

BerGenBio ASA (OSE: BGBIO)

Corporate update: March 2019



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BGBIO – Investment Highlights



AXL inhibitors – potential cornerstone of cancer therapy

Leaders in developing selective AXL inhibitors

Bemcentinib (Ph2), AXL-antibody BGB149 (Ph1), AXL ADC ADCT-601 (Ph1)

AXL is a novel oncology target to overcome immune evasion, therapy resistance & spread

Pipeline opportunities in multiple cancers and fibrosis



Ph2 data in AML & NSCLC with selective AXL inhibitor bemcentinib

Monotherapy and combinations with immune-, targeted and chemotherapies

Biomarker correlation across programme, parallel CDx development

AXL positive patients:

43% ORR in R/R AML/MDS (monotherapy)
40% ORR in 2L NSCLC (KEYTRUDA combo)

Late stage clinical trials to start H2'19



Resourced to deliver significant milestones

Clinical trial collaborations with Merck and leading academic centres

AXL antibody out licensed to ADC Therapeutics SA

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

Cash NOK 360m/USD 41m

Increasing profile and recognition of bemcentinib at international clinical congresses in 2018

January	February	March	April	May	June	July	August	September	October	November	December	
<div>✓</div> <div>ASCO-SITC Lung cancer, TNBC and AML trial update</div> <div><ul style="list-style-type: none">✓ KEYTRUDA combo well tolerated✓ Bemcentinib induces diversification of T-cell receptor repertoire (AML)</div>	<div>✓</div> <div>AACR Preclinical Update</div> <div><p>Bemcentinib increases efficacy of checkpoint inhibitors</p></div>	<div>✓</div> <div>ASCO NSCLC, AML, Melanoma and biomarker update</div> <div><p>Bemcentinib enhances responses to</p><ul style="list-style-type: none">✓ IO,✓ chemo,✓ targeted therapies✓ and has monotherapy efficacy</div>	<div>✓</div> <div>EHA AML trial update</div> <div><p>Responses to bemcentinib monotherapy correlated with AXL biomarker</p></div>	<div>✓</div> <div>WCLC Lung cancer trials update</div> <div><ul style="list-style-type: none">✓ 40% ORR in AXL+ pts in combo w/ KEYTRUDA✓ Improved PFS in combo with erlotinib and chemo</div>	<div>✓</div> <div>ESMO Biomarker update</div> <div><ul style="list-style-type: none">✓ AXL biomarkers identified✓ Melanoma clinical update✓ AXL's role in low-risk MDS (pre-clinical)</div>						<div>✓</div> <div>SITC NSCLC data late breaking</div> <div><p>Late-breaking abstract: 5.9m PFS in AXL+ previously treated NSCL in combo w/ KEYTRUDA (c80% improvement in AXL+ pts vs AXL-)</p></div>	<div>✓</div> <div>ASH AML trial data update</div> <div><p>43% CR/Cri/CRp rate in AXL biomarker positive pts</p></div>



Key data presented in Q4 supports future strategy for late-stage clinical development of bemcentinib in AML/MDS and NSCLC

Two significant late stage development opportunities



2L AML
monotherapy



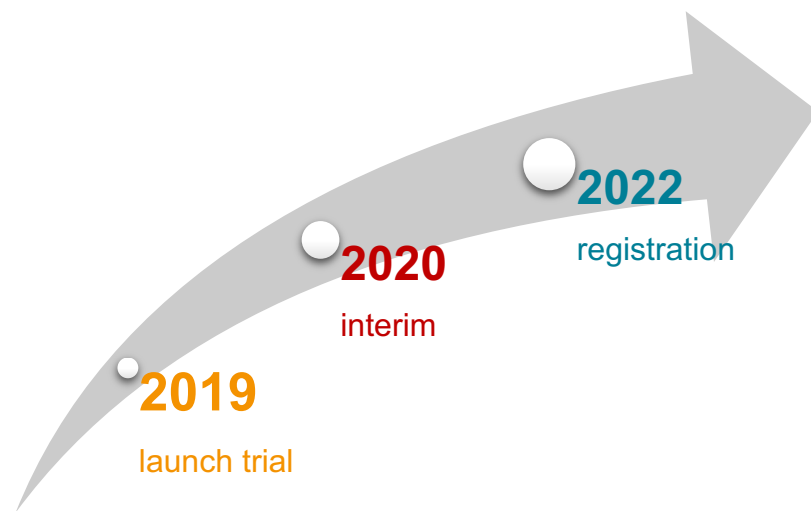
1L NSCLC
+ anti-PD(L)1 inhibitor

Defined patient population, potential
first & accelerated path to registration

Potential to significantly increase
addressable patient population

Bemcentinib

First-in-class oral,
selective AXL
inhibitor



Checkpoint inhibitor effective

PDL1 high

Checkpoint inhibitor not effective

PDL1 neg/low

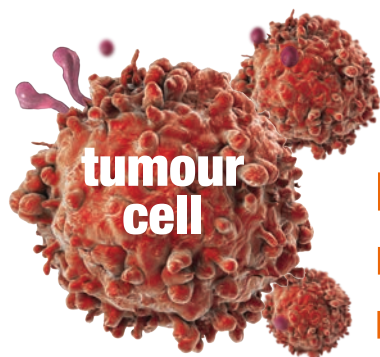
Effective and safe monotherapy treatment
option for frail patient population

Unlock promise of IO combo in larger patient
population through effective biomarker

AXL drives aggressive cancer



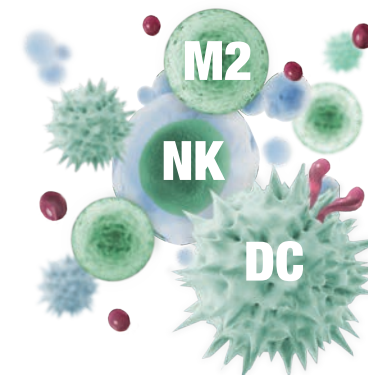
AXL receptor tyrosine kinase drives aggressive disease including therapy resistant, immune-evasive tumours



**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

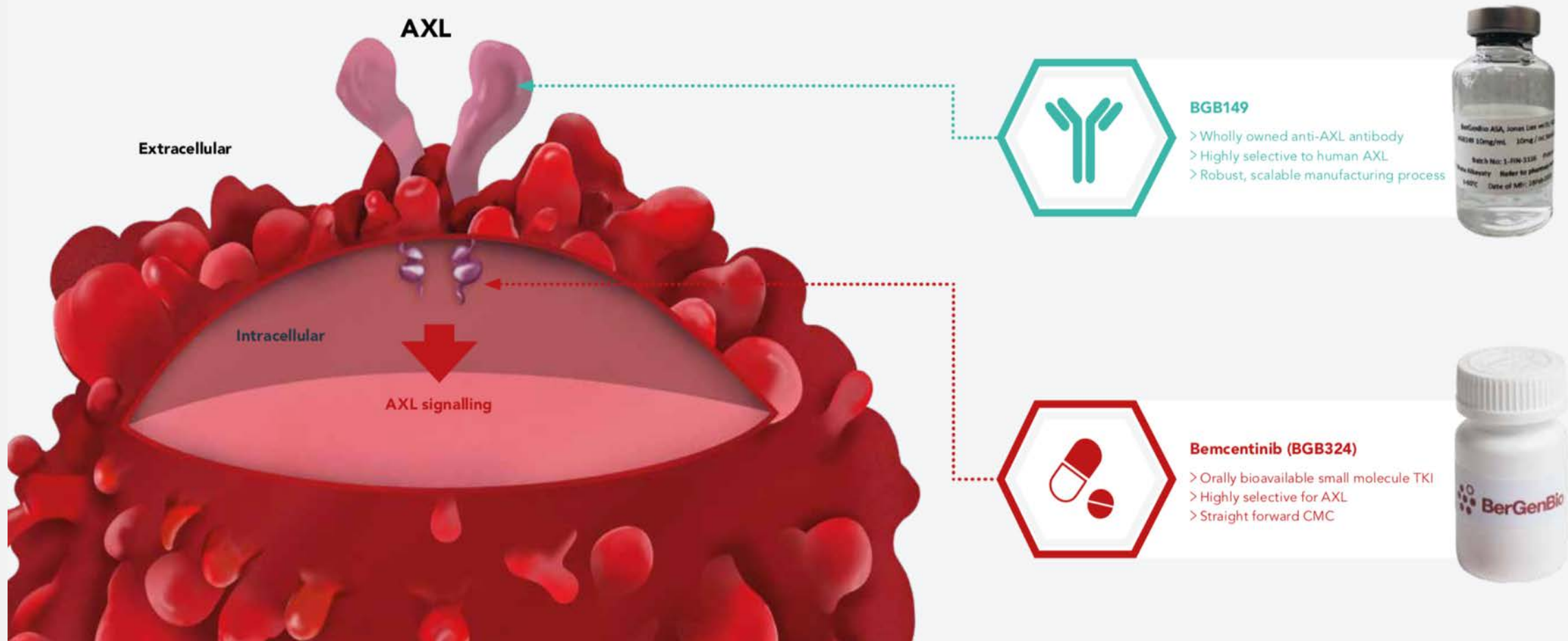
very low expression under healthy
physiological conditions (ko mouse
phenotypically normal)

overexpressed in response to **hypoxia**,
immune reaction, **cellular stress** /
therapy

overexpression correlates with **worse
prognosis in most cancers**

Two AXL-targeting drug candidates in clinical development

Block AXL signalling, reverse aggressive tumour traits & counteract immune escape



Bemcentinib: once-a-day pill

Highly selective, orally bioavailable small molecule, administered once a day, in phase II clinical trials

Blocks AXL signalling, reverses aggressive tumour traits & counteracts immune escape

Clinical PoC in AML and NSCLC as a monotherapy and in combination

Correlation of clinical efficacy with AXL biomarkers observed


Excellent clinical safety profile, ca. 200 pts treated

Randomised, late stage clinical trials planned to start in H2 2019

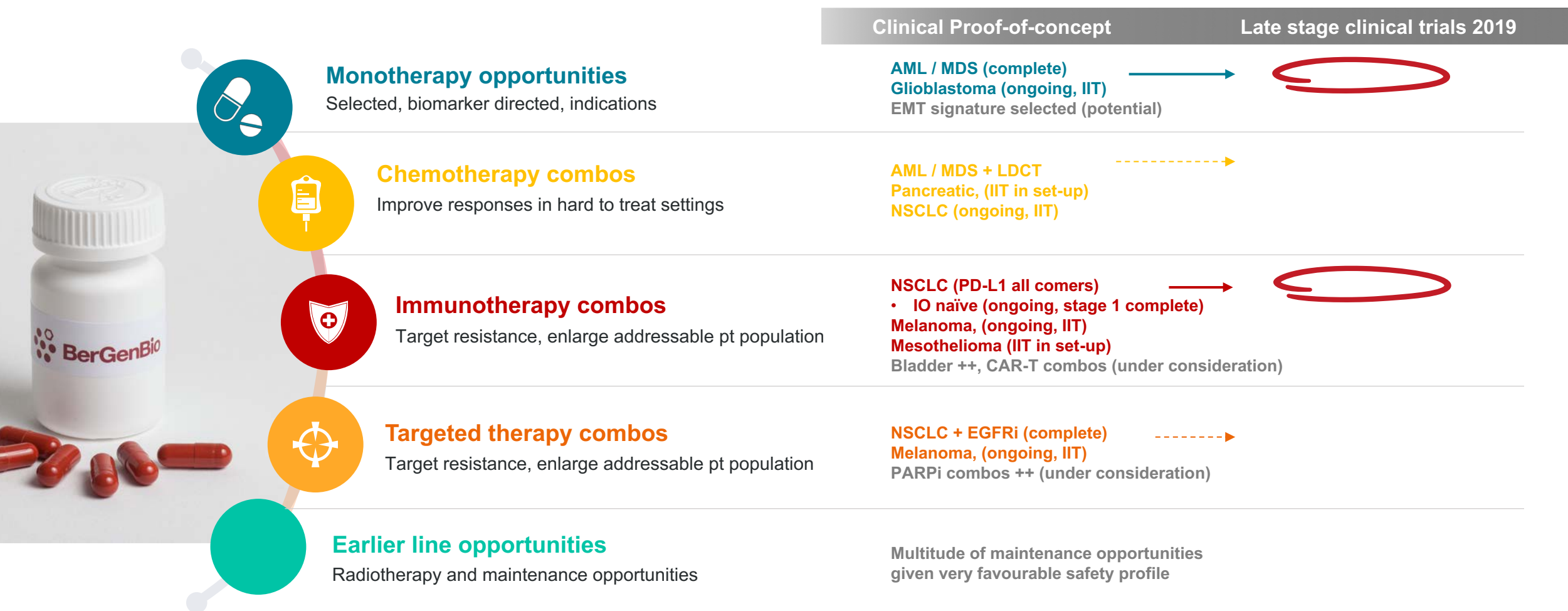


Portfolio of selective AXL inhibitors

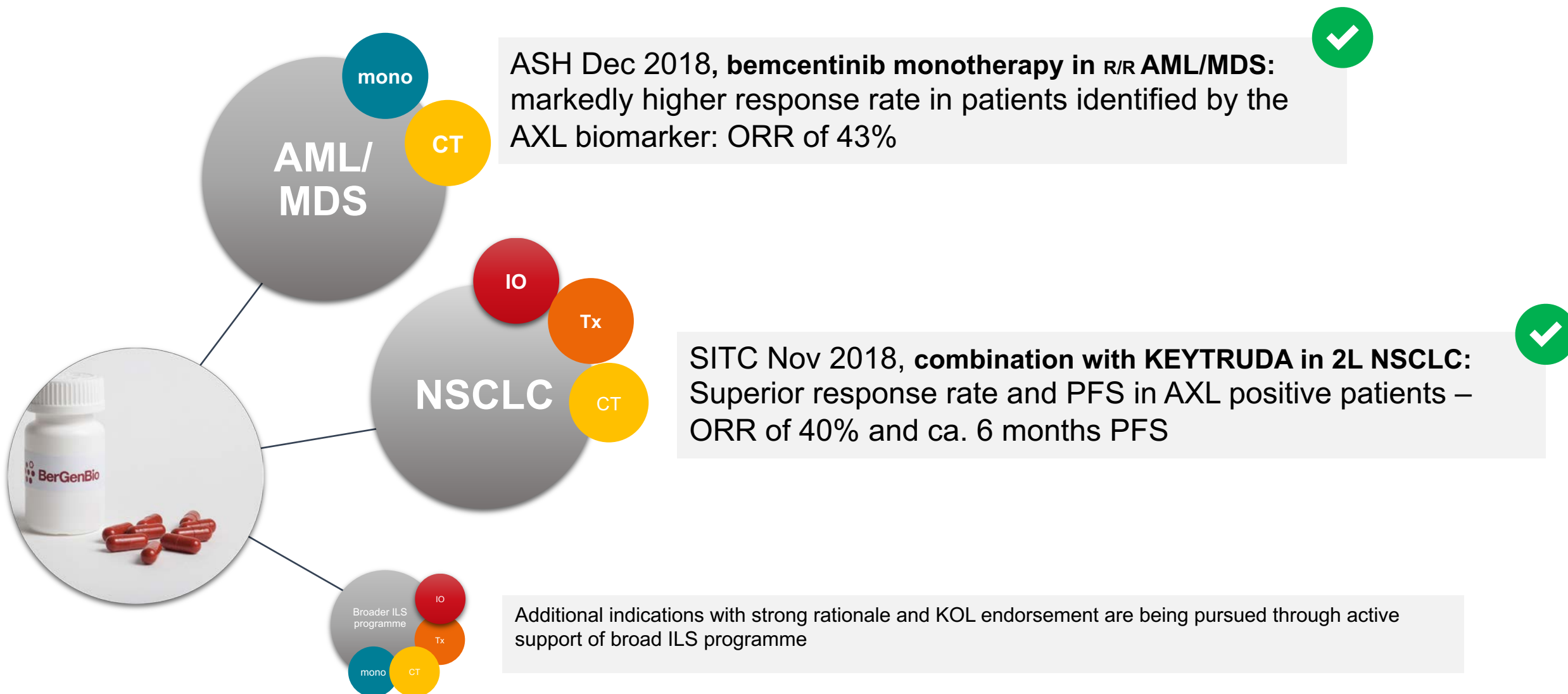
Late stage programme in NSCLC and AML planned for H2 2019

		Discovery	Clinical PoC	Late stage development	Registration
Selective AXL kinase inhibitors					
Bemcentinib: selective oral small molecule AXL inhibitor					
NSCLC	Randomised trial (TBC)	Planned for 2H 2019			
	1L & 2L combos with anti-PD1, targeted- or chemotherapy	+ pembrolizumab 2L, IO naive: stage 1 complete ¹ + erlotinib 1L & 2L: complete + docetaxel 2L+: ongoing			
AML/MDS	2L AML monotherapy	Planned for 2H 2019			
	2L single agent + 1L & 2L combos	monotherapy, relapsed/refractory: complete + LDAC 1L & 2L: completed enrolment + decitabine 1L & 2L: ongoing			
ILS support ²	additional advanced tumour indications	Numerous 1L & 2L			
BGB149: anti-AXL mAb					
Therapeutic focus not yet disclosed	First in patient phase 1 trial	Planned for 2H 2019			
	Healthy volunteers – phase 1a dose escalation	SAD			
BGB601: AXL ADC outlicensed					
Metastatic cancers	First in man phase 1 solid tumour trial	Monotherapy 2L+ Out-licensed to 			

Clinical Development opportunities for bemcentinib



Clinical development focus: Leukaemia & Lung Cancer



Companion Diagnostics Programme

Biomarkers and Assays



AXL IHC

- ✓ Improved ORR and PFS in AXL +ve NSCLC pts treated with bemcentinib + KEYTRUDA*



AXL liquid biopsy

- ✓ Improved response in relapsed/refractory AML/MDS with lower plasma amounts of inactive AXL (soluble AXL)

Contemporaneous regulatory approval strategy

Clinical PoC

Late stage development

Registration

Research Use Only

Clinical trial Assay

Investigational Use → launch

Ref. BGBC003 / NCT02488408

Bemcentinib in myeloid malignancies: monotherapy & combos

PoC clinical data from monotherapy, combination data in H1 2019

- ✔ *43% ORR in AXL +ve R/R AML and MDS patients*
- ✔ *chemo combos in 1L ongoing*



MDS & AML: Disease characteristics

New strategies to treat **older & relapsed/ refractory patients** is an urgent, unmet need

Myelodysplastic syndromes (MDS) *(pre-leukaemia or smoldering leukaemia)*

Occurs when the blood-forming cells in the bone marrow (the soft inner part of certain bones, where new blood cells are made), become abnormal. This leads to low numbers of one or more types of blood cells.

~ 40,000 new cases
per year (U.S. only)³

Most diagnoses made in
70s or 80s¹

MDS 40% risk of
developing into
AML.⁴

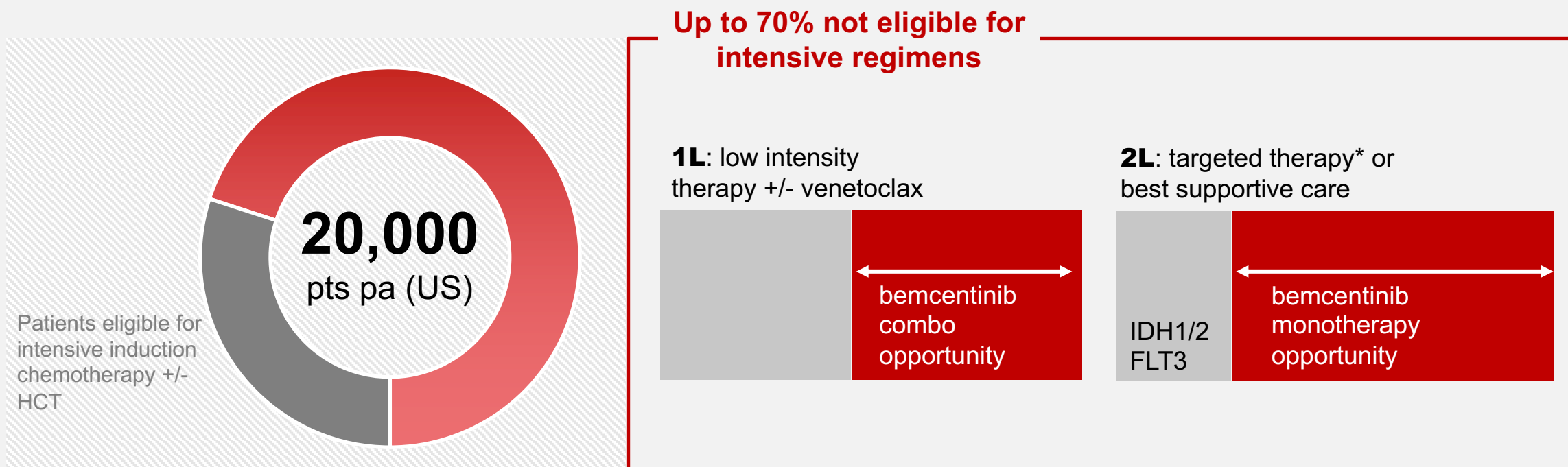
Acute Myeloid Leukaemia (AML)

Cancer of the myeloid line of blood cells, characterized by rapid growth of abnormal cells that build up in the bone marrow and blood and interfere with normal blood cells

~ 20,000 new cases
diagnosed and >10,000 deaths (2018, U.S.)²

Most common type of
acute leukaemia in adults¹

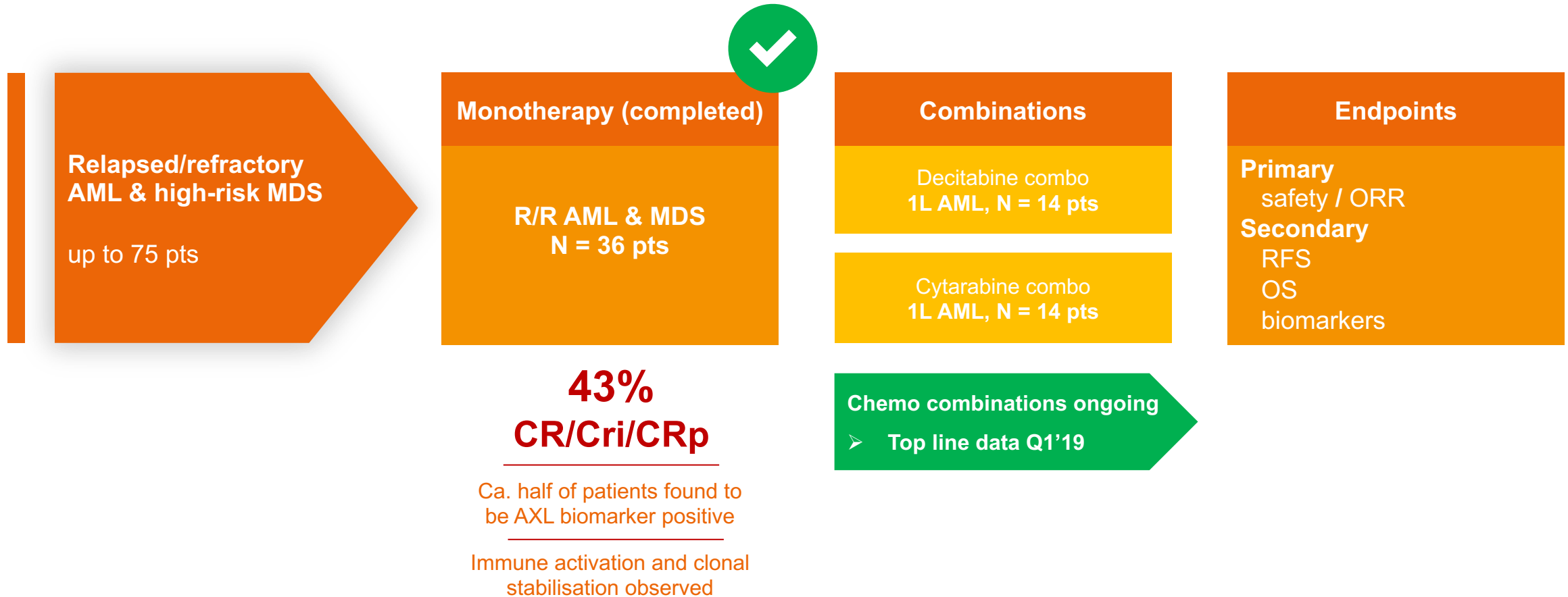
Favourable safety profile opens treatment opportunity for a large group of AML & MDS



The primary treatment goal is the induction of complete remission followed by a stem cell transplant if available. A large number of patients however relapse after initial remission or fail to respond, this is particularly common among patients unable to tolerate intensive induction therapy.

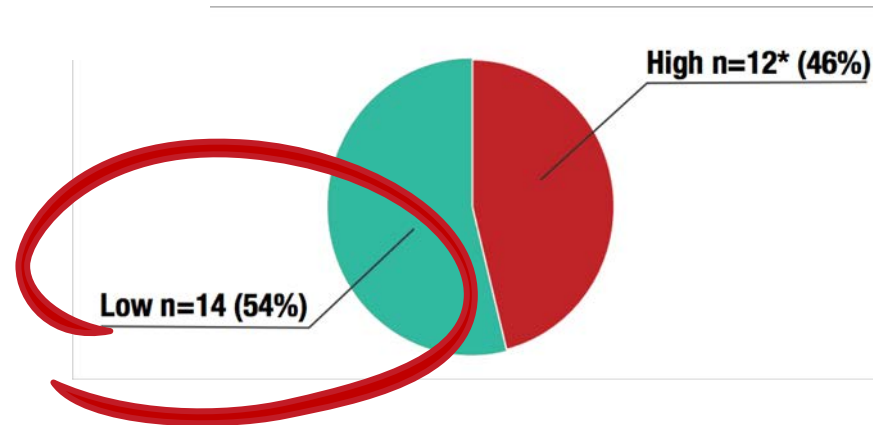
Phase II PoC in AML/high risk MDS:

Monotherapy and combination with LDCT*



Bemcentinib monotherapy exhibits potent anti-leukaemic activity 2L R/R patients

Biomarker:
Soluble AXL (sAXL) at screen:
Inversely correlated with AXL receptor activity



Superior response rate in patients positive for AXL biomarker

	Overall (n=27)		sAXL low (n=14)		sAXL high (n=11)	
	n	%	n	%	n	%
CR/CRi/CRp	6	22%	6	43%	0	0%
SD	8	30%	3	21%	5	45%
PD*	13	48%	5	36%	6	55%
ORR	6	22%	6	43%	0	0%

• 2 evaluable patients were not evaluable for sAXL status
 • Monotherapy responses. One additional response was reported in combination with decitabine for a total of 7 responses in phase I/II.
 • 1 CR, 4 CRi, 1 CRp

* PD includes patients who progressed or came off study before having completed 3 cycles of treatment.

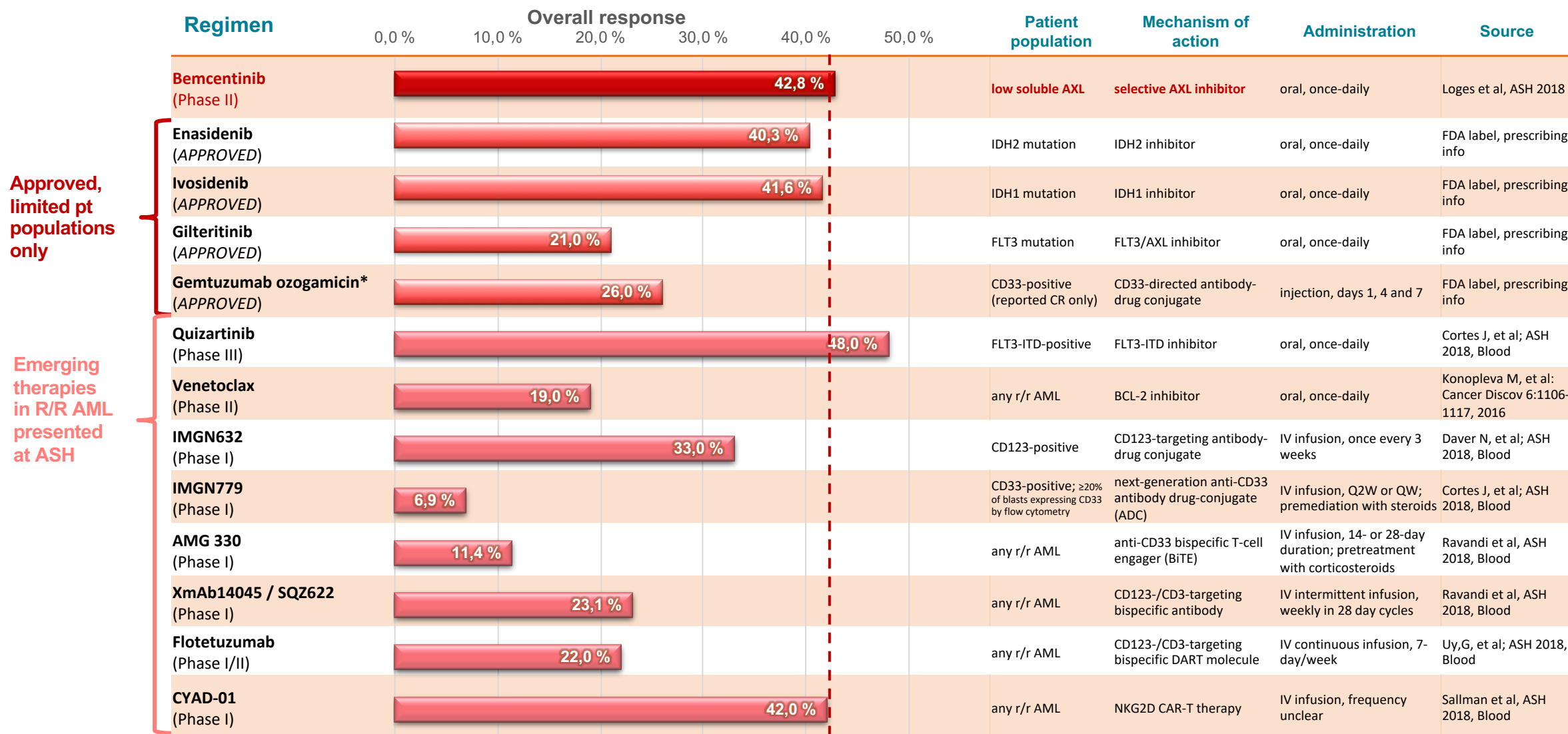
Median age of all patients: 74.5

Responses included poor risk and secondary disease

- ✓ Bemcentinib monotherapy is well tolerated: mild and manageable side effect profile with low incidence of Grade 3/4 events
- ✓ Low incidence of hematological adverse effects

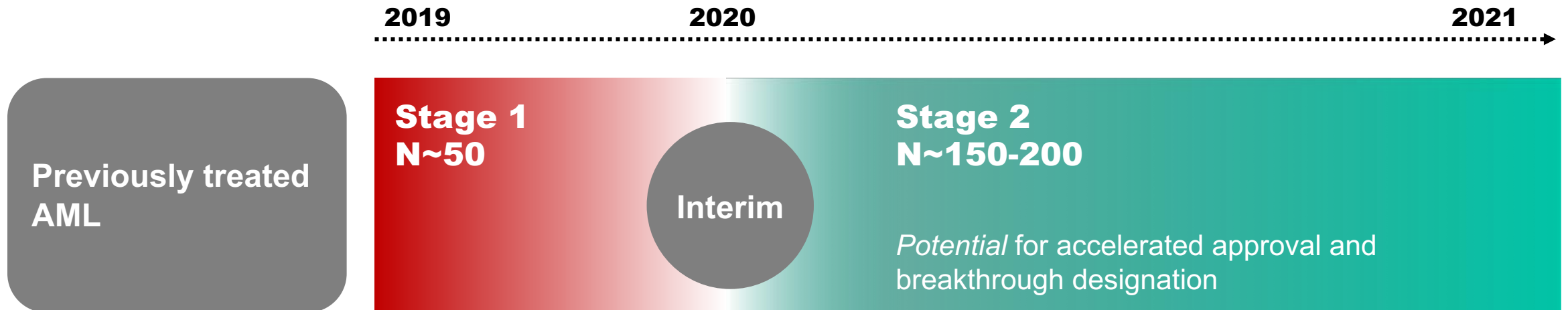
Intention-to-treat population included 36 patients, 9 of whom were not evaluable for efficacy (8 were exposed to treatment for <21 days, 1 was a first line patient). sAXL levels were available for 25 evaluable patients.
Source: Loges, et al. ASH 2018.

Monotherapy shows promising efficacy in comparison to approved & emerging regimens



Late stage development in AML:

Monotherapy activity is registerable endpoint in previously treated AML



Ref. BGBC008 / NCT03184571

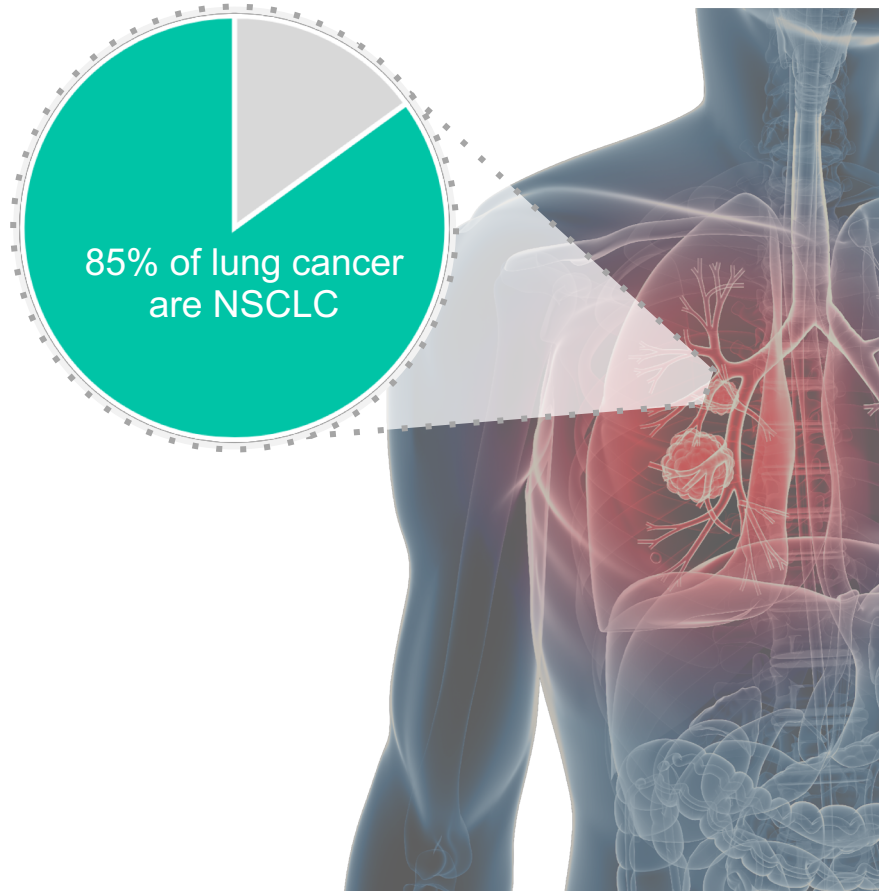
Bemcentinib in NSCLC: Combination with anti-PD(L)1

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

- ✔ **27% ORR in PD-L1 –ve patients**
- ✔ **40% ORR in AXL+ve patients**



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

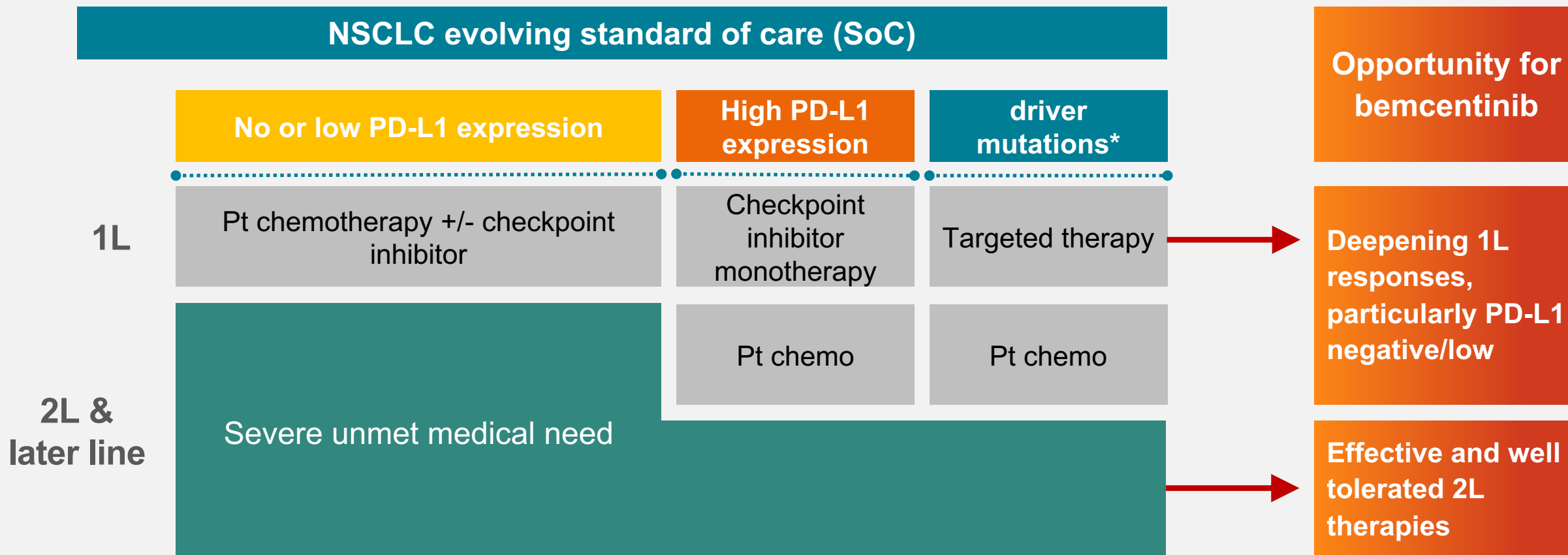


The largest cancer killer, most patients depend on drug therapy

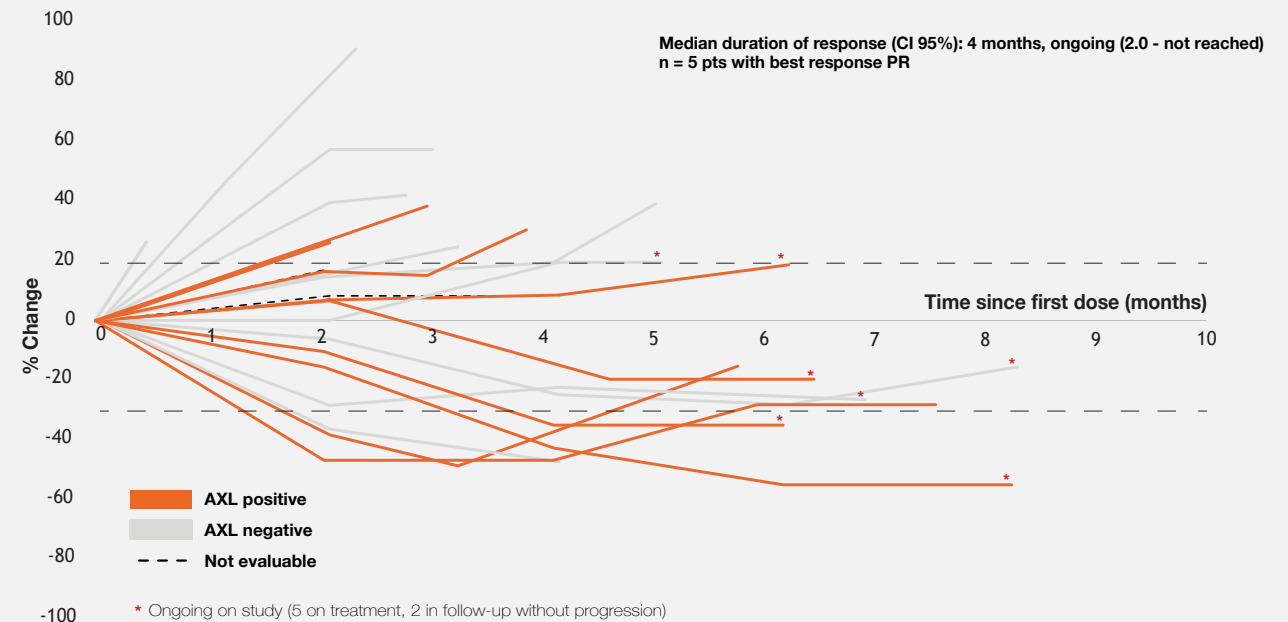
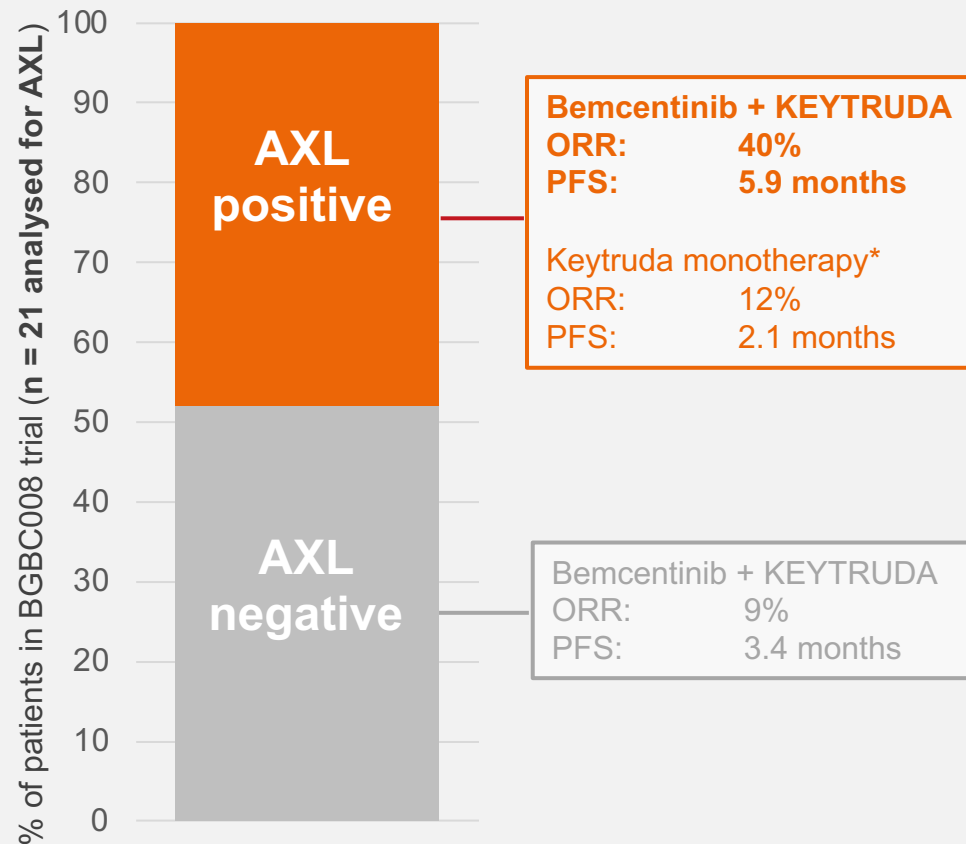
- 2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases¹
- 1.76 million lung cancer deaths/yr worldwide¹
- In the U.S, 5-year survival rate is approximately 18.6%, and **4.7%** in patients with distant metastases²

Non-small cell lung cancer is the most common type of lung cancer, making up 80-85% of lung cancers

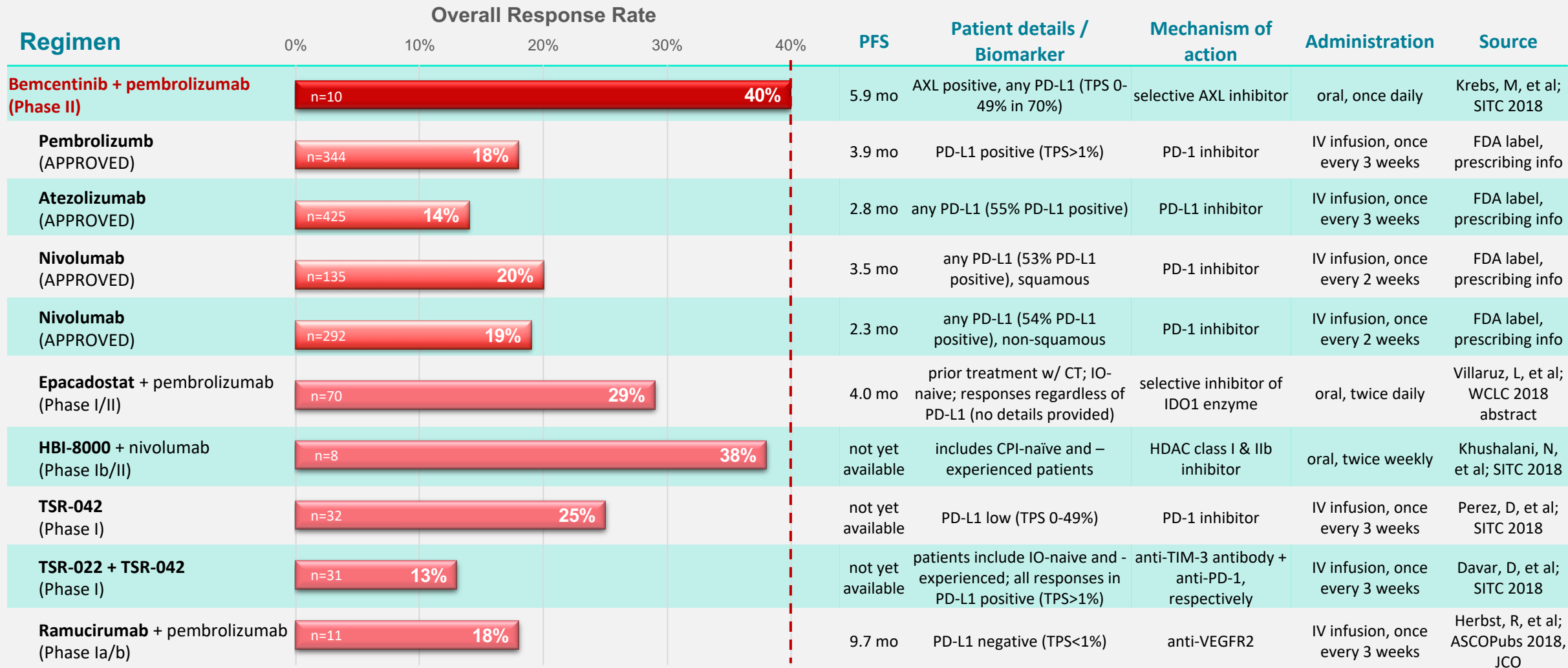
Rapidly emerging SoC creates opportunities for novel effective, chemo free regimens



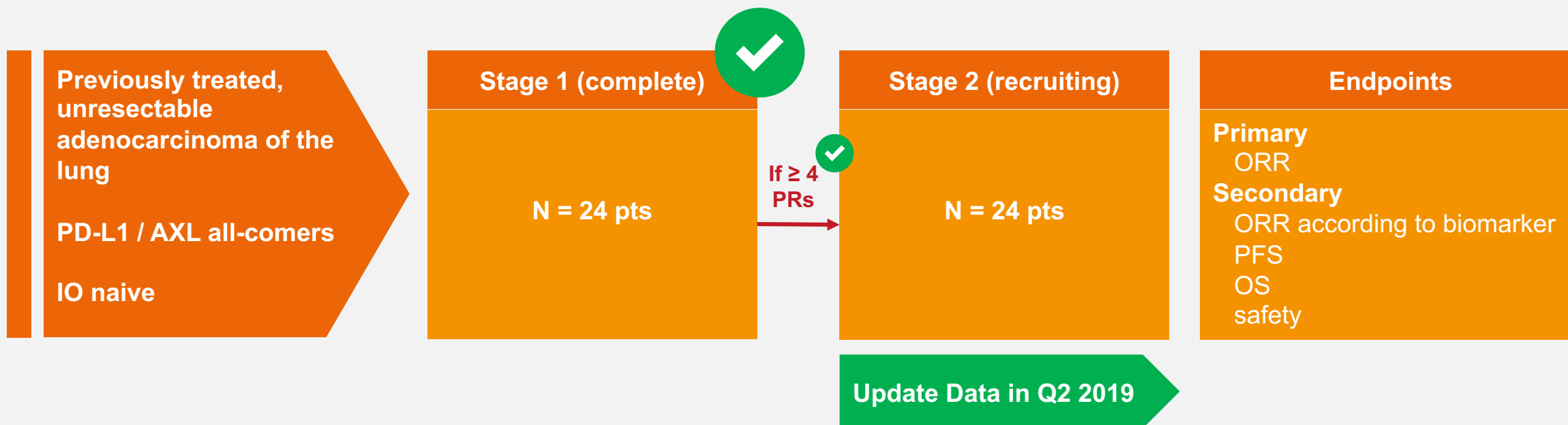
2L PoC data bemcentinib + KEYTRUDA: Superior efficacy in AXL +ve pts. Previously treated NSCLC, IO naive



Promising efficacy in comparison to approved monotherapy and emerging combinations*



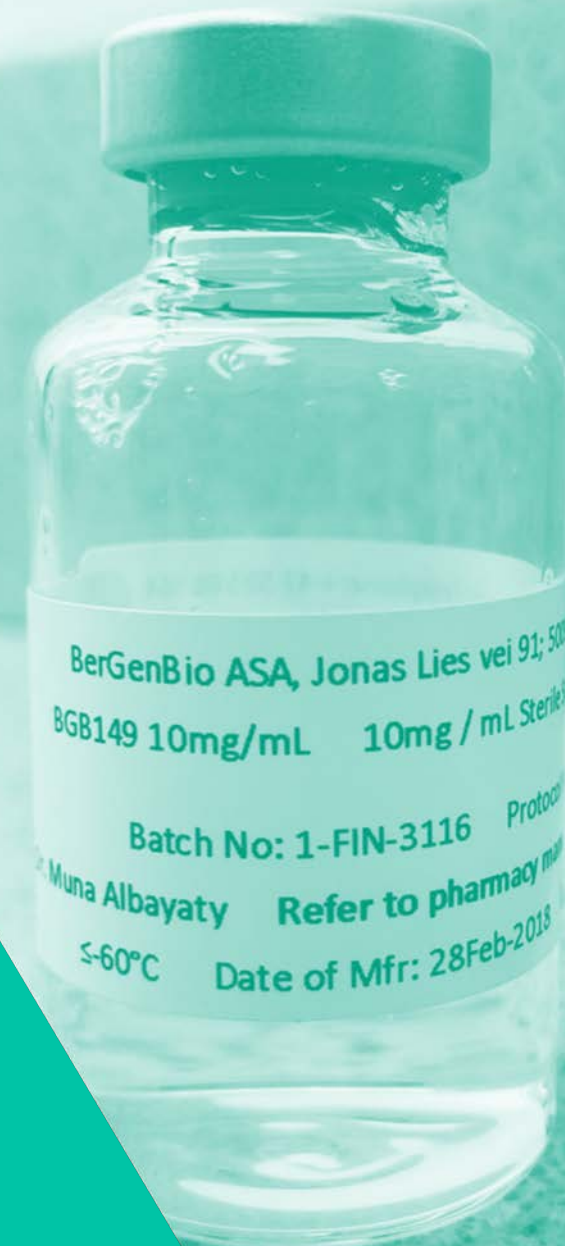
Phase II 2L NSCLC study of bemcentinib with KEYTRUDA



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

BGB149 – a monoclonal anti-AXL antibody



BGB149: Anti-AXL monoclonal antibody

Phase I clinical trial initiated January 2019

Functionally blocking humanised monoclonal antibody

Binds human AXL, blocks AXL signalling

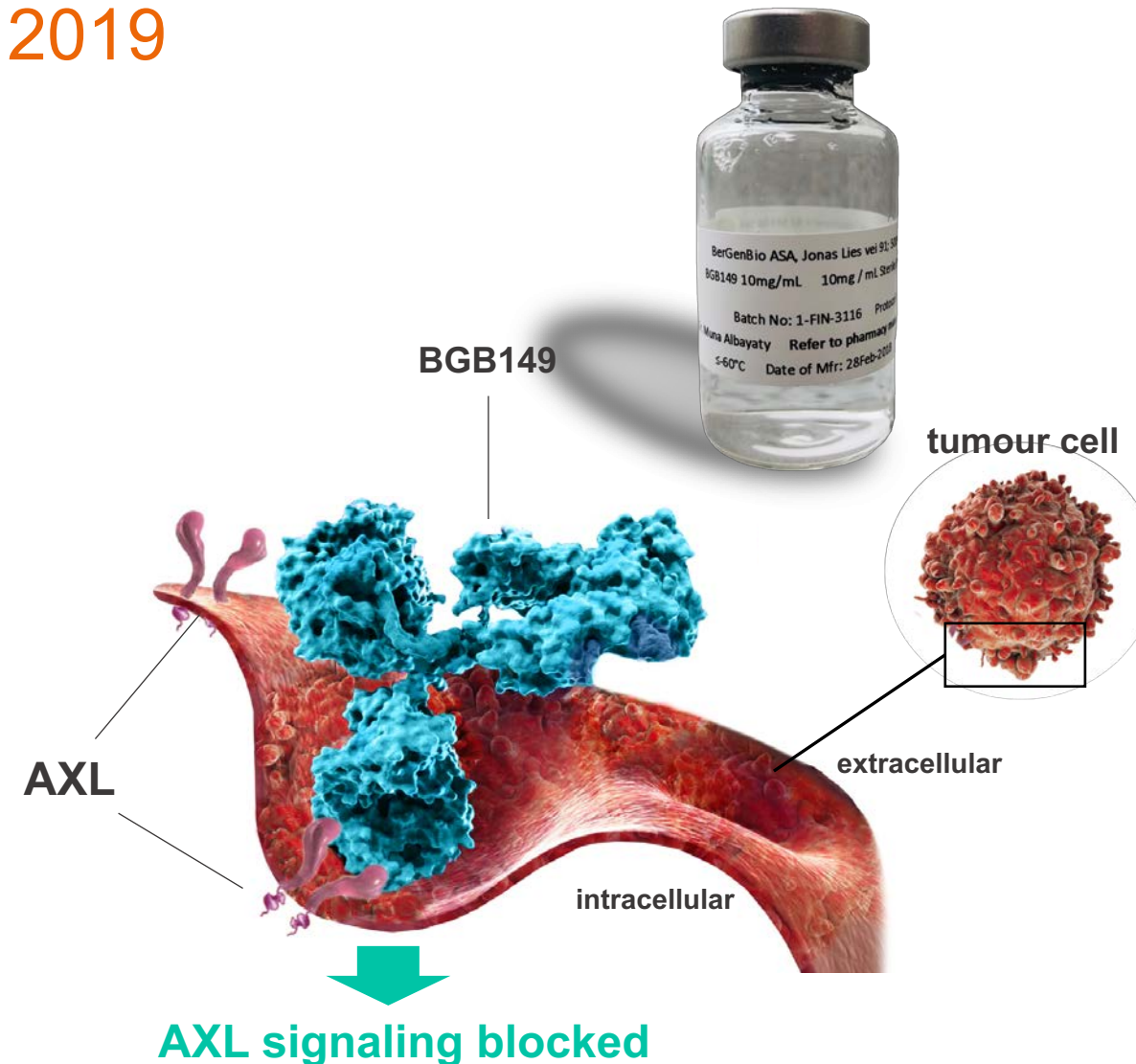
High affinity (KD: 500pM), Anti-tumour efficacy demonstrated *in vivo*

Robust manufacturing process established, 18 months stability

First-in-human healthy volunteer Phase I study initiated

- Up to 36 subjects
- Safety, PK/PD

First-in-patient trial expected in H2 2019

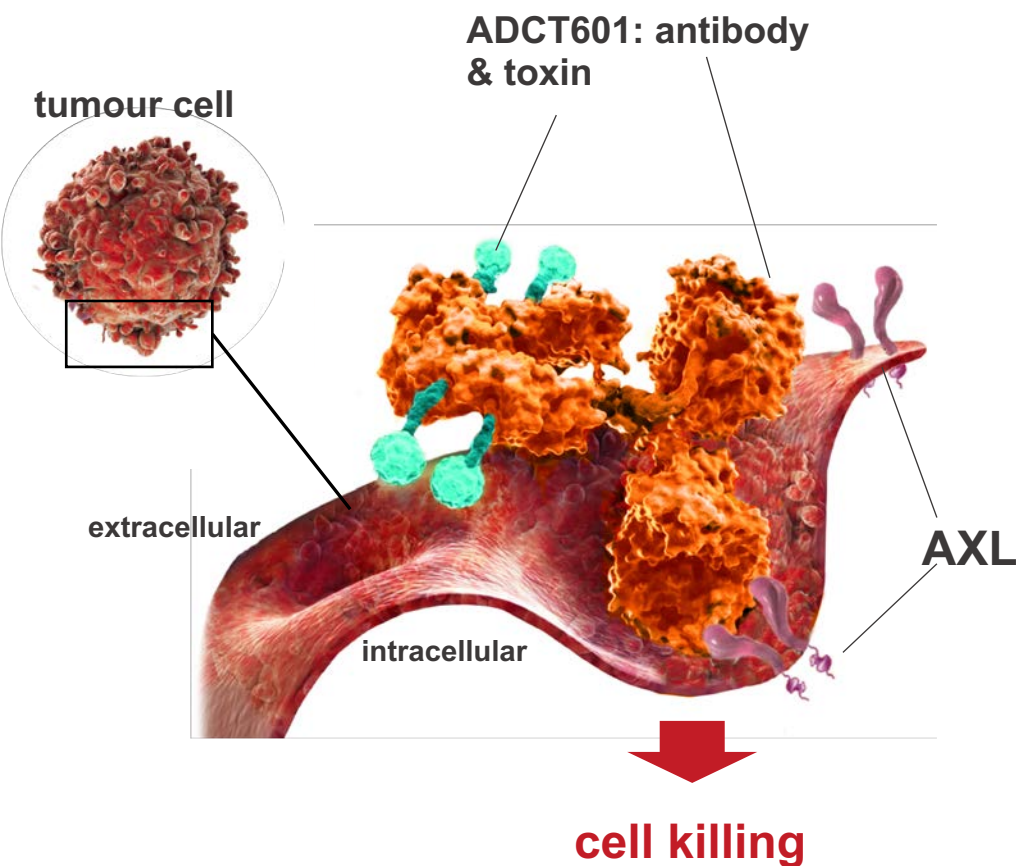


ADCT-601 – AXL ADC



BGB601/ADCT-601: Anti-AXL ADC

Phase 1 in solid tumours started January 2019



Antibody Drug Conjugate (ADC)

Targets human tumour AXL, induces cell death when internalised

Potent and specific anti-tumour activity demonstrated preclinically¹

First-in-human Phase I study initiated in Jan 2019

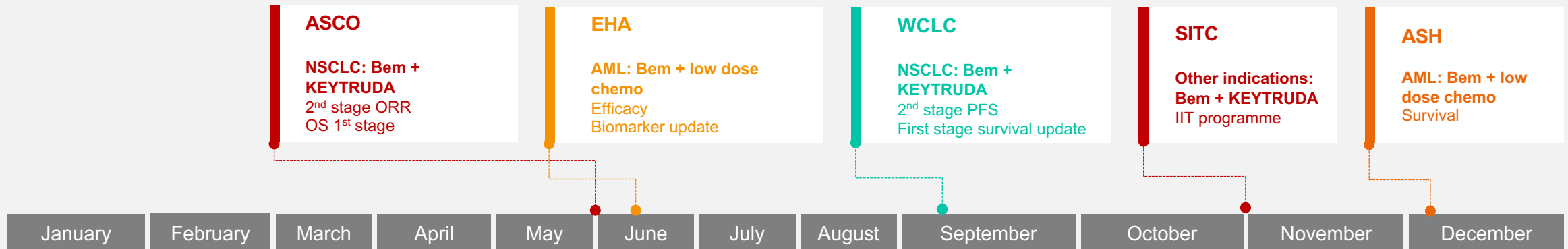
- Solid tumours
- Up to 75 patients
- Safety, PK/PD, preliminary efficacy

Based on anti-AXL antibody BGB601 licensed from BerGenBio

Near term goals and news flow



Expected newsflow in 2019



Q1

- 1L/2L AML chemo combo top line data
- Complete recruitment stage 2 bem + KEYTRUDA (NSCLC)

Q2/Q3

- **Initiate randomised programme**
- Complete Phase 1 BGB149

Q4

- Initiate first-in-patient trials BGB149

Upcoming company news flow and value creating catalysts

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

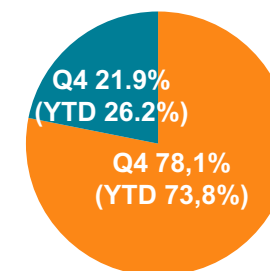
Finance



Key financial figures

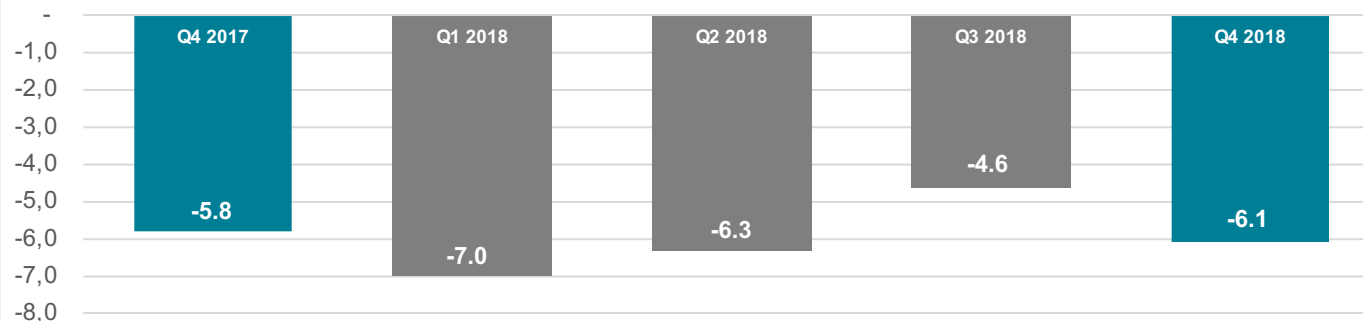
(USD million)	Q4 2018	Q4 2017	FY 2018	FY 2017
Operating revenues	0.3	0	0.3	0
Operating expenses	6.3	5.8	24.2	22.2
Operating profit (loss)	-6.1	-5.8	-23.9	-22.2
Profit (loss) after tax	-6.1	-5.8	-23.6	-22.0
Basic and diluted earnings (loss) per share (USD)	-0.11	-0.12	-0.44	-0.48
Net cash flow in the period	-4.5	-3.5	-1.0	25.2
Cash position end of period	41.5	45.1	41.5	45.1

Operating expenses Q4 2018



■ R&D ■ Administration

Operating profit (loss) USDm

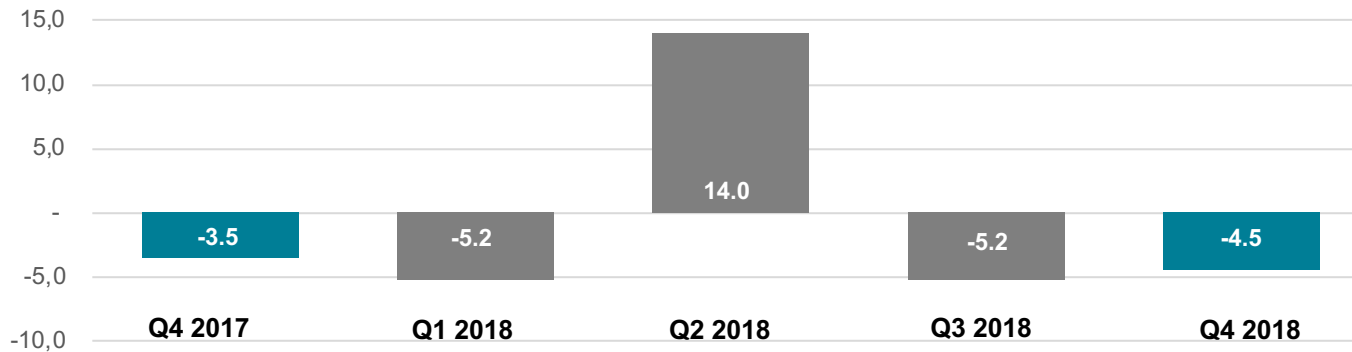


- Effective organisation
- 78.1% (YTD 73.8%) of operating expenses in Q4 2018 attributable to Research & Development activities

- Q4 18 operating loss reflecting level of research and development activities in the quarter
 - Revenue USD 0.3 million, licence revenue triggered by pre-clinical milestone (ADCT-601)
 - Stage 2 of NSCLC combination with Keytruda re-opened in Q4 18 and ongoing (mandatory safety review in Q3 18)

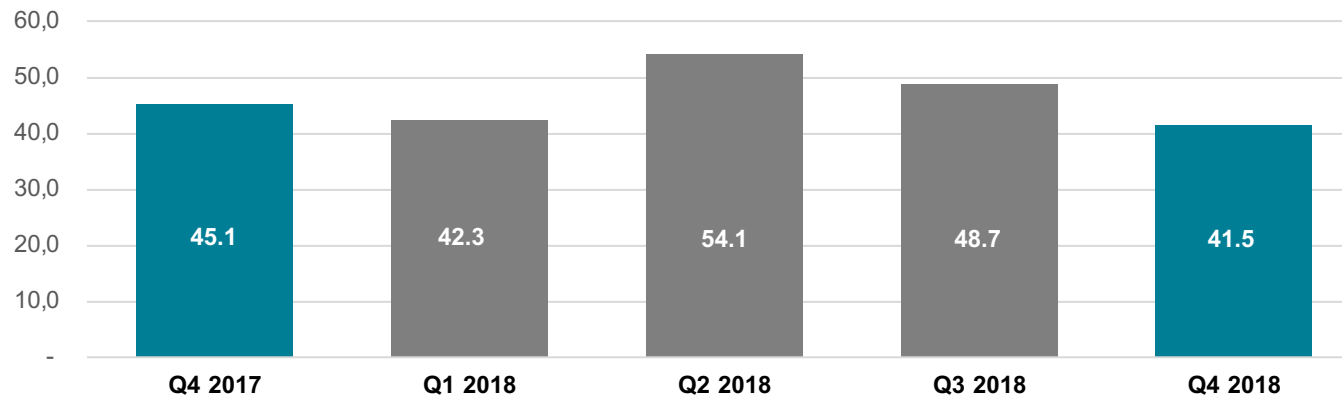
Cash flow and cash position

Cash flow USDm



- Private placement Q2,18 strengthened cash position - gross funds raised USD 24m
- Quarterly cash burn average 2018 at USD 5.7 million

Cash position USDm



- Cash position gives runway to deliver key clinical read outs from ongoing clinical studies
- Cash runway into 2020 based on current burn rate

BGBIO – Summary



**AXL inhibitors – potential
cornerstone of cancer therapy**

**Pipeline opportunities
in multiple cancers and
fibrosis**



**Ph2 data in AML & NSCLC with
selective AXL inhibitor bemcentinib**

**Late stage clinical trials
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**Resourced to deliver
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Cash NOK 360m/USD 41m