BerGenBio ASA (OSE:BGBIO) Results Second Quarter 2018

21 August 2018

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BerGenBio

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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

BerGenBio

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

Well funded

Cash runway through to 2020

Included in the OSEBX index from 1st June 2018

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)

Experienced Team

35 staff

Headquarters and research in Bergen, Norway

Clinical Trial Management in Oxford, UK

*formerly referred to as BGB324

Q2 2018 results

Encouraging clinical data emerging from several Phase II trials with bemcentinib

Advanced Lung Cancer (NSCLC): First efficacy endpoint met in combination with KEYTRUDA

- ✓ First stage fully recruited and efficacy threshold to trigger start of second stage surpassed
- ✓ Encouraging results observed in PD-L1 negative patients (interim data presented at ASCO)

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

- ✓ Superior response rates observed in biomarker subgroup analysis, presented at ASCO and EHA
- ✓ Evidence of immune activation following bemcentinib monotherapy

Advanced Triple Negative Breast Cancer (TNBC): Negative for AXL & PD-L1, efficacy endpoint not met

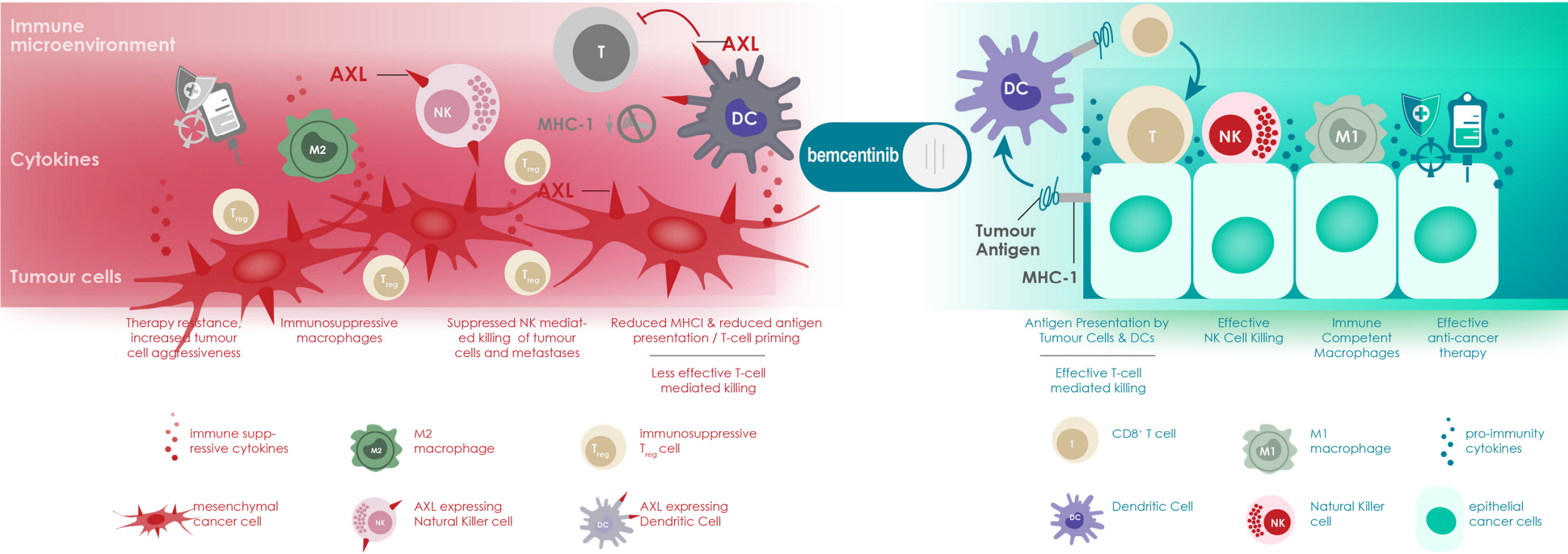
Biomarker programme: Correlation reported with patient benefit

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

Pipeline development: AXL antibody preparing for phase 1 clinical trial

Corporate: Cash position NOK441m

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



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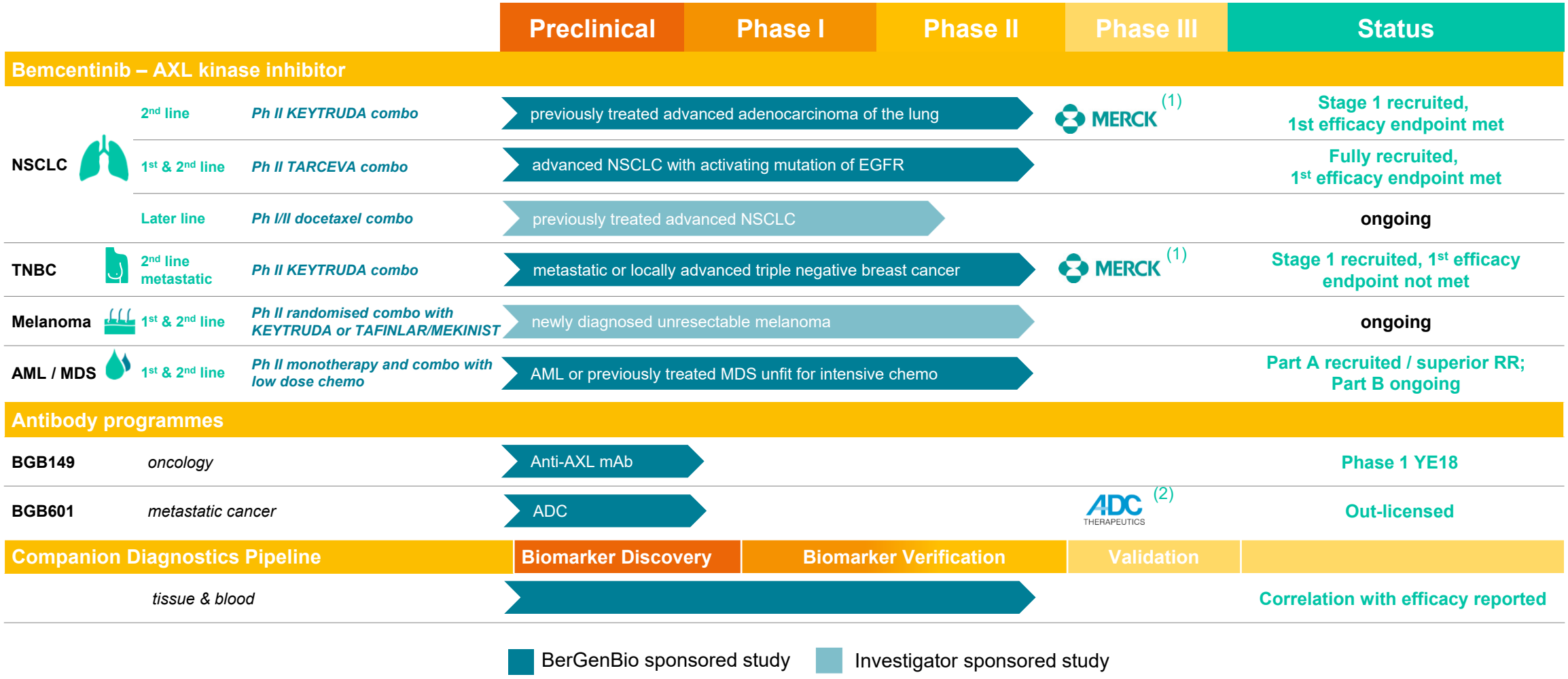
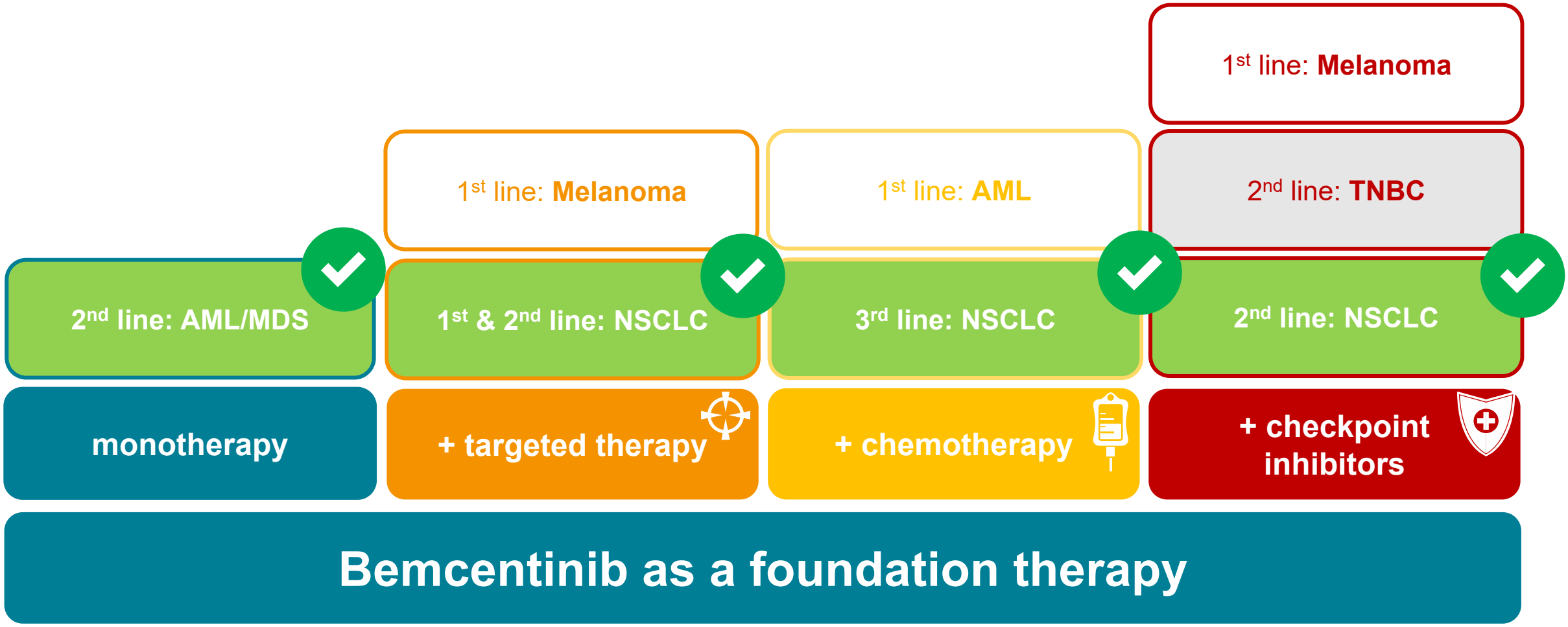
Pipeline of innovative AXL inhibitors



(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



H2 2018 News flow

Sep 2018: World Conference of Lung Cancer (WCLC)
Update on BerGenBio lung cancer trials

Oct 2018: European Society for Medical Oncology meeting (ESMO)
Biomarker update

Dec 2018: BGB149 Phase I clinical trial (anticipated)

Nov 2018: Society for Immunotherapy of Cancer (SITC) meeting (anticipated)

Dec 2018: American Society for Hematology (ASH) meeting (anticipated)

Advanced Lung Cancer (NSCLC)

Lung Cancer

The largest cancer killer globally

- **> 1.8 million new cases**/yr worldwide[1]
- **> 1.5 million lung cancer deaths**/yr worldwide[1]

85% cases are non-small cell lung cancer (NSCLC), mostly:

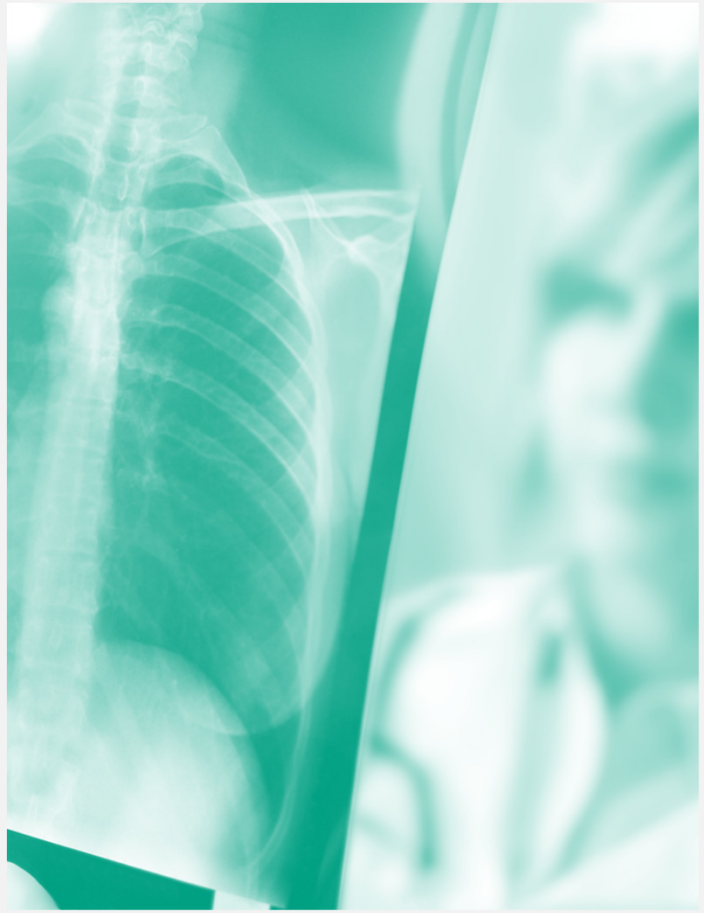
- **Adenocarcinoma** (40% of all lung cancers)[3]
- **Squamous cell carcinoma** (25-30% of all lung cancers)[3]

Drug therapy is the only option for most patients, with little benefit:

- **> 50% of cases detected late** and can thus not be treated with surgery alone[2]
- **5 year survival < 5%** for cases detected late[2]

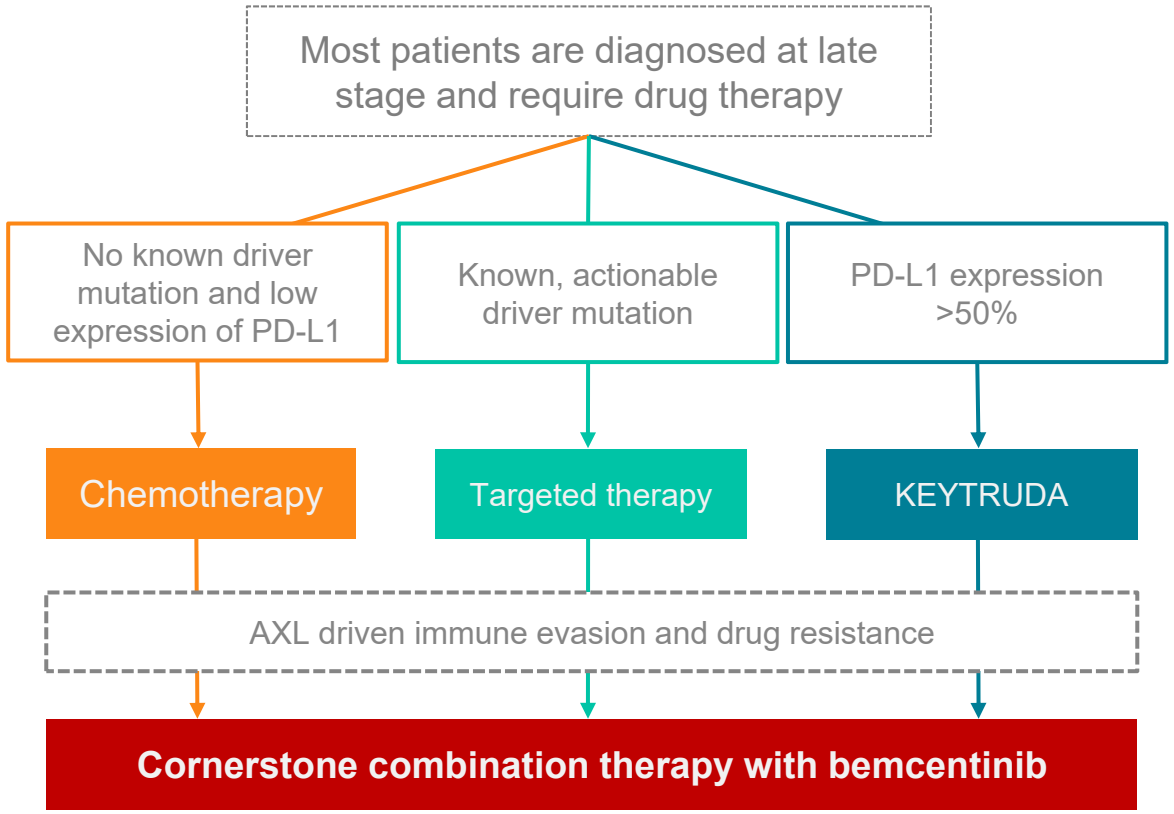
Large growing market driven by targeted therapies & immuneoncology

- **> $35bn global lung cancer market** (in 2023)[4]
- **NSCLC has 80% share** (of total lung cancer market)[4]



(1) WHO: Globocan 2012 (2) NIH: seer.cancer.gov, accessed August 2018 (3) American Cancer Society (4) Market Research Future: «Lung Cancer Market Research Report - Global Forecast to 2023», 2017

Potential for bemcentinib to become a cornerstone therapy for lung cancer (NSCLC)

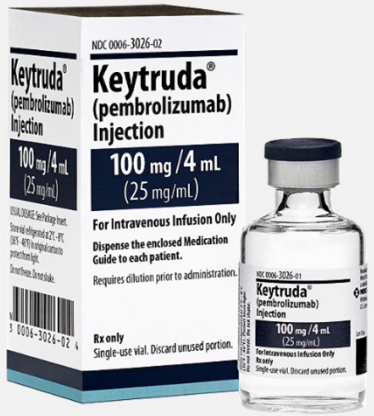


- Lung cancer is the most frequent cause of cancer-related death in developed countries
- Strategy to position bemcentinib as the cornerstone of treatment for NSCLC by combining with standard of care therapies

Bemcentinib Proof of Concept at Phase II

- ✓ **Combination with Chemo drugs**
- ✓ **Combination with Targeted drugs**
- ✓ **Combination with KEYTRUDA**

The development of immune checkpoint inhibitors in NSCLC: KEYTRUDA emerged as the SOC for PD-L1 positive NSCLC



KEYNOTE-001[1]: all comer NSCLC patients, treat with KEYTRUDA monotherapy*

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

39%	38%	23%
PD-L1 negative	**1-49% PD-L1**	**> 50% PD-L1**
9% response	16% response	44% response
Remains unmet need (not better than SOC chemo)	**Proceed to registration trials: Monotherapy now approved in 1L (>50%)[2] and 2L (>1%)[3]**	

(1) KEYNOTE-001: Garon et al, NEJM (2015); previously treated NSCLC patients (2) KEYNOTE-024: Reck NEJM (2016) (3) KEYNOTE-010: Herbst Lancet (2016)
* randomised control with SOC chemo and ** PD-L1 expression given as tumor proportion score; reference: Garon NEJM (2016), Patient disposition: Fugure S4; response according to biomarker status (previously treated patients only):Table S7

Strategy to develop bemcentinib in combination with KEYTRUDA in NSCLC patients, with the objective to enlarge the addressable patient population and offer a chemo free combination option

BGBC008: all comer, 2L, IO naïve NSCLC patients

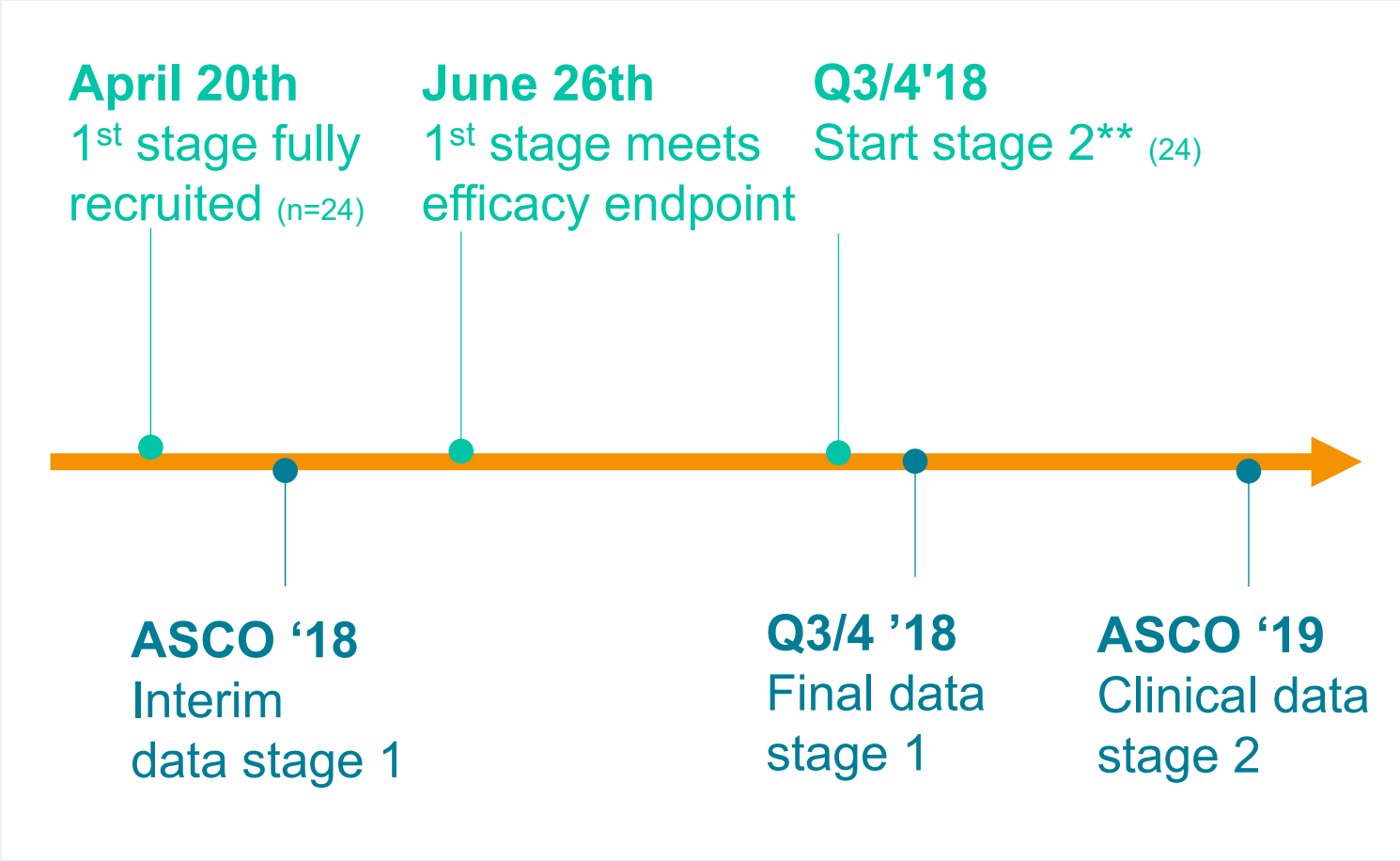
KEYTRUDA + bemcentinib*

↓

Sub-group analysis:
Efficacy according to PD-L1, AXL (and others)

↓

Strategy for randomised and pivotal trials

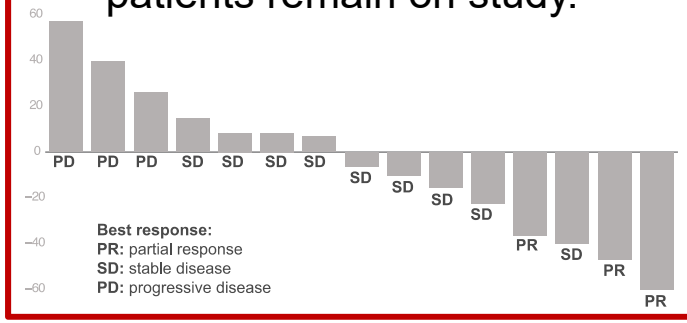


* Single arm study **anticipated, subject to customary approvals

BGBC008 interim data reported at ASCO 2018

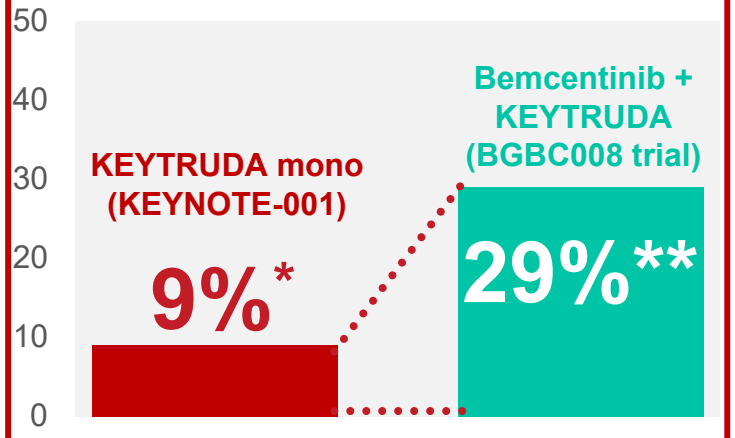
Encouraging interim efficacy data

- ✓ 8 out of 15 patients reported tumour shrinkage by radiographic evaluation (ASCO)
- ✓ 4 PRs (RECIST v1.1; June 26th announcement)
- ✓ Durable responses, many patients remain on study.



Results particularly promising in PD-L1 negative patients

- ✓ Encouraging efficacy in 7 PD-L1 negative patients (ASCO):
  - 2 PRs (2/7 = 29%)
  - 4 SDs (4/7 = 57%)
  - 1 PD (1/7 = 14%)



Safety

- ✓ Combination generally well tolerated
- ✓ No new safety findings, mostly low grade, no grade 4 or 5 events

Data subject to ongoing analysis

Comprehensive analysis of stage 1 will be presented at future medical congresses

* KEYNOTE-001: Garon et al, NEJM (2015); previously treated, PD-L1 negative patients ** Status ASCO 2018

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

Ca 40%[1] of patients are PDL-1 negative

PDL-1 negative patients do not benefit from KEYTRUDA monotherapy

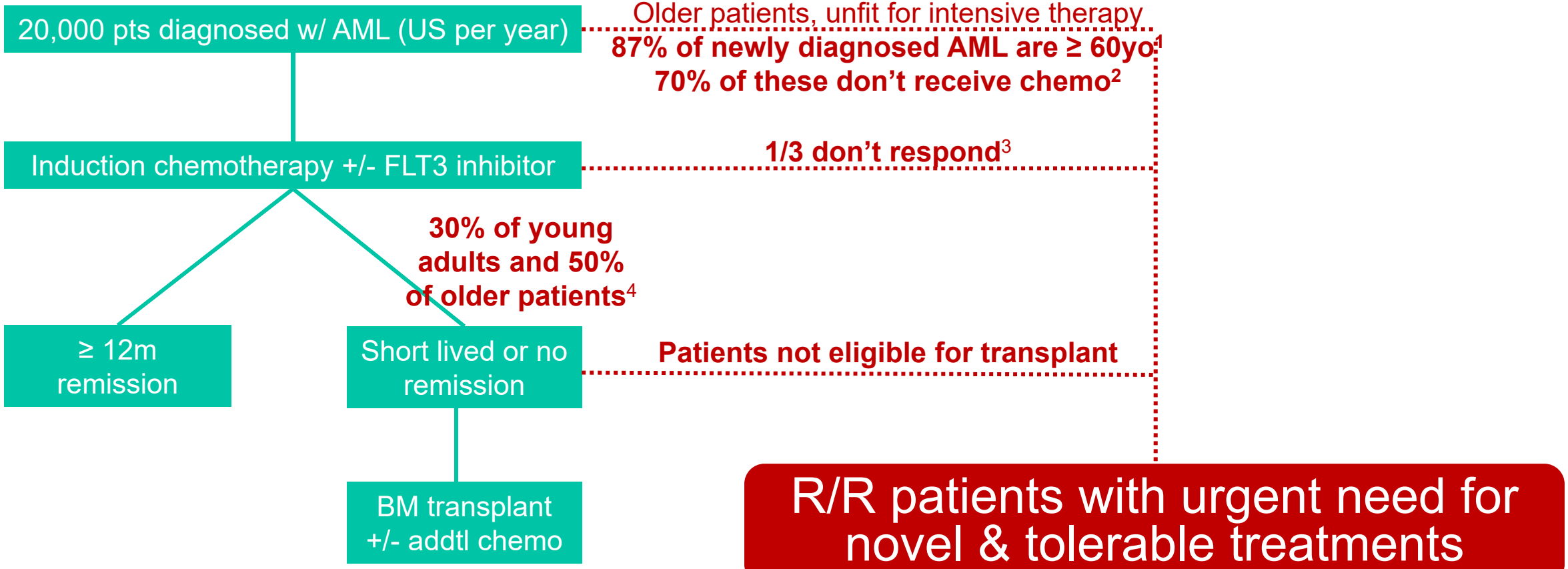
Opportunity to increase addressable market by adding bemcentinib

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

(1) KEYNOTE-001: Garon et al, NEJM (2015); previously treated patients with advanced NSCLC (2) BGBC008 interim data stage 1 (status ASCO 2018)

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

Relapsed/refractory AML & MDS – Blood cancer, difficult to treat malignancies, predominantly elderly frail patient population.



MDS: Myelodysplastic syndrome

Source: (1) Juliusson, Blood (2009) (2) Erba, Leukemia Research (2015) (3) cancer.org (4) uotodate.com

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)

↓

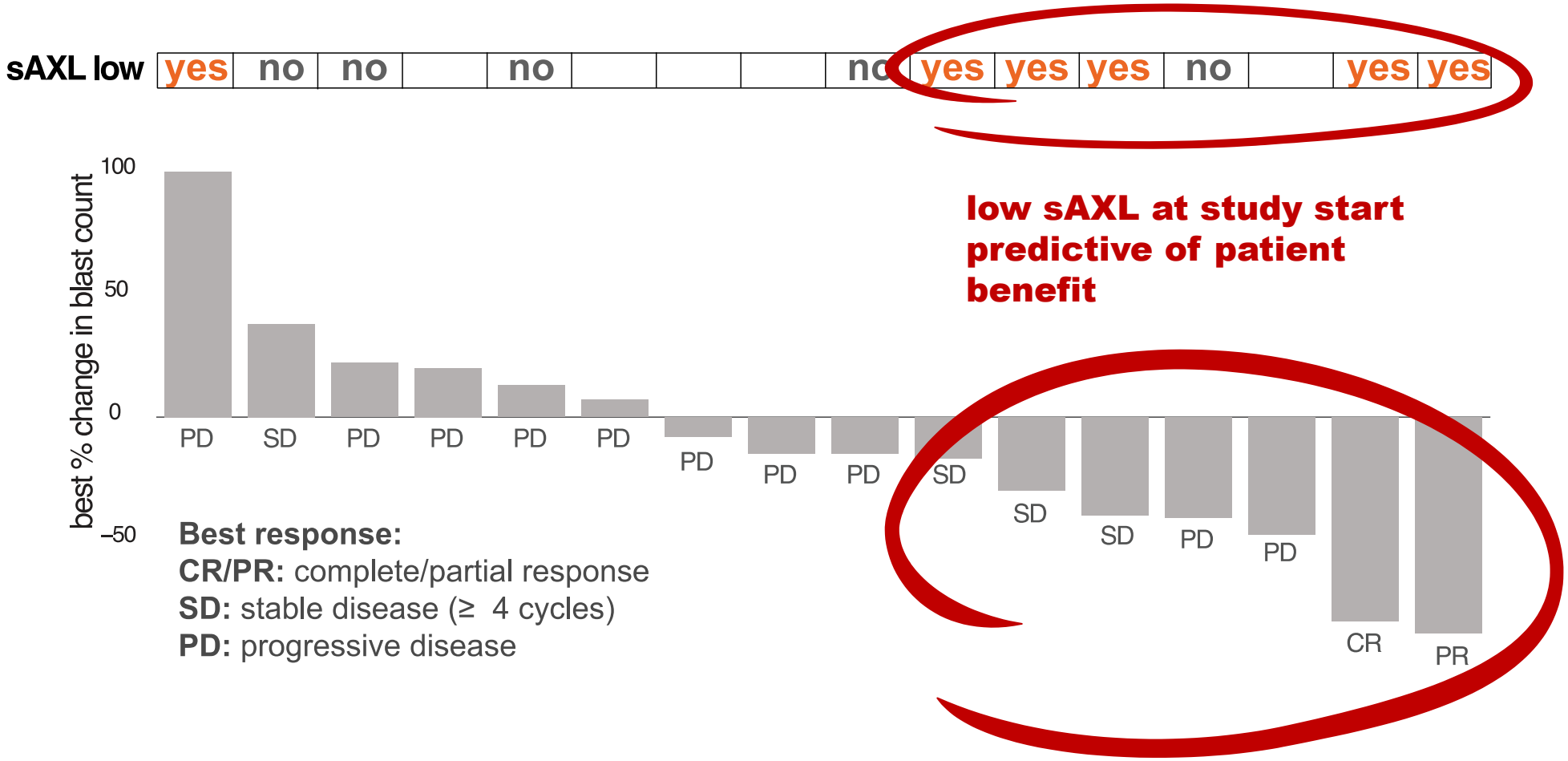
Strategy for randomised and pivotal trials

Programme key points

- ✓ **4 arm study:**
  - ➢ MDS – 2L monotherapy
  - ➢ AML
    - 2L monotherapy
    - 1L/2L combo with azacitidine
    - 1L/2L combo with decitabine
- ✓ **Monotherapy efficacy demonstrated**
- ✓ **Predictive biomarker candidate identified:** sAXL, measured in blood (non-invasive liquid biopsy)
- ✓ **Immune activation observed** following bemcentinib monotherapy

* Single arm study **anticipated, subject to customary approvals

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



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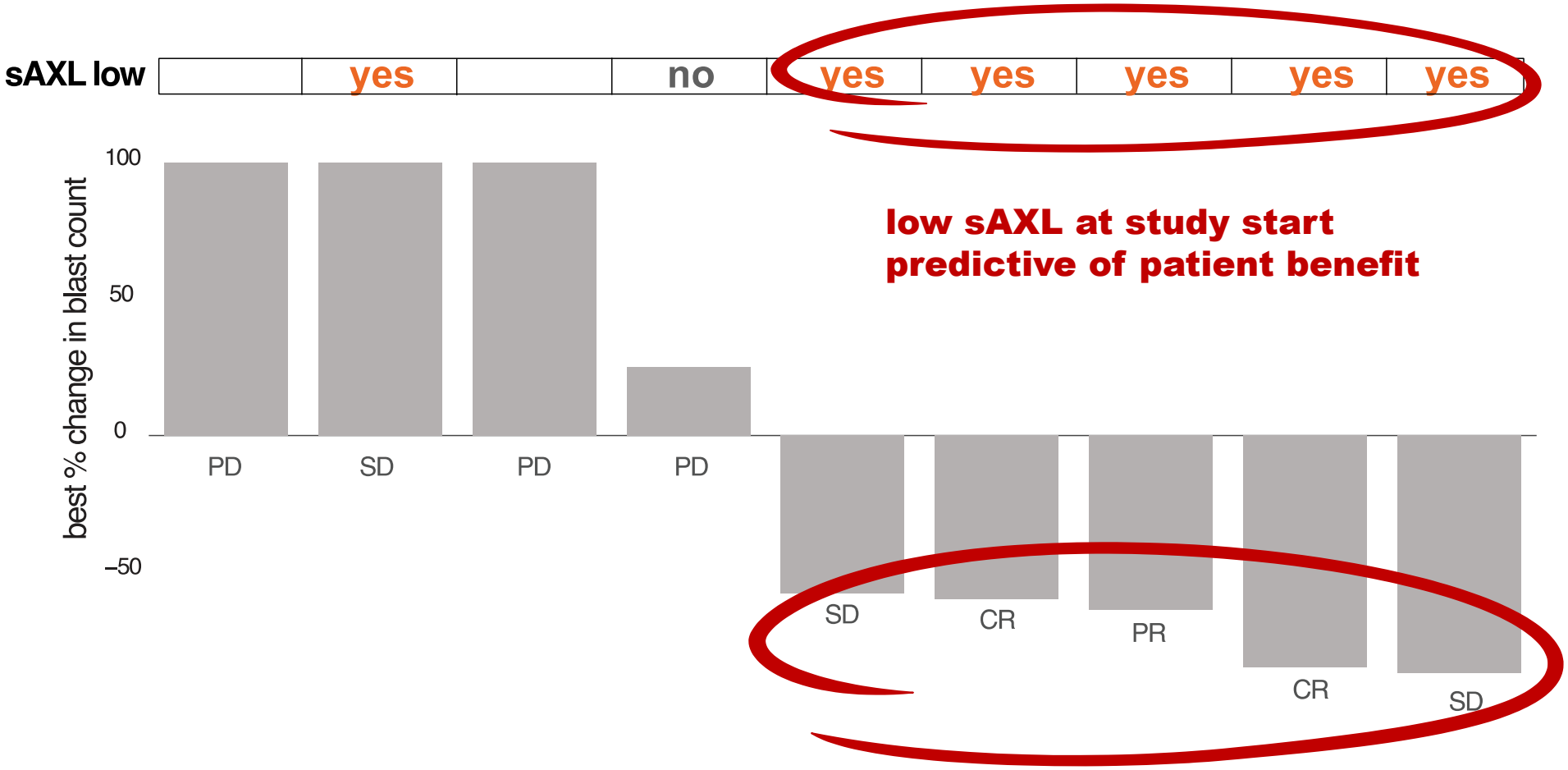
ASCO: Strong efficacy seen in MDS patients with low plasma soluble AXL (sAXL)



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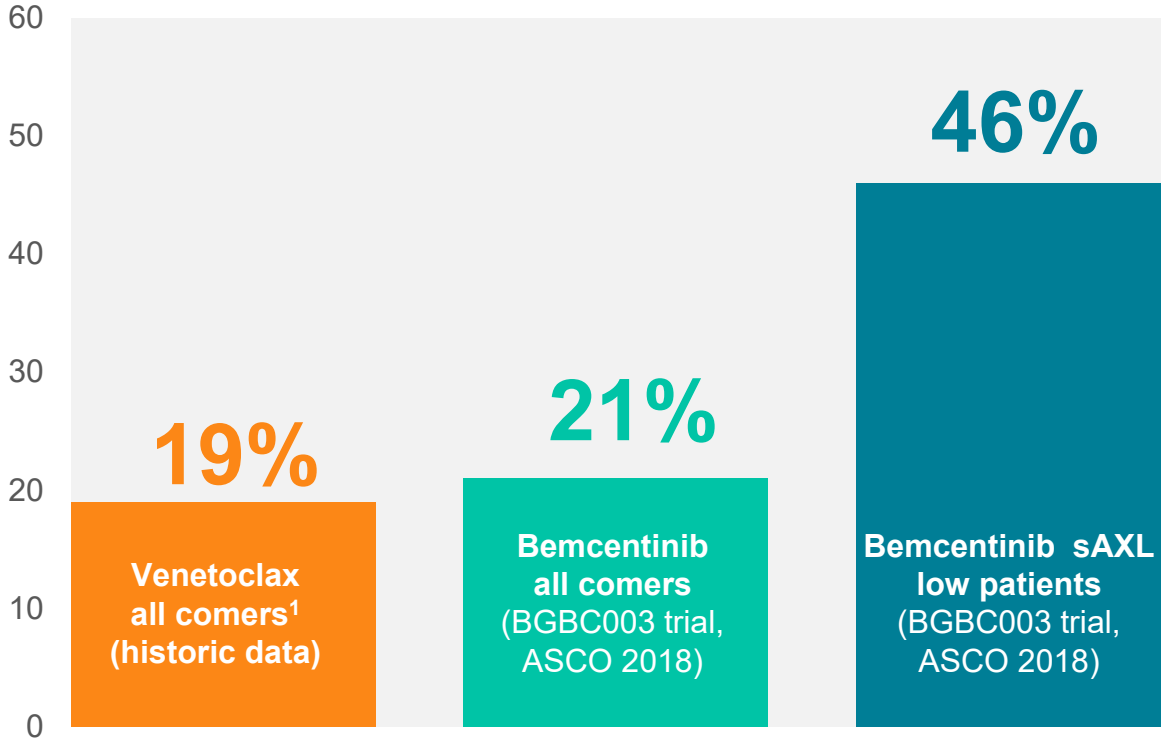
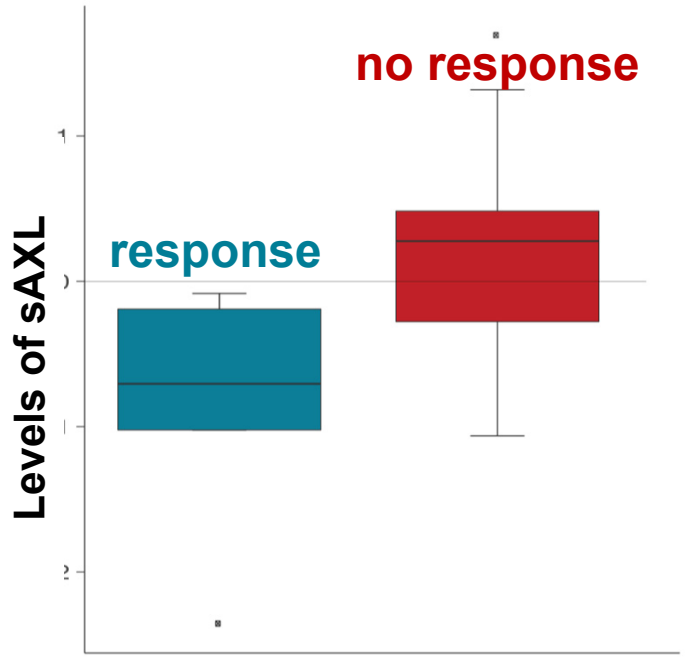
ASCO: Superior efficacy in patients with low sAXL

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



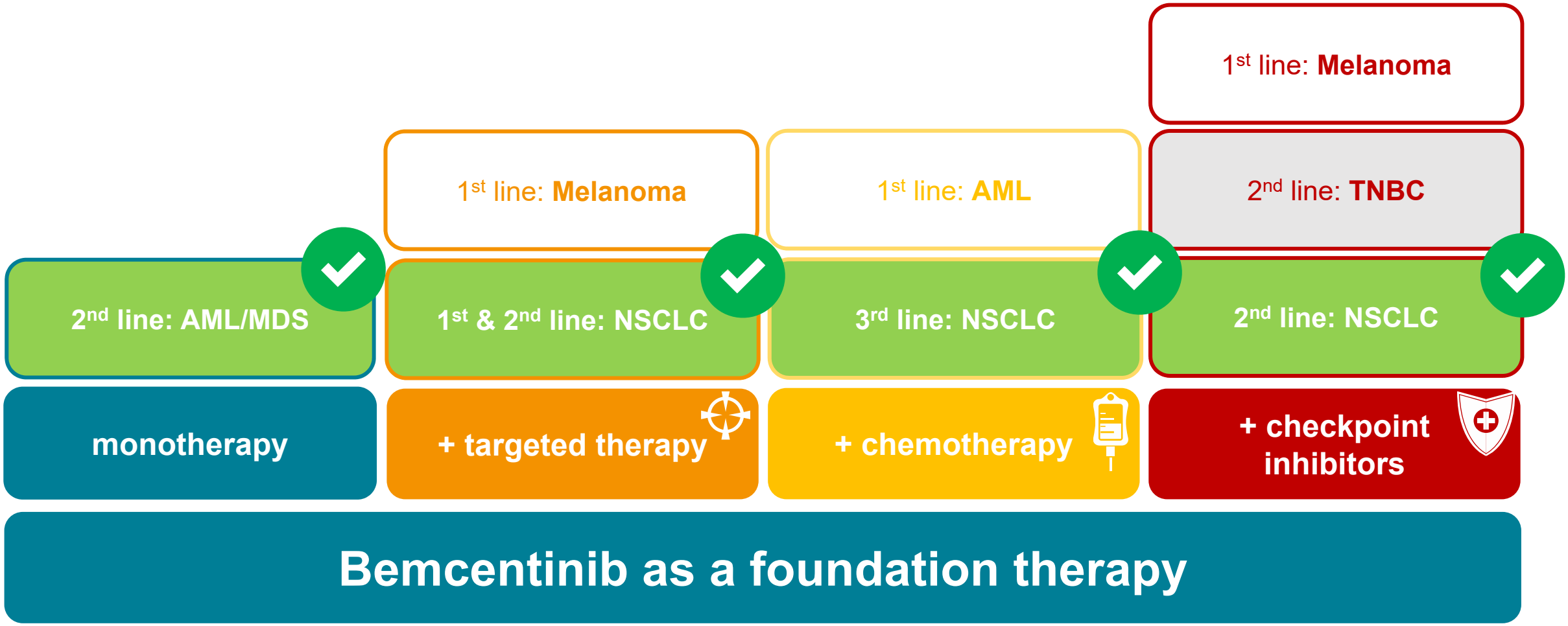
Venetoclax: oral BCL-2 inhibitor approved for CLL. Received recent attention for encouraging monotherapy efficacy in R/R AML unfit for intensive. Breakthrough designation for 1L AML in combo with LDCT; not approved in R/R AML

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



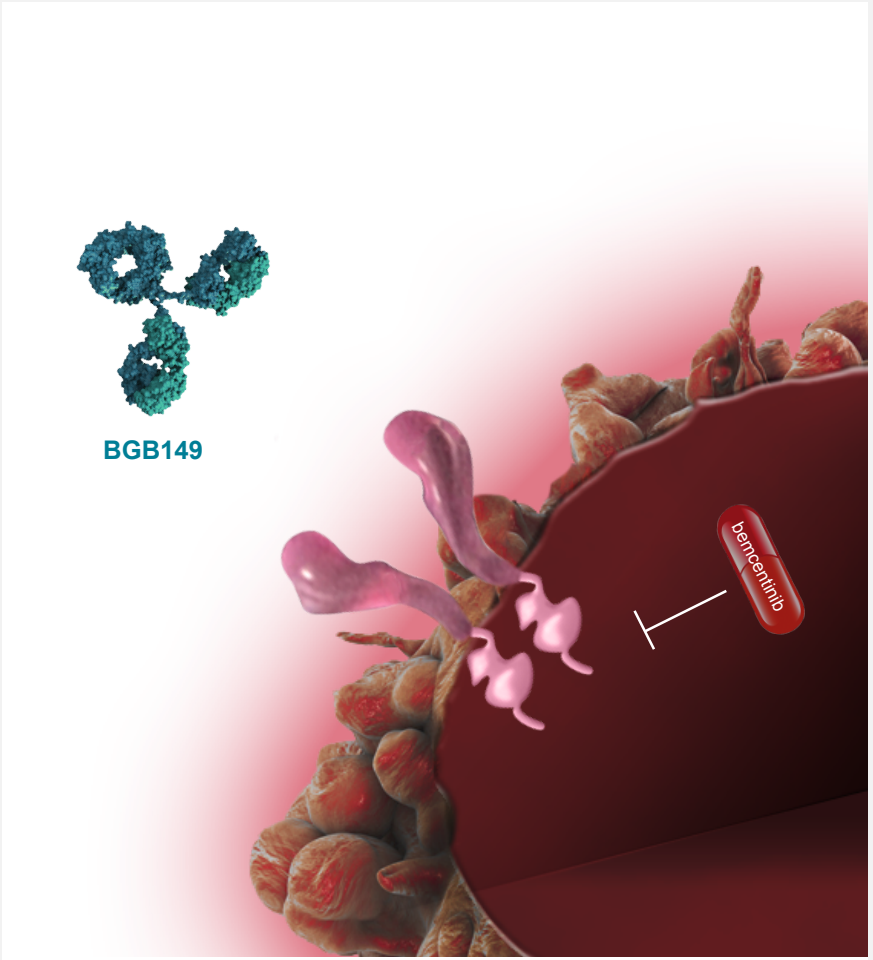
(1) Konopleva *et al: Cancer Discovery* online first (2016) **ORR:** %age of patients who's bone marrow blasts were reduced by at least 50% (partial response, PR) or fell below 5% total (complete response, CR)

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



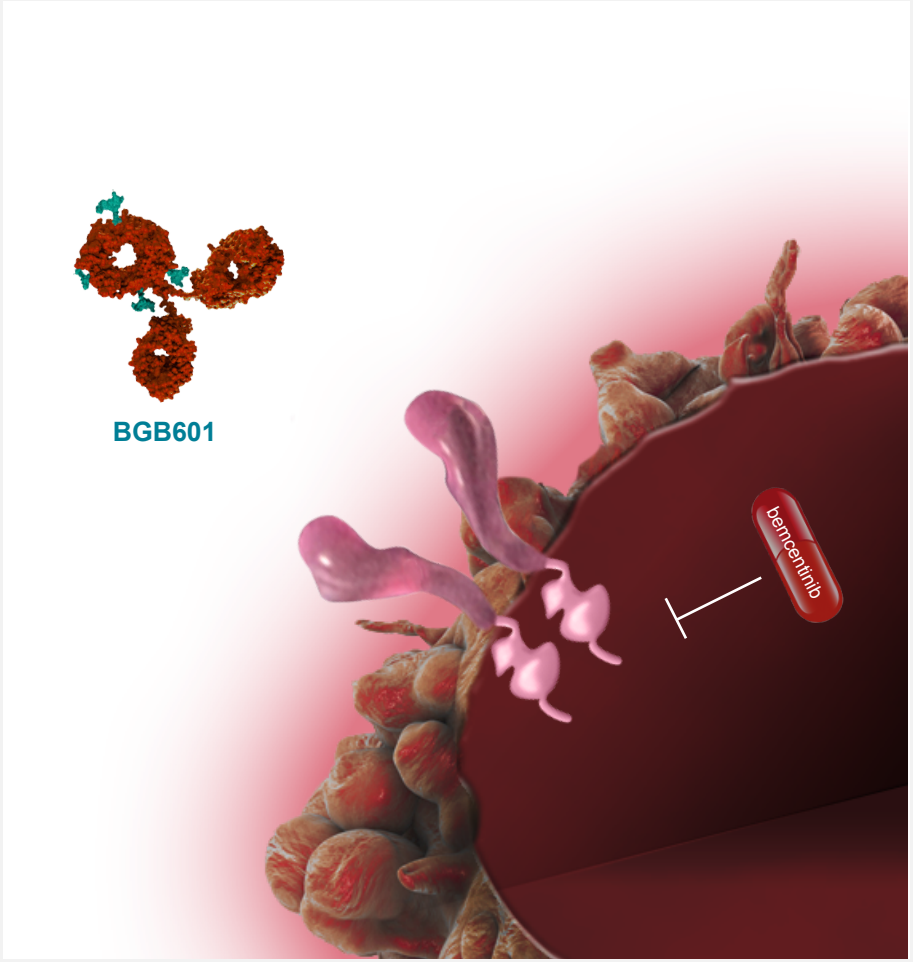
Pipeline update:
Translating leadership in understanding AXL biology into a diversified portfolio of novel AXL inhibitors

BGB149: AXL function blocking antibody drug



- ✓ First in class anti AXL monoclonal antibody
- ✓ Phase I clinical trial anticipated YE'18
- ✓ Wholly owned asset
- ✓ Board and long IP coverage
- ✓ Potent molecule and differentiated clinical position

BGB601 (ADCT-601): AXL Antibody Drug Conjugate



AXL antibody Drug Conjugate (ADC)

Targeted killing of AXL expressing tumour cells

Outlicensed to ADC Therapeutics (Switzerland)

Begin of clinical trial will trigger milestone payment by ADCT to BerGenBio

AACR (April '18)[1]:

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

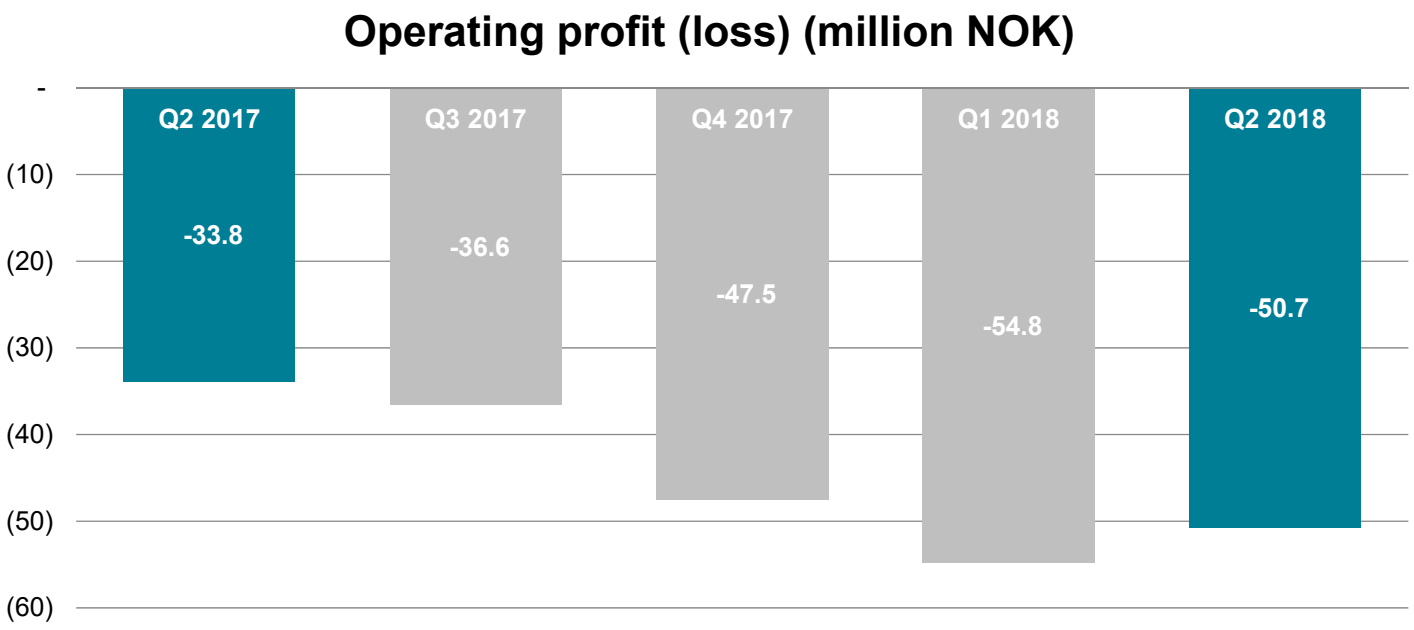
1: Zamarchi *et al:* AACR 2018

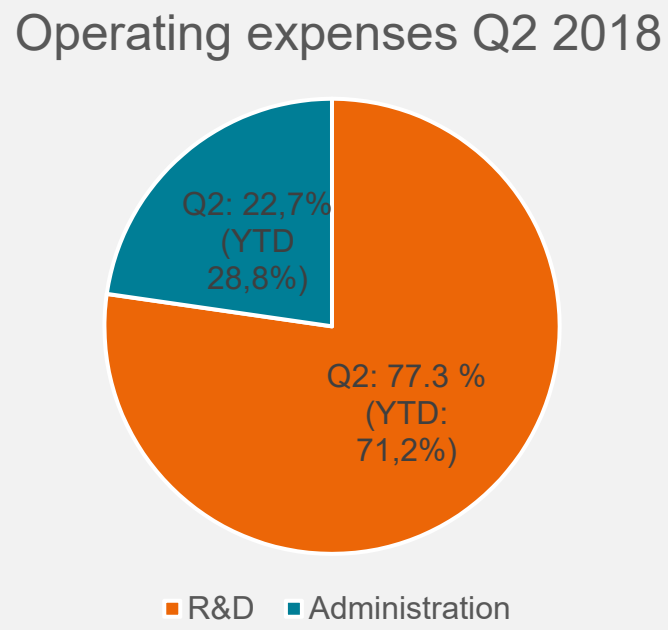
Financial review:
Cash position strengthened

Rune Skeie

CFO

Operating profit (loss)



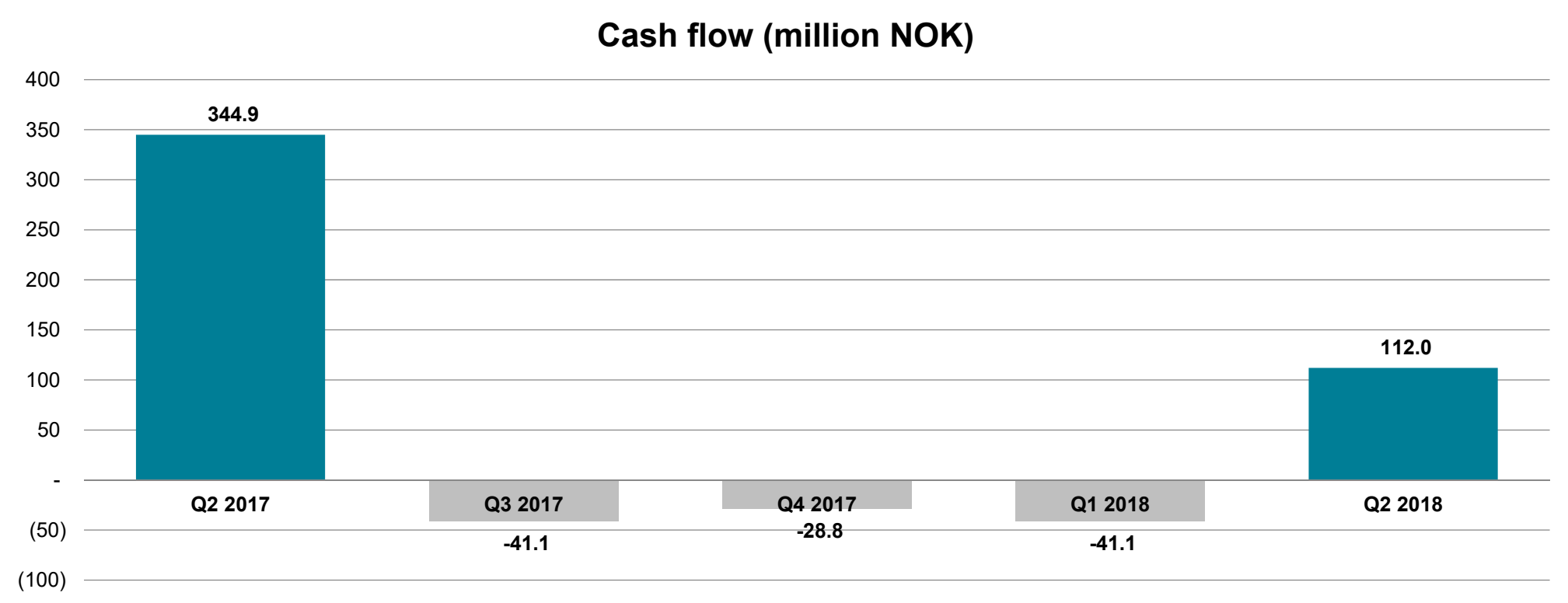


- Q1'18 increase in operating loss associated with increased social security tax provision (no cash effect) related to share price and share option scheme (NOK 8,4 million)

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

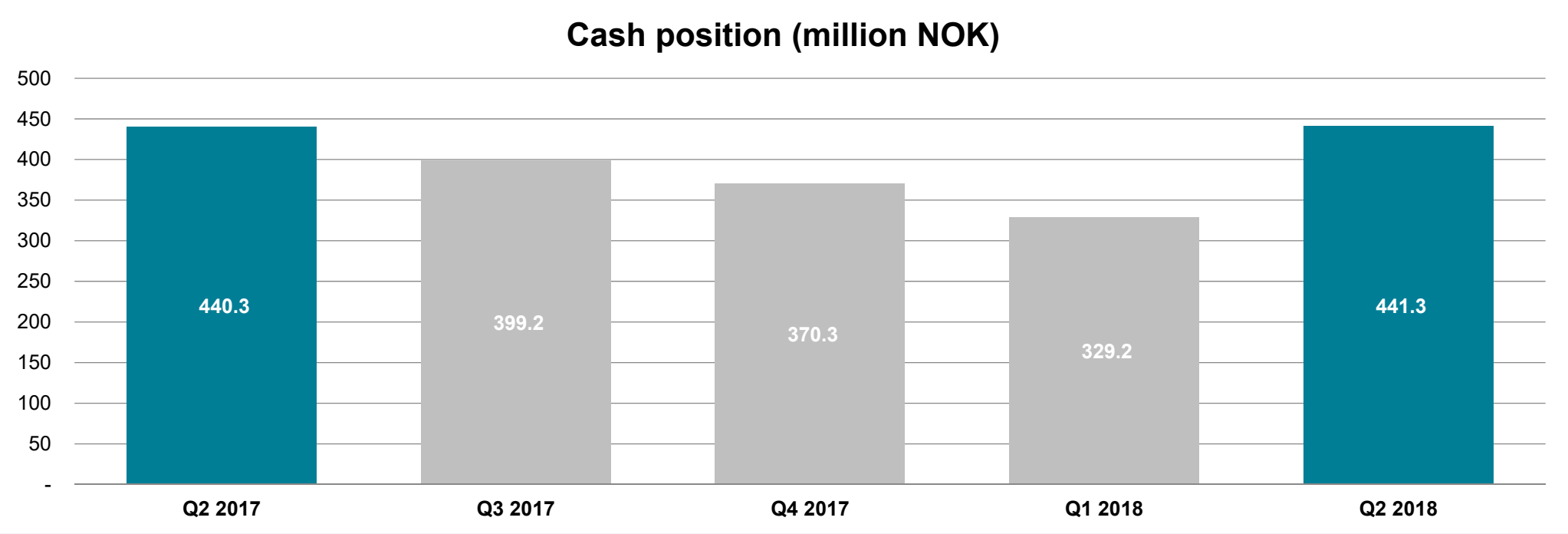
http://www.bergenbio.com/investors/reports/quarterly-reports/

Cash flow



- Private placement completed in April 2018 - gross fund raise NOK 187,5 million

Cash position



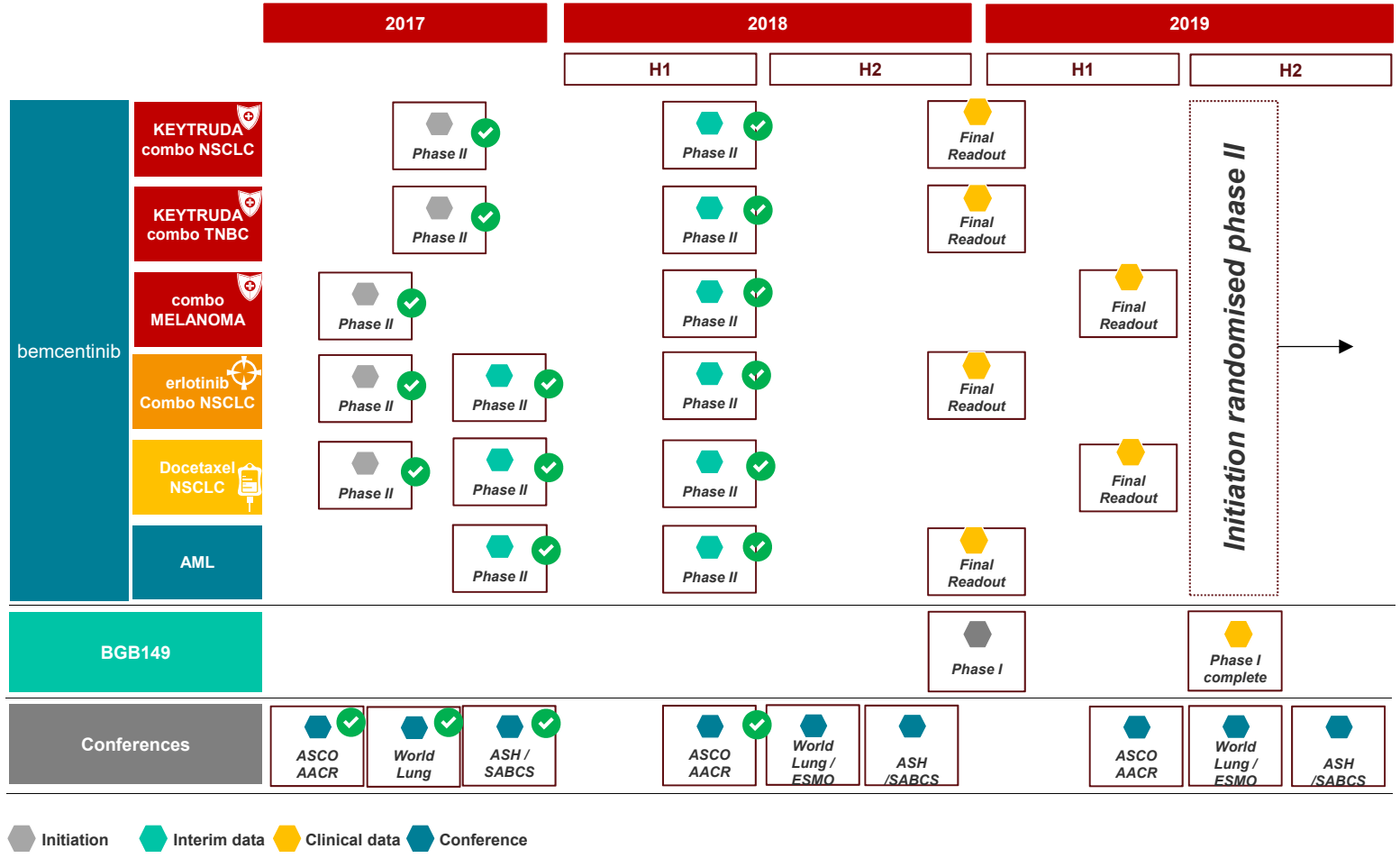
- Gross fund raise NOK 187,5 million completed in April – strengthening cash position
- Shareholder base broadened with addition of US-based specialist healthcare funds
- Cash position gives runway to deliver key clinical read outs on ongoing clinical studies
- Cash runway into 2020 based on current burn rate

Summary & Outlook:
A number of significant milestones expected in H2 2018 and 2019

Richard Godfrey

CEO

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

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

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 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	Q2 2018	Q2 2017	YTD 2018	YTD 2017	Full year 2017
Revenue		0	0	0	0	0
Expenses						
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
Total operating expenses		**50 732**	**33 846**	**105 513**	**99 635**	**183 707**
Operating profit		**-50 732**	**-33 846**	**-105 513**	**-99 635**	**-183 707**
Finance income		1 622	541	2 668	1 660	4 168
Finance expense		128	778	172	1 173	2 668
Financial items, net		**1 495**	**-236**	**2 496**	**487**	**1 500**
Profit before tax		**-49 238**	**-34 082**	**-103 017**	**-99 148**	**-182 207**
Income tax expense		0	0	0	0	0
Profit after tax		**-49 238**	**-34 082**	**-103 017**	**-99 148**	**-182 207**
Other comprehensive income						
Items which will not be reclassified over profit and loss						
Actuarial gains and losses on defined benefit pension plans		0	0	0	0	0
Total comprehensive income for the period		**-49 238**	**-34 082**	**-103 017**	**-99 148**	**-182 207**
Earnings per share:						
- Basic and diluted per share	7	-0,92	-0,70	-1,99	-2,41	-4,01

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Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	30 JUN 2018	30 JUN 2017	31 DEC 2017
ASSETS				
Non-current assets				
Property, plant and equipment		518	467	557
Total non-current assets		**518**	**467**	**557**
Current assets				
Other current assets	5, 8	14 135	16 552	13 430
Cash and cash equivalents		441 263	440 300	370 350
Total current assets		**455 398**	**456 852**	**383 780**
TOTAL ASSETS		**455 917**	**457 319**	**384 336**
EQUITY AND LIABILITIES				
Equity				
Paid in capital				
Share capital	9	5 471	4 974	4 992
Share premium	9	398 521	406 301	325 018
Other paid in capital	4, 9	20 687	18 969	20 340
Total paid in capital		**424 678**	**430 245**	**350 350**
Total equity		**424 678**	**430 245**	**350 350**
Non-current liabilities				
Pension liability	10	0	0	0
Total non-current liabilities		**0**	**0**	**0**
Current liabilities				
Accounts payable		16 646	10 826	21 575
Other current liabilities		5 443	12 605	9 391
Provisions		9 150	3 643	3 020
Total current liabilities		**31 238**	**27 074**	**33 986**
Total liabilities		**31 238**	**27 074**	**33 986**
TOTAL EQUITY AND LIABILITIES		**455 917**	**457 319**	**384 336**

View Q2 2018 report for notes: http://www.bergenbio.com/investors/reports/quarterly-reports/

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	YTD 2018	YTD 2017
Cash flow from operating activities			
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
Net cash flow from operating activities		**-106 015**	**-96 545**
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	375 020
Paid in, not registered capital increase	9	0	159
Net cash flow from financing activities		**176 998**	**375 179**
Net increase/(decrease) in cash and cash equvivalents		70 914	278 475
Cash and cash equivalents at beginning of period		370 350	161 825
Cash and cash equivalents at end of period		**441 263**	**440 300**

View Q2 2018 report for notes: http://www.bergenbio.com/investors/reports/quarterly-reports/

Clinical trial update bemcentinib

BGBC003: + chemo or monotherapy

- ✓ **sAXL blood test predicts patient benefit – superior efficacy observed in patients with low sAXL at study start**
- ✓ Immunomodulatory effect observed following bemcentinib monotherapy (ASCO-SITC, ASCO and EHA)

BGBC008: + KEYTRUDA

- ✓ **First stage fully enrolled (n = 24 pts) and first efficacy endpoint met**
- ✓ Promising activity in patients who are not expected to benefit from KEYTRUDA monotherapy (ASCO 2018)

BGBC004: + EGFR inhibitors

- ✓ **Efficacy endpoint met in first stage of ph2 part combining with TARCEVA in pts who progressed on EGFR therapy (arm B)**
- ✓ Enrolling 1st line combo arm in patients who have received their maximum benefit from TARCEVA monotherapy, deepening of responses observed

BGBIL005: + docetaxel

- ✓ **Superior responses seen in patients who derive little or no benefit from chemotherapy alone**
- ✓ 3 of 7 evaluable patients had PRs - soluble predictive biomarker candidates identified

BGBIL006 + KEYTRUDA or TAF/MEK

- ✓ **All combos well tolerated, 15 of 19 pts evaluated to date showed tumour shrinkage (incl 2 CRs and 8 PRs) (ASCO 2018)**
- ✓ All ph2 arms open and recruiting at four sites in Norway

BGBC007: + KEYTRUDA

- ✓ **First stage fully enrolled (n = 28)**
- ✓ Low prevalence of AXL in tissue biopsies observed (14 of 18 pts analysed) and correspondingly low rates of response seen
- ✓ Interim efficacy endpoint not met