BerGenBio

Q2 / Half Year Report 2019

19th August 2019

Richard Godfrey , CEO

Rune Skeie, CFO

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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

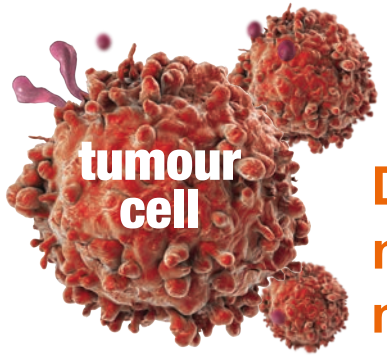
Clinical trial collaborations with Merck and leading academic centres

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

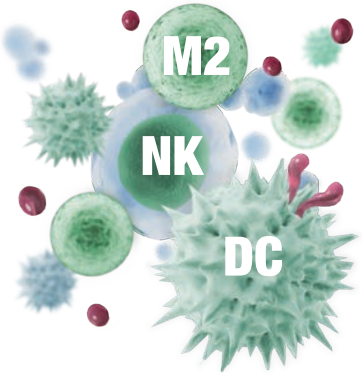


Drives tumour cell plasticity: non-genetic resistance mechanism

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**

Q2 2019 highlights

Preliminary Phase II clinical data from AML trial presented at EHA 24 and ASCO 2019
Bemcentinib in combination with low dose cytarabine is efficacious and well tolerated in elderly AML patients.

New Phase II clinical data from in NSCLC presented at ASCO 2019
Bemcentinib in combination with KEYTRUDA® promising preliminary ORR and OS data in 2L AXL positive patients

Completed recruitment (cohort A) of patients in Phase II NSCLC in combination with KEYTRUDA®
2L Chemo relapse (IO naïve) patients

Initiated enrolment (cohort B) of patients in Phase II NSCLC in combination with KEYTRUDA®
2L IO relapse patients & expanded to include IO+chemo relapse patients

Private placement completed, raising gross proceeds of NOK74.2m

Cash and Cash equivalents at end of Q2 2019 NOK324.4m
Operating loss of NOK52m in Q2 and NOK97.8m in H1 2019.

* Partnered to ADCT

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]

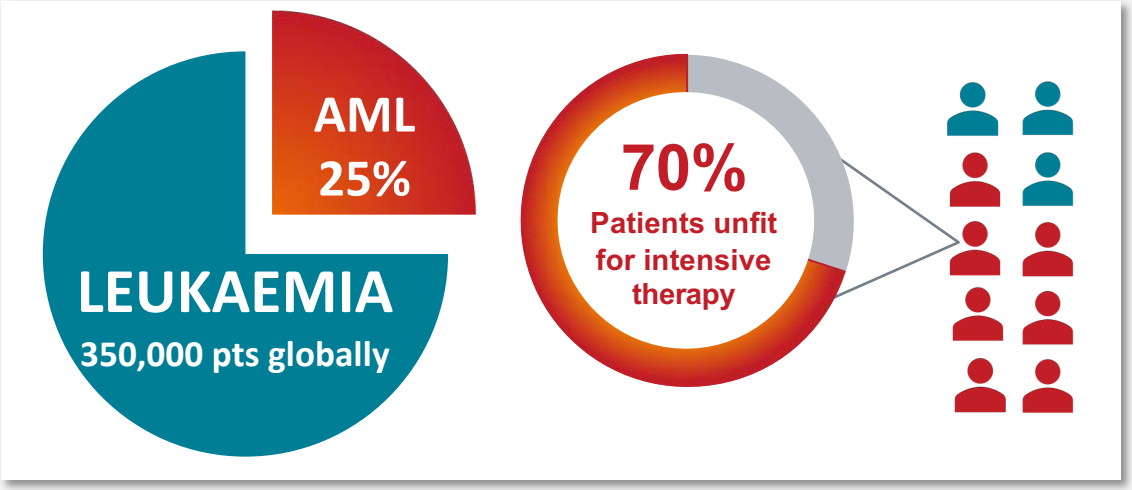
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

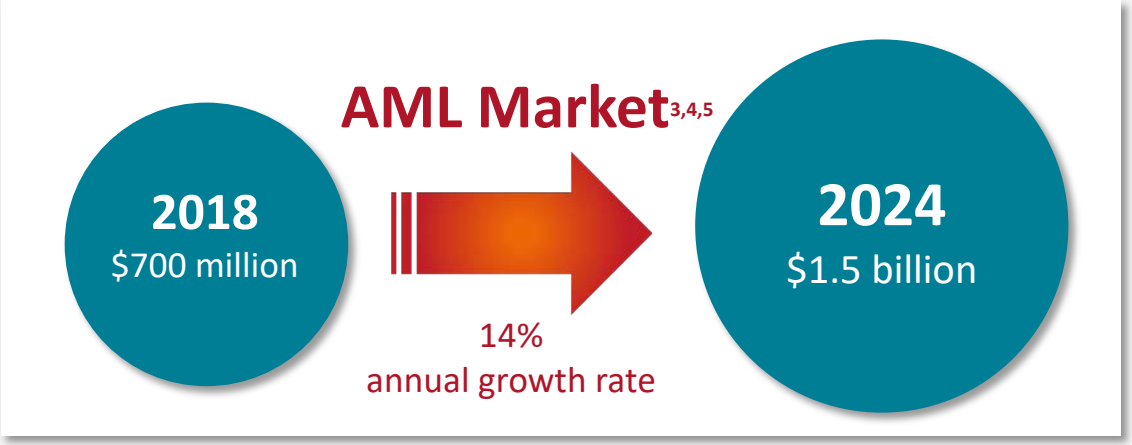
~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018[2]

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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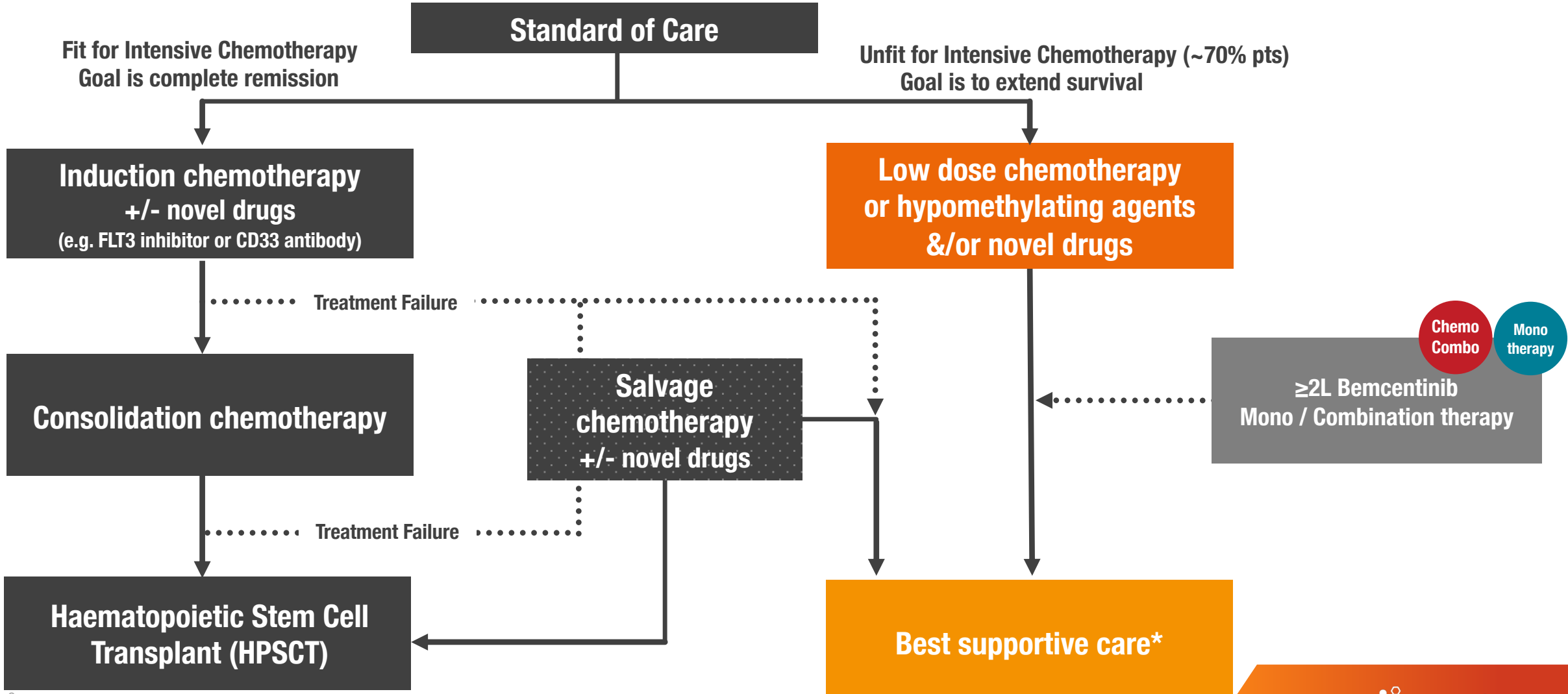
Acute myeloid leukemia (AML)

One of the most aggressive blood cancers, with a very low survival rate and few options for patients who are ineligible for intensive chemotherapy



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

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Bemcentinib efficacy signal in AML

AUGUST 2019 Update

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***

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

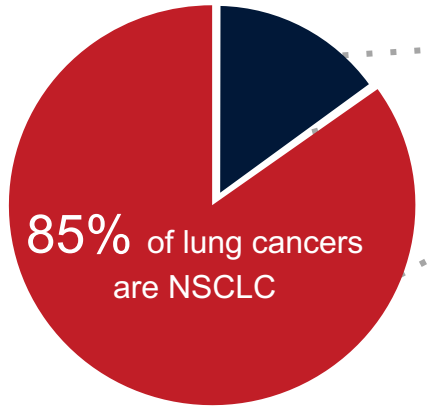
The largest cancer killer, most patients depend on drug therapy

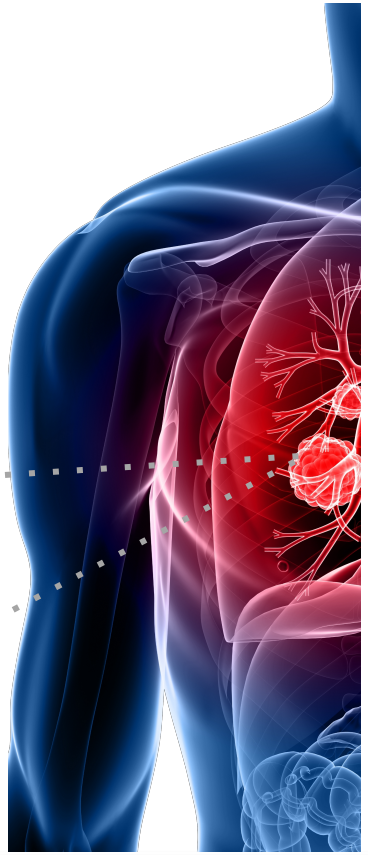
The most common type of cancer

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%

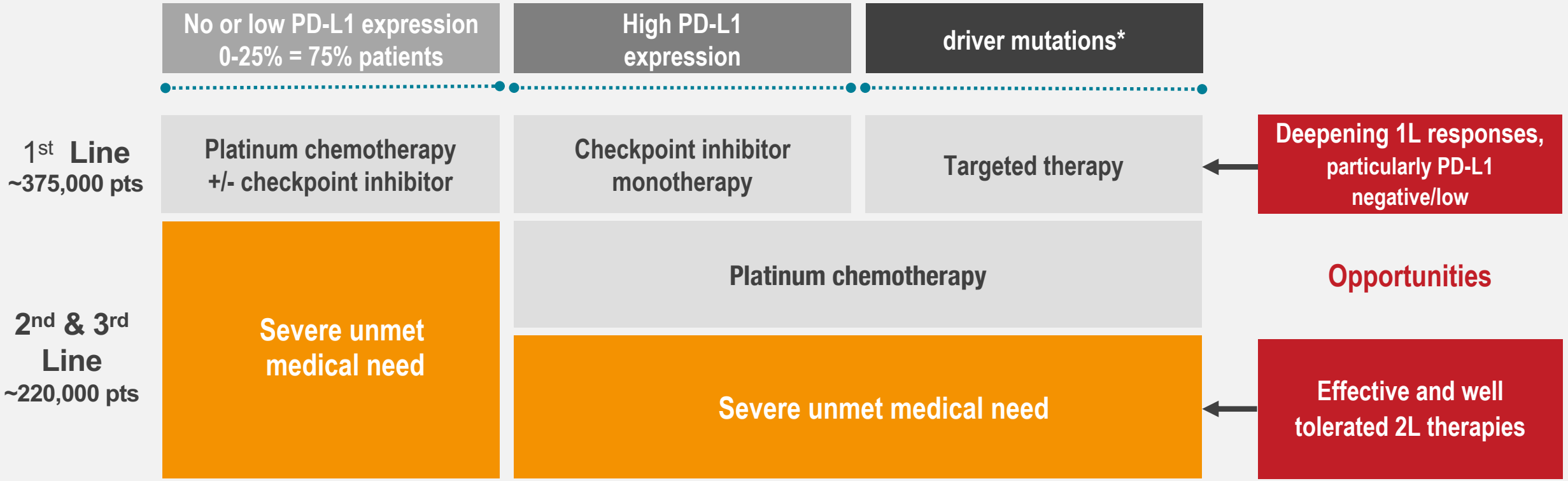




(1) fortunebusinessinsights.com/industry-reports/non-small-cell-lung-cancer-therapeutics-market-100484

Non- Small Cell Lung Cancer (NSCLC)

Rapidly emerging SoC creates opportunities for novel effective, chemo free regimens



* 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

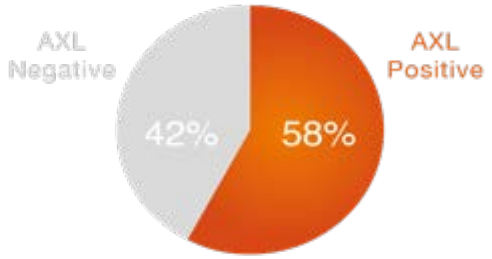
Stage 1		Stage 2
COMPLETE	If ≥ 4 PRs	COMPLETE
Society for Immunotherapy in Cancer (SITC)		ASCO 2019
November 2018		Preliminary Data
Efficacy & mPFS		
N = 26 pts	If ≥ 1 PRs	Up to 32 pts
RECRUITING		

Key objectives

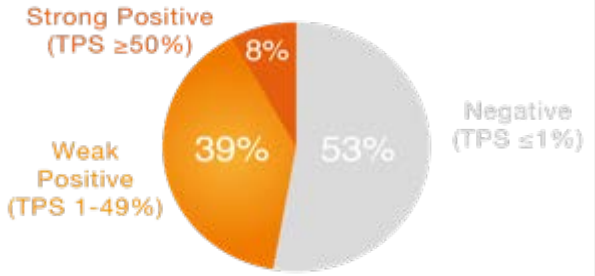
- Evaluate safety of the combination and response to treatment with the combination
- Characterise patients by PD-L1 and AXL status
- Evaluate efficacy of patients by biomarker status, and assess predictive qualities of biomarkers
- Assess survival measures in patients by biomarker status

Cohort A preliminary biomarker data

AXL Status: n=33
28 with at least 1 radiological assessment



PD-L1 Status: n=38
29 with at least 1 radiological assessment



Bemcentinib Ph II POC data 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)

- Venetoclax + chemo is emerging 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

- Pt.based chemo remains 1L SoC in low PD-L1 patients (in some regions)
- 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

- CPI + Pt.based chemo emerging 1L SoC for all patients (world wide)
- 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

Bemcentinib clinical development – REFINED AUG'19

Multiple attractive opportunities in many cancers

		Indication	Discovery	Cinical PoC	Late stage development	Registration	Current Status
Bemcentinib Selective oral small molecule AXL inhibitor	Randomised trial (TBA)	NSCLC					START UP INITIATED: GO-NO-GO DEPENDENT ON 2L KEYTRUDA COMBO DATA
	2L combination						1. + KEYTRUDA 2L (ongoing) - EXPANDED 2. + erlotinib 1L & 2L (complete) 3. + docetaxel >2L+ (ongoing)
	2L AML monotherapy	AML/MDS					START UP INITIATED: GO-NO-GO DEPENDENT ON LDAC EXPANSION DATA
	monotherapy & chemo combination						1. Monotherapy (complete) 2. + LDAC (fully enrolled) EXPANSION H2'19 3. + decitabine (fully enrolled)
	Additional advanced tumour indications	ILS Support					Numerous ongoing trials as mono therapy, or in combination with targeted drugs or check-point inhibitors.

Study in planning or start up stage

Our other anti-AXL drug candidates

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

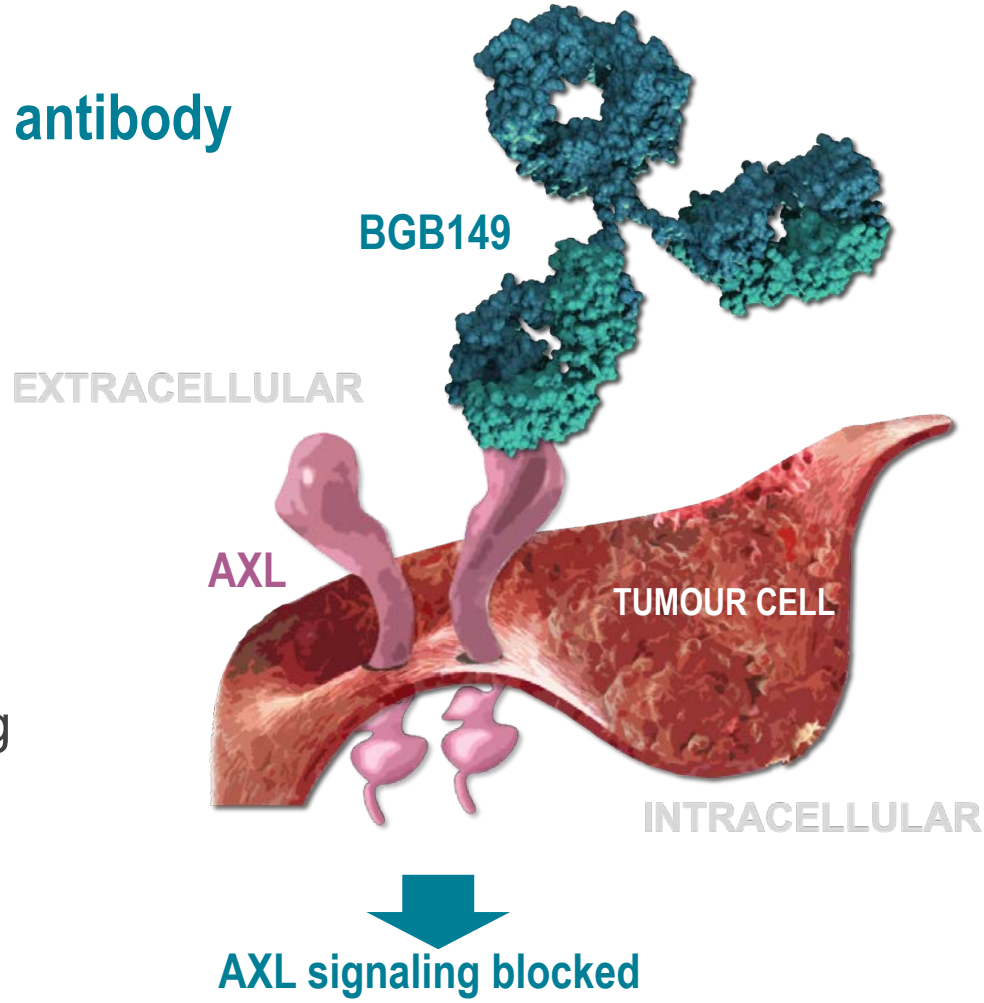
Ref. BGB149-101 / NCT03795142

BGB149: Anti-AXL monoclonal antibody

Phase I clinical trial ongoing

Functional blocking fully-humanised IgG1 monoclonal antibody

- Binds human AXL, blocks AXL signalling
- High affinity (KD: 500pM), Anti-tumour efficacy demonstrated in vivo
- Robust manufacturing process established,
- 18 months stability
- First-in-human healthy volunteer Phase I study ongoing with up to 36 subjects; Safety, PK/PD
  - No safety concern identified
- First-in-patient ph IIa trial expected in H1 2020

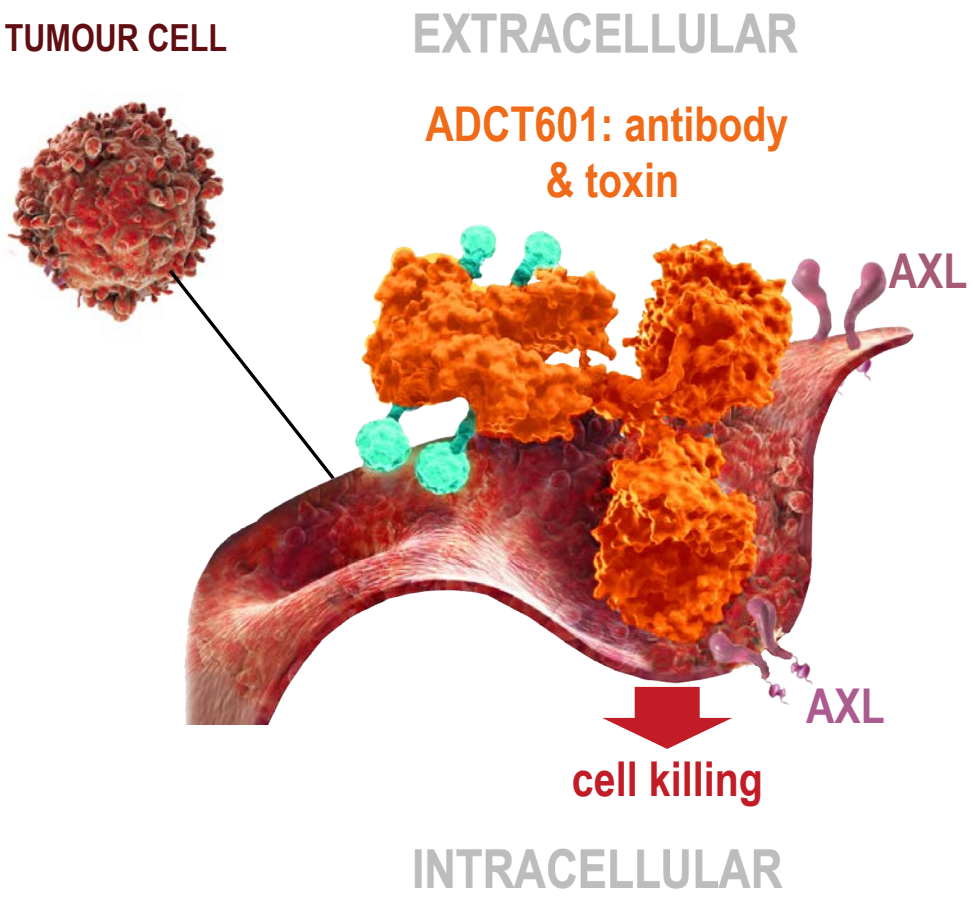


Ref. NCT03700294

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 when internalised
- Potent and specific anti-tumour activity demonstrated preclinically[1]
- First-in-human Phase I study initiated in Jan 2019
  - Solid tumours
  - Up to 75 patients
  - Safety, PK/PD, preliminary efficacy
- Based on anti-AXL antibody BGB601 licensed from BerGenBio

3 selective AXL inhibitors in clinical development – REFINED AUG'19

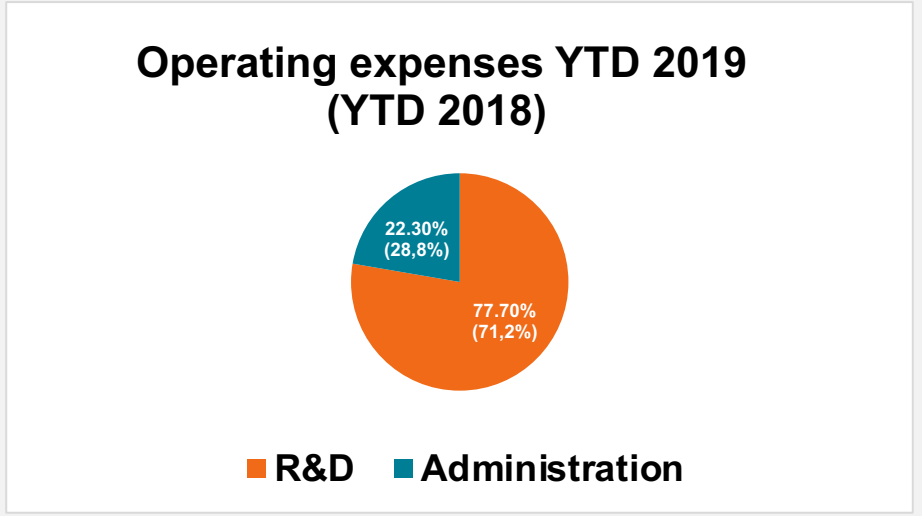
Multiple attractive opportunities in many cancers

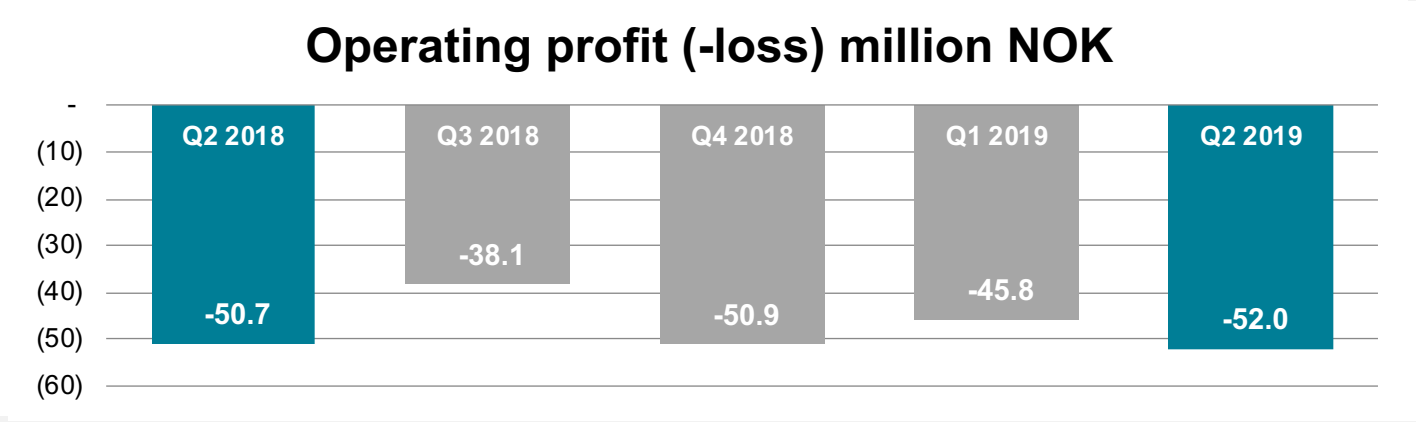
Finance Report

Rune Skeie - CFO

Key financial figures

(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



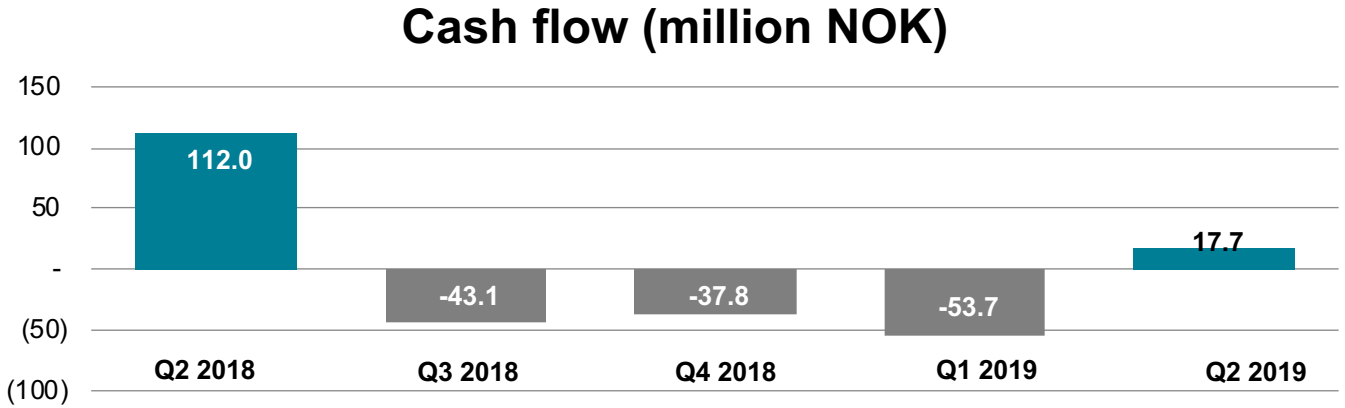


- Focus on R&D activities
- 77.3% of operating expenses YTD 2019 (YTD 2018: 71,2%) attributable to Research & Development activities

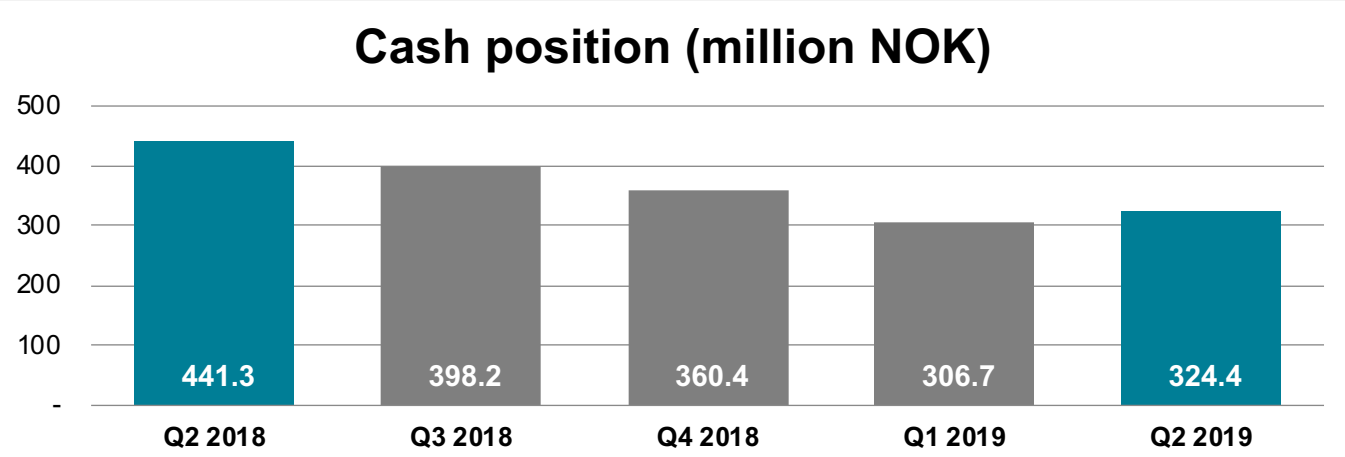
- No cash effect on P&L Operating expenses, that was reduced by a smaller provision for social and security tax on share options, positive effect on result Q2 2019 NOK – 6.1 million (negative effect on result Q2 2018 + 4.2 million).

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

Financial calendar

2019

13 March 2019	Annual General Meeting
8 May 2019	Quarterly Report – Q1 2019
19 August 2019	Half-year and Q2 report 2019
19 November 2019	Quarterly Report – Q3 2019

BerGenBio

Analyst coverage

H.C. Wainwright & Co

Joseph Pantginis
Telephone: +1 646 975 6968
E-mail: jpantginis@hcwresearch.com

ABG Sundal Collier

Øystein Elton Lodgaard
Telephone: +47 22 01 60 26
E-mail: oystein.lodgaard@abgsc.no

Arctic Securities

Pål Falck
Telephone:+47 229 37 229
E-mail: pal.falck@arctic.com

Jones Trading

Soumit Roy
Telephone: +1 646 454 2714
E-mail: sroy@jonestrading.com

DNB Markets

Patrik Ling
Telephone: +46 8 473 48 43
E-mail: patrik.ling@dnb.se

Trinity Delta

Mick Cooper, PhD
Telephone: +44 20 3637 5042
mcooper@trinitydelta.org

Q2 Summary &
Near term goals and milestones

Q2 was a period of significant progress for BerGenBio

Presented strong efficacy signal and extended DoR for the combination with low dose cytarabine in AML patients
> initiate an expansion cohort to confirm signal and to direct optimal registration path

Strong preliminary ORR and OS results from ongoing trial of bemcentinib in combination with Keytruda® in 2L AXL+ve chemo relapse NSCLC patients

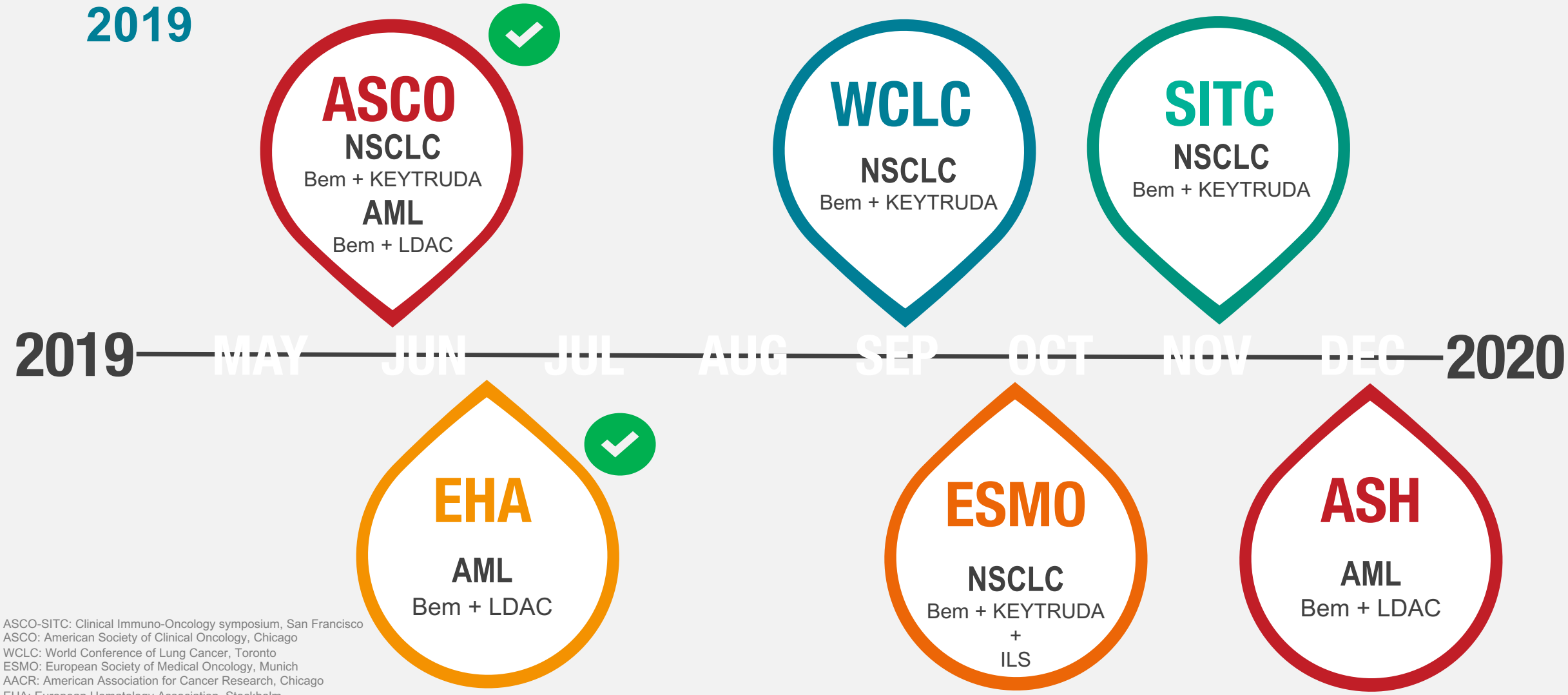
Initiated and expanded phase II trial in 2L IO & IO+chemo relapse NSCLC patients

Continue enrolment in phase I dose escalation study with BGB149

Private placement completed, raising gross proceeds of NOK74.2m

Cash and Cash equivalents at end of Q2 2019 NOK324.4m

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

Refined Outlook accounting for clinical data and market opportunity

Strategic priority		Goals	
Late stage clinical trials with bemcentinib	H2 2018 H2 2018 H1 2019 ~~H2 2019~~ ~~H2 2020~~	Clinical PoC monotherapy AML Clinical PoC combo in NSCLC Clinical PoC combo in AML Start late stage clinical programme Interim read-out late stage clinical programme	✓ ✓ ✓ **H1'20** **H1'21**
Develop Companion Diagnostics	H2 2018 H2 2020 H2 2021	Identify biomarkers that correlate with efficacy Validate biomarkers in late stage clinical trials Clinical assay developed	✓
BGB149 anti-AXL antibody programme	H2 2018 ~~H2 2019~~ ~~H2 2020~~	Initiate first-in-man phase I trial Initiate first-in-patient ~~ph~~ Ib trial Ph IIa Interim readout	✓ **H1'20** **H1'21**
Maximise value for bemcentinib	H1 2019	Initiate pipeline opportunities for bemcentinib via IITs	✓

IIT: Investigator initiated Trials

Questions