

# BerGenBio ASA (OSE:BGBIO)

20th Annual Rodman & Renshaw Global Investment Conference, NYC

5 September 2018

Richard Godfrey, CEO



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# Agenda

1. Introduction and Q2 2018 highlights
2. Advanced Lung Cancer (NSCLC): First efficacy endpoint met in phase II trial combining with KEYTRUDA
3. Advanced leukaemia (R/R AML/MDS): Monotherapy efficacy in a hard to treat patient population
4. Pipeline update
5. Finance report
6. Outlook
7. Q&A

# Introduction & Q2 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:** NSCLC, TNBC, AML/MDS, melanoma

## Pipeline with significant milestones in 2018/19



**Proof of Concept Phase 2 data** with bemcentinib

**Phase 1 clinical trial** with AXL antibody & AXL ADC (partnered)

## Well funded



Cash runway through to 2020

Included in the OSEBX index from 1<sup>st</sup> June 2018

## Experienced Team



35 staff

Headquarters and research in Bergen, Norway

Clinical Trial Management in Oxford, UK

# Q2 2018 results

## Efficacy reported in several Phase II trials with bemcentinib

### First efficacy endpoint met: Phase II combination trial with KEYTRUDA in advanced lung cancer (NSCLC)

- ✓ Efficacy threshold of at least 4 responses in the first 22 patients exceeded in 2-stage trial
- ✓ ASCO: Interim data from first 15 evaluable patients – 6 out of 7 PD-L1 negative pts reported benefit including 2 PRs (29%)

### Monotherapy efficacy reported: Phase II trial in advanced leukaemia (R/R AML and high risk MDS)

- ✓ ASCO and EHA: Superior response rates observed in biomarker subgroup analysis
- ✓ Evidence of immune activation following bemcentinib monotherapy observed in 7 out of 11 (64%) pts analysed

### Biomarker correlation reported: CDx pipeline evaluating soluble and tissue marker candidates

- ✓ Tissue: AXL IHC method reported encouraging correlation data
- ✓ Blood-based biomarkers: Low plasma soluble AXL predicts patient benefit in R/R AML/MDS

### Low prevalence of AXL and PD-L1 reported in TNBC: Phase II combination trial with

- ✓ 14 of 18 pts analysed negative for AXL and reported no clinical benefit
- ✓ First efficacy endpoint in 2-stage trial not met

### Cash position NOK441m, completed private placement of USD24m incl. US specialist investors



# AXL is a receptor tyrosine kinase

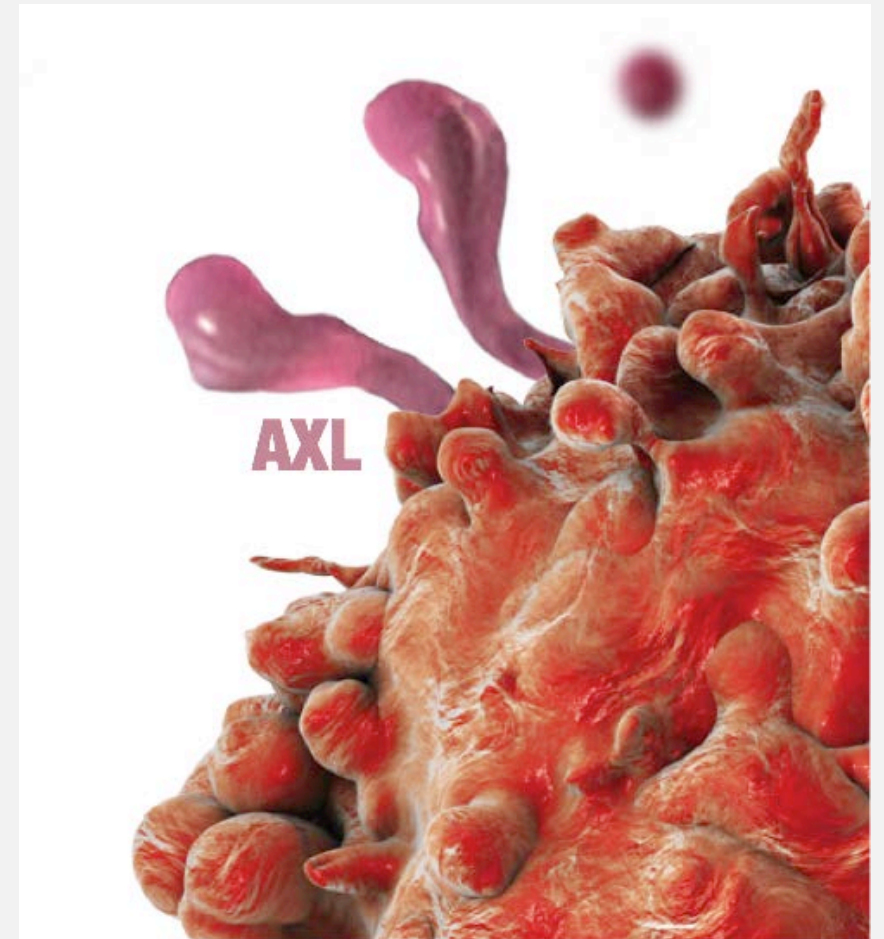
**Increased expression correlates with poor patient prognosis** in most solid and haematological tumours and other aggressive diseases

**Essential mediator of aggressive cancer traits:** acquired drug resistance, immune evasion and metastasis

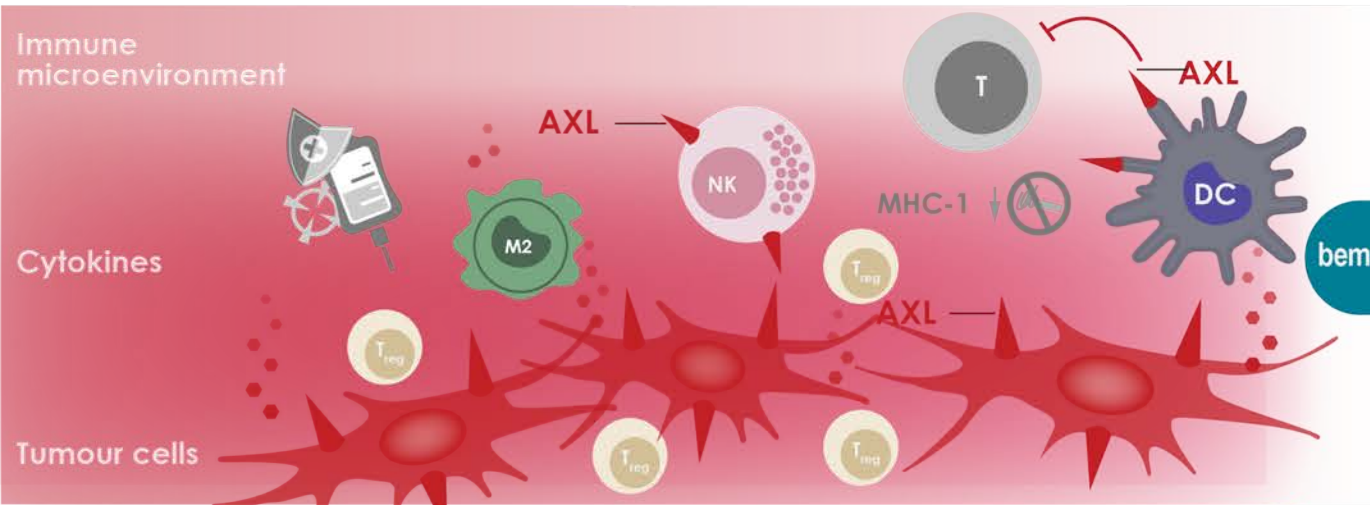
**Upregulated in hostile tumour microenvironment**, including hypoxia, inflammation, toxicity and cellular stress.

**Expressed on cancer cells, macrophages, NK & dendritic cells**

**Very low expression in normal tissues;** AXL knockout mouse is phenotypically normal



# Bemcentinib: selectively inhibits AXL kinase, this prevents immune evasion, restores sensitivity to chemo therapy and blocks spread.



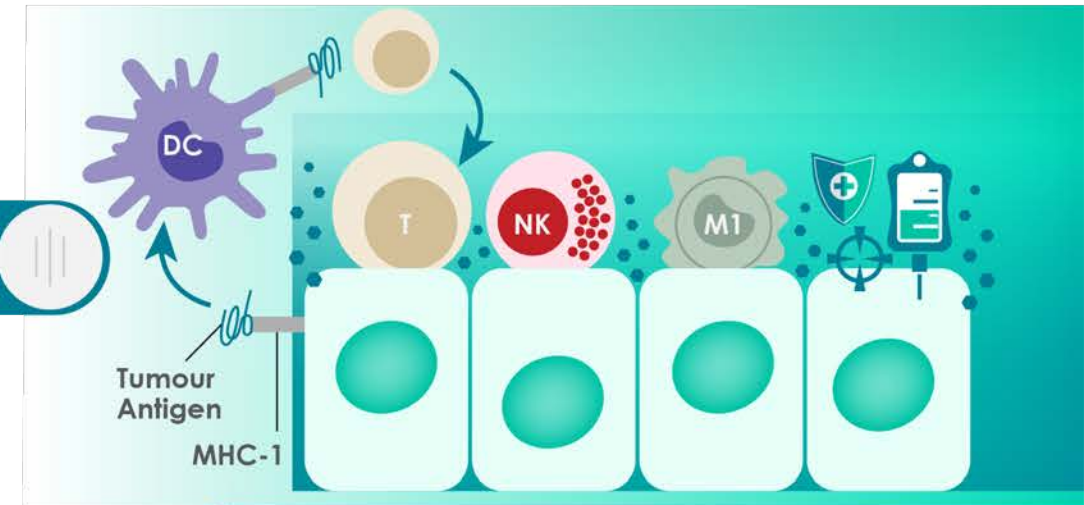
Therapy resistance, increased tumour cell aggressiveness

Immunosuppressive macrophages

Suppressed NK mediated killing of tumour cells and metastases

Reduced MHC-I & reduced antigen presentation / T-cell priming

Less effective T-cell mediated killing



Antigen Presentation by Tumour Cells & DCs

Effective NK Cell Killing

Immune Competent Macrophages

Effective anti-cancer therapy

Effective T-cell mediated killing





# Bemcentinib, first in class highly selective AXL inhibitor



**Selective, orally bioavailable**, small molecule AXL kinase inhibitor

**Predictable PK with once daily dosing**

**Robust and reproducible CMC**

**3 years stability**

**Strong patent position**

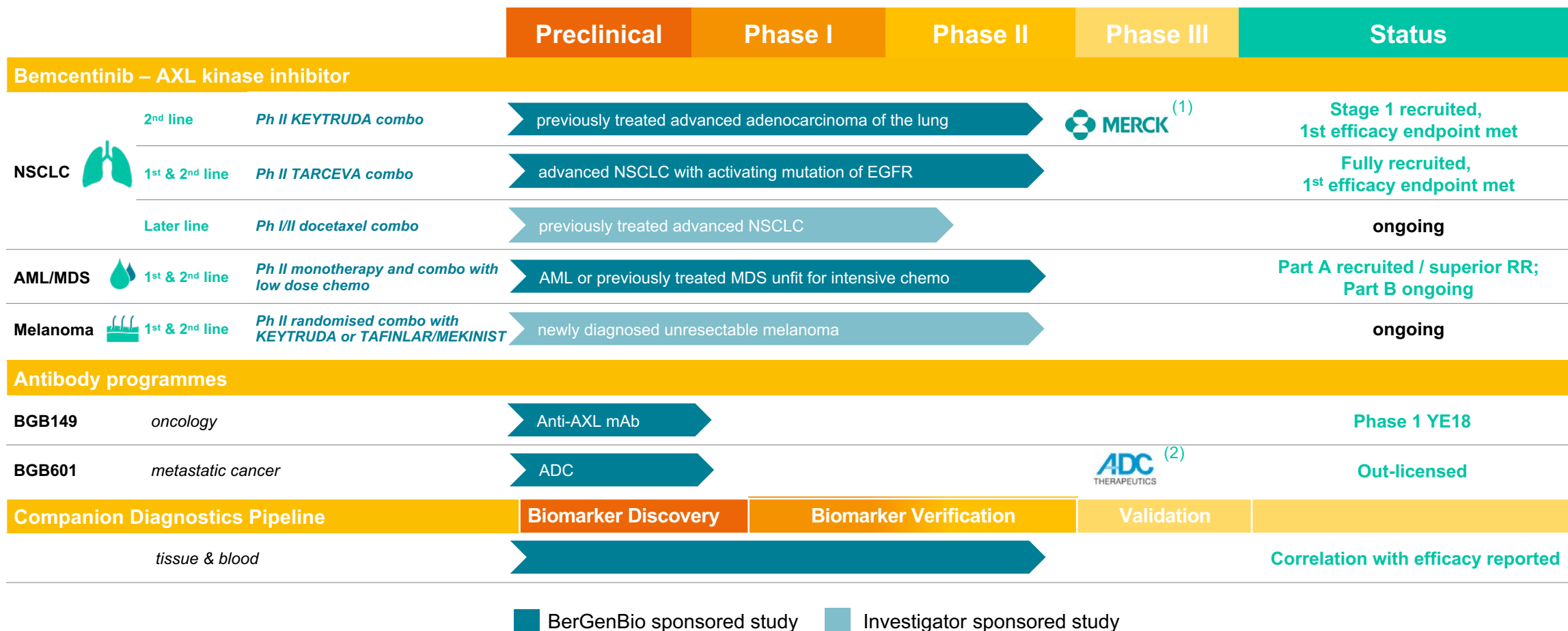
**Well tolerated over extended periods of time**

Safely combined with chemo, targeted and IO drugs

**50-100 fold selective cf. TAM kinases**

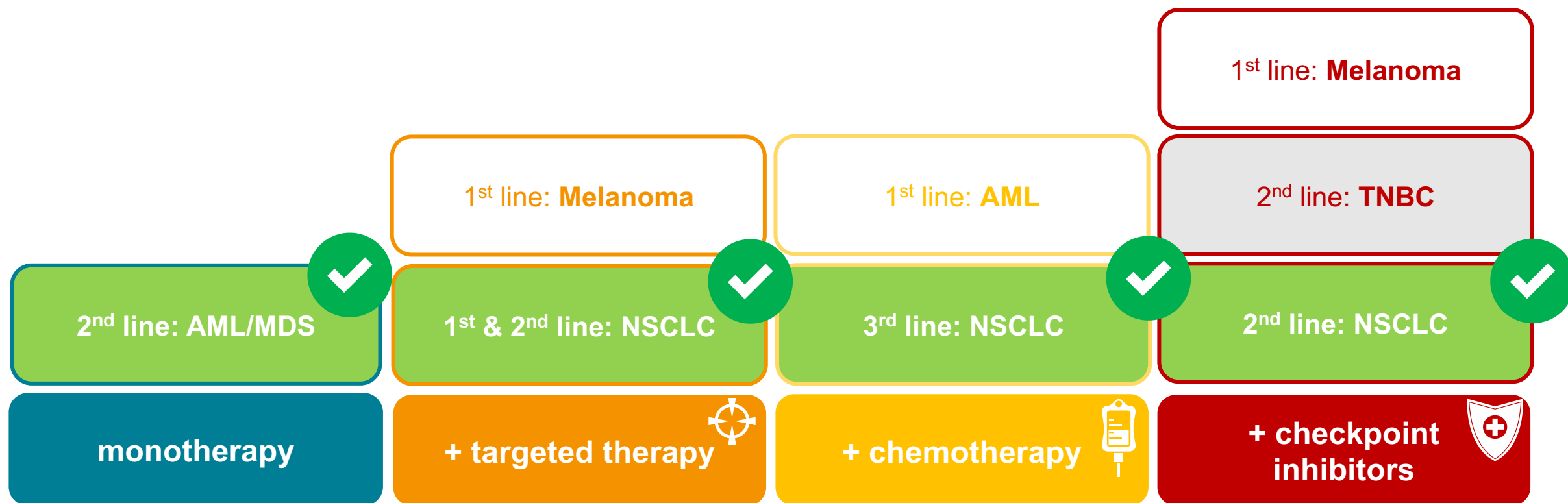
$IC_{50} = 14 \text{ nM}$

# Active pipeline of development programmes



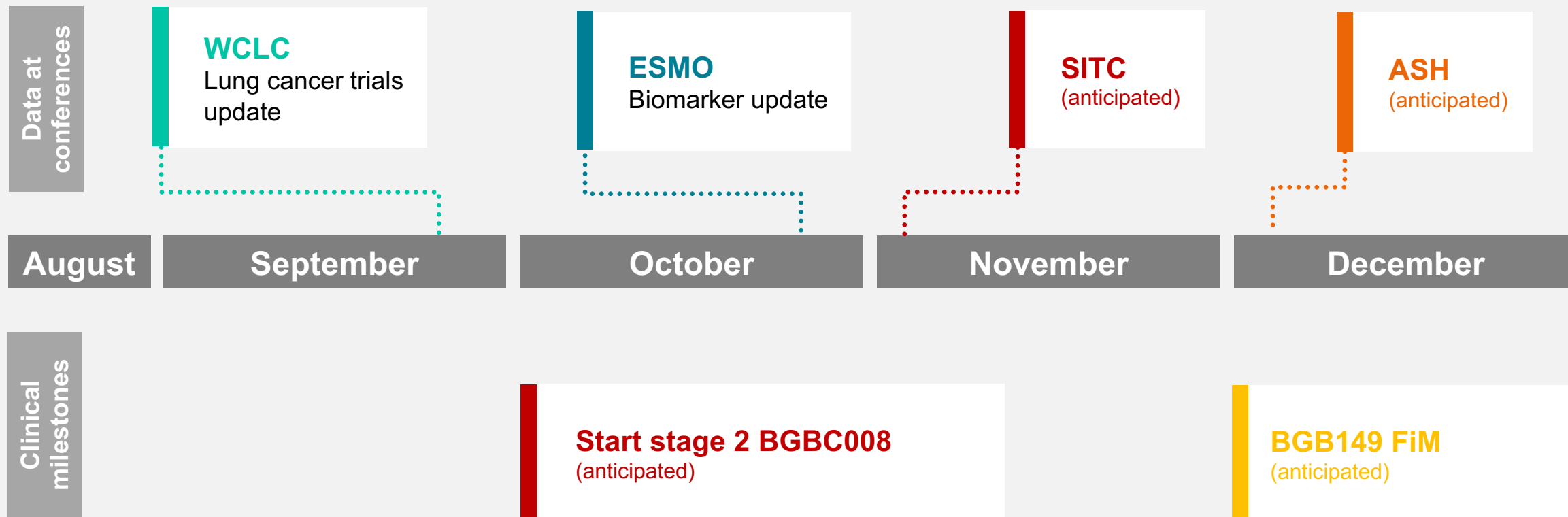
<sup>10</sup> (1): Clinical trial collaboration, no preferential rights (2): out licensed

# AXL inhibition as cornerstone for cancer therapy: bemcentinib proof-of-concept Phase II clinical trials



**Bemcentinib as a foundation therapy**

# H2 2018 News flow



# Non-small Cell Lung Cancer (NSCLC)

Bemcentinib holds much potential in NSCLC combining with emerging and standard of care therapies





# Lung Cancer: evolving SoC

## - but still lacking promising CT free regimens

### The largest cancer killer, most patients depend on drug therapy

- > 1.5 million lung cancer deaths/yr worldwide<sup>1</sup>
- > 50% of cases detected late and can not be treated with surgery alone<sup>2</sup>

### First line NSCLC\* SoC evolving towards IO +/- CT:

- **All comor patients: KEYTRUDA + CT**
  - **May 2017:** KEYTRUDA + CT approved in non-squamous (KEYNOTE-021, cohort G<sup>3</sup>)
  - **AACR 2018:** KEYNOTE-189 (non-squamous) meets dual primary endpoint of OS & PFS<sup>4</sup>
  - **ASCO 2018:** KEYNOTE-407 (squamous) shows OS benefit<sup>5</sup>
- **PD-L1 positive: KEYTRUDA monotherapy**
  - **Oct 2016:** KEYTRUDA monotherapy approved in > 50% PD-L1 (KEYNOTE-024<sup>6</sup>)
  - **ASCO 2018:** KEYNOTE-042 shows OS benefit in >1% PD-L1<sup>7</sup>







### Second line NSCLC – pts progressed on chemo or targeted therapy

- **PD-L1 positive – KEYTRUDA monotherapy:** approved (KEYNOTE-010<sup>8</sup>)
- **PD-L1 negative – no IO option:** KEYTRUDA not superior to 2L CT (KEYNOTE-001<sup>9</sup>)





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

	Targeted therapy 	PD-1 blockade 	Chemotherapy 
Current SoC	1L adeno NSCLC w/ actionable mutations (eg EGFR)	PD-L1 positive NSCLC	PD-L1 negative patients w/o actionable mutations + 2L
Bemcentinib PoC phase II programme			
+ bemcentinib	<b>BGBC004</b>  Reverse (2L) and prevent resistance (1L) to EGFR targeted therapy	<b>BGBC008</b>  Increase response rate - especially in PD-L1 negative	<b>BGBIL005</b>  Increase response rate



# Increasing the number of cancer patients who respond to KEYTRUDA without combining with CT is a major opportunity

Ca 40%<sup>1</sup> of patients are PDL-1 negative

PDL-1 negative patients do not benefit from KEYTRUDA monotherapy

Opportunity to increase addressable market by adding bemcentinib









*Data subject to ongoing analysis. Comprehensive analysis of stage 1 will be presented at future medical congresses*



# Potential strategic positioning of 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

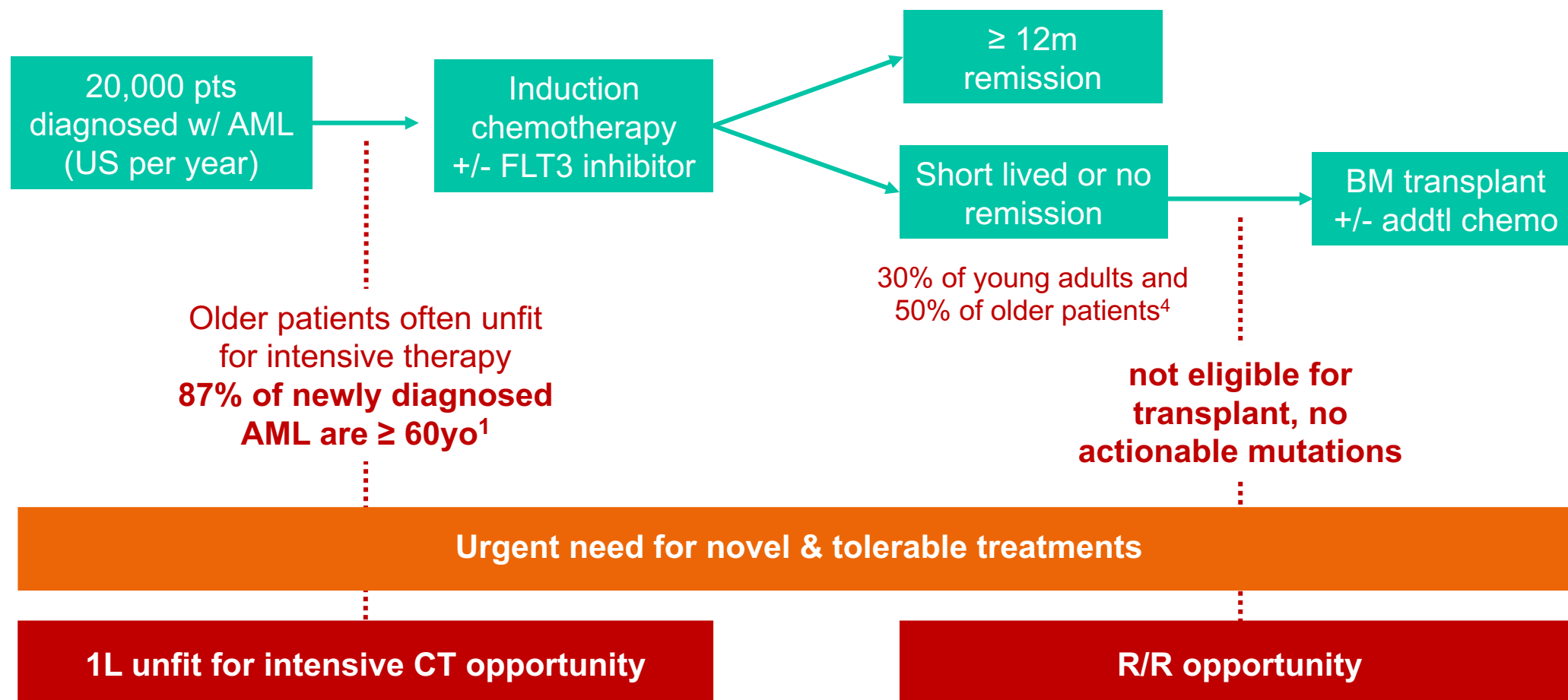
Targeted therapy 		PD-1 blockade 	Chemotherapy 
Bemcentinib PoC phase II programme			
bemcentinib single arm combos	<b>BGBC004</b>  Reverse (2L) and prevent resistance (1L) to EGFR targeted therapy (Tx)	<b>BGBC008</b>  Increase response rate - especially in PD-L1 negative	<b>BGBIL005</b>  Increase response rate
Strategic considerations for randomised phase II programme based on phase II PoC			
Bemcentinib randomised combos	<b>1L</b> <ul style="list-style-type: none"><li>First line Tx +/- bemcentinib</li></ul> <b>2L</b> <ul style="list-style-type: none"><li>non-mutation driven resistance to Tx</li></ul>	<b>1L</b> <ul style="list-style-type: none"><li>CT free combo (incl. PD-L1 neg)</li><li>Add to Pt CT</li></ul> <b>2L</b> <ul style="list-style-type: none"><li>Add to IO upon progression</li></ul>	<b>2L</b> <ul style="list-style-type: none"><li>Combo with docetaxel in IO / Pt CT / Tx progressors</li></ul>



# Advanced leukaemia (R/R AML/MDS): Monotherapy efficacy in a hard to treat patient population



# AML & MDS – difficult to treat malignancies, predominantly elderly frail patient population.



# Evaluation of bemcentinib as a single agent and in combination with SOC low dose chemotherapy (LDCT) in relapsed/refractory (R/R) AML or MDS patients

BGBC003: all comer, R/R AML or high-risk MDS patients unfit for intensive chemotherapy

**Bemcentinib +/- LDCT**



**Sub-group analysis:**  
Efficacy according to plasma soluble AXL (sAXL; and others)



**Strategy for randomised and pivotal trials**

## Programme key points

### ✓ Monotherapy & LDCT combo:

AML	MDS
1L combo w/ Cytarabine or Decitabine	
2L monotherapy	2L monotherapy

### ✓ Monotherapy efficacy reported in R/R AML and MDS

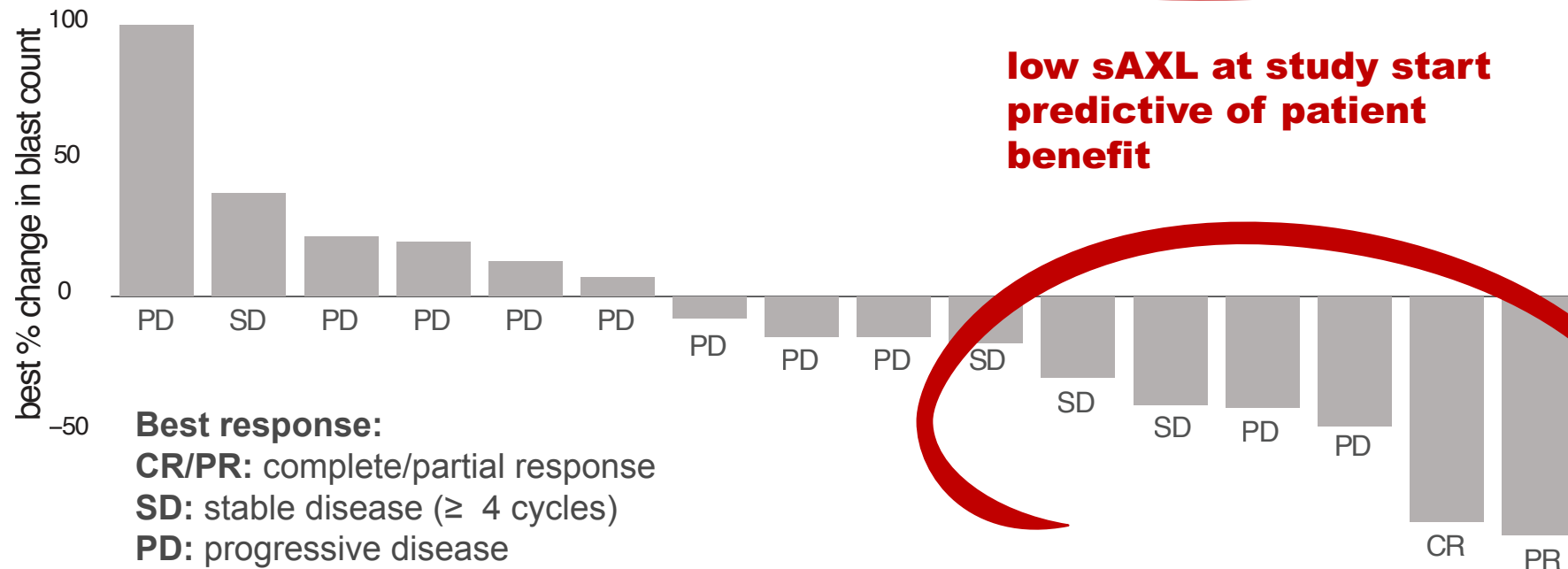
### ✓ Predictive biomarker candidate: low soluble plasma AXL (sAXL) predicts response

### ✓ Immune activation observed following bemcentinib monotherapy: 7 out of 11 (64%) pts analysed showed T- and/or B-cell receptor diversification in blood and/or BM



# ASCO: Strong efficacy seen in AML patients with low plasma soluble AXL (sAXL)

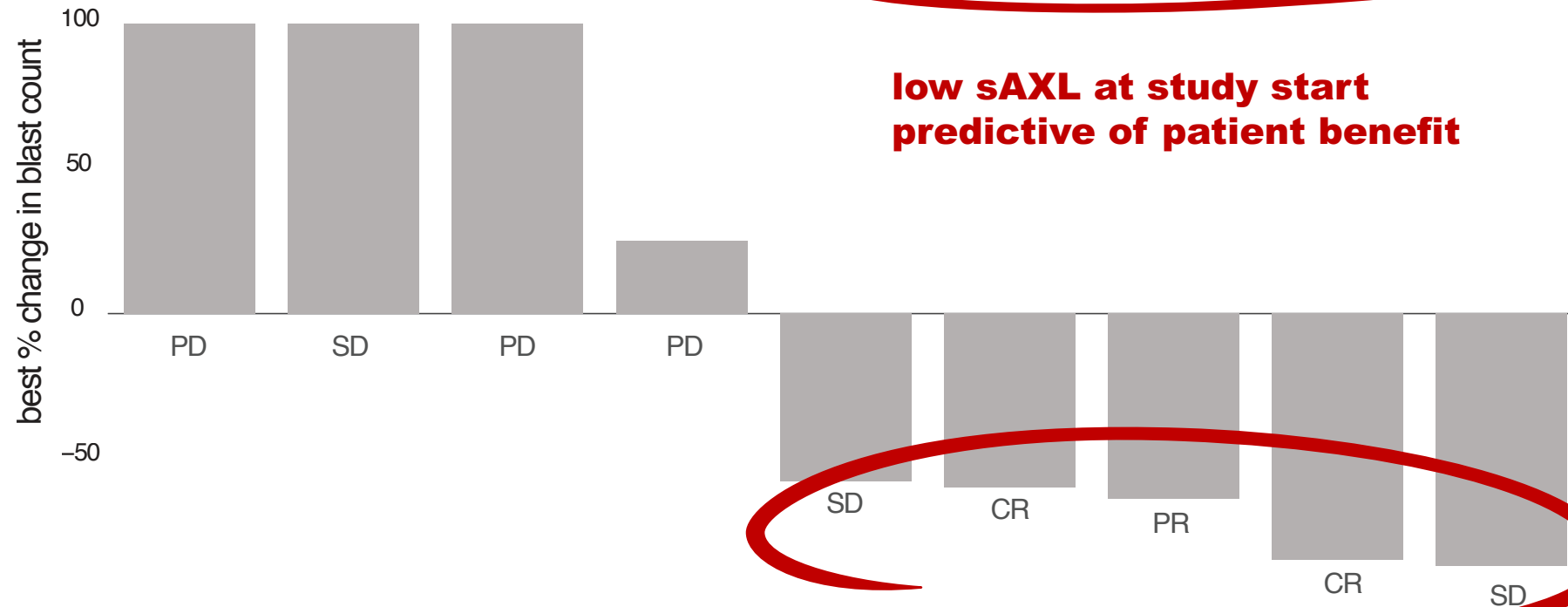
sAXL low **yes** no no no no no no no **yes yes yes no yes yes**



# ASCO: Strong efficacy seen in MDS patients with low plasma soluble AXL (sAXL)

sAXL low

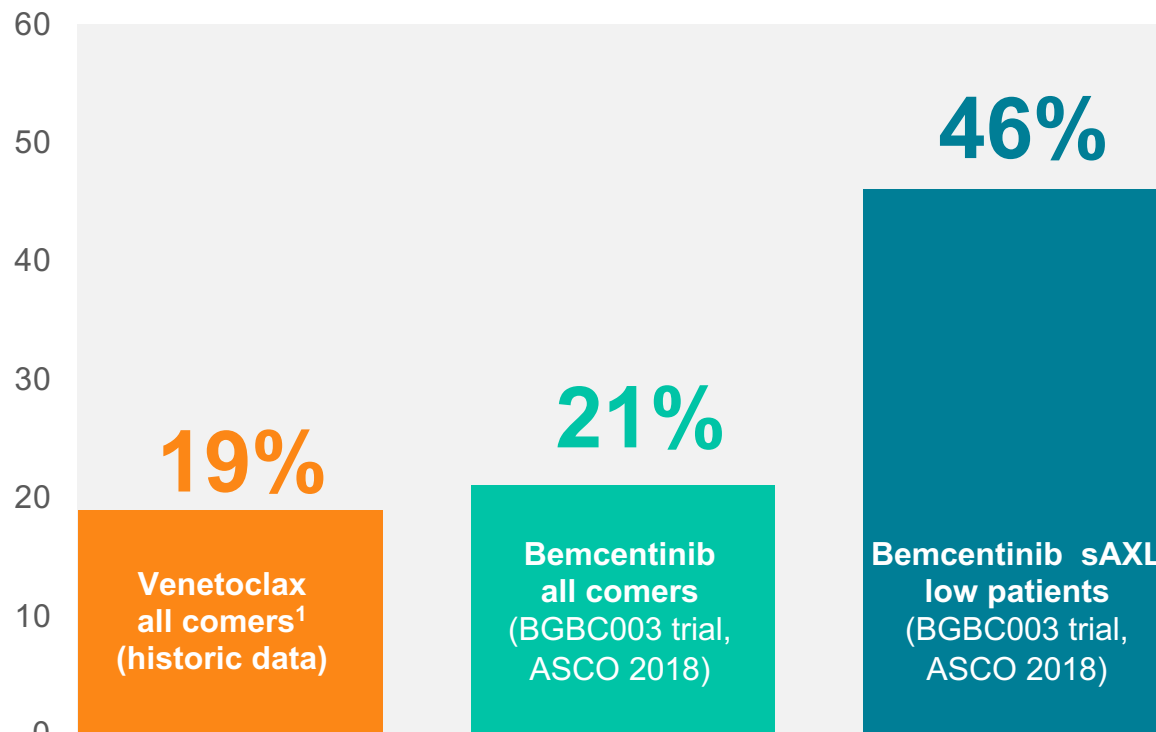
	yes		no	yes	yes	yes	yes	yes
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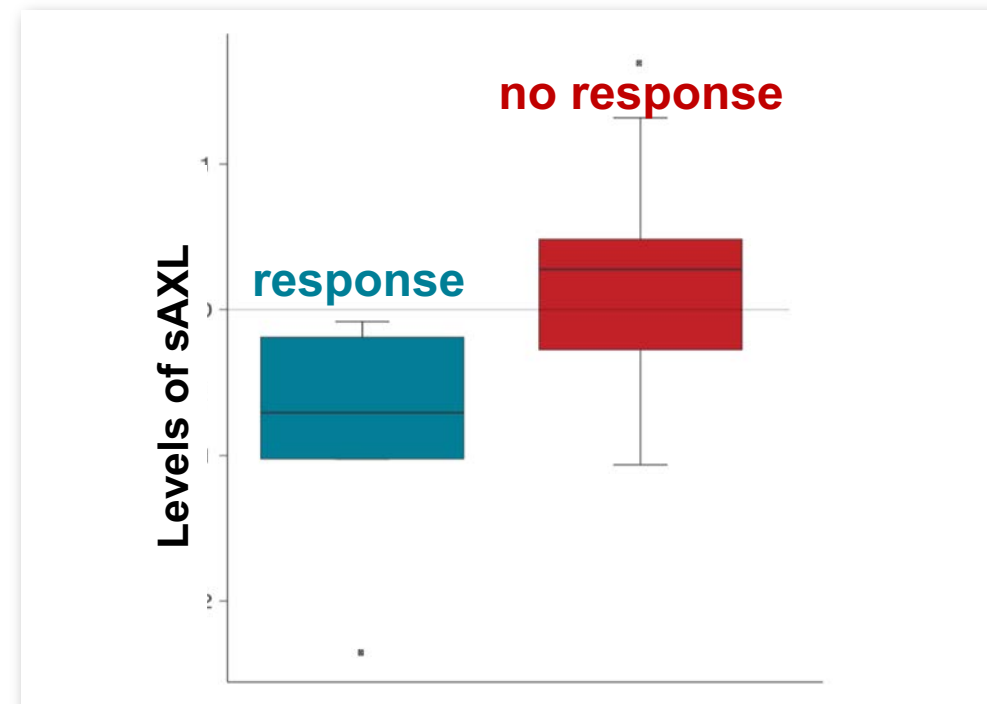
# ASCO: Superior efficacy in patients with low sAXL

## ORR in R/R AML & MDS patients Bemcentinib compared to another experimental drug

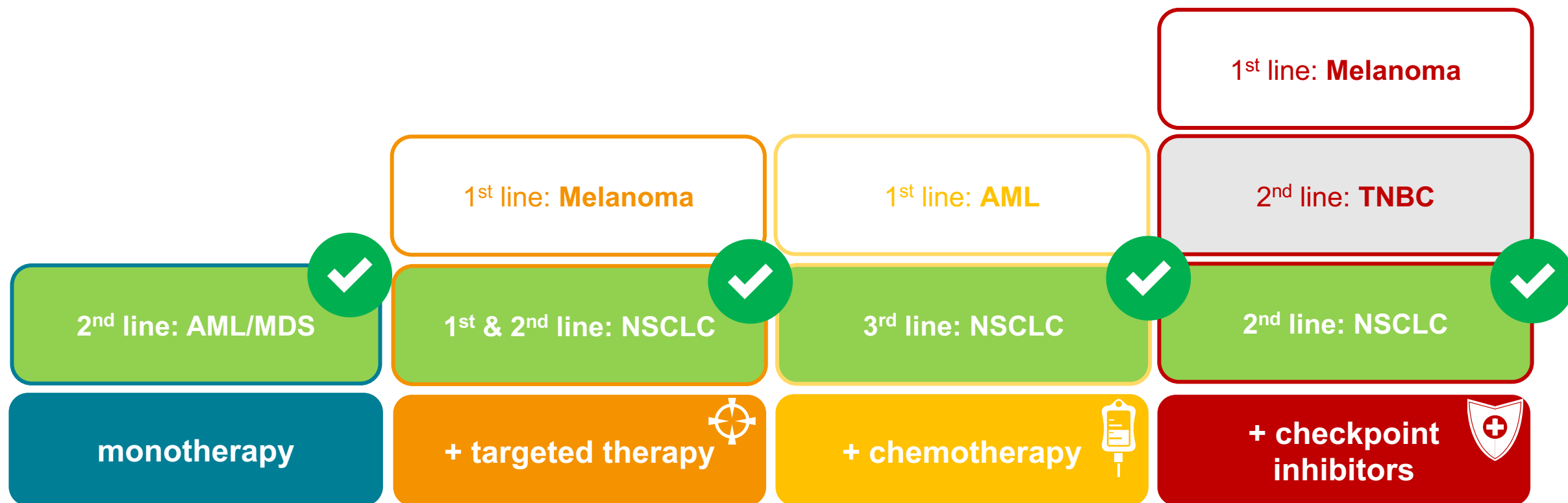


**Venetoclax:** oral BCL-2 inhibitor approved for CLL. Received recent attention for encouraging monotherapy efficacy in R/R AML unfit for intensive. Breakthrough designation for 1L AML in combo with LDCT; not approved in R/R AML

## Soluble AXL biomarker (sAXL): measured in blood (non-invasive liquid biopsy)



# AXL inhibition as cornerstone for cancer therapy: bemcentinib proof-of-concept Phase II clinical trials



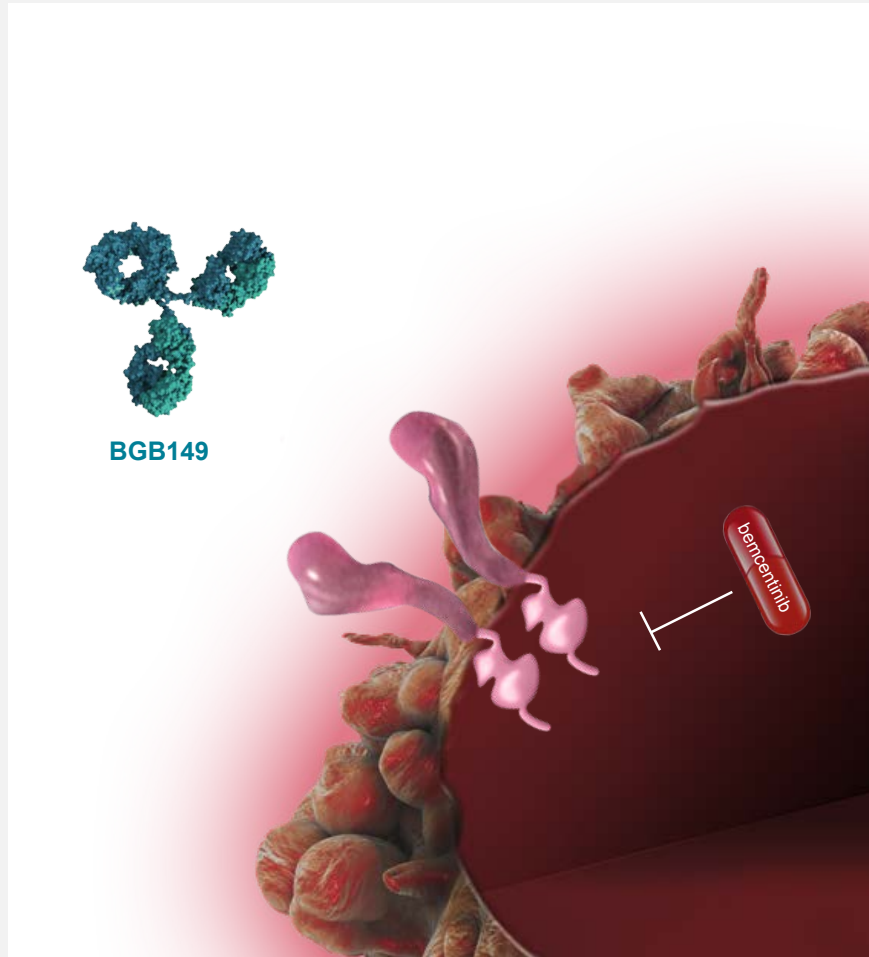
**Bemcentinib as a foundation therapy**

## Pipeline update:

Translating leadership in understanding AXL biology into a diversified portfolio of novel AXL inhibitors



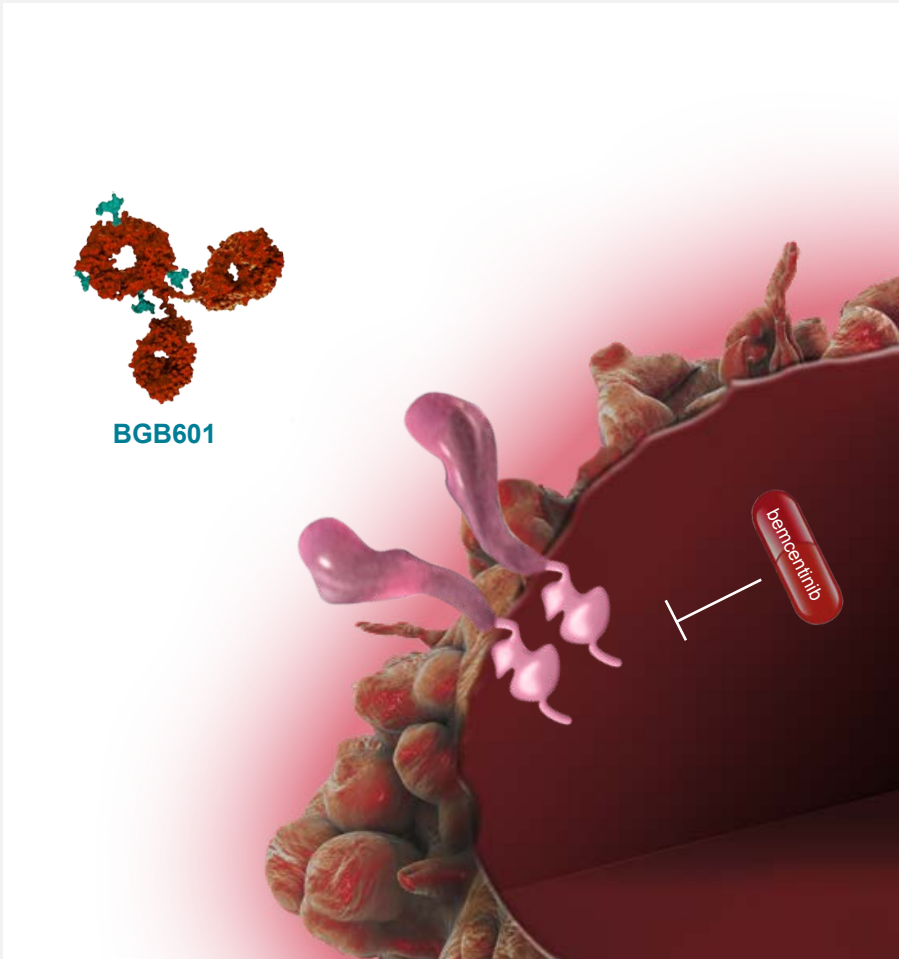
# BGB149: AXL function blocking antibody drug



- ✓ First in class anti AXL monoclonal antibody
- ✓ Healthy volunteer Ph I clinical trial anticipated YE'18
- ✓ Broad and long IP coverage
- ✓ Potent molecule and differentiated clinical position



# BGB601 (ADCT-601): AXL Antibody Drug Conjugate



Highly targeted drug constructs that combine monoclonal antibodies specific to AXL with the latest generation of a novel class of highly potent pyrrolobenzodiazepine (PBD) dimer toxins

**Outlicensed to ADC Therapeutics (Switzerland)**

- Development milestone payments
- Royalties

**AACR (April '18)<sup>1</sup>:**

Preclinical data on safety, tolerability and *in vivo* anti-tumour activity demonstrated (renal, breast, pancreatic), supports anticipated clinical development



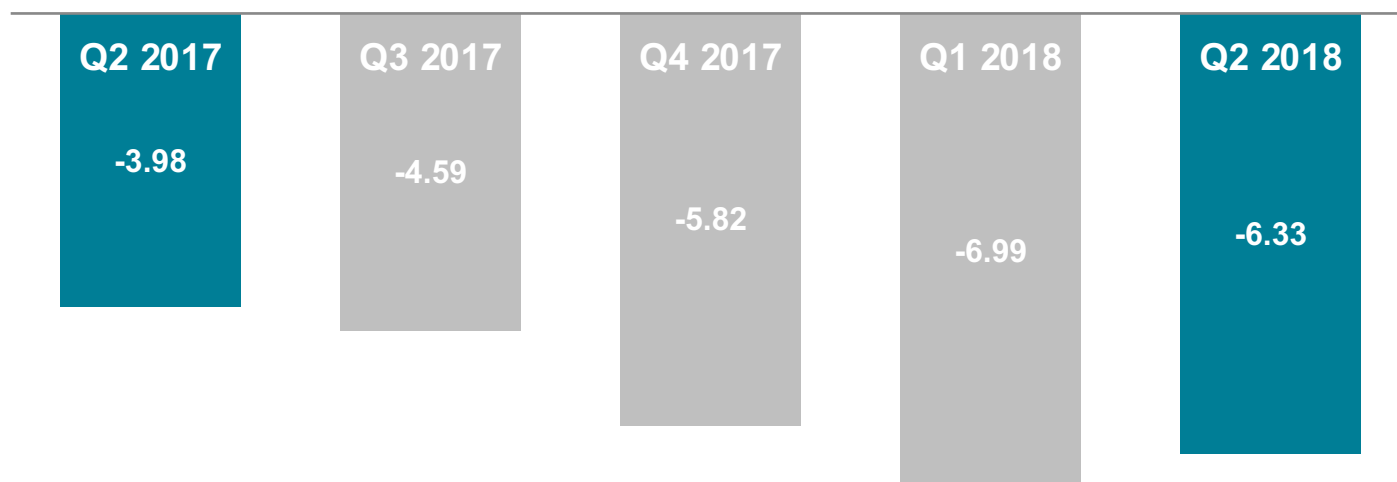
# Financial review:

## Cash position strengthened



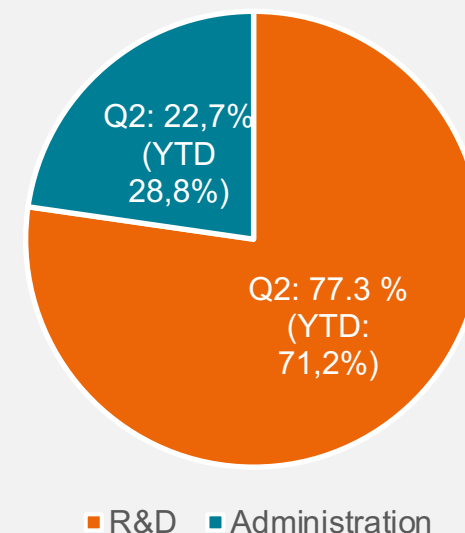
# Operating profit (loss)

Operating profit (loss) (million USD)



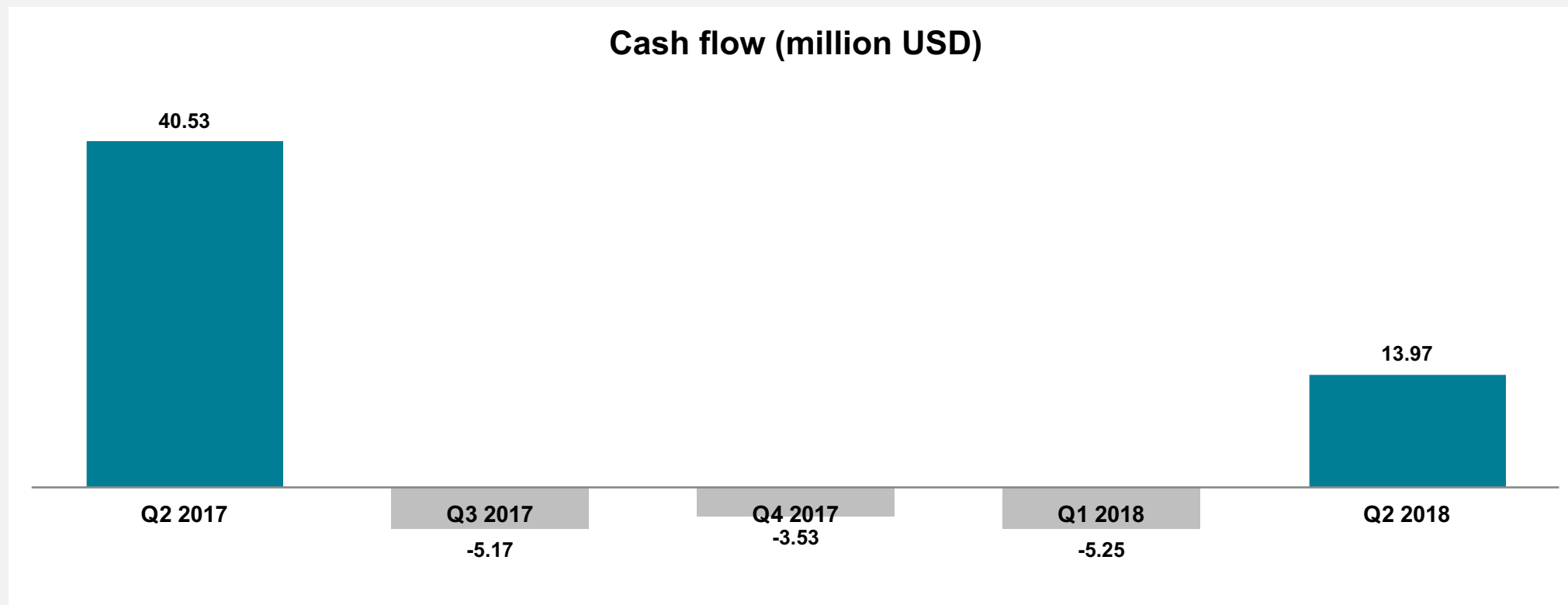
- Q1'18 increase in operating loss associated with increased social security tax provision (no cash effect) related to share price and share option scheme (USD 1.07 million)

Operating expenses Q2 2018



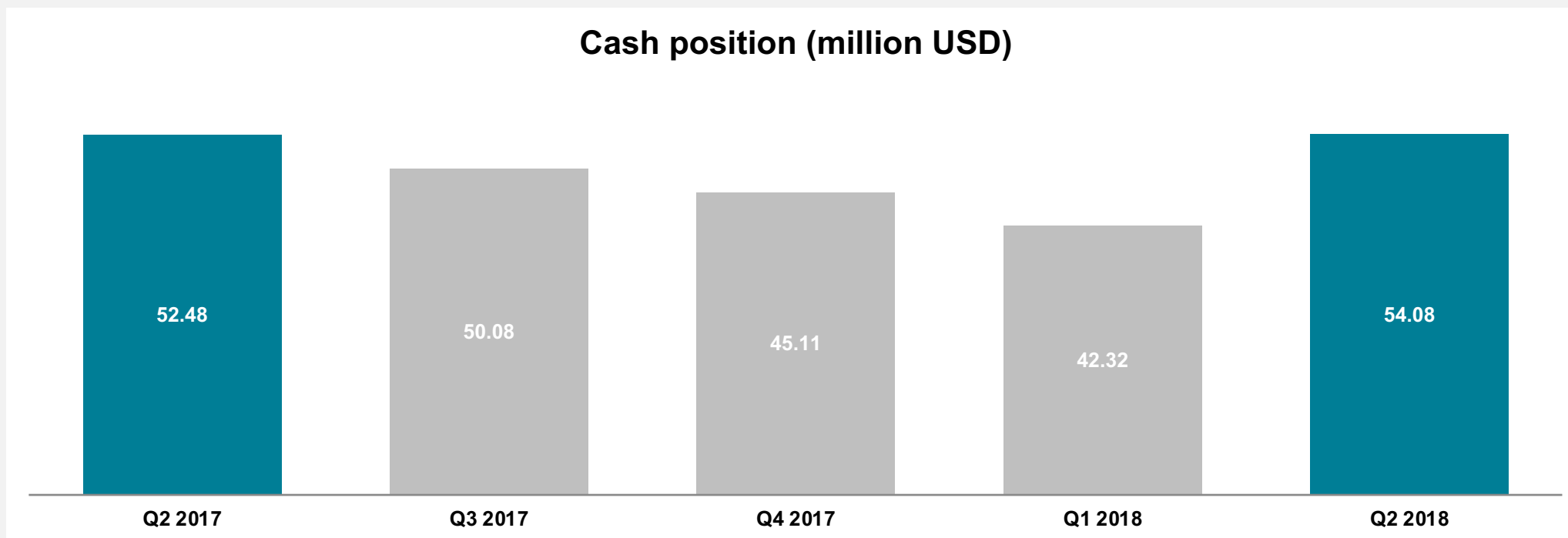
- Effective organisation
- 77,3% (YTD 71,2%) of operating expenses in Q2 2018 attributable to R&D activities

# Cash flow



- Private placement completed in April 2018 - gross funds raised USD 24 million

# Cash position



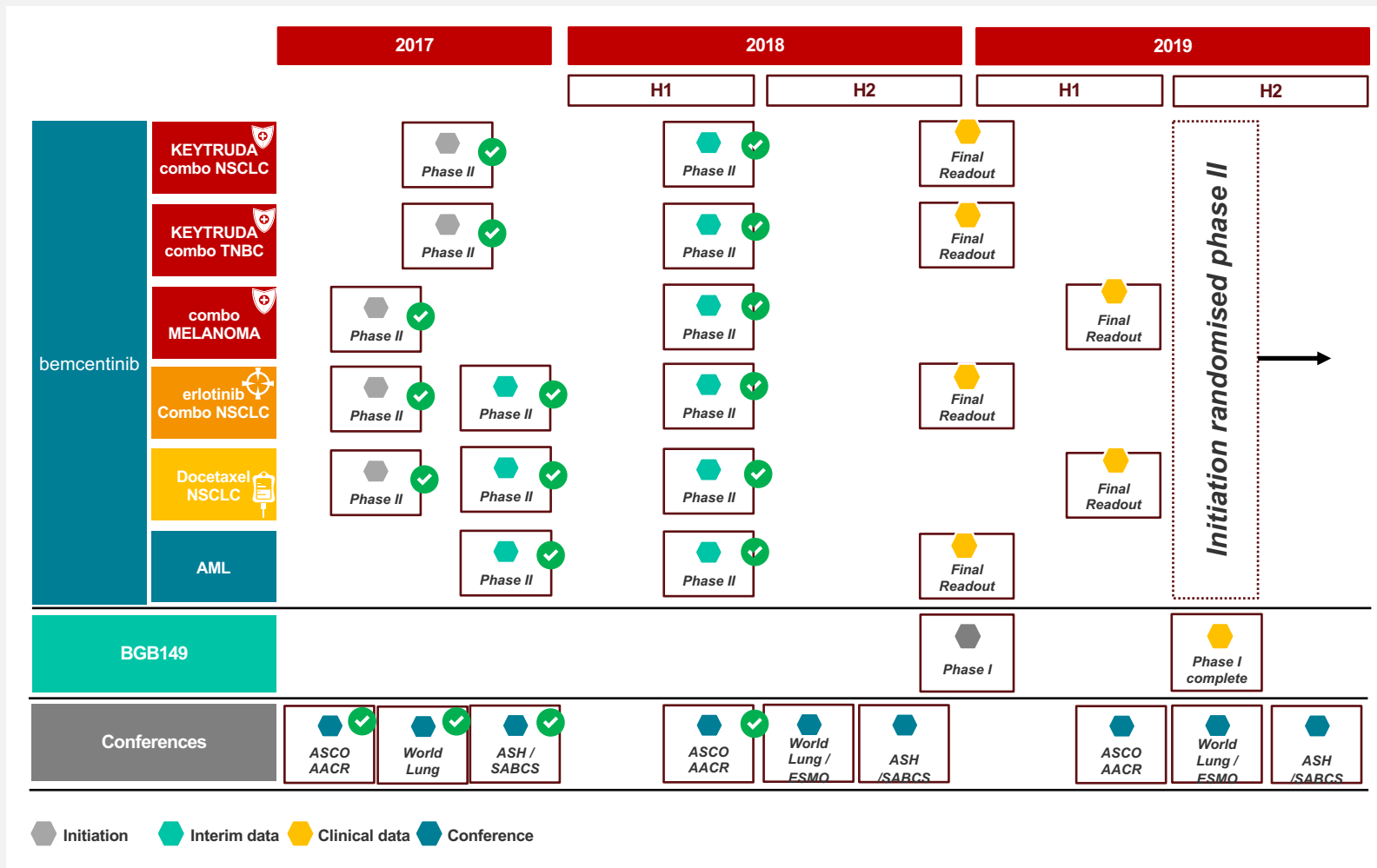
- Gross fund raise USD 24 million completed in April – strengthening cash position
- Shareholder base broadened with addition of US-based specialist healthcare funds
- Cash position gives runway to deliver key clinical read outs on ongoing clinical studies
- Cash runway into 2020 based on current burn rate

## Summary & Outlook:

A number of significant milestones expected in H2 2018 and 2019



# Significant milestones expected in 2018 & 2019



## Significant milestones expected in H2 2018

### 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 clinical data from broad phase II programme with bemcentinib, selective AXL inhibitor**

Interim data from ongoing phase II trials supporting proof of concept for bemcentinib to become a cornerstone of cancer therapy

## **Positioned to deliver significant value inflection points over the next 18 months**

- Key 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 1<sup>st</sup> June



***Thank you for your attention***

**Q&A**

# Appendix

# Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited

	Note	Q2 2018	Q2 2017	YTD 2018	YTD 2017	Full year 2017
<b>Revenue</b>		0	0	0	0	0
<b>Expenses</b>						
Employee benefit expenses	3	6 300	5 895	21 972	12 189	28 827
Depreciation		54	51	108	101	193
Other operating expenses	6	44 378	27 899	83 433	87 345	154 686
<b>Total operating expenses</b>		<b>50 732</b>	<b>33 846</b>	<b>105 513</b>	<b>99 635</b>	<b>183 707</b>
<b>Operating profit</b>		<b>-50 732</b>	<b>-33 846</b>	<b>-105 513</b>	<b>-99 635</b>	<b>-183 707</b>
Finance income		1 622	541	2 668	1 660	4 168
Finance expense		128	778	172	1 173	2 668
<b>Financial items, net</b>		<b>1 495</b>	<b>-236</b>	<b>2 496</b>	<b>487</b>	<b>1 500</b>
<b>Profit before tax</b>		<b>-49 238</b>	<b>-34 082</b>	<b>-103 017</b>	<b>-99 148</b>	<b>-182 207</b>
Income tax expense		0	0	0	0	0
<b>Profit after tax</b>		<b>-49 238</b>	<b>-34 082</b>	<b>-103 017</b>	<b>-99 148</b>	<b>-182 207</b>
<b>Other comprehensive income</b>						
<i>Items which will not be reclassified over profit and loss</i>						
Actuarial gains and losses on defined benefit pension plans		0	0	0	0	0
<b>Total comprehensive income for the period</b>		<b>-49 238</b>	<b>-34 082</b>	<b>-103 017</b>	<b>-99 148</b>	<b>-182 207</b>
<b>Earnings per share:</b>						
- Basic and diluted per share	7	-0,92	-0,70	-1,99	-2,41	-4,01

# Condensed consolidated statement of financial position

Note 30 JUN 2018 30 JUN 2017 31 DEC 2017

(NOK 1000) Unaudited

## ASSETS

### Non-current assets

Property, plant and equipment		518	467	557
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<b>Total non-current assets</b>		<b>518</b>	<b>467</b>	<b>557</b>
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### Current assets

Other current assets	5, 8	14 135	16 552	13 430
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Cash and cash equivalents		441 263	440 300	370 350
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<b>Total current assets</b>		<b>455 398</b>	<b>456 852</b>	<b>383 780</b>
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<b>TOTAL ASSETS</b>		<b>455 917</b>	<b>457 319</b>	<b>384 336</b>
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## EQUITY AND LIABILITIES

### Equity

#### Paid in capital

Share capital	9	5 471	4 974	4 992
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Share premium	9	398 521	406 301	325 018
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Other paid in capital	4, 9	20 687	18 969	20 340
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<b>Total paid in capital</b>		<b>424 678</b>	<b>430 245</b>	<b>350 350</b>
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<b>Total equity</b>		<b>424 678</b>	<b>430 245</b>	<b>350 350</b>
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### Non-current liabilities

Pension liability	10	0	0	0
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<b>Total non-current liabilities</b>		<b>0</b>	<b>0</b>	<b>0</b>
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### Current liabilities

Accounts payable		16 646	10 826	21 575
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Other current liabilities		5 443	12 605	9 391
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Provisions		9 150	3 643	3 020
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<b>Total current liabilities</b>		<b>31 238</b>	<b>27 074</b>	<b>33 986</b>
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<b>Total liabilities</b>		<b>31 238</b>	<b>27 074</b>	<b>33 986</b>
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<b>TOTAL EQUITY AND LIABILITIES</b>		<b>455 917</b>	<b>457 319</b>	<b>384 336</b>
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# Condensed consolidated statement of cash flow

(NOK 1000) Unaudited

## Cash flow from operating activities

	Note	YTD 2018	YTD 2017
Loss before tax		-103 017	-99 148
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		108	101
Calculated interest element on convertible loan		0	0
Share-based payment expense	3, 4	347	944
Movement in provisions and pensions		6 130	-1 200
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		-705	-4 250
Increase in trade and other payables		-8 878	7 008

<b>Net cash flow from operating activities</b>		<b>-106 015</b>	<b>-96 545</b>
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## Cash flows from investing activities

Purchase of property, plant and equipment		-70	-159
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<b>Net cash flow used in investing activities</b>		<b>-70</b>	<b>-159</b>
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## Cash flows from financing activities

Proceeds from issue of share capital	9	176 998	375 020
Paid in, not registered capital increase	9	0	159

<b>Net cash flow from financing activities</b>		<b>176 998</b>	<b>375 179</b>
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Net increase/(decrease) in cash and cash equivalents		70 914	278 475
Cash and cash equivalents at beginning of period		370 350	161 825

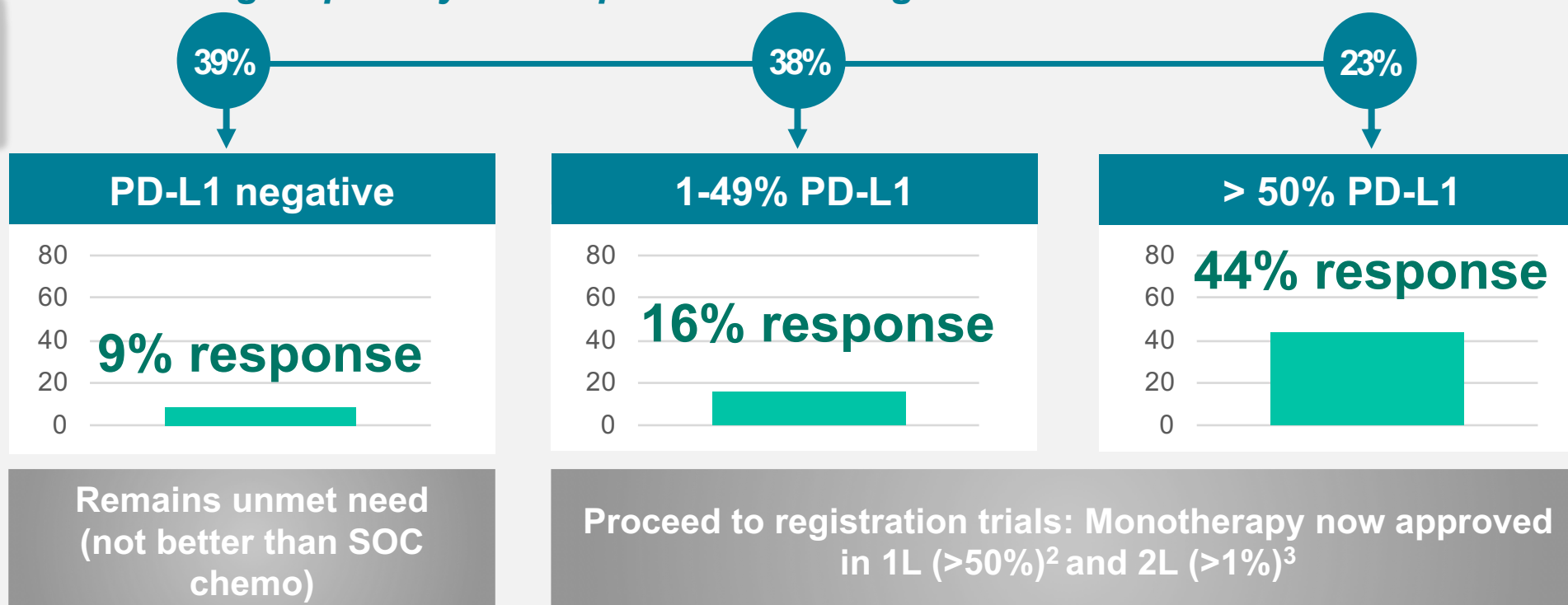
<b>Cash and cash equivalents at end of period</b>		<b>441 263</b>	<b>440 300</b>
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# The development of immune checkpoint inhibitors in NSCLC: KEYTRUDA emerged as the SOC for PD-L1 positive NSCLC















**KEYNOTE-001<sup>1</sup>**: all comer NSCLC patients, treat with KEYTRUDA monotherapy\*

*Sub-group analysis: response according to PD-L1 biomarker status\*\**



# Clinical trial update bemcentinib

<b>BGBC003:</b> <b>+ chemo or monotherapy</b> 	<ul style="list-style-type: none"> <li>✓ <b>sAXL blood test predicts patient benefit – superior efficacy observed in patients with low sAXL at study start</b></li> <li>✓ Immunomodulatory effect observed following bemcentinib monotherapy (ASCO-SITC, ASCO and EHA)</li> </ul> 
<b>BGBC008:</b> <b>+ KEYTRUDA</b> 	<ul style="list-style-type: none"> <li>✓ <b>First stage fully enrolled and first efficacy endpoint met</b></li> <li>✓ Promising activity in patients who are not expected to benefit from KEYTRUDA monotherapy (ASCO 2018)</li> </ul> 
<b>BGBC004:</b> <b>+ EGFR inhibitors</b> 	<ul style="list-style-type: none"> <li>✓ <b>Efficacy endpoint met in first stage of ph2 part combining with TARCEVA in pts who progressed on EGFR therapy (arm B)</b></li> <li>✓ Enrolling 1<sup>st</sup> line combo arm in patients who have received their maximum benefit from TARCEVA monotherapy, deepening of responses observed</li> </ul> 
<b>BGBIL005:</b> <b>+ docetaxel</b> 	<ul style="list-style-type: none"> <li>✓ <b>Superior responses seen in patients who derive little or no benefit from chemotherapy alone</b></li> <li>✓ 3 of 7 evaluable patients had PRs - soluble predictive biomarker candidates identified</li> </ul> 
 <b>BGBIL006</b> <b>+ KEYTRUDA or TAF/MEK</b> 	<ul style="list-style-type: none"> <li>✓ <b>All combos well tolerated, 15 of 19 pts evaluated to date showed tumour shrinkage (incl 2 CRs and 8 PRs) (ASCO 2018)</b></li> <li>✓ All ph2 arms open and recruiting at four sites in Norway</li> </ul> 
<b>BGBC007:</b> <b>+ KEYTRUDA</b> 	<ul style="list-style-type: none"> <li>✓ <b>First stage fully enrolled</b></li> <li>✓ Low prevalence of AXL in tissue biopsies observed (14 of 18 pts analysed) and correspondingly low rates of response seen</li> <li>✓ Interim efficacy endpoint not met</li> </ul> 