# OSE:BGBIO
# Result First Quarter 2018

**May 15th 2018**

**Richard Godfrey, CEO**

BerGenBio

# Disclaimer

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# Corporate Snapshot

## Background

**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**

## Bemcentinib (BGB324)

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

Broad phase II clinical programme in NSCLC, TNBC, AML/MDS, melanoma

## Pipeline

Bemcentinib (BGB324)

AXL antibody

AXL ADC (partnered)

Immunomodulatory small molecules

## OSE:BGBIO

Cash runway through to 2020

Included in the OSEBX index from 1st June 2018

+117% year to date share price increase

## Corporate

35 staff

Headquarters and research in Bergen, Norway; Clinical Trial Management in Oxford, UK

# Agenda

1. **Q1 2018 Highlights**
2. Bemcentinib's aspiring leadership position as the future cornerstone of cancer combination treatments
3. Q1 update on bemcentinib's global phase II development programme on track and delivering promising clinical data
4. Companion Diagnostic
5. Promising pre-clinical data supporting BerGenBio's pipeline
6. Finance report
7. Outlook
8. Q&A

# Q1 2018 results

## Good progress advancing bemcentinib's phase II clinical development

- ✓ First efficacy endpoint met in Phase II trial of bemcentinib/TARCEVA® combination in NSCLC
- ✓ Recruitment completed in first stage of Phase II trial of bemcentinib/KEYTRUDA® combination in TBNC
- ✓ Bemcentinib shown to be well tolerated in all patients enrolled across three combination trials with KEYTRUDA
- ✓ Single agent therapy with bemcentinib led to increased immune activity in relapsed / refractory AML & MDS patients

## Post period

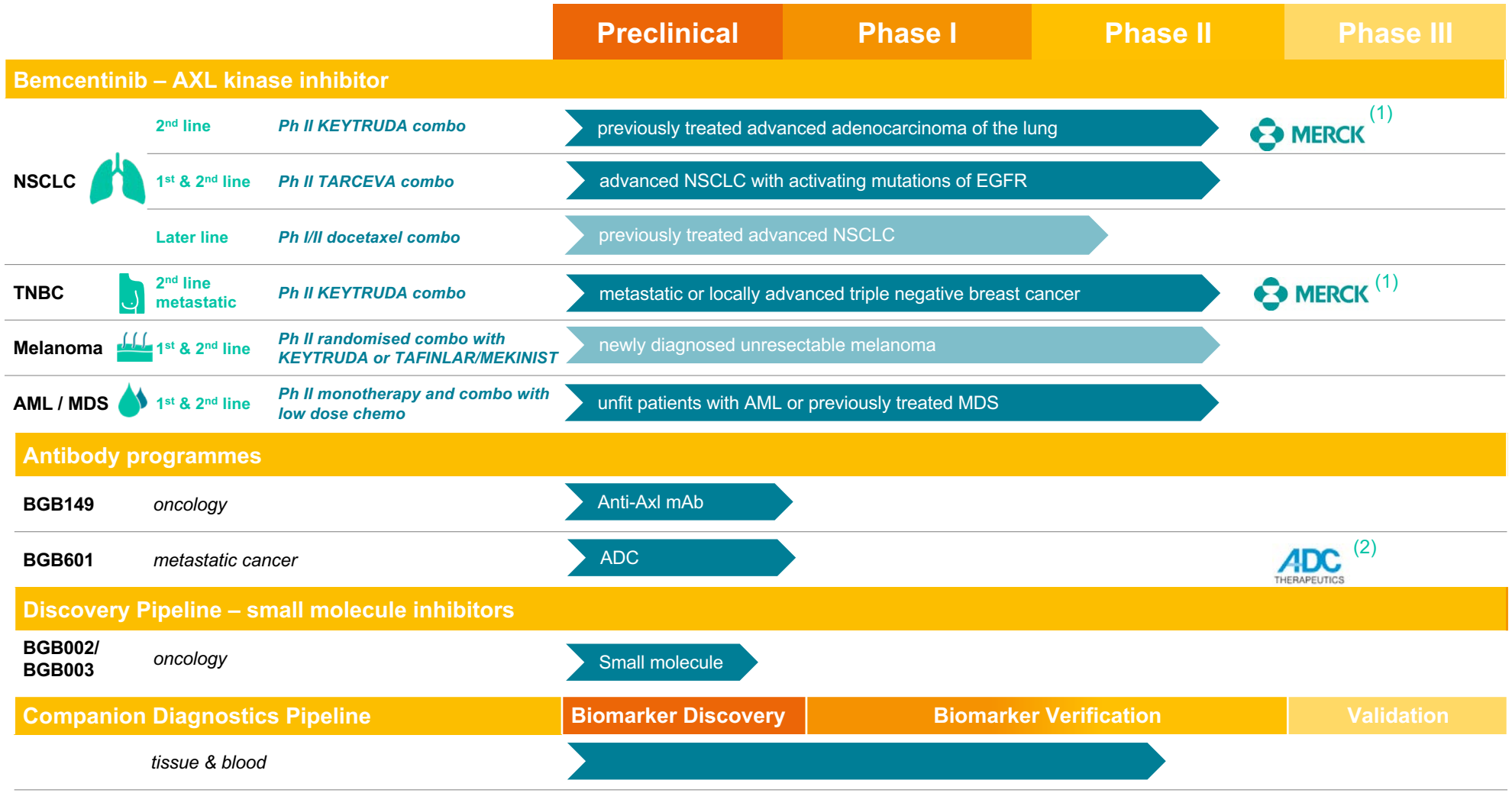
Recruitment completed in first stage of Phase II trial of bemcentinib/KEYTRUDA® combination in NSCLC

Private placement raising NOK 187.5 million

Emerging promising pre-clinical data continues to support BerGenBio pipeline development

- Data highlighting potential of selective AXL inhibition to treat advanced non-alcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF) presented at EASL annual meeting and pubished in American Journal of Respiratory and Critical Care Medicine, respectively
- Promising data highlighting bemcentinib's potential to reverse tumour immune suppression and enhance immune checkpoint inhibitor efficacy presented at AACR annual meeting
- Pre-clinical data supporting the clinical development of out-licensed AXL ADC BGB601 presented at AACR annual meeting

# Pipeline of innovative AXL inhibitors




Patients:
**>350**

Sites in Europe and North America:
**50**

Key read-outs:
**2018**

(1): Clinical trial collaboration, no preferential rights (2): out licensed

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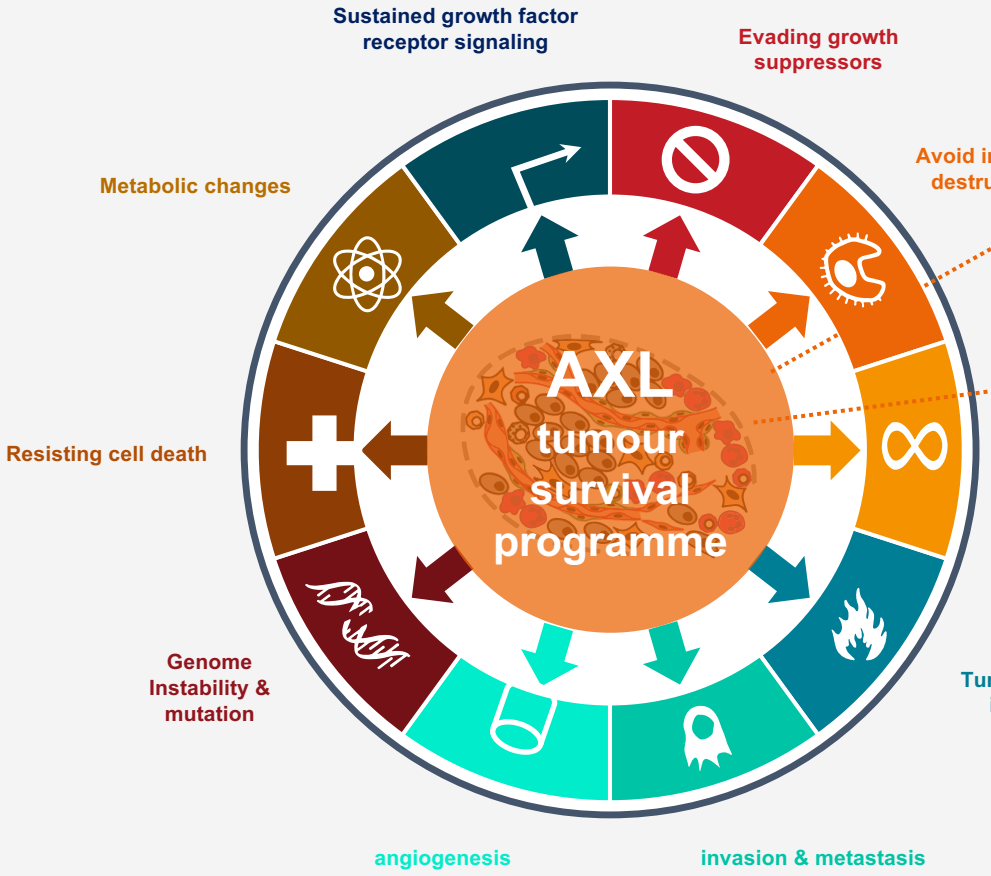
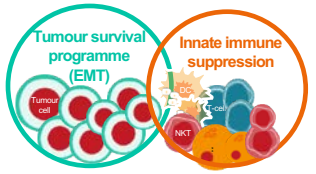
# AXL supports the hallmarks of cancer*

## - it drives key tumor survival programmes




**AXL is expressed on cancer & immune cells**




- Drives therapy resistance
- Immune evasion
- Cancer spread

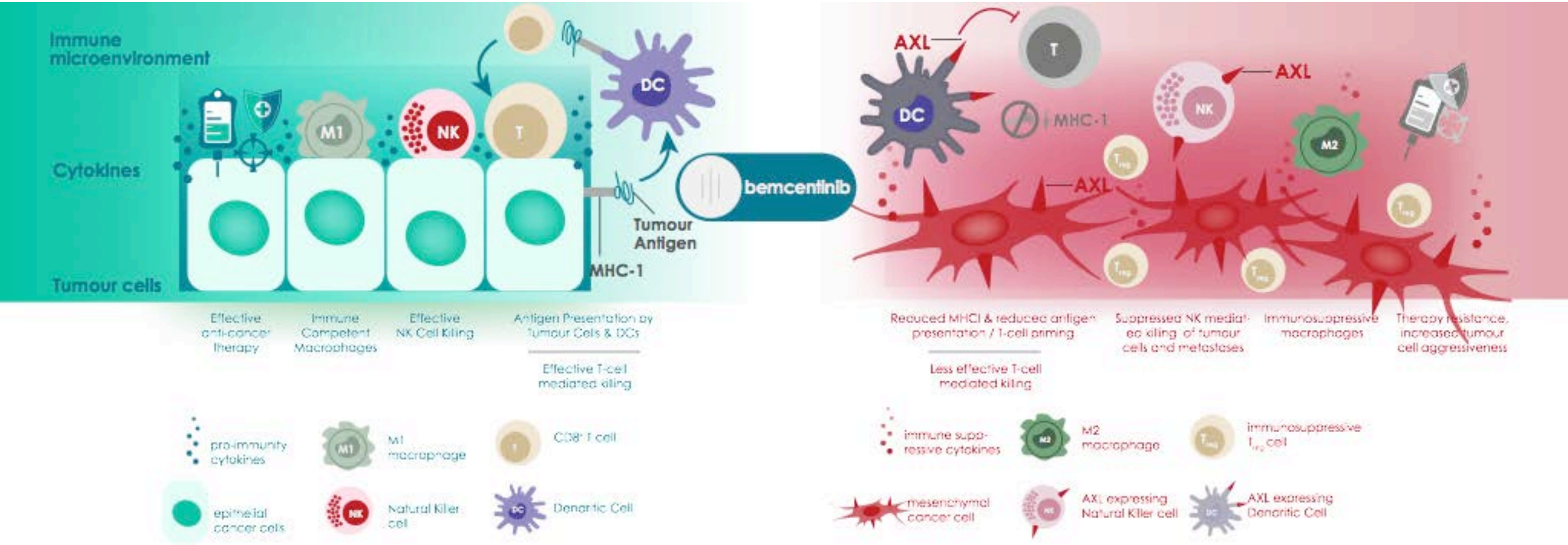
**AXL inhibition**

- ✓ Blocks tumour survival programme
- ✓ Prevents & reverse immune suppression
- ✓ Synergises with established & emerging anti-cancer drugs



* Hanahan and Weinberg, Cell, 2011

# Bemcentinib's mechanism: restore sensitivity to immune cell attack and therapy as well as prevent spread



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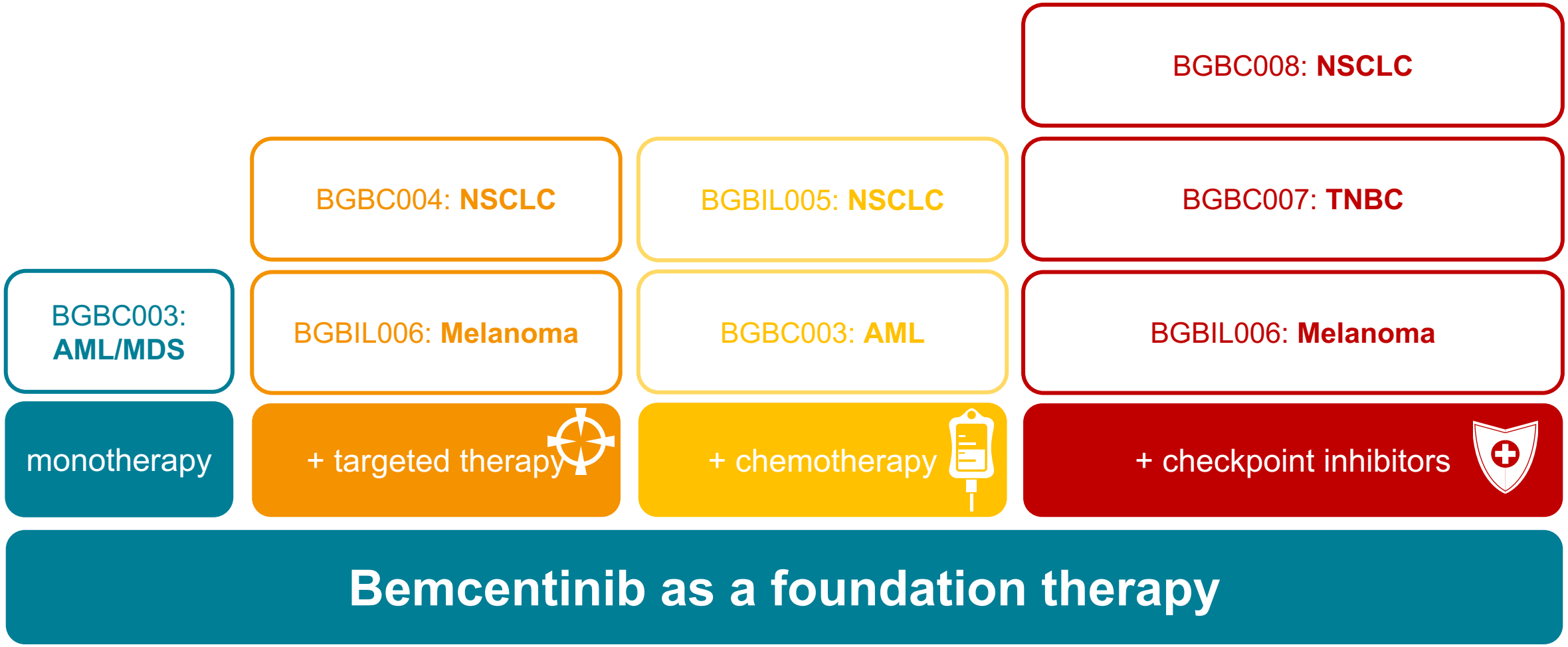
# AXL inhibition as cornerstone for cancer therapy bemcentinib proof-of-concept Phase II clinical trials



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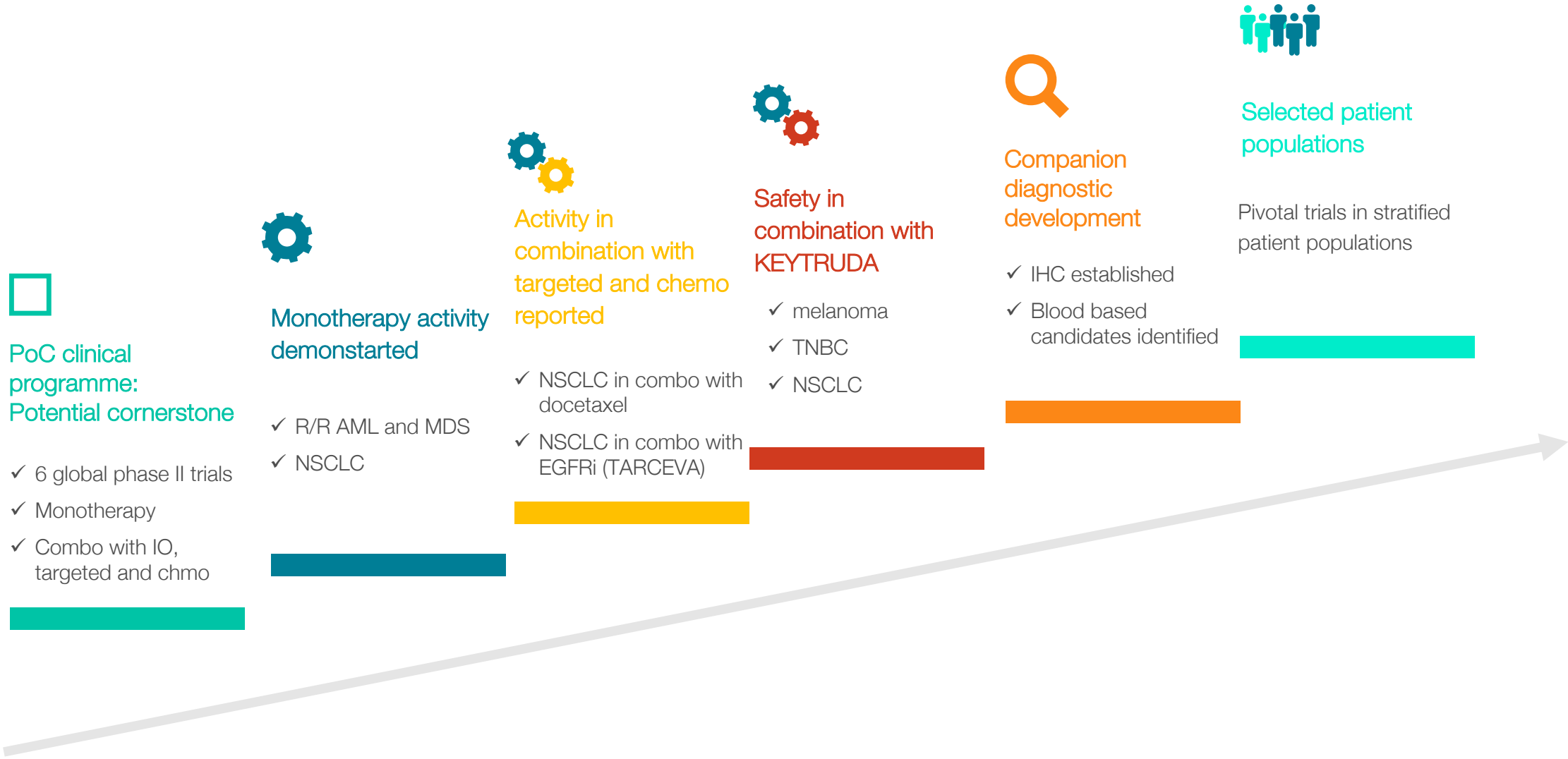
# Bemcentinib clinical development summary



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# BGBC003 trial in AML/MDS

*AML and high-risk MDS patients unfit for high intensity chemotherapy remain a very challenging patient population with no treatment options when driver mutations are absent*

The BGBC003 trial is designed to test the hypothesis whether AXL inhibition with bemcentinib can

- Elicit **single agent** effect and / or
- **Enhance responses** to low dose chemotherapy

when given as a single agent in relapsed / refractory AML and high risk MDS or in combination with azacitidine or decitabine in treatment naïve AML patients

# BGBC003: Phase Ib/II trial in AML/high risk MDS

**Bemcentinib monotherapy and/or in combination with chemo**

**Relapsed/refractory AML & high-risk MDS**

up to 75 pts

**Dose escalation**

| | | |
|---|---|---|
| AML | 2nd line monotherapy | Safety & efficacy |
| AML | 1st line combo bemcentinib + decitabine / | |
| MDS | 2nd line monotherapy | |

**Q1 2018 status**

- ✓ **2L monotherapy efficacy**
  - ✓ 19% response rate (2 Cri, 5 PR & 4 SD)
  - ✓ Predicative biomarker candidates identified
  - ✓ Immune activation reported
- ✓ **Sites open in US, Norway, Germany + 4 new sites in Italy**



Source: NCT02424617

# BGBC004 trial in NSCLC

*NSCLC patients tend to initially respond well to targeted therapies but virtually all acquire resistance over time.*

The BGBC004 trial is designed to test the hypothesis whether AXL inhibition can

- **Reverse** and / or
- **Prevent** resistance to EGFRm targeted therapies

when given in combination with erlotinib in EGFRm NSCLC patients who have either progressed on or have just started EGFRm targeted therapy

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

**Stage IIIb or IV disease EGFR mutation positive**

33 enrolled as of March 15th 2018

**Dose escalation & expansion (ongoing)**

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

**Q1 2018 status**

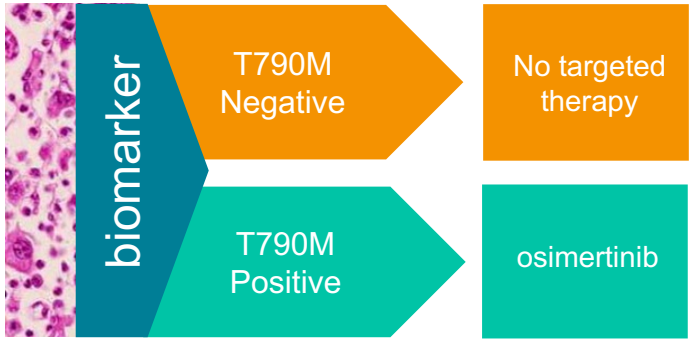
- ✓ **Arm A1 - monotherapy: 25% CBR**
  2 SD including tumour shrinkage (19%) n=8
- ✓ **Arm A2– combination with erlotinib: 50% CBR**
  1 PR and 3 SD n=8. PR ongoing in excess of 2 years
- ✓ **Arm B – 2L / combo w/ erlotinib: 33% CBR**
  First efficacy endpoint met
  1 PR & 2 SD n=9
- ✓ **Arm C – resistance prevention combo w/ erlotinib:**
  Ongoing and recruiting, 1 PR reported



Source: NCT02424617

# BGBC004: Phase II Arm B, erlotinib resistance reversal
# Primary efficacy end point met

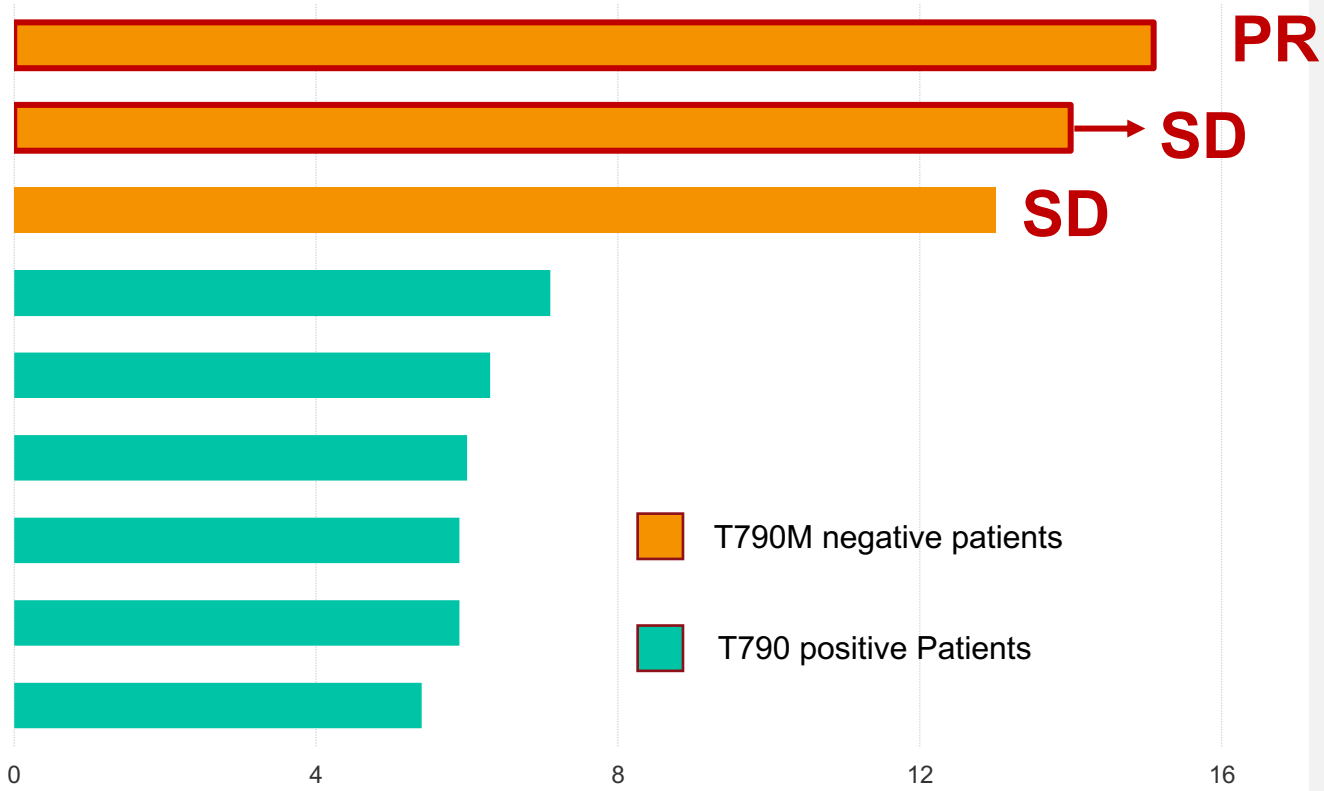
## No targeted therapy available for 2nd line T790M negative patients*




## Arm B patient population

- **Progressed on 1st line approved EGFR TKI therapy** (erlotinib, afatinib, gefitinib)
- **Median 3 lines (2 – 12)** prior therapy
- **Typical EGFRm population**
  - 5 of 9 pts are Asian, 6 females

## Duration of treatment (weeks)




* Astra Zeneca press release Sep 8th 2017: »Tagrisso shows potential as a new standard of care in 1st-line EGFR-mutated lung cancer at ESMO 2017 Congress»



BerGenBio

# BGBC007/8 trials in TNBC and NSCLC

*KEYTRUDA monotherapy showed 4% response rate in previously treated TNBC patients and 18% in NSCLC. PD-L1 negative patients remain particularly challenging.*

The BGBC007 and 008 trials are designed to test the hypothesis whether AXL inhibition can

- **Enhance** responses to immunotherapy when given in combination with KEYTRUDA (pembrolizumab) in previously treated, immunotherapy-naïve TNBC or NSCLC patients, respectively.

Clinical collaboration with Merck & Co. (MSD) MERCK

# Combination studies with KEYTRUDA

## BGBC008 Phase 2 – Adenocarcinoma of the lung

| | | | |
|---|---|---|---|
| **Previously treated, unresectable adenocarcinoma of the lung**<br>up to 48 pts<br>any PD-L1 expression<br>any AXL expression<br>no prior IO | **Simon two stage (interim after 22 pts)** | **Single arm**<br>bemcentinib 200mg/d<br>KEYTRUDA 200mg/3w | **ORR** |

**Q1 2018 status**

- ✓ **First stage fully recruited**
- ✓ **Combination tolerated (ASCO-SITC Jan 2018)**

## BGBC007 Phase 2 – TNBC

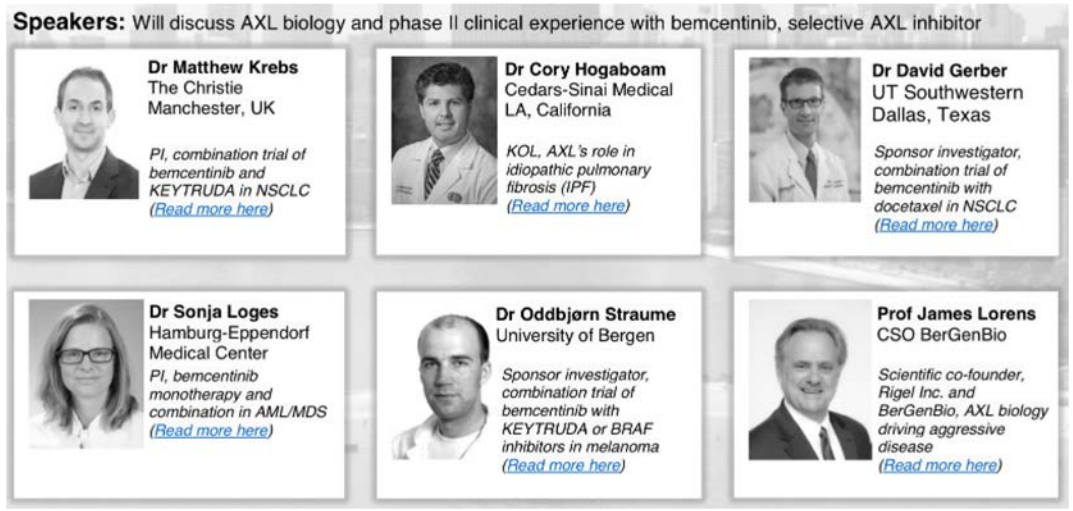
| | | | |
|---|---|---|---|
| **Previously treated, unresectable or metastatic TNBC**<br>up to 56 pts<br>any PD-L1 expression<br>any AXL expression<br>no prior IO | **Simon two stage (interim after 28 pts)** | **Single arm**<br>bemcentinib 200mg/d<br>KEYTRUDA 200mg/3w | **ORR** |

**Q1 2018 status**

- ✓ **First stage fully recruited ahead of schedule**
- ✓ **Combination tolerated (ASCO-SITC Jan 2018)**

# BerGenBio reception at *ASCO* – 2nd June 2018
## Presentation of AXL biology and interim clinical data with bemcentinib


**Saturday June 2nd 2018: 6-8 p.m. (Central)**




### ASCO conference and KOL reception

- **ASCO:**
  - **4 abstracts to be presented, interim clinical data**
  - ➢ NSCLC – BGBC008
  - ➢ AML/MDS – BGBC003
  - ➢ Melanoma – BGBIL006
  - ➢ Companion diagnostics programme

  → Full abstracts available on May 16th

- **BerGenBio KOL reception**
  - **Short talks by KOLs and PIs**
  - ➢ AXL biology
  - ➢ Bemcentinib interim clinical data

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2. Bemcentinib's aspiring leadership position as the future cornerstone of cancer combination treatments
3. Q1 update on bemcentinib's global phase II development programme on track and delivering promising clinical data
4. **Companion Diagnostic**
    - Predictive biomarker candidates identified – soluble and cellular (Dec '17)
    - AXL IHC established and rolled out for BGBC007 and BGBC008 (Jan '18)
5. Promising pre-clinical data supporting BerGenBio's pipeline
6. Finance report
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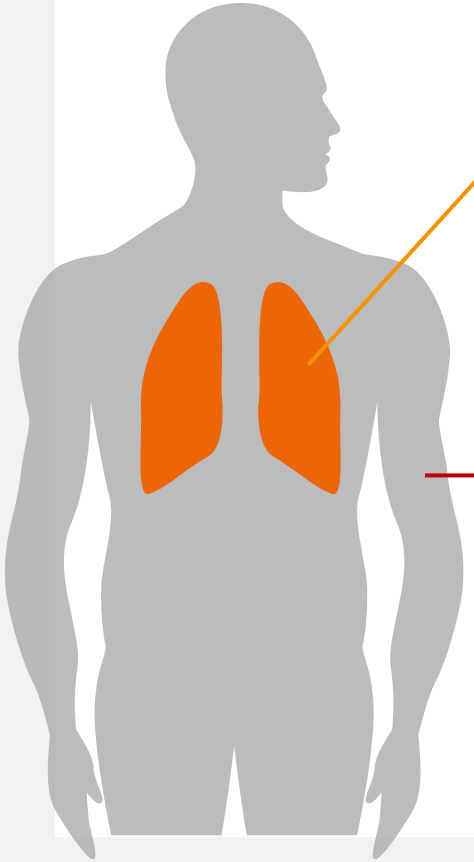
# BerGenBio companion diagnostics programme aligned with gold standard & emerging practice for personalised medicine

## Cancer Diagnosis:
## Standard (tissue) and emerging (blood) pathology techniques are used to diagnose cancer and determine optimal, personalised treatment



### Tumour tissue biopsy – "the main way cancer is diagnosed"[1]

- Gold standard for diagnosing cancer & determining course of treatment
- Determine actionable driver mutations
  - eg: EGFR, ALK, KRAS, BRAF, HER2, ROS1, and RET
- Determine PD-L1 status for check point inhibitors

→ Purpose of BerGenBio tissue CDx:
determine AXL expression as part of routine assessments

### Liquid biopsy – emerging technology

- Minimally invasive technique, less risky and can be done more frequently
- New technology can measure
  - ctDNA to determine mutations
  - Proteins: cytokine profiles, soluble receptors, etc.

→ Purpose of BGB blood CDx:
predict and monitor response to treatment by measuring BerGenBio biomarkers

## Advantages of Companion Diagnostics (CDx)

### Patients:

- Receive only treatments that are predicted o offer benefit

### Drug developers:

- Patient stratification reduces clinical trial cost and time
- Defined patient populations offer regulatory and reimbursement advantages

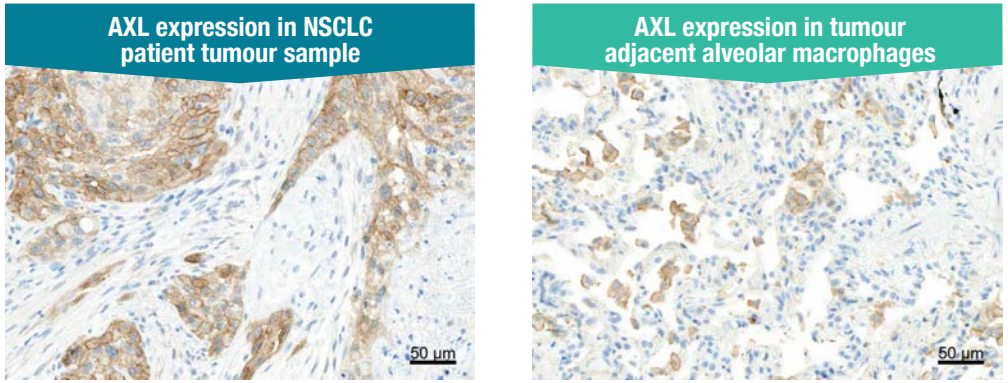


(1) https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/screening

# AXL immunohistochemistry (IHC) test developed and validated, predictive blood biomarker candidates identified

## AXL immunohistochemistry (IHC) developed and validated[1], used with standard tissue biopsy analysis

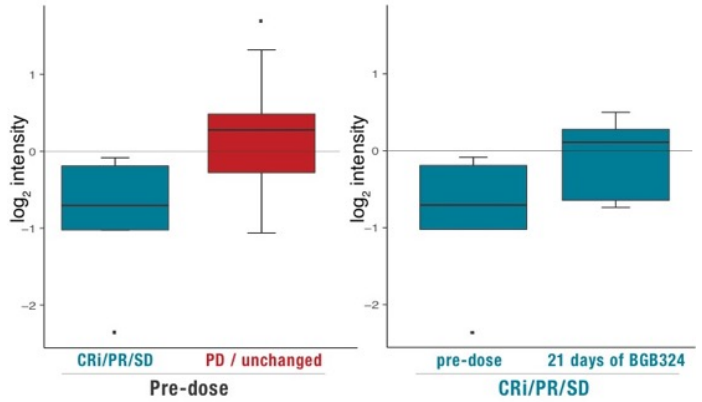
- ✓ AXL detected in tumour and immune cells
- ✓ Tumours were found to have a varying degree of AXL, determined by a positive stain when tested with BerGenBio IHC method, in a prospective study performed on banked tumour samples (1)




Shown are squamous cell carcinoma FFPE patient samples stained for AXL (brown) as per BerGenBio's proprietary AXL IHC assay

## Predictive biomarker candidates identified in relapsed & refractory AML/MDS[2]

- ✓ BGBM001 can be detected in blood as part of a routine blood draw
- ✓ Levels of BGBM001 were low in patients deriving benefit from bemcentinib treatment
- ✓ BGBM001 levels increase upon treatment with bemcentinib in patients deriving benefit






(1) Davidsen *et al* AACR 2018 (2) Loges *et al* ASCO-SITC 2018

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5. **Promising pre-clinical data supporting BerGenBio's pipeline**
    - Role of AXL and AXL inhibition via bemcentinib in fibrosis presented at leading conferences
    - Pre-clinical data highlighting potential to improve efficacy of checkpoint inhibitors and chemotherapy presented at AACR
6. Finance report
7. Outlook
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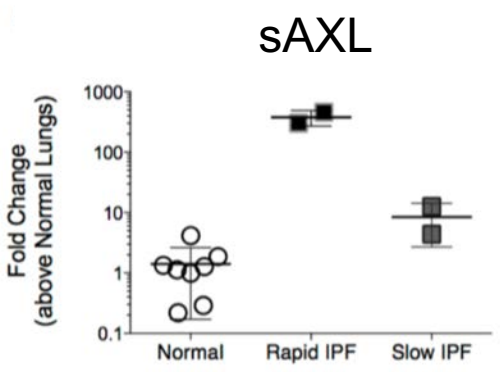
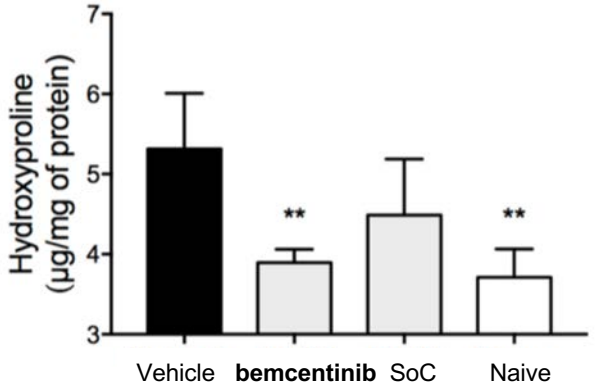
# AXL inhibition as a potential therapy in fibrotic diseases

## - Pre-clinical research data presented in Q1 by international KOLs

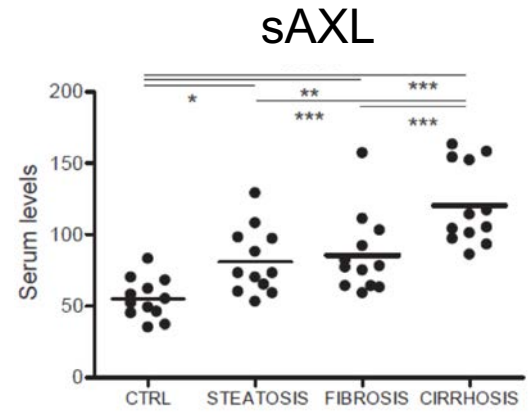
### Idiopathic Pulmonary Fibrosis

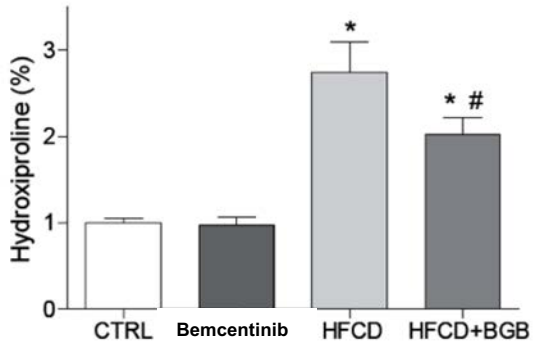



**Serum AXL elevated in Idiopathic Pulmonary Fibrosis, selective AXL inhibition superior to SoC *in vivo*[1]**

### Non Alcoholic Steatohepatitis (NASH)




**Serum AXL elevated in NASH, selective AXL inhibition active *in vivo*[2]**

**HFCD** = high-fat, choline deficient diet
Leads to NASH in animal models



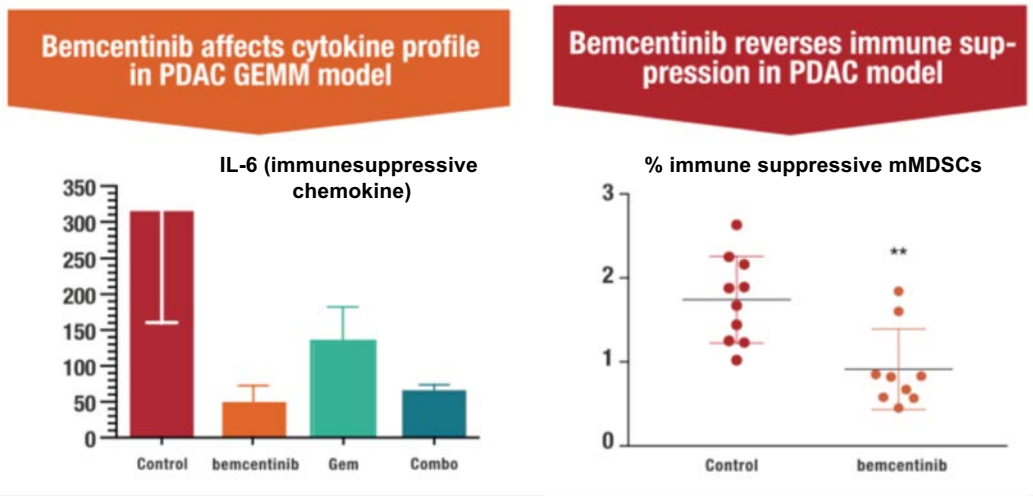
(1) Espindola *et al* American Journal of Respiratory and Critical Care Medicine 2018 (2) Barcena EASL 2018

# Bemcentinib reverses immune suppression and enhances chemotherapy and immune checkpoint blockade

## – preclinical data presented at AACR 2018[1]

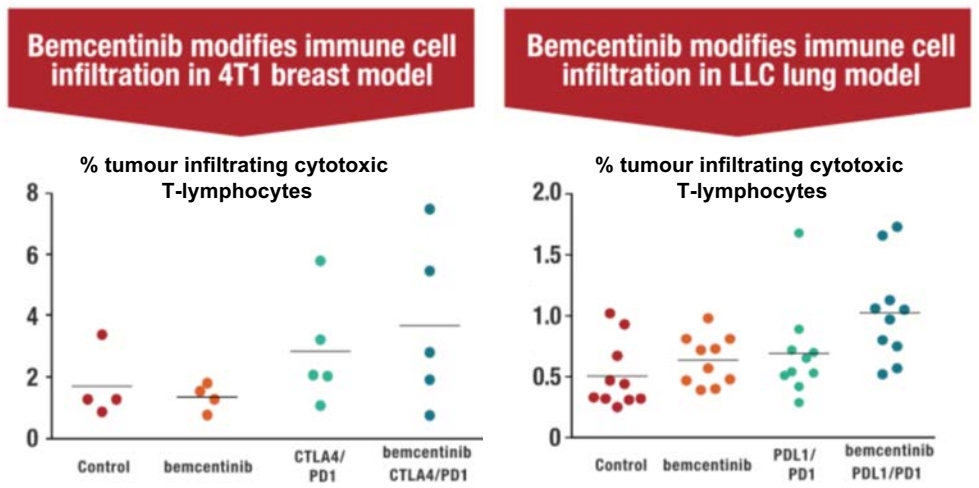
### Bemcentinib is active in combination with chemotherapy

- ✓ Increased response
- ✓ Reduced immunosuppression




### Bemcentinib is active in combination with immune checkpoint inhibitors

- ✓ Increased response
- ✓ Reduced immunosuppression






(1) Davidsen *et al* AACR 2018

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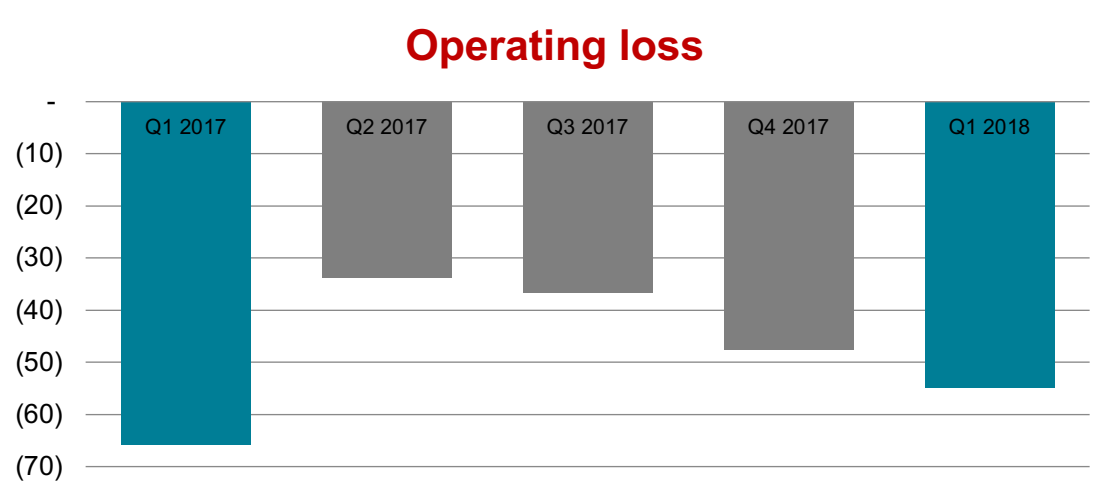
6. **Finance report & business update**
    - Welcome to Rune Skeie, CFO
    - Finance report
    - Cash runway
7. Outlook
8. Q&A

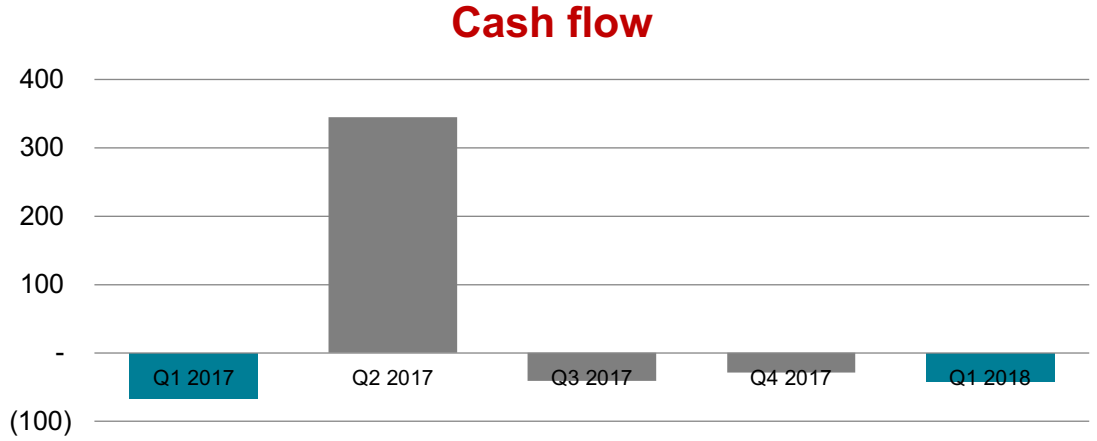
# Welcome to Rune Skeie, CFO

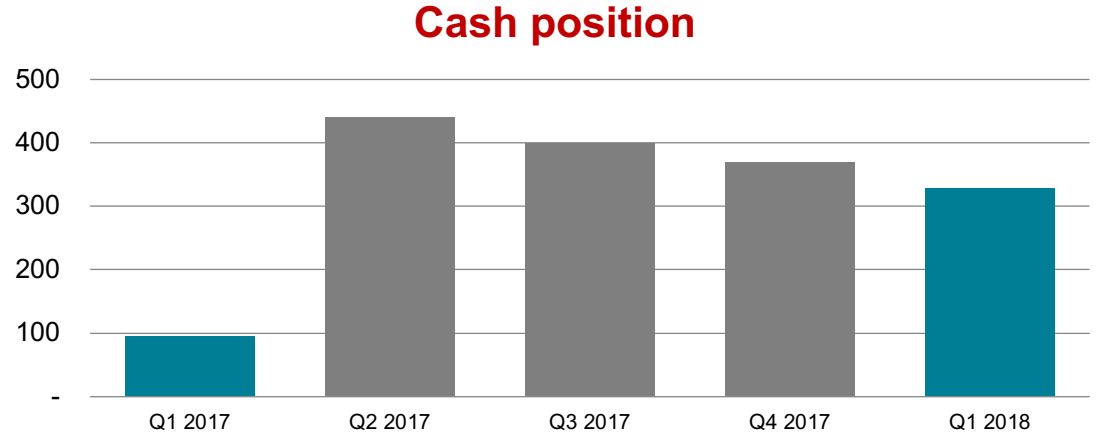
- Joined BerGenBio in March 2018
- Registered Accountant and State Authorised Public Accountant
- 20 years experience: financial management, corporate development and governance, public and private
- Most recent positions:
  - Executive Director **EY**
  - CFO **REMA Franchise Norge AS (Bergen)**

# Key financials

| Key Figures (NOK million) | Q1 2018 | Q1 2017 | FY2017 |
|---|---|---|---|
| Operating revenues | - | - | - |
| Operating expenses | 54,8 | 65,8 | 183,7 |
| Operating profit (loss) | -54,8 | -65,8 | -183,7 |
| Profit (loss) after tax | -53,8 | -65,1 | -182,2 |
| Basic and diluted earnings (loss) per share (NOK) | -1,08 | -1,93 | -4,01 |
| Net cash flow in the period | -41,1 | -66,4 | 208,5 |
| Cash position end of period | 329,2 | 95,4 | 370,3 |




- OPEX sequentially increased by 15% in Q118 from Q417, mainly because of increased social security tax on employee share option scheme.
- Robust cash position gives runway to deliver key clinical read outs on our ongoing clinical studies.
- Updated cash position at 11 May 2018: NOK 495 million), included fund raised from private placement announced April 13th.

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

# Cash runway / strengthened financial position

- ✓ **Anticipated cash runway to 1H 2020 based on current burn rate**
  - ✓ Cash position as at end Q1 2018 – MNOK 329.2
  - ✓ Private placement completed in April – gross fund raise MNOK 187.5
- ✓ **Shareholder structure broadened and enhanced**
  - ✓ Adding institutional investors in the US specialising in the biotechnology industry
- ✓ **Strengthened financial position to execute strategy**
  - ✓ To complete ongoing bemcentinib Phase II clinical development program
  - ✓ To support clinical development activities
  - ✓ To prepare regulatory strategy

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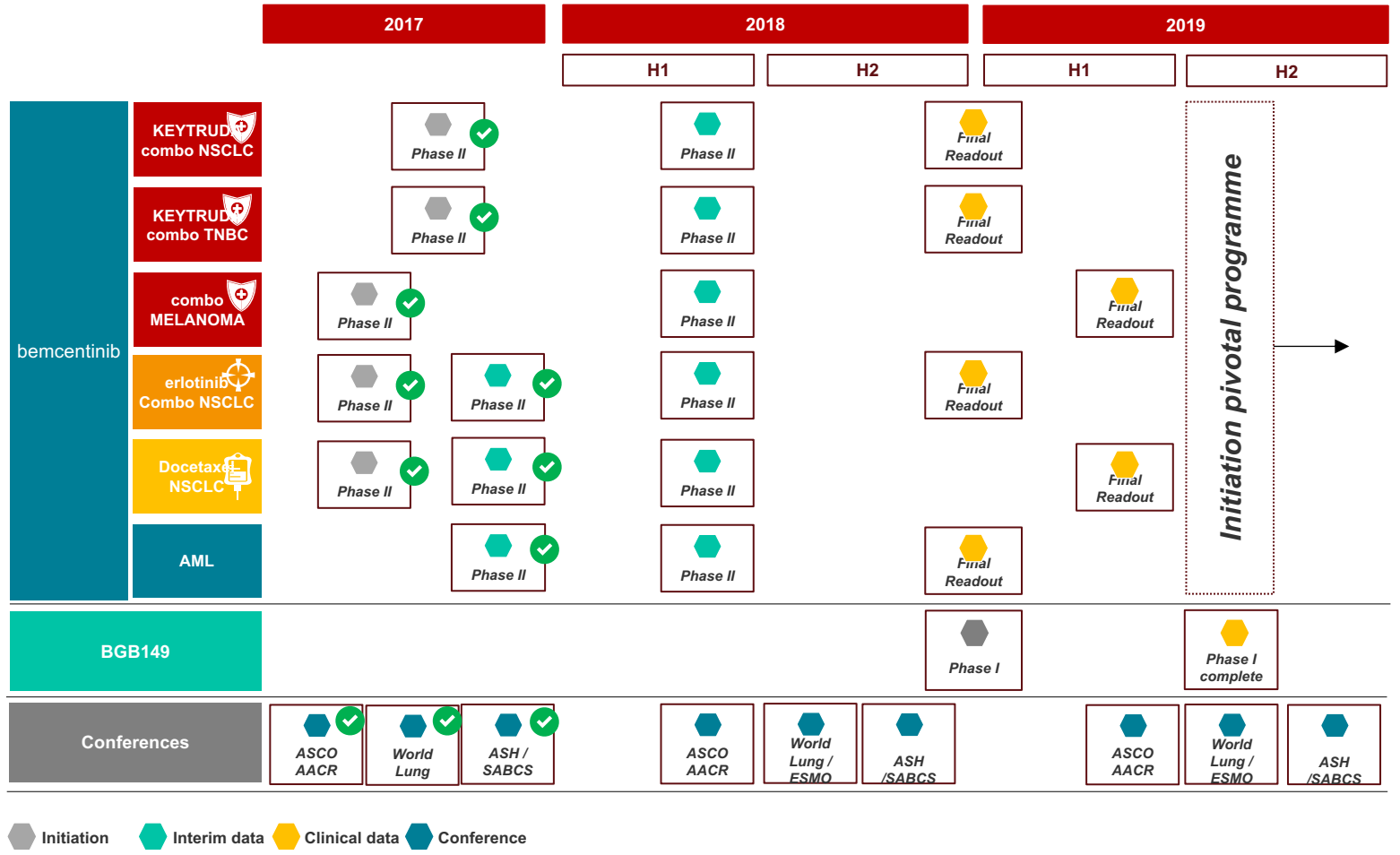
6. Finance report
7. **Outlook**
    - Significant milestones expected in next12-18 months
8. Q&A

# Significant milestones expected in 2018 & 2019




## Significant milestones expected over the next 12 months:

### Bemcentinib

- **Interim clinical data** from 6 ph II trials **at ASCO**
- **Final readout** from 4 phase 2 trials **in H2**

### BGB149

- **Initiation of AXL antibody** BGB149 clinical trials **in H2**

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

# BGBIO Investment case

- First-in-class AXL inhibitors for aggressive cancers with addressable market in excess of $20bn
- Axl mechanism now widely accept by Pharma industry as a ‘hot’ target of great interest
- Well funded & experienced organisation to deliver milestones
- Bemcentinib preliminary Phase II proof-of-concept data already reported
- Bemcentinib additional Phase II proof-of-concept data anticipated June 2018

# Appendix

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

| *(NOK 1000) Unaudited* | Note | Q1 2018 | Q1 2017 | Full year 2017 |
|---|---|---|---|---|
| **Revenue** | | - | - | - |
| **Cost** | | | | |
| Employee benefit expenses | 3 | 15 672 | 6 294 | 28 827 |
| Depreciation | | 54 | 50 | 193 |
| Other operating expenses | 6 | 39 055 | 59 445 | 154 686 |
| **Total operating expenses** | | **54 781** | **65 789** | **183 707** |
| **Operating profit** | | **-54 781** | **-65 789** | **-183 707** |
| | | | | |
| Finance income | | 1 046 | 1 119 | 4 168 |
| Finance expense | | 44 | 395 | 2 668 |
| **Financial items, net** | | **1 001** | **724** | **1 500** |
| **Profit before tax** | | **-53 780** | **-65 065** | **-182 207** |
| | | | | |
| Income tax expense | | | - | - |
| **Profit after tax** | | **-53 780** | **-65 065** | **-182 207** |
| | | | | |
| **Other comprehensive income** | | | | |
| *Items which will not be reclassified over profit and loss* | | | | |
| | | | | |
| Actuarial gains and losses on defined benefit pension plans | | - | - | - |
| | | | | |
| **Total comprehensive income for the period** | | **-53 780** | **-65 065** | **-182 207** |
| | | | | |
| **Earnings per share:** | | | | |
| - Basic and diluted per share | 7 | -1,08 | -1,93 | -4,01 |



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# Condensed consolidated statement of financial position

| *(NOK 1000) Unaudited* | Note | 31 MAR 2018 | 31 MAR 2017 | 31 DEC 2017 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | | 503 | 518 | 557 |
| **Total non-current assets** | | **503** | **518** | **557** |
| **Current assets** | | | | |
| Other current assets | 5, 8 | 11 884 | 13 090 | 13 430 |
| Cash and cash equivalents | | 329 224 | 95 387 | 370 350 |
| **Total current assets** | | **341 108** | **108 477** | **383 780** |
| **TOTAL ASSETS** | | **341 610** | **108 996** | **384 336** |
| | | | | |
| **EQUITY AND LIABILITIES** | | | | |
| **Equity** | | | | |
| **Paid in capital** | | | | |
| Share capital | 9 | 4 993 | 3 374 | 4 992 |
| Share premium | 9 | 271 478 | 67 336 | 325 018 |
| Other paid in capital | 4, 9 | 20 376 | 18 593 | 20 340 |
| **Total paid in capital** | | **296 846** | **89 303** | **350 350** |
| **Total equity** | | **296 846** | **89 303** | **350 350** |
| **Non-current liabilities** | | | | |
| Pension liability | 10 | - | - | - |
| **Total non-current liabilities** | | **-** | **0** | **0** |
| **Current liabilities** | | | | |
| Accounts payable | | 19 314 | 10 654 | 21 575 |
| Other current liabilities | | 14 001 | 4 520 | 9 391 |
| Provisions | | 11 449 | 4 519 | 3 020 |
| **Total current liabilities** | | **44 764** | **19 693** | **33 986** |
| **Total liabilities** | | **44 764** | **19 693** | **33 986** |
| **TOTAL EQUITY AND LIABILITIES** | | **341 610** | **108 996** | **384 336** |


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# Condensed consolidated statement of cash flow

Need to be ready to explain these deviations

| *(NOK 1000) Unaudited* | Note | YTD 2018 | YTD 2017 |
|---|---|---|---|
| **Cash flow from operating activities** | | | |
| Loss before tax | | -53 780 | -65 065 |
| Non-cash adjustments to reconcile loss before tax to net cash flows | | | |
| Depreciation of property, plant and equipment | | 54 | 50 |
| Calculated interest element on convertible loan | | - | - |
| Share-based payment expense | 3, 4 | 36 | 567 |
| Movement in provisions and pensions | | 8 429 | - 324 |
| Working capital adjustments: | | | |
| Decrease in trade and other receivables and prepayments | | 1 546 | - 789 |
| Increase in trade and other payables | | 2 348 | -1 249 |
| **Net cash flow from operating activities** | | **-41 366** | **-66 810** |
| **Cash flows from investing activities** | | | |
| Purchase of property, plant and equipment | | | - 159 |
| **Net cash flow used in investing activities** | | **-** | **- 159** |
| **Cash flows from financing activities** | | | |
| Proceeds from issue of share capital | 9 | 240 | 531 |
| **Net cash flow from financing activities** | | **240** | **531** |
| | | | |
| Net increase/(decrease) in cash and cash equvivalents | | -41 126 | -66 438 |
| Cash and cash equivalents at beginning of period | | 370 350 | 161 825 |
| **Cash and cash equivalents at end of period** | | **329 224** | **95 387** |



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