BerGenBio

H. C. Wainwright & Co.

21st Annual Global Investment Conference

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Richard Godfrey , CEO

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# BGBIO – Corporate Snapshot

## World leaders in understanding AXL biology

AXL is a novel drug target that mediates immune evasion, therapy resistance & spread

AXL upregulates PDL1 on dendritic cells and blocks T-cell activity

AXL inhibitors – potential cornerstone of cancer therapy

**Pipeline opportunities in multiple cancers and fibrosis**

## 3 selective AXL inhibitors in clinical development

Bemcentinib,
AXL-antibody BGB149, AXL ADCT601*

Monotherapy and combinations with immune-, targeted and chemotherapies

Biomarker correlation across programme, parallel CDx development

Bemcentinib clinical Proof of Concept
**AML** (monotherapy), **AML** (chemo-combo)
**NSCLC** (KEYTRUDA combo)

## Resourced to deliver significant milestones

Listed on Oslo Børs: BGBIO

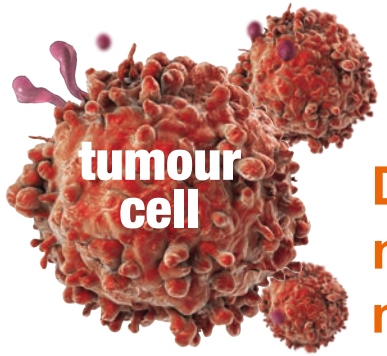
Clinical trial collaborations with Merck and leading academic centres

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

**Q2'19 Cash NOK 324m (USD 38m)**

*AXL antibody out licensed to ADC Therapeutics SA

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

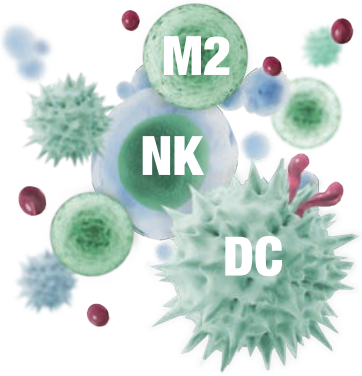



## Drives tumour cell plasticity: non-genetic resistance mechanism

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**

# Bemcentinib: once-a-day pill

- Highly selective, potent, orally bioavailable
- Blocks AXL signalling, reverses aggressive tumour traits & counteracts immune escape
- Once-a-day administration
- Clinical PoC in AML and NSCLC as a monotherapy and in combination
- Correlation of clinical efficacy with AXL biomarkers observed
- Combines successfully with chemo, targeted and CPI drugs
- Excellent clinical safety profile: >250 subjects dosed

# Phase II clinical proof of concept studies for bemcentinib

| | | Clinical Proof-of-concept | Late stage Opportunities |
|---|---|---|---|
| **Monotherapy**<br>Selected, biomarker directed patients | AML / MDS | Completed | |
| | Glioblastoma (IIT) | Ongoing | |
| | Ovarian (EMT signature selected) | Potential | |
| **Chemotherapy Combinations**<br>Improve responses in hard to treat settings | AML + LDCT (LDAC) | Complete. -EXPANSION | |
| | Pancreatic, (IIT) | Ongoing | |
| | NSCLC (IIT) | Ongoing | |
| **Immunotherapy Combinations**<br>Target resistance, enlarge addressable patient population | NSCLC (PD-L1 / AXL all comers) | Cohort A Complete<br>Cohort B ongoing | |
| | Melanoma, (IIT) | Ongoing | |
| | Mesothelioma (IIT) | In set-up | |
| | Bladder ++, CAR-T combos | Under consideration | |
| **Targeted Therapy Combinations**<br>Target resistance, enlarge addressable patient population | NSCLC + EGFRi | Completed | |
| | Melanoma, (IIT) | Ongoing | |
| | PARPi combos ++ | Under consideration | |
| **Earlier Line Opportunities**<br>Radiotherapy and maintenance opportunities | Multitude of maintenance opportunities given very favourable safety profile | | |

See appendix for interim data from IIT studies

Ref. BGBC003 / NCT02488408

# Acute Myeloid Leukaemia (AML)

Bemcentinib is being evaluated as a monotherapy and in combination with standard of care to treat AML

- ***Monotherapy: 43% ORR in AXL +ve R/R AML***
- ***LDAC chemo combination: 43% ORR all-comer patients***

# Acute Myeloid Leukaemia (AML)

*Most common type of acute leukaemia in adults[1]*

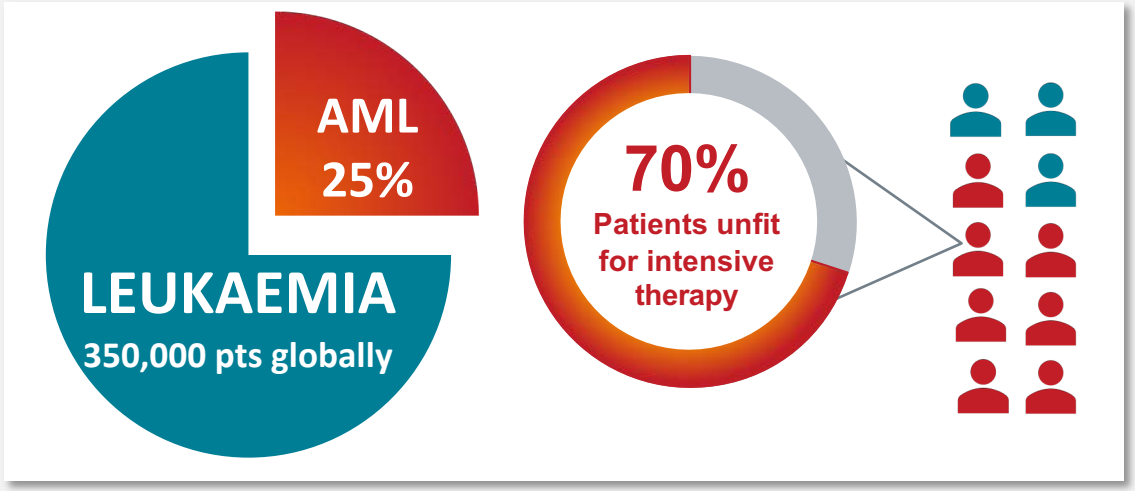
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

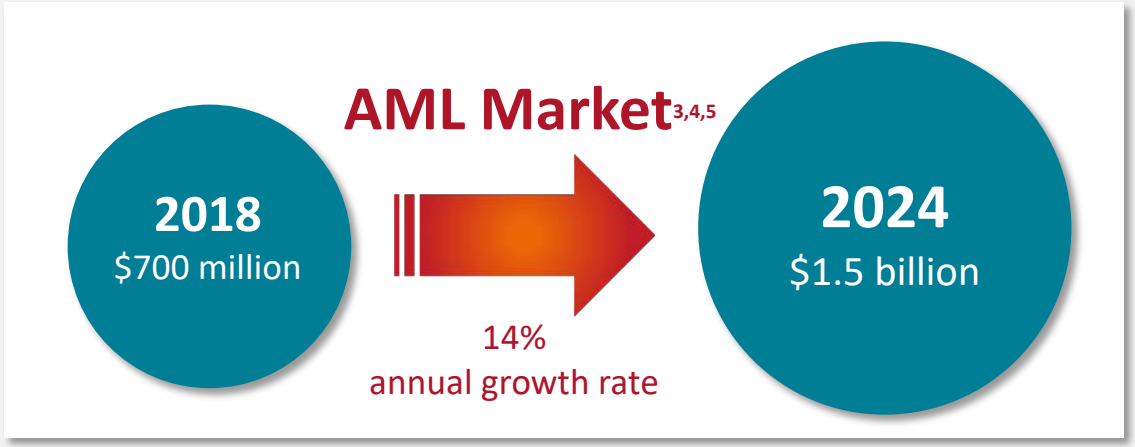
~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018[2]

AML makes up 32% of all adult leukaemia cases

Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years [6]

5 year survival rates of 3-8% in patients over 60 years old [7]




(1) Cancer.gov; (2) SEER; (3) https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble
(4) https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics (5) https://www.businesswire.com/news/home/20190319005442/en/ (6) http://asheducationbook.hematologylibrary.org/content/2010/1/62.long, (7) https://www.ncbi.nlm.nih.gov/books/NBK65996/



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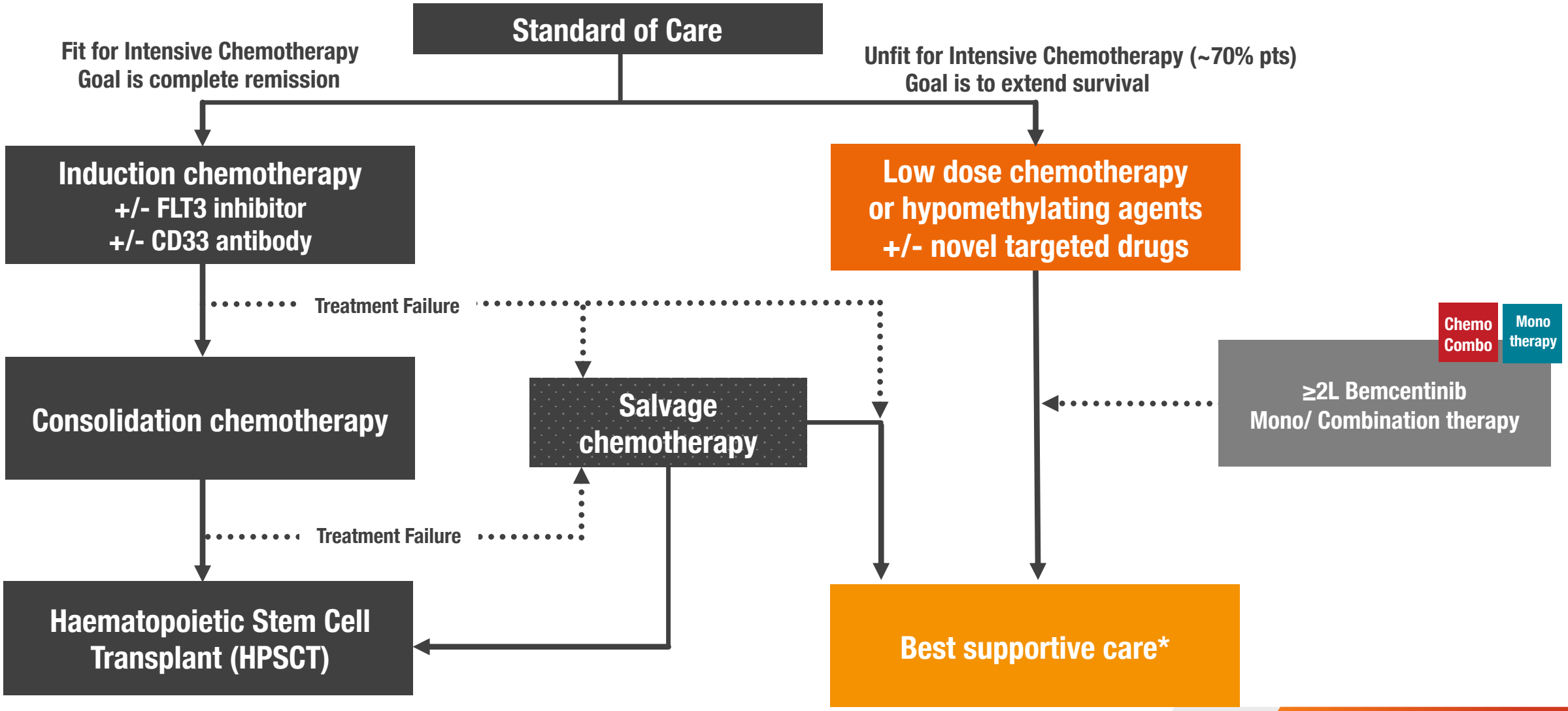
# Acute Myeloid Leukaemia (AML)
## Standard of Care & bemcentinib positioning




*A small number of patients may be eligible for targeted therapy



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Ref. BGBC003 / NCT02488408

# Bemcentinib in AML

## Monotherapy & in combination with low-dose chemotherapy

**2L Monotherapy (completed)**

**2L and later-line R/R AML & MDS N = 36 pts**

**43%* CR/CRi/CRp in Axl +ve pts**

* Ca. half of patients found to be AXL positive

Immune activation and clonal stabilisation observed

**1L & 2L Combination Therapy (complete)**

**Decitabine combo**
AML, N = 14 pts

**Low-dose cytarabine (LDAC) combo**
AML, N = 14 pts

**ASCO 2019**

**46% ORR in LDAC combo AXL all comers**

**Endpoints**

Primary
- safety / ORR

Secondary
- RFS
- OS
- biomarkers

*LDCT: approved low dose chemotherapy regimens

# Bemcentinib efficacy signal in AML

## ASH Dec 2018
### Bemcentinib Monotherapy
*Relapse patients >75yrs*
*No approved SoC*

*AXL +ve* patients*
*14/27*
***52%***

*CR/Cri/CRp*
*6/14*
***43%***

*Stable Disease*
*3/14*
***21%***

*mDOR* **3.1mo. (5.5* mo.)**

Safety profile was well tolerated

## EHA 2019
### Bemcentinib + LDAC
*R/R elderly patients*
*1L & 2L*

*CR/Cri/CRp*
*6/14*
***43%***

*mDOR* ***>8Mo.***

Responses occurred early, improved over time and included poor risk, previously treated patients. Bemcentinib appears well tolerated in combination with LDAC.

Expansion cohort to initiate H2'19 to confirm signal in larger R/R patient population

* including 2 patients with low dose decitabine, one remains in CR after 20 months

Ref. BGBC008 / NCT03184571

# Bemcentinib in NSCLC: Combination with anti-PD(L)1

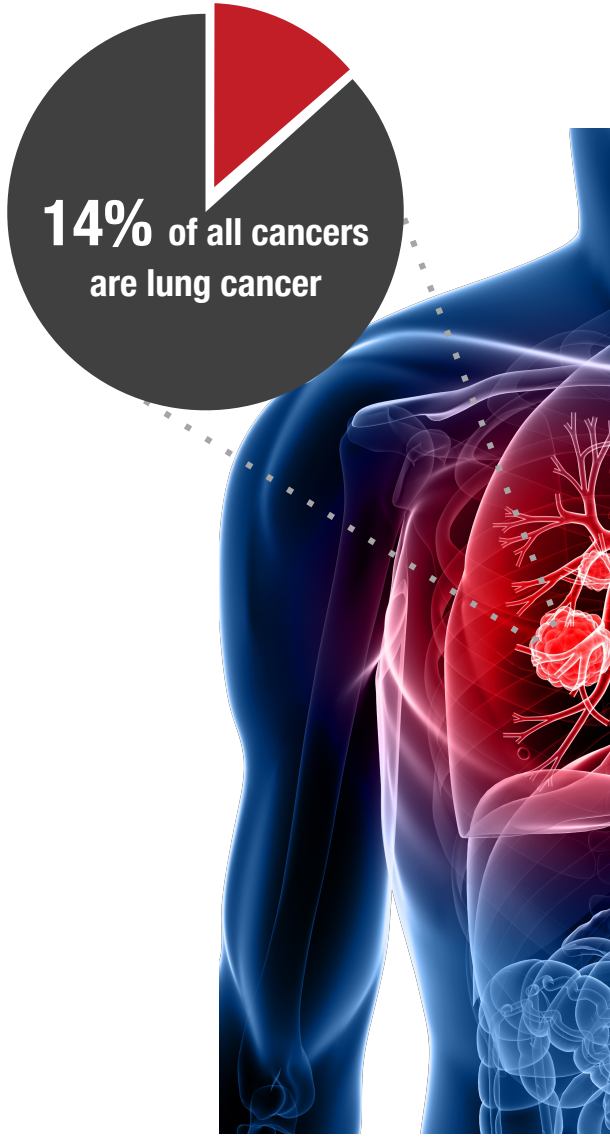
PoC data in combo with KEYTRUDA, previously treated, IO naïve NSCLC:

- ***27% ORR in PD-L1 –ve patients***
- ***40% ORR in AXL+ve patients***
- ***mOS 12.2 months***

# Non- Small Cell Lung Cancer (NSCLC)

## What is NSCLC?

- Lung cancer (both small cell and non-small cell) is the second most common cancer in both men and women.
- 2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases[1]
- 1.76 million lung cancer deaths/yr worldwide[1]
- Most people diagnosed with lung cancer are 65 or older & the average age at the time of diagnosis is about 70.




| Average Age at Diagnosis | 5-Year Survival Rate PD-L1 1-49%[2] | 5-Year Survival Rate PD-L1 <1%[2] |
|---|---|---|
| 70 years | 12.6% patients | 3.5% patients |

(1) Globocan 2018
(2) Garon, E.B. et al. 5-Year Long-Term Overall Survival for Patients With Advanced NSCLC Treated With Pembrolizumab: Results from KEYNOTE-001. 2019 ASCO Annual Meeting.
(3) Key statistics for NSCLC

# NSCLC causes more cancer related deaths than breast, colon, pancreas and prostate combined

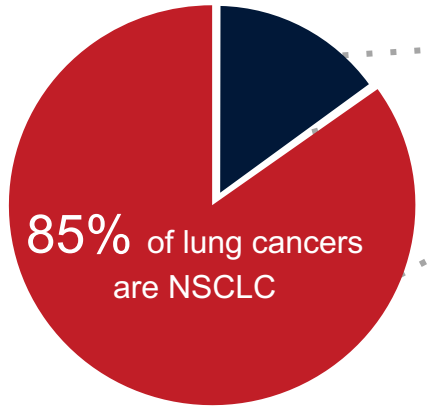
*The largest cancer killer, most patients depend on drug therapy*

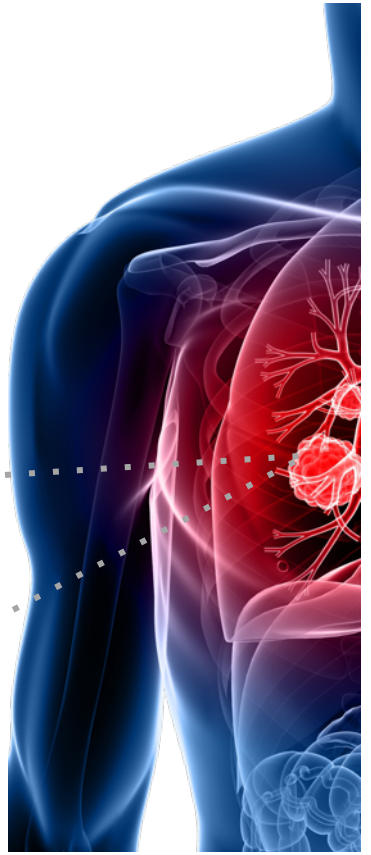
**The most common type of cancer**

2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases[1]

1.76 million lung cancer deaths/yr worldwide[1]

5-year survival rate is 3.5% in patients with PD-L1 <1%, and **12.6%** in patients PD-L1 1-49%

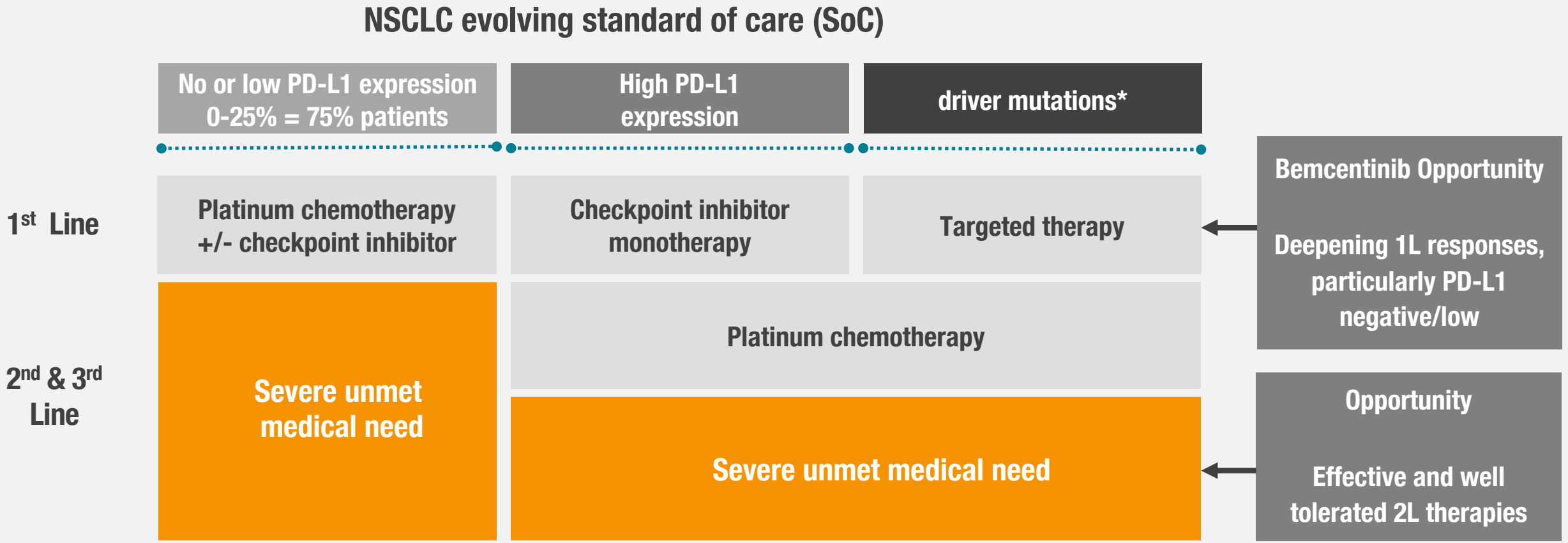





(1) fortunebusinessinsights.com/industry-reports/non-small-cell-lung-cancer-therapeutics-market-100484

# Non- Small Cell Lung Cancer (NSCLC)
## Standard of Care






* Mutations / rearrangements with available targeted therapies such as EGFR and ALK

Ref. BGBC008 / NCT03184571 – clinical trial collaboration with Merck & Co.

# Bemcentinib + KEYTRUDA in relapse NSCLC

## Phase 2 Study Design

**Cohort A**
Previously treated, unresectable adenocarcinoma of the lung

PD-L1 / AXL all-comers

Chemo relapse (IO naïve)

**Cohort B**

PD-L1 / AXL all-comers

IO relapse – study expanded to include IO+Chemo relapse patients

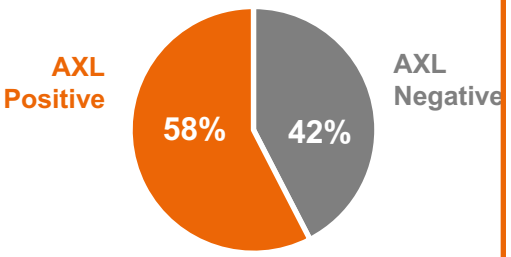
| Stage 1 | | Stage 2 |
|---|---|---|
| COMPLETE | If ≥ 4 PRs | COMPLETE |
| Society for Immunotherapy in Cancer (SITC) | | ASCO 2019 |
| November 2018 | | Preliminary Data |
| Efficacy & mPFS | | |
| N = 26 pts | If ≥ 1 PRs | Upto 32 pts |
| RECRUITING | | |

### Key objectives

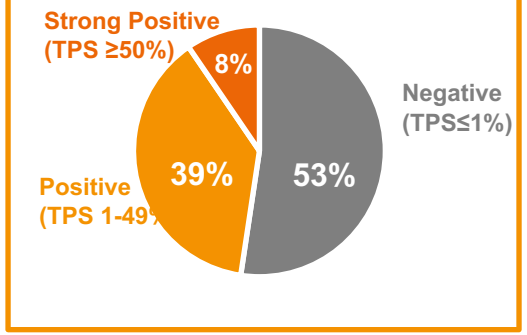
- Evaluate safety of the combination and response to treatment with the combination
- Characterise patients by PD-L1 and AXL status
- Evaluate efficacy of patients by biomarker status, and assess predictive qualities of biomarkers
- Assess survival measures in patients by biomarker status

## Cohort A preliminary biomarker data

**AXL status**
n = 33
(28 with at least 1 response assessment



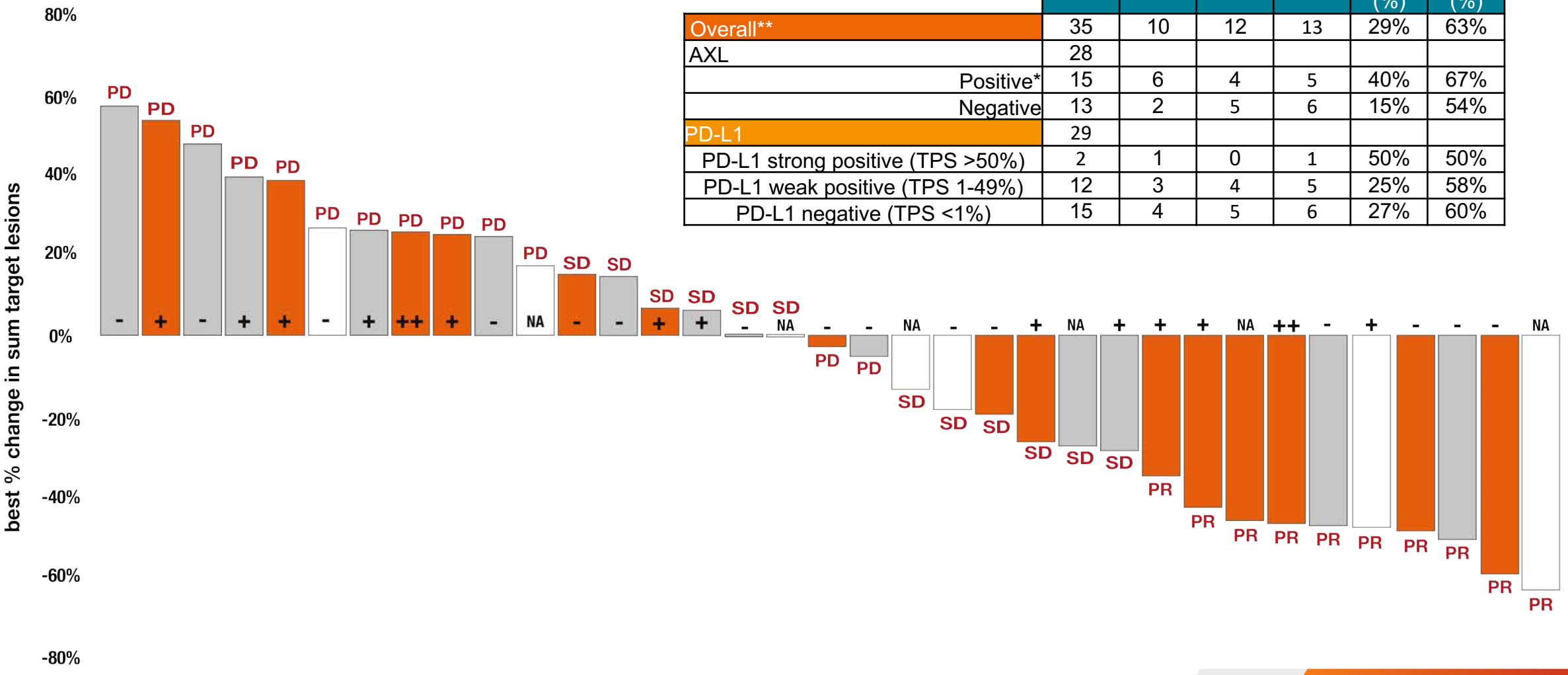

**PD-L1 status**
n = 38
(29 with at least 1 response assessment)



# Antitumour activity Change in tumour size from baseline (by AXL IHC)

## 40% ORR & 67% Clinical benefit in AXL+ve patients, irrespective of PD-L1 status.

| | n | PR | SD | PD | ORR (%) | CBR (%) |
|---|---|---|---|---|---|---|
| Overall** | 35 | 10 | 12 | 13 | 29% | 63% |
| AXL | 28 | | | | | |
| Positive* | 15 | 6 | 4 | 5 | 40% | 67% |
| Negative | 13 | 2 | 5 | 6 | 15% | 54% |
| PD-L1 | 29 | | | | | |
| PD-L1 strong positive (TPS >50%) | 2 | 1 | 0 | 1 | 50% | 50% |
| PD-L1 weak positive (TPS 1-49%) | 12 | 3 | 4 | 5 | 25% | 58% |
| PD-L1 negative (TPS <1%) | 15 | 4 | 5 | 6 | 27% | 60% |



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# Comparison of: KEYTRUDA + bemcentinib (2L) vs KEYTRUDA + Chemotherapy (1L)

| | | ORR | mPFS | mOS | TEAE's ≥3 |
|---|---|---|---|---|---|
| **1L NSCLC New SoC Keytruda + Chemotherapy** | PD-L1 <1%* | 32% | 6.1 mo | 15 mo | 67% |
| | PD-L1 1-49%* | 48% | 9.0 mo | NR | |
| **2L NSCLC – IO naïve, predominantly PD-L1 low Keytruda + bemcentinib BGB008** | AXL +ve | 40% | 5.9 mo (stage 1) | 12.2 mo (stage 1) | 17% |

**2L** Bemcentinib + Keytruda in AXL +ve / PD-L1 –ve/low patients revivals **1L** new SoC



* KN189

# Bemcentinib is well positioned in an emerging clinical context

## AML

### >2L r/r Patients (>75yrs)

- No approved SoC
  (best palliative – support care)
- mOS ca.3mo.
- est. 4000 pts/yr (USA)

Bemcentinib POC Data

**monotherapy**

- ORR 43% (AXL +ve patients)
  Strong correlation between remission and sAxl
- mDoR – 3.1mo. - 5.5* mo.
- Well tolerated

### 1/2L r/r Patients (>60yrs)

- New 1L SoC
- No approved 2L SoC
  (low dose chemo / best palliative)
- est. 6500 pts/yr (USA)

Bemcentinib clinical signal

**LDAC combo**

- ORR 43% (all patients)
  LDAC historical 18%
- mDoR >8mo. (immature)
- Well tolerated

Data requires confirmation in expansion cohort 2L r/r

## NSCLC

### 2L chemo relapse Patients

- Chemo remains 1L SoC in low PD-L1 patients
- 2L SoC is CPI
- est. 65000 pts/yr (USA)

Bemcentinib 2L POC Data

**KEYTRUDA combo**

- ORR 40% (AXL +ve patients)
  Keytruda historical 12%
- mPFS 5.9mo.
- mOS 12.2mo.
- Well tolerated

### 2L CPI*+/-chemo relapse Pts

- New 1L SoC: CPI + chemo is emerging
- 2L SoC docetaxel
- est. 65000 pts/yr (USA)

Bemcentinib 2L Data

**KEYTRUDA combo**

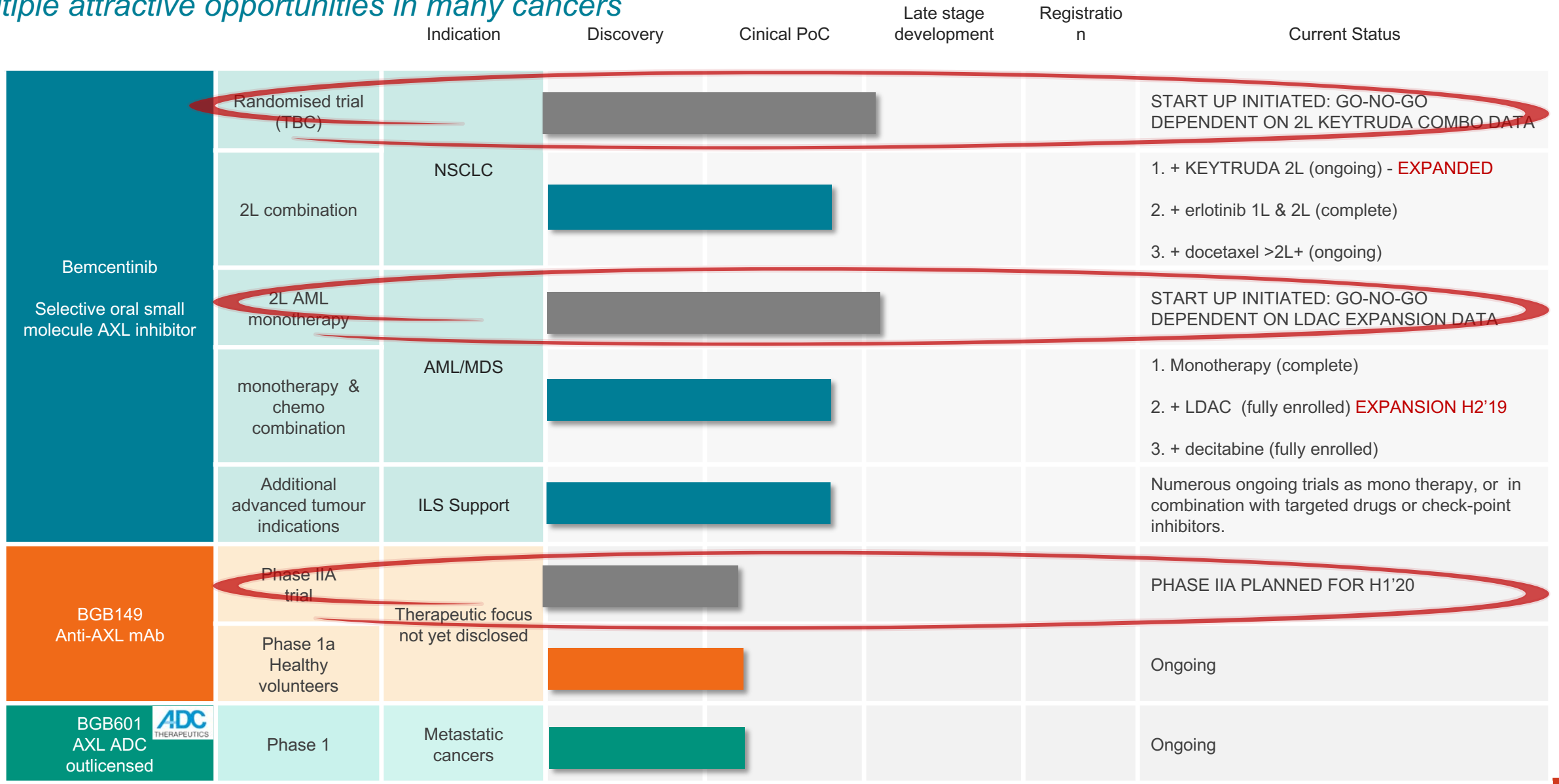
Trial recruitment is ongoing

* including 2 patients with low dose decitabine, one remains in CR after 20 months

* Check Point Inhibitor

# 3 selective AXL inhibitors in clinical development

*Multiple attractive opportunities in many cancers*



# Our other anti-AXL drug candidates

- *BGB149 – anti-AXL humanised monoclonal antibody (BGB wholly owned)*
- *BGB601 – anti -AXL antibody-drug conjugate (partnered ADCT)*

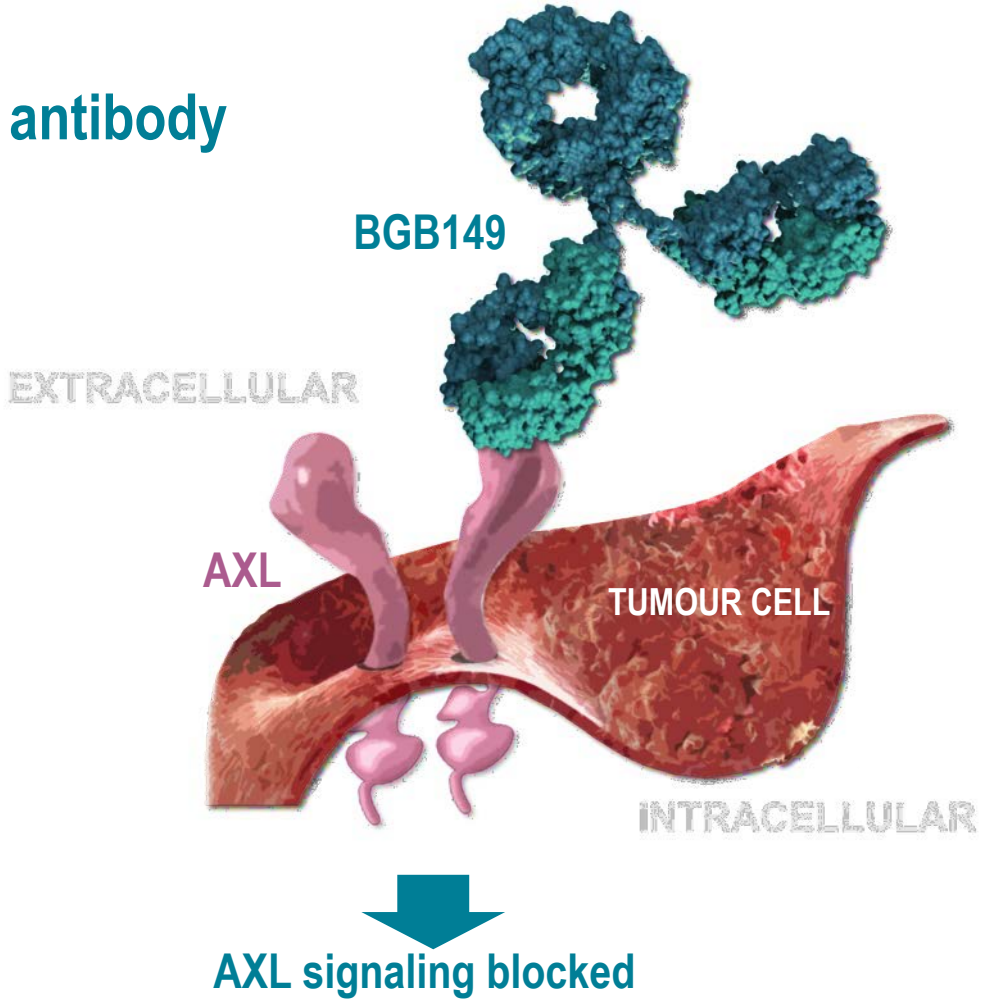
Ref. BGB149-101 / NCT03795142

# BGB149: Anti-AXL monoclonal antibo

*Phase I clinical trial ongoing*

## Functional blocking fully-humanised IgG1 monoclonal antibody

- Binds human AXL, blocks AXL signalling
- First-in-human healthy volunteer Phase I study ongoing
  - No safety concern identified
- First-in-patient ph IIa trial expected in H1 2020

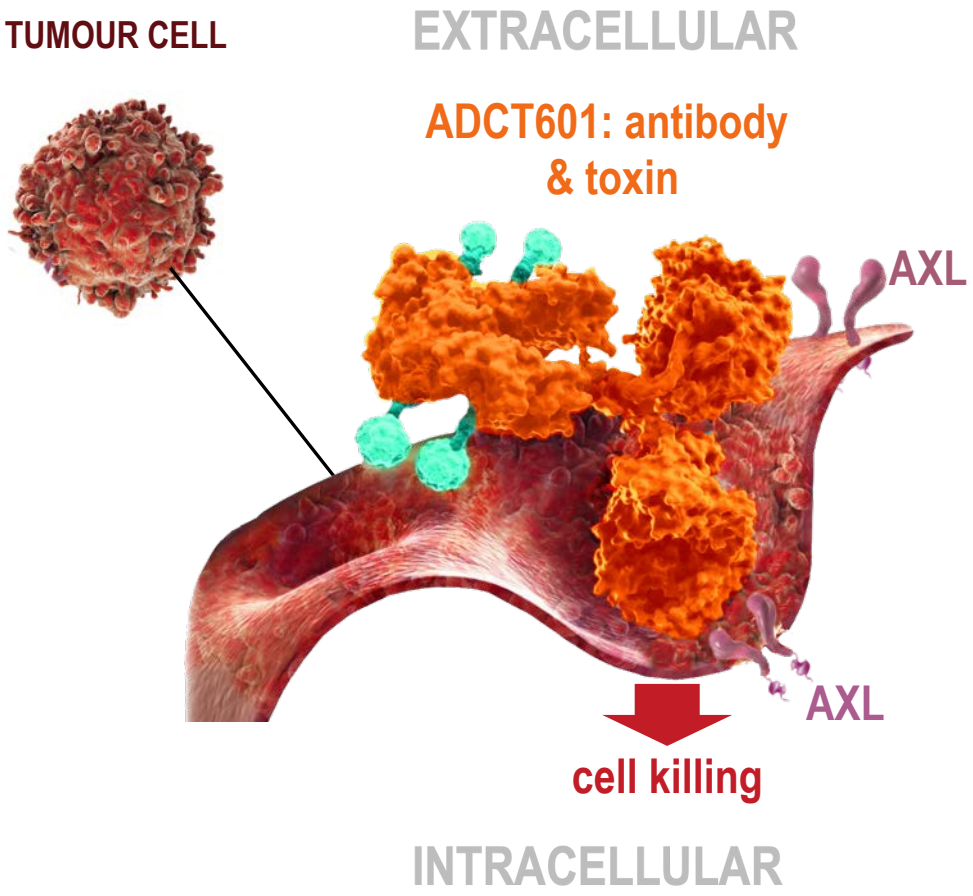


Ref. NCT03700294

# BGB601/ADCT-601: Anti-AXL ADC

*Phase 1 in solid tumours ongoing*

Out-licensed to ADC THERAPEUTICS



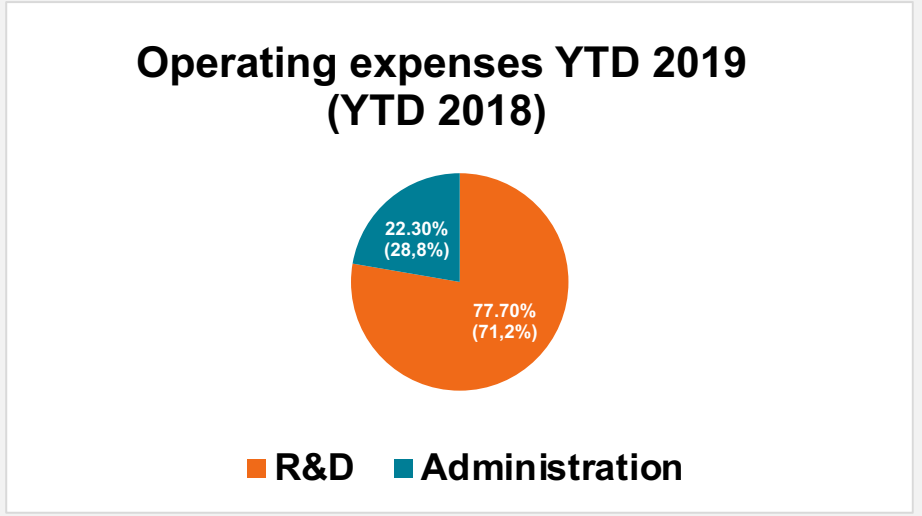

## Antibody Drug Conjugate (ADC)

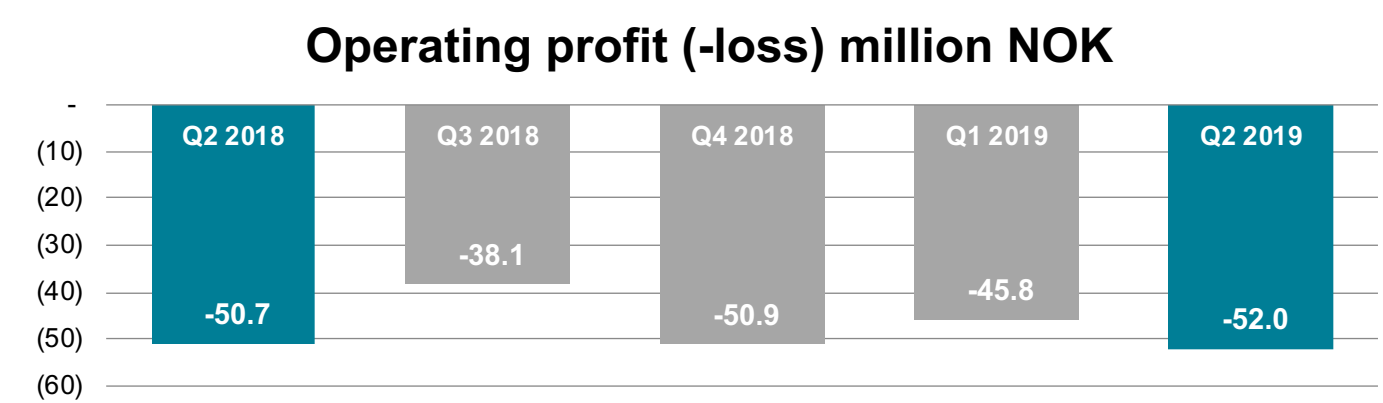
- Targets human tumour AXL, induces cell death
- First-in-human Phase I study initiated in Jan 2019
- Based on anti-AXL antibody BGB601 licensed from BerGenBio

# Finance Report

# Key financial figures Q2'19

| (NOK million) | Q2 2019 | Q2 2018 | YTD 2019 | YTD 2018 | FY 2018 |
|---|---|---|---|---|---|
| Operating revenues | 0 | 0 | 8,7 | 0 | 2,3 |
| Operating expenses | 52,0 | 50,7 | 106,5 | 105,5 | 196,9 |
| Operating profit (-loss) | -52,0 | -50,7 | -97,8 | -105,5 | -194,5 |
| Profit (-loss) after tax | -52,8 | -49,2 | -97,1 | -103,0 | -191,7 |
| | | | | | |
| Basic and diluted earnings (loss) per share (NOK) | -0,95 | -0,92 | -1,76 | -1,99 | -3,60 |
| Net cash flow in the period | 17,7 | 112,0 | -36,0 | 70,9 | -9,9 |
| Cash position end of period | 324,4 | 441,3 | 324,4 | 441,3 | 360,4 |



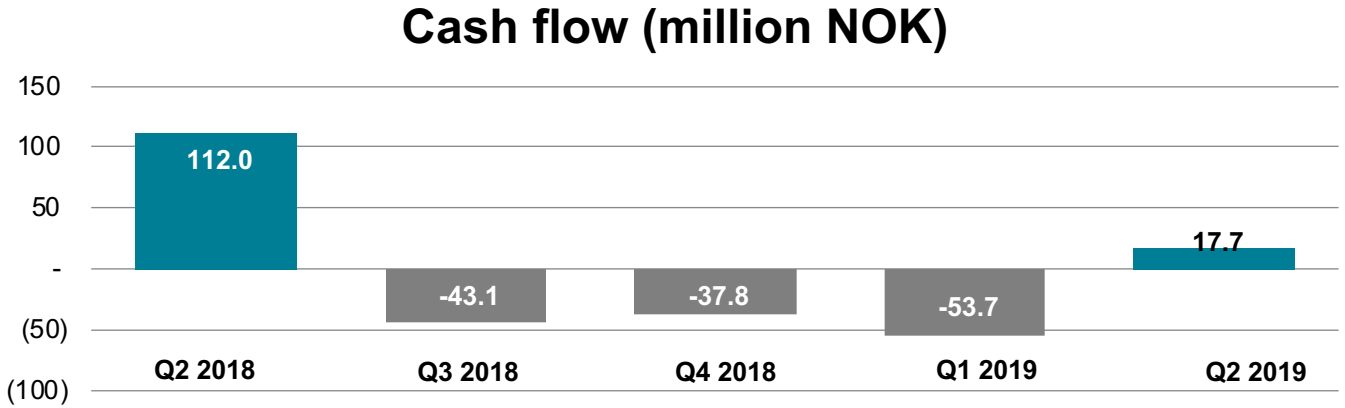

- Focus on R&D activities
- 77.3% of operating expenses YTD 2019 (YTD 2018: 71,2%) attributable to Research & Development activities

- No cash effect on P&L Operating expenses, that was reduced by a smaller provision for social and security tax on share options, positive effect on result Q2 2019 NOK – 6.1 million (negative effect on result Q2 2018 + 4.2 million).

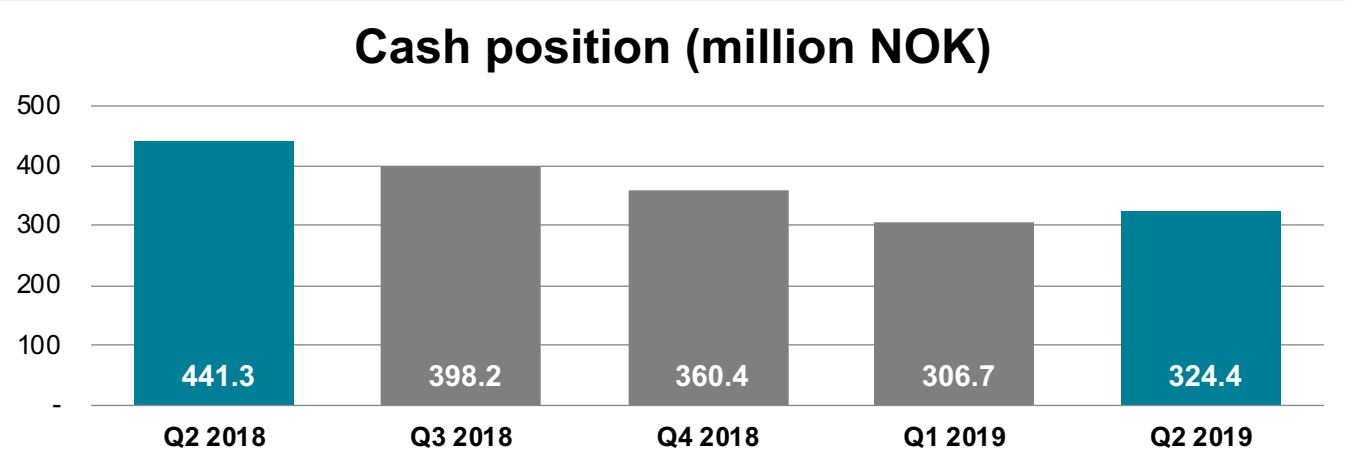


http://www.bergenbio.com/investors/reports/quarterly-reports/

# Cash flow and cash position




- Private placement Q2 19 strengthened cash position - gross funds raised NOK 74 million (USD 9 million)
- Quarterly cash burn average (Q218 – Q219) NOK 51.7 million (USD 6.2 million)




- Cash position Q2 2019 NOK 324.4 million (USD 38.1 million) - gives runway to deliver key clinical read outs from ongoing clinical studies

# Analyst coverage

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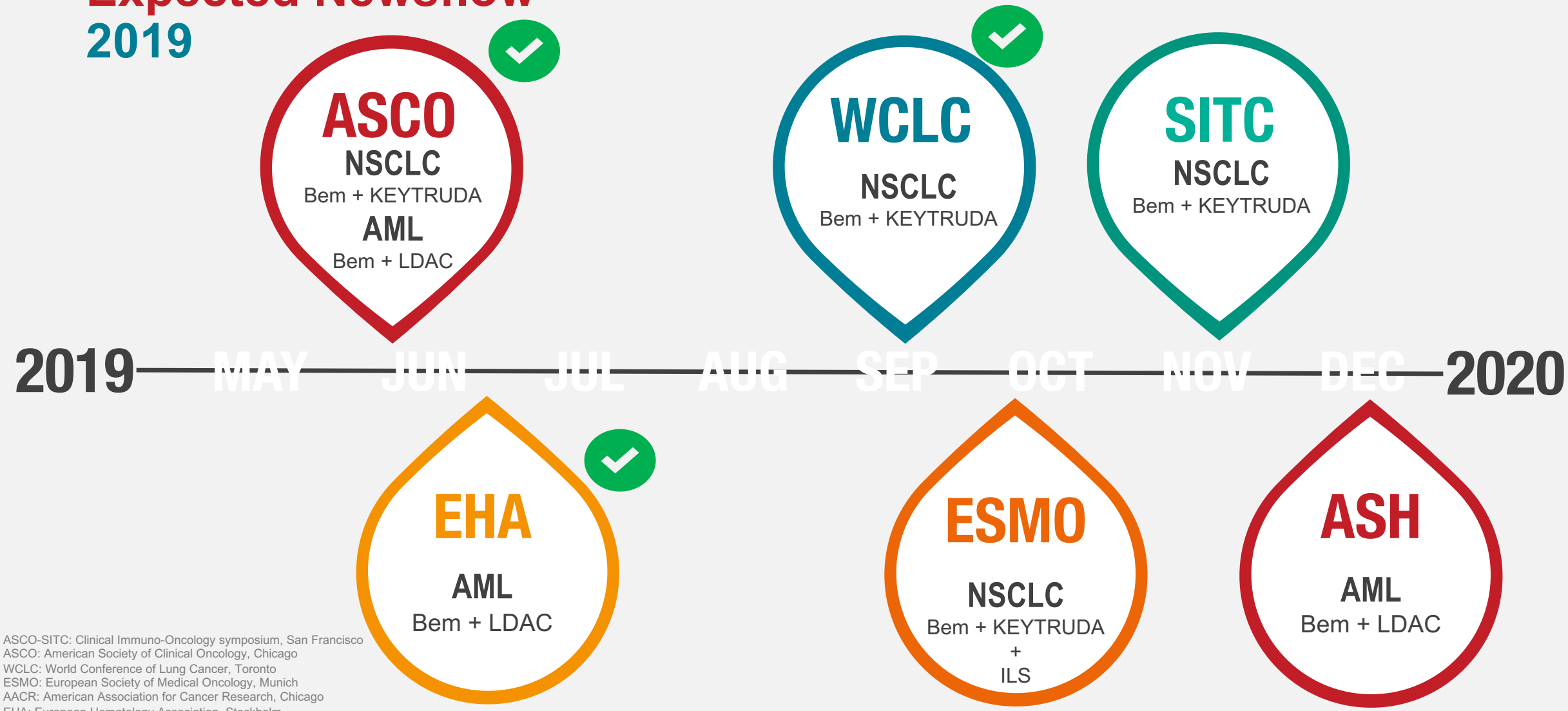
# Expected Newsflow 2019




ASCO-SITC: Clinical Immuno-Oncology symposium, San Francisco
ASCO: American Society of Clinical Oncology, Chicago
WCLC: World Conference of Lung Cancer, Toronto
ESMO: European Society of Medical Oncology, Munich
AACR: American Association for Cancer Research, Chicago
EHA: European Hematology Association, Stockholm
SITC: Society for Immunotherapy of Cancer, DC
ASH: American Society for Hematology, San Diego

# Thank you ……
# Questions