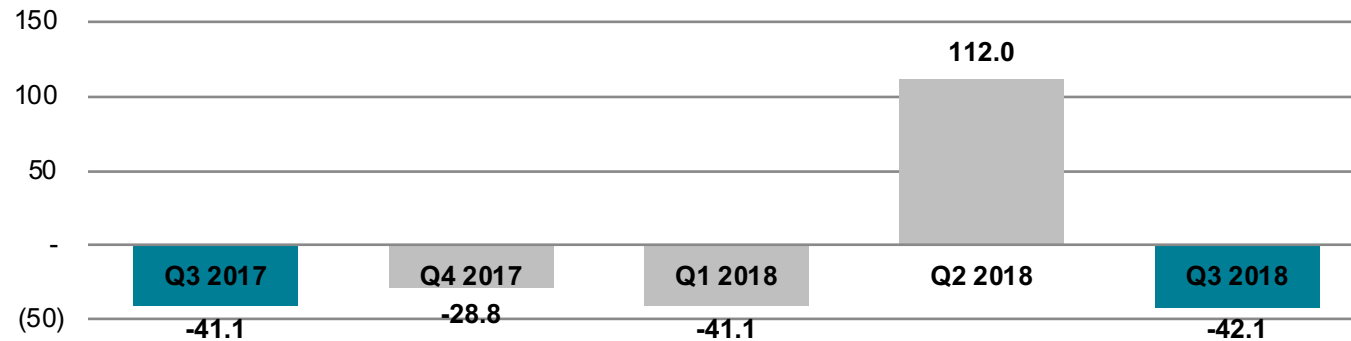
Operating expenses Q3 2018



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

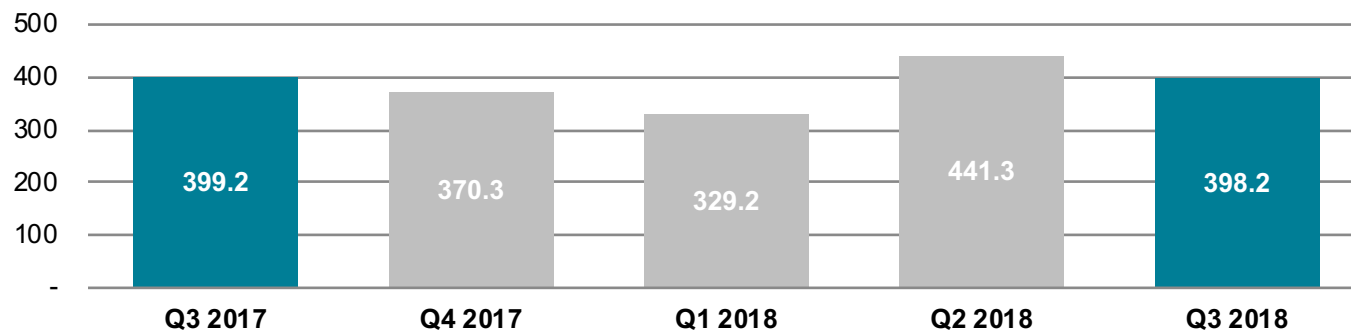
Cash flow and cash position

Cash flow (mill NOK)



- Private placement Q2,18 strengthened cash position - gross funds raised NOK 187.5m
- Quarterly cash burn average at NOK 44.8m

Cash position (mill NOK)



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

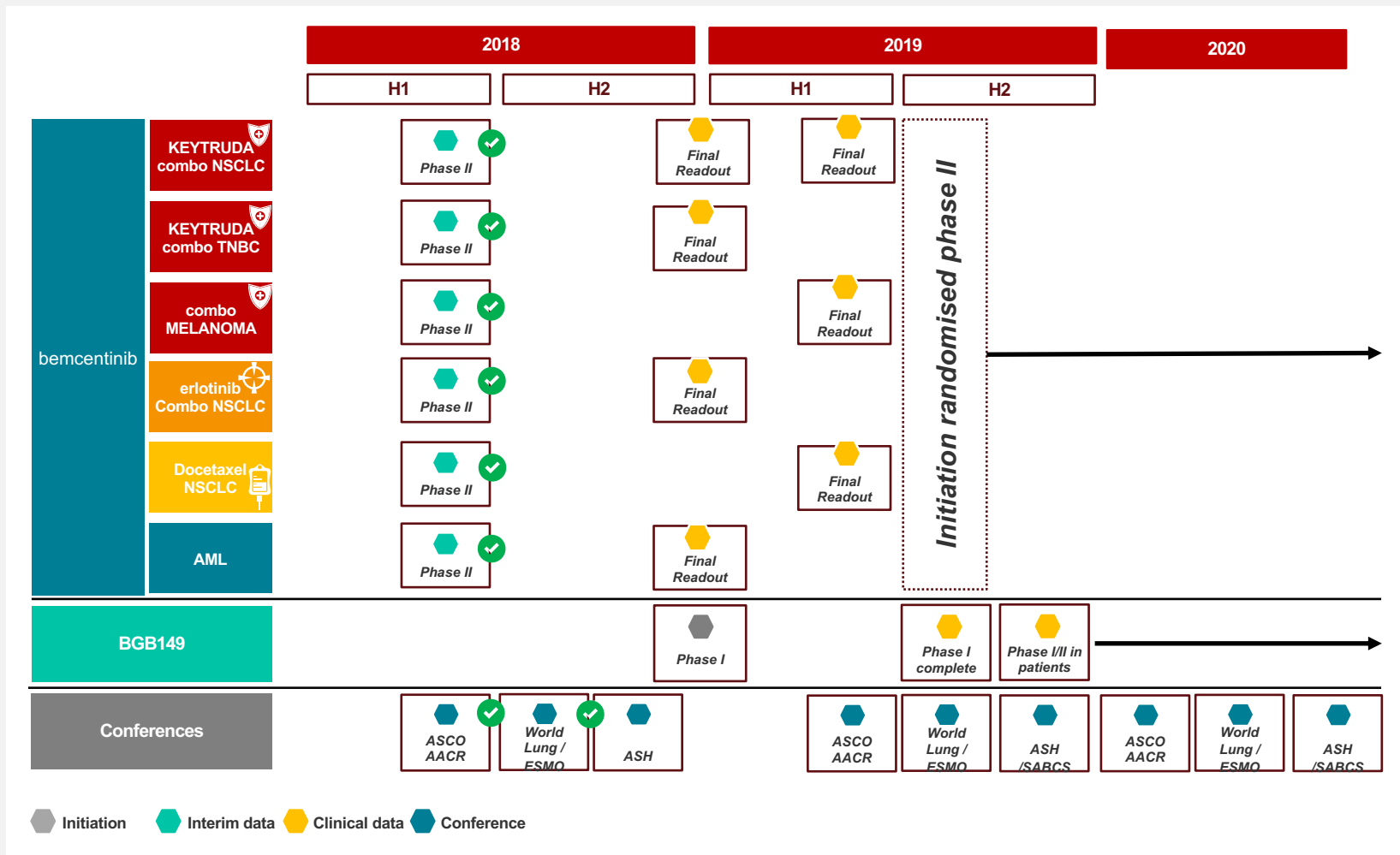
Summary & Outlook:

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

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

Appendix

Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited

	Note	Q3 2018	Q3 2017	YTD 2018	YTD 2017	Full year 2017
Revenue		0	0	0	0	0
Expenses						
Employee benefit expenses	3	9 285	6 336	31 257	18 525	28 827
Depreciation		59	51	167	152	193
Other operating expenses	6	28 773	30 174	112 206	117 519	154 686
Total operating expenses		38 116	36 561	143 630	136 197	183 707
Operating profit		-38 116	-36 561	-143 630	-136 197	-183 707
Finance income		974	1 596	3 642	3 256	4 168
Finance expense		513	461	685	1 634	2 668
Financial items, net		461	1 135	2 956	1 622	1 500
Profit before tax		-37 656	-35 426	-140 673	-134 574	-182 207
Income tax expense		-	0	-	0	0
Profit after tax		-37 656	-35 426	-140 673	-134 574	-182 207
Other comprehensive income						
<i>Items which will not be reclassified over profit and loss</i>						
Actuarial gains and losses on defined benefit pension plans		-	0	-	0	0
Total comprehensive income for the period		-37 656	-35 426	-140 673	-134 574	-182 207
Earnings per share:						
- Basic and diluted per share	7	-0,69	-0,71	-2,66	-3,06	-4,01

Condensed consolidated statement of financial position

(NOK 1000) Unaudited

ASSETS

Non-current assets

	Note	30 SEP 2018	30 SEP 2017	31 DEC 2017
Property, plant and equipment		460	416	557

Total non-current assets		460	416	557
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Current assets

Other current assets	5, 8	21 868	18 466	13 430
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Cash and cash equivalents		398 166	399 152	370 350
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Total current assets		420 034	417 618	383 780
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TOTAL ASSETS		420 494	418 034	384 336
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EQUITY AND LIABILITIES

Equity

Paid in capital

Share capital	9	5 471	4 976	4 992
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Share premium	9	360 865	371 063	325 018
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Other paid in capital	4, 9	21 396	20 237	20 340
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Total paid in capital		387 731	396 276	350 350
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Total equity		387 731	396 276	350 350
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Non-current liabilities

Pension liability	10	0	0	0
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Total non-current liabilities		0	0	0
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Current liabilities

Accounts payable		9 373	13 751	21 575
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Other current liabilities		15 195	4 917	9 391
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Provisions		8 194	3 091	3 020
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Total current liabilities		32 762	21 759	33 986
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Total liabilities		32 762	21 759	33 986
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TOTAL EQUITY AND LIABILITIES		420 494	418 034	384 336
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Condensed consolidated statement of cash flow

(NOK 1000) Unaudited

	Note	YTD 2018	YTD 2017
Cash flow from operating activities			
Loss before tax		-140 673	-134 574
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		167	152
Calculated interest element on convertible loan		0	0
Share-based payment expense	3, 4	1 056	2 212
Movement in provisions and pensions		5 174	-1 752
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		-8 438	-6 164
Increase in trade and other payables		-6 398	2 245
Net cash flow from operating activities		-149 112	-137 882
Cash flows from investing activities			
Purchase of property, plant and equipment		-70	-159
Net cash flow used in investing activities		-70	-159
Cash flows from financing activities			
Proceeds from issue of share capital	9	176 998	375 368
Paid in, not registered capital increase	9	0	
Net cash flow from financing activities		176 998	375 368
Net increase/(decrease) in cash and cash equivalents		27 817	237 328
Cash and cash equivalents at beginning of period		370 350	161 825
Cash and cash equivalents at end of period		398 166	399 152

View Q3 2018 report for notes: <http://www.bergenbio.com/investors/reports/quarterly-reports/>