

AXL inhibitors as cornerstone of combination cancer therapy

Q4 and Full Year Results 2017 presentation, 13 February 2018

Richard Godfrey, CEO



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Corporate snapshot

Background



Leaders in developing therapeutics that target AXL, a protein that makes cancers and their environment highly aggressive and which is associated with poorer outcomes across many 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 supported by biomarker tests

BGB324 (Bemcentinib)



First-in-class highly selective small molecule AXL inhibitor

Broad phase II proof of concept clinical trials ongoing in NSCLC, TNBC, AML/MDS, melanoma.

Pipeline



BGB324 (Bemcentinib)

AXL antibody

AXL ADC (partnered)

Immunomodulatory small molecules

OSE:BGBIO



Raised NOK400m in IPO on OSE in April '17

NOK1.8bn market cap (Feb 12th 2018)

Corporate



35 staff

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

BGB324
is now called
bemcentinib



Agenda

1. **Highlights Q4 and FY 2017**
2. Bemcentinib's aspiring leadership position as the future cornerstone of cancer combination treatments
3. Bemcentinib in Lung Cancer – compelling clinical data presented
4. Other clinical trial data
5. Companion Diagnostic development
6. BGB149 – solid progress towards starting clinical trials
7. Finance report
8. Outlook
9. Q&A

Highlights Full year 2017

IPO (NOK 400m) enabling broad and ambitious Phase II clinical development programmes

Clinical collaborations (2) with Merck & Co. (MSD) to combine bemcentinib with KEYTRUDA, its blockbuster anti-PD-1 immune-oncology drug

Clinical development plan designed to establish clinical proof-of-concept and bemcentinib's potential to become a cornerstone of cancer therapy across multiple indications

Six international Phase II trials underway (350 patients, 50 sites, 6 countries) with multiple read-outs expected during 2018

All project milestones met in 2017

Companion diagnostic development made good progress using blood and tumour biomarkers

Scientific data presented at numerous conferences and journals demonstrate bemcemntib is an IO drug

BGB149 anti-AXL antibody on track to enter clinical trials in H2 2018

UK subsidiary (Oxford) established for efficient management of clinical trial operations

Highlights Q4

Clinical efficacy data presented at ASH: 2nd Line R/R AML 19% ORR

Clinical efficacy data presented at World Conference on Lung Cancer

Two non-dilutive grants (ca NOK 40m) received to support clinical trials of bemcentinib

Robust cash position of NOK 370.3 million at the end of Q4 2017

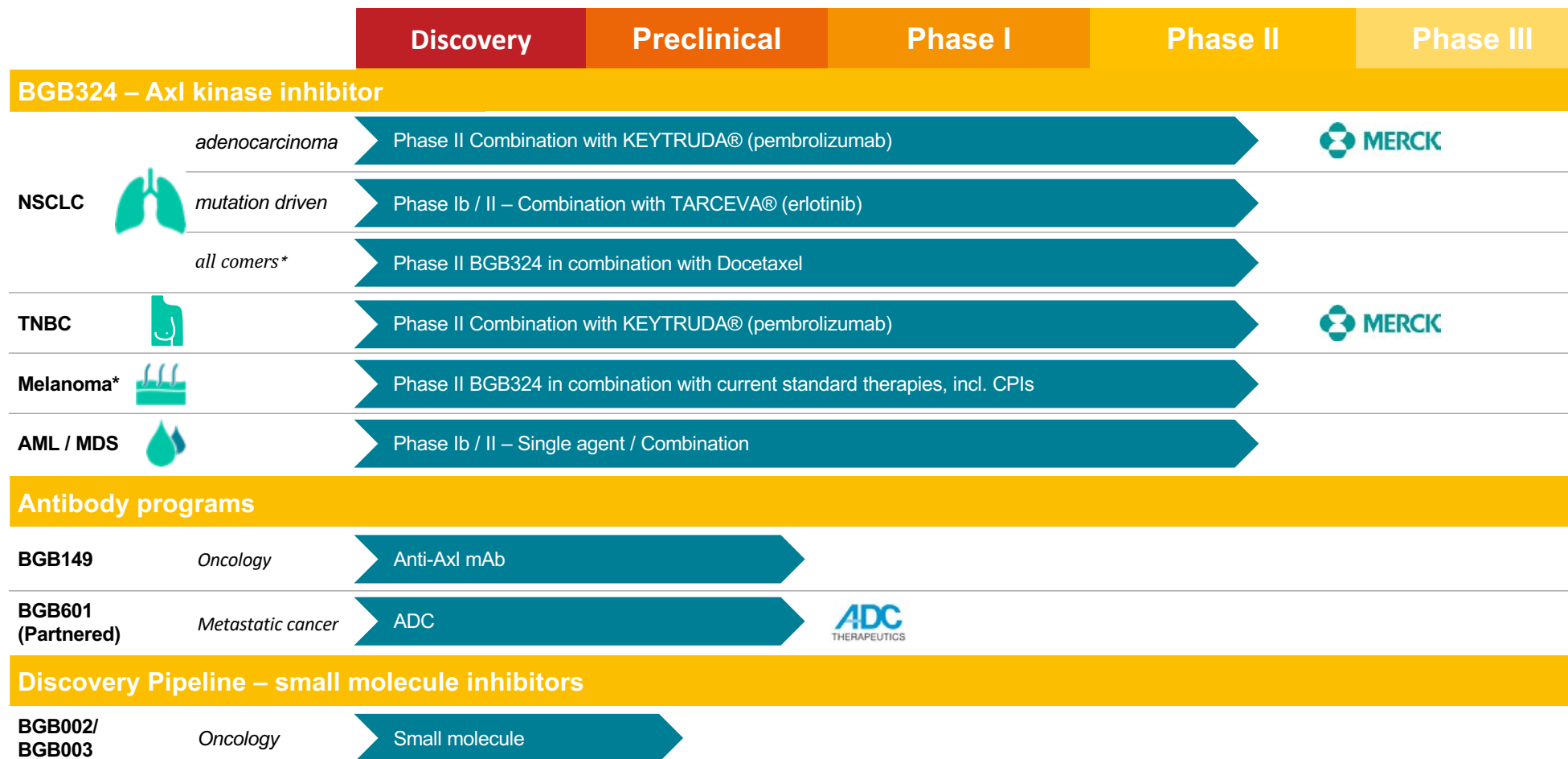
Cash sufficient to deliver key read-outs from Phase II trials during 2018

Strong progress in 2017, achieving all milestones outlined at IPO and well-positioned to deliver key proof-of-concept read-outs from clinical development programme designed to position bemcentinib as a cornerstone of cancer therapy

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Advancing a broad clinical development pipeline



Patients:

>350

50

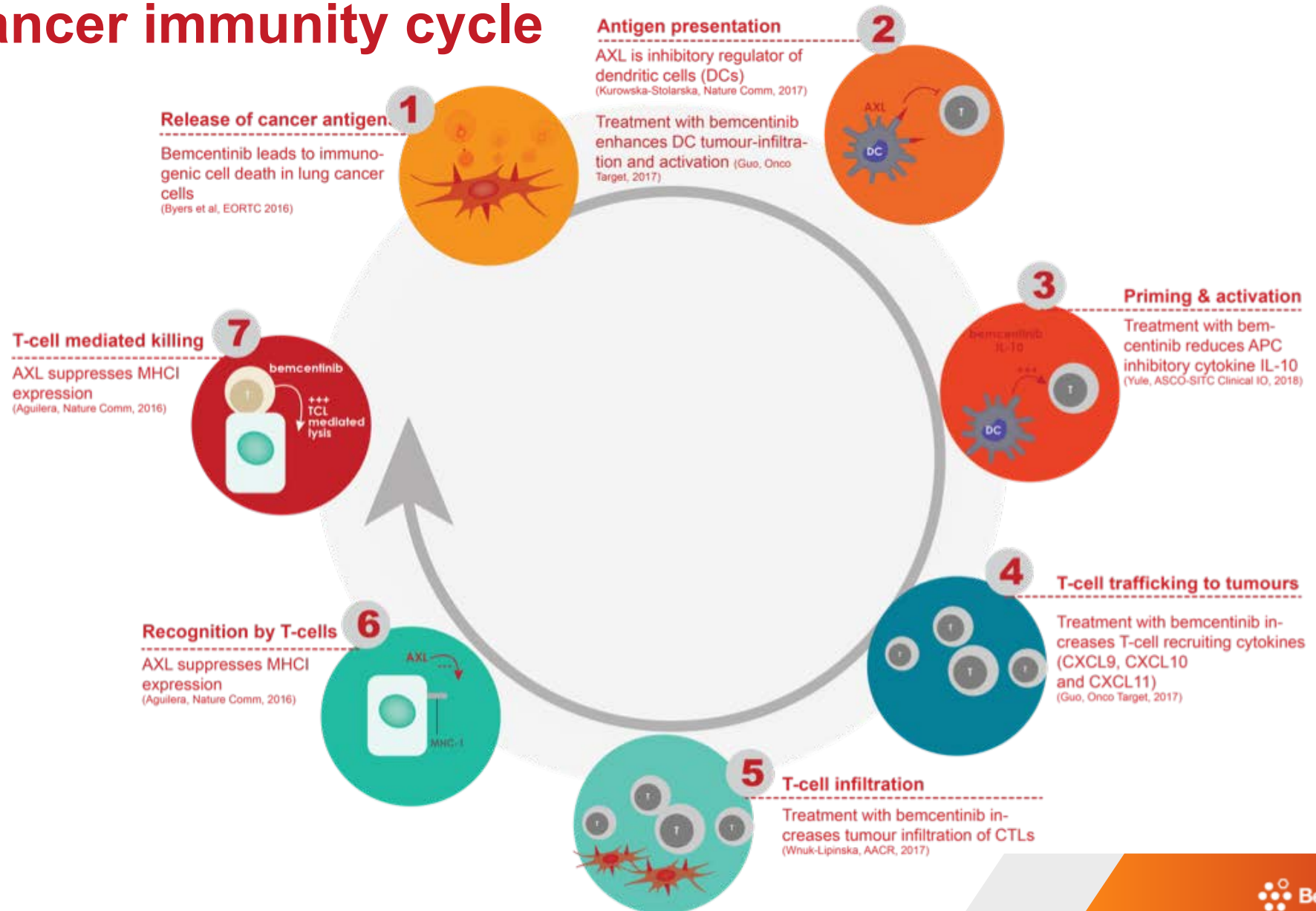
sites in Europe and North America.

Key read-outs:

2018

*Investigator-sponsored trials

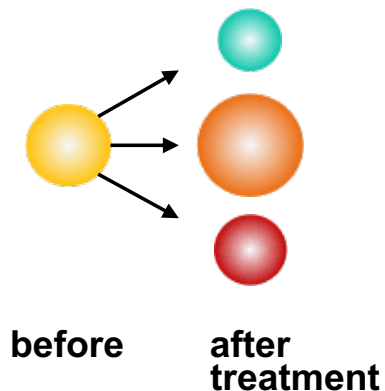
Bemcentinib is active through-out the complete cancer immunity cycle



Clinical PoC for bemcentinib's immunomodulatory activity: Immune activation reported in BGBC003 patients

T-cell-repertoire (TCR):

- Measures the number and size of T-cell clones in a patient tissue before and after treatment
- An increase in diversity over time indicates an immune activation

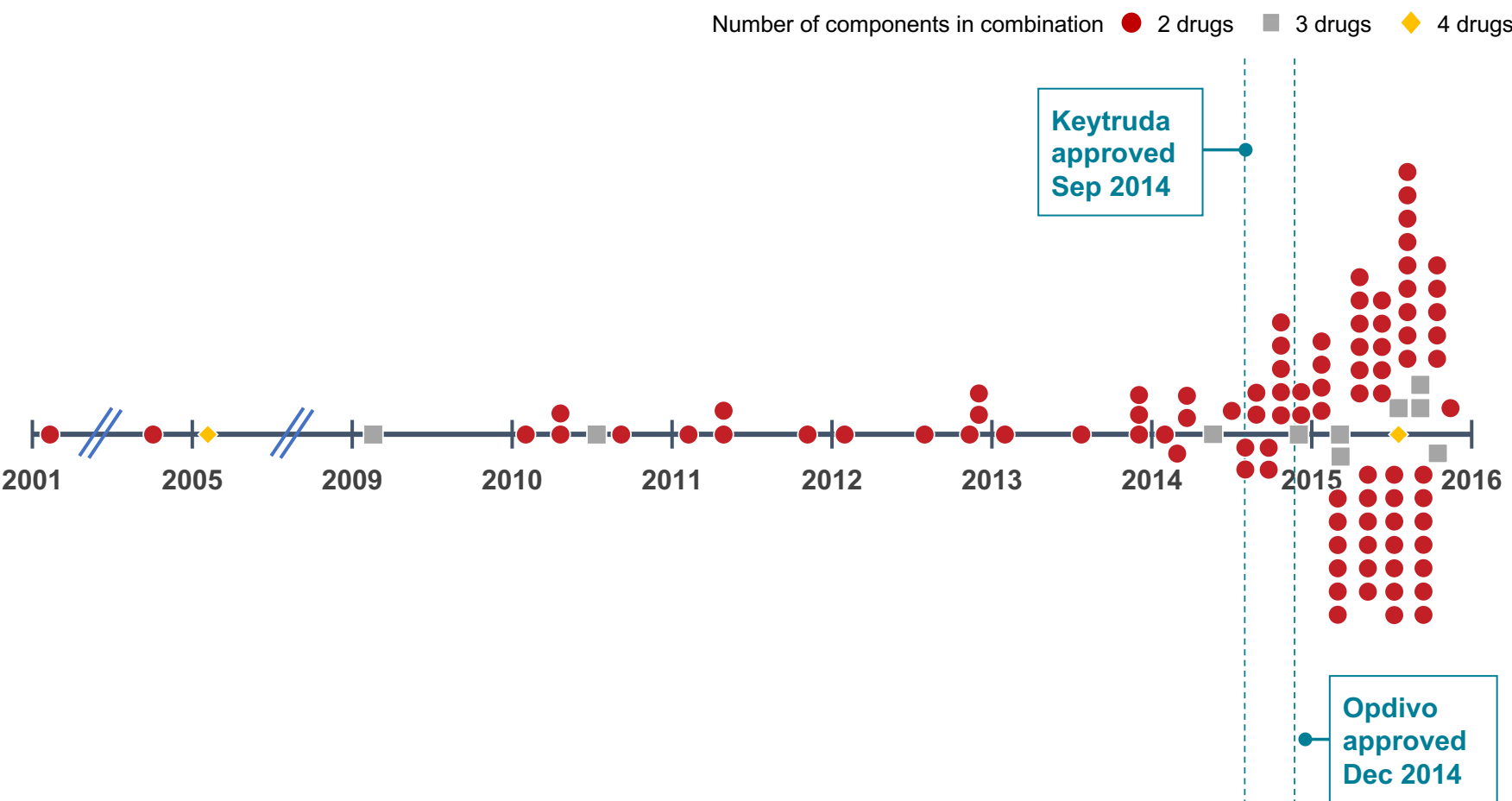


TCR diversification reported after bemcentinib monotherapy

Elderly (61 – 80 yrs) and immune compromised R/R AML & MDS patient population had their TCR measured before and after monotherapy treatment with bemcentinib

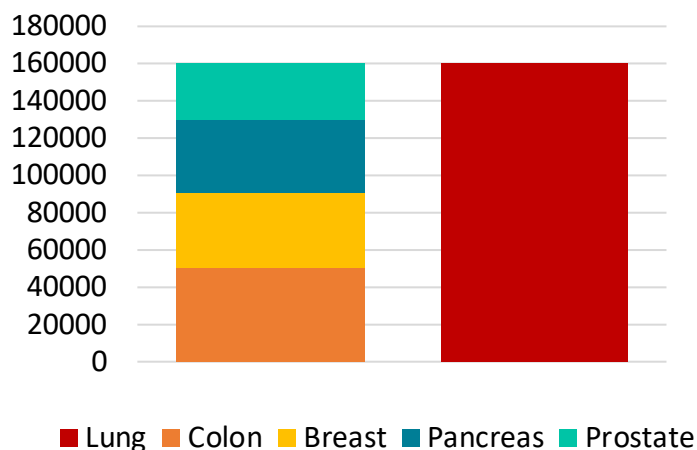
- ✓ 6 out of 9 patients showed increased TCR diversity in either their blood or bone marrow or both after treatment with bemcentinib monotherapy
- ✓ These results suggest that bemcentinib monotherapy may have immunomodulatory effect

Combination therapies to unlock the full potential and promise of novel therapies – example anti-PD-1 therapy

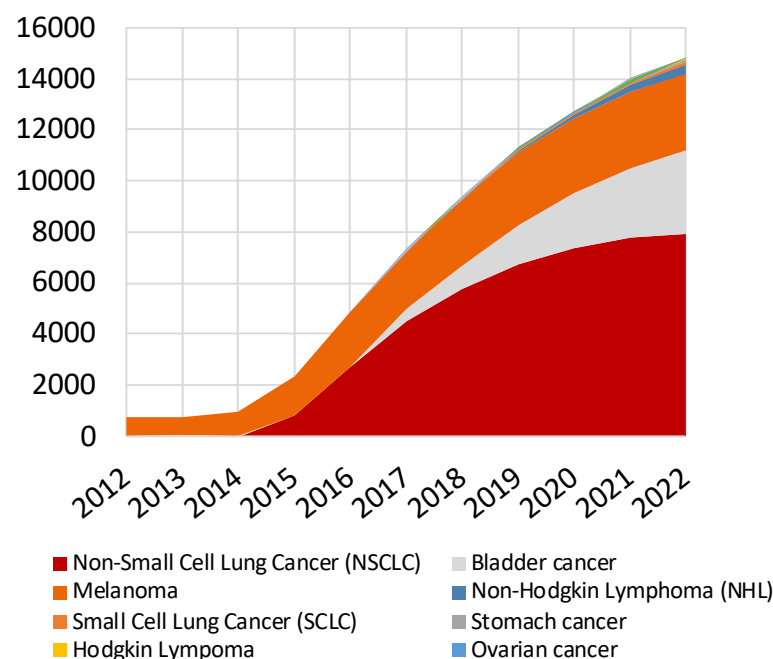


Lung cancer: Largest oncology indication by fatalities and driver for IO growth

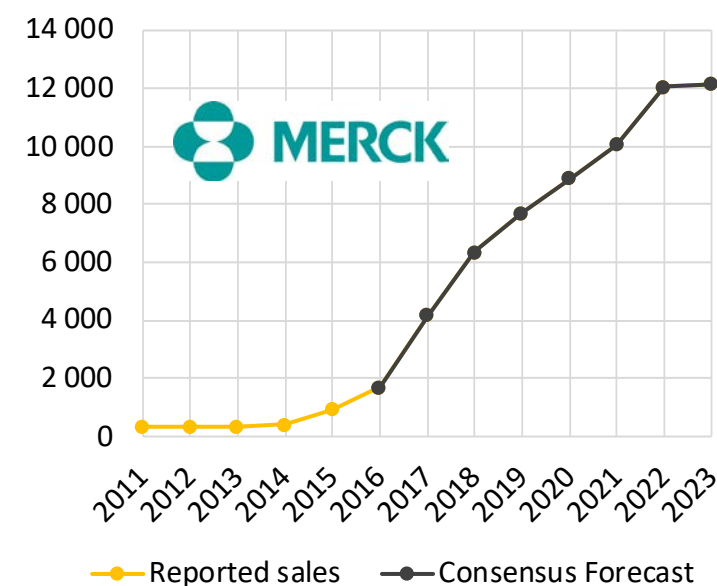
Lung cancer fatalities outnumber colon, breast, pancreas and prostate combined ¹



Lung cancer is driver for anti-PD-1 therapies sales forecast

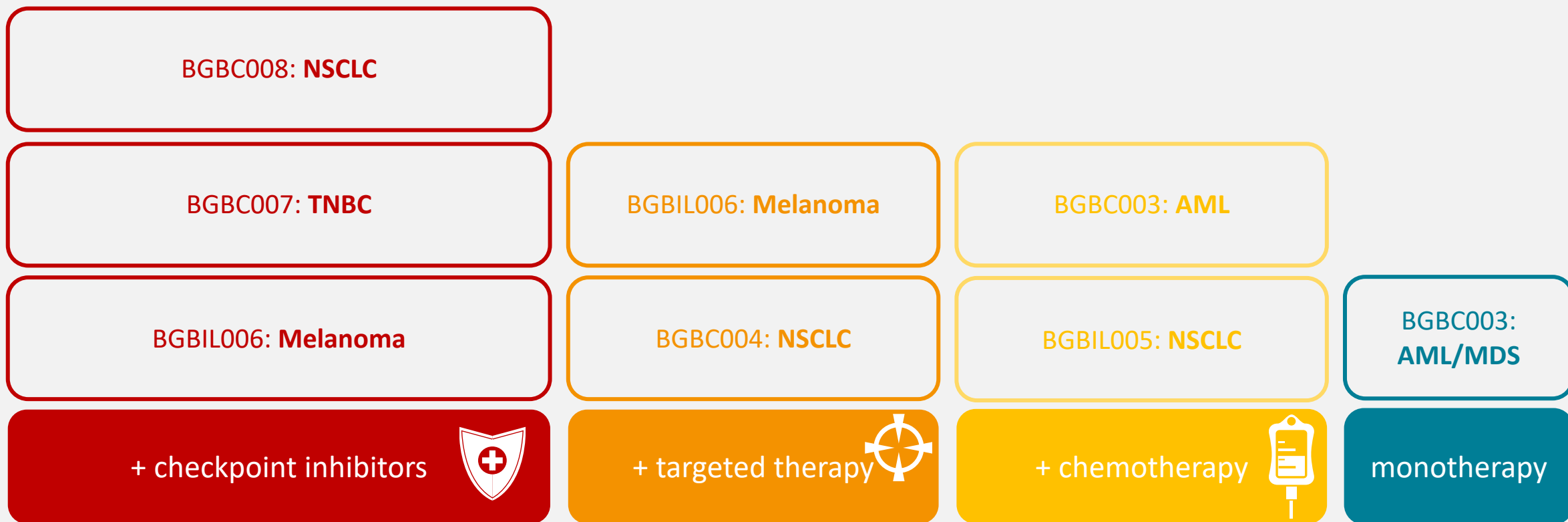


Pembrolizumab alone expected to reach \$10bn annual sales



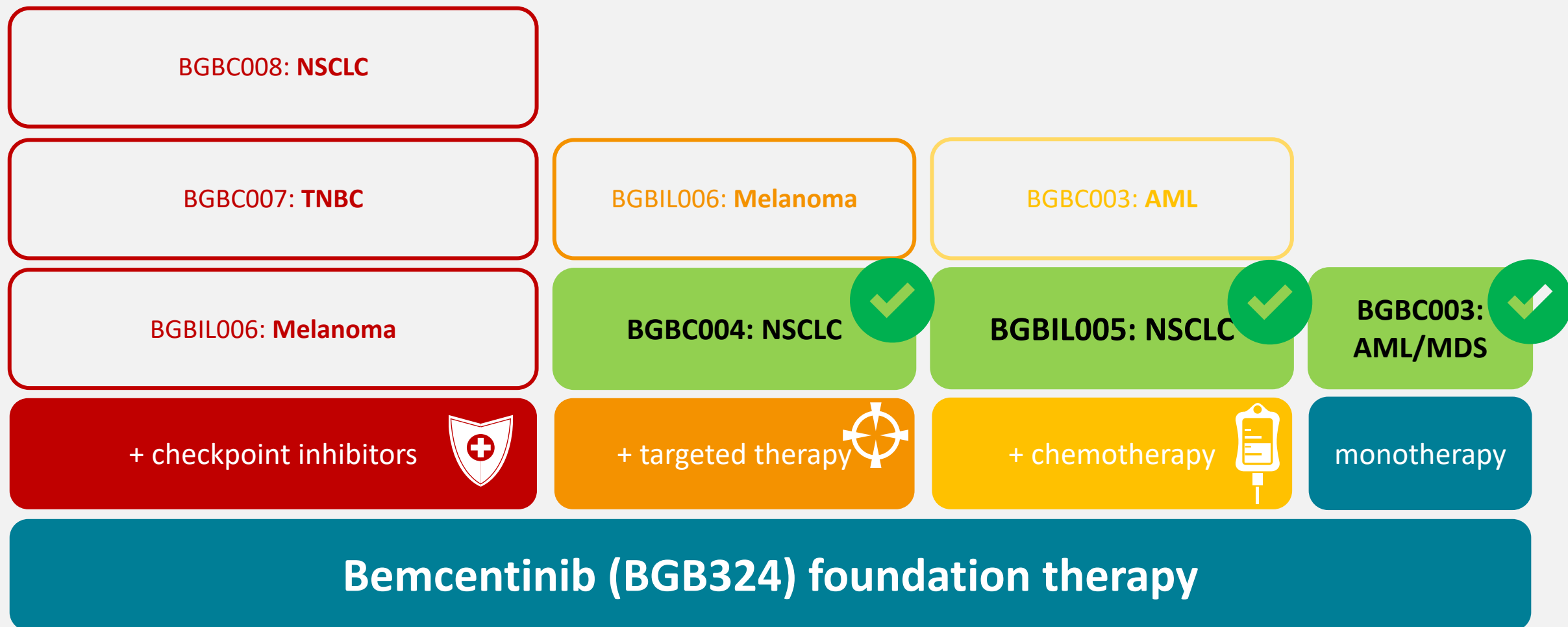
AXL inhibition as cornerstone for cancer therapy

Bemcentinib (BGB324) proof of concept Phase II clinical trials



Bemcentinib (BGB324) foundation therapy

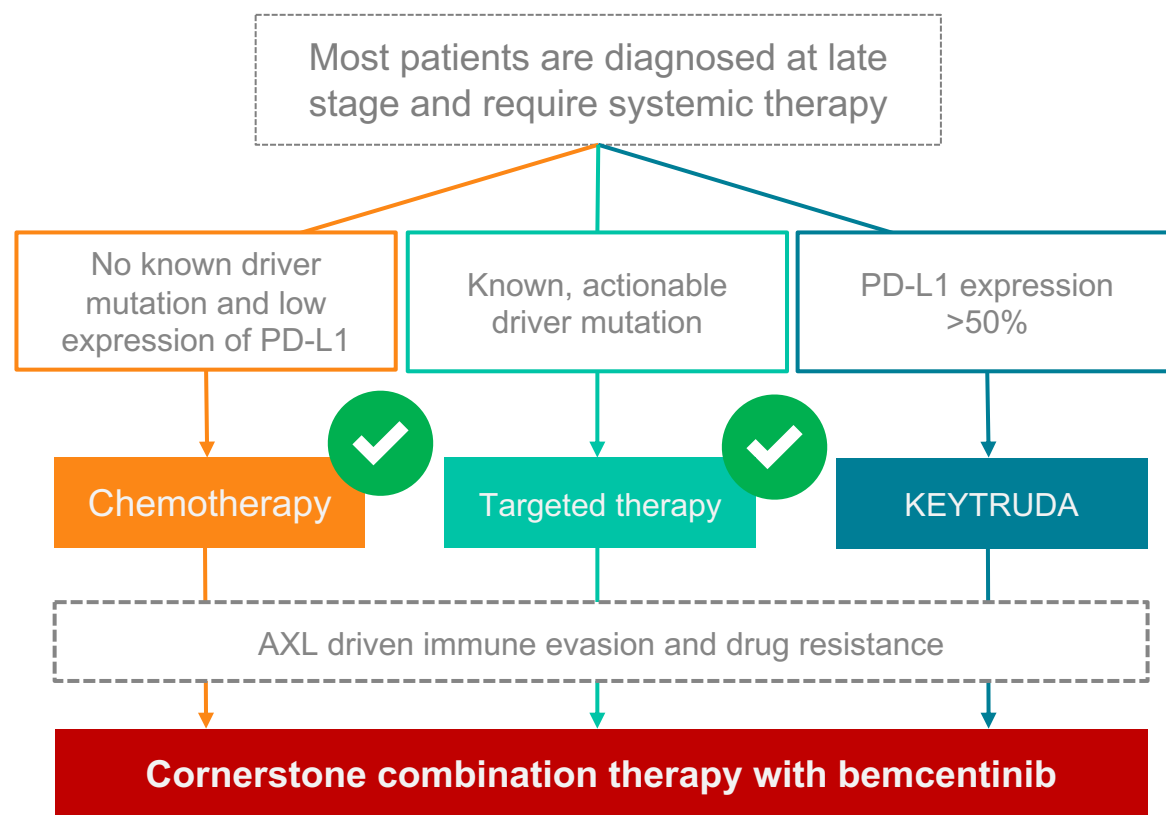
Bemcentinib recently reported Proof of Concept Phase II data



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3. **Bemcentinib in Lung Cancer – compelling clinical data presented**
 - **First stage of BGBC004 – reversal of erlotinib resistance – successfully completed (Jan '18)**
 - **Early efficacy for combination of bemcentinib with docetaxel reported (Dec '17)**
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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

Proof of Concept Phase II data

- ✓ **Combination with Chemo drugs**
- ✓ **Combination with Targeted drugs**
- ✓ **Well-tolerated in combination with KEYTRUDA**

BGBIL005 trial in NSCLC

Docetaxel is standard second line chemo in NSCLC patients without activating mutations or low PD-L1 expression and common last line treatment option. Docetaxel is not well tolerated by patients, response rates are very low and PFS short.

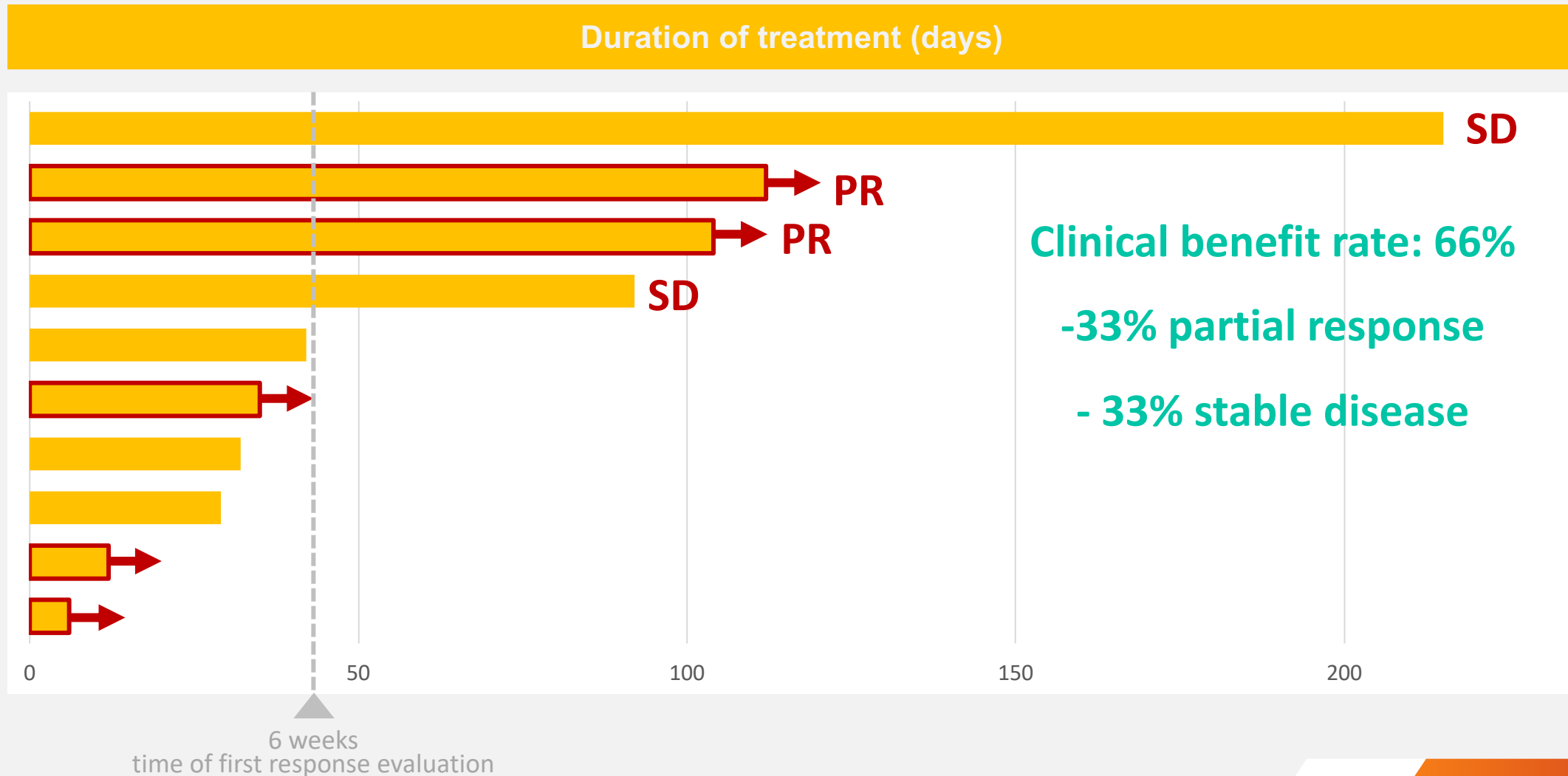
The BGBIL005 trial is designed to test the hypothesis whether AXL inhibition with bemcentinib can

- Enhance responses to chemotherapy

when given in combination with docetaxel in previously treated NSCLC patients



Bemcentinib + docetaxel in NSCLC patients



Docetaxel is main treatment option in NSCLC after chemo failure and as last line after failure of chemo, targeted and/or IO

Recent results in recurrent NSCLC (chemo failure) with docetaxel

	Study	Intervention	ORR
Single agent	CheckMate 057: Borghaei <i>et al</i> ¹ 582 patients randomised Pt chemo failures	Nivolumab vs Docetaxel	19% 12%
	OAK trial: Marinis <i>et al</i> ² 850 patients randomised Pt chemo failures	Atezo vs Docetaxel	14% 14%
	KEYNOTE 010 ³ ≥ 1% PDL1	Pembro Docetaxel	19% 9%
Combination	BGBIL005	Bemcentinib + docetaxel	33%
	Levy <i>et al</i> ⁴ 95 patients randomised	Docetaxel + PX-866 (PI3K inhibitor) vs Docetaxel alone	6% 0%
	Ramlau <i>et al</i> ⁵ 913 patients randomised	Docetaxel + Aflibercept (anti-VEGF) vs Docetaxel alone	23% 9%



BGBC004 trial in NSCLC

NSCLC patients tend to initially respond well to targeted therapies but virtually all develop resistance in less than 1 year.

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

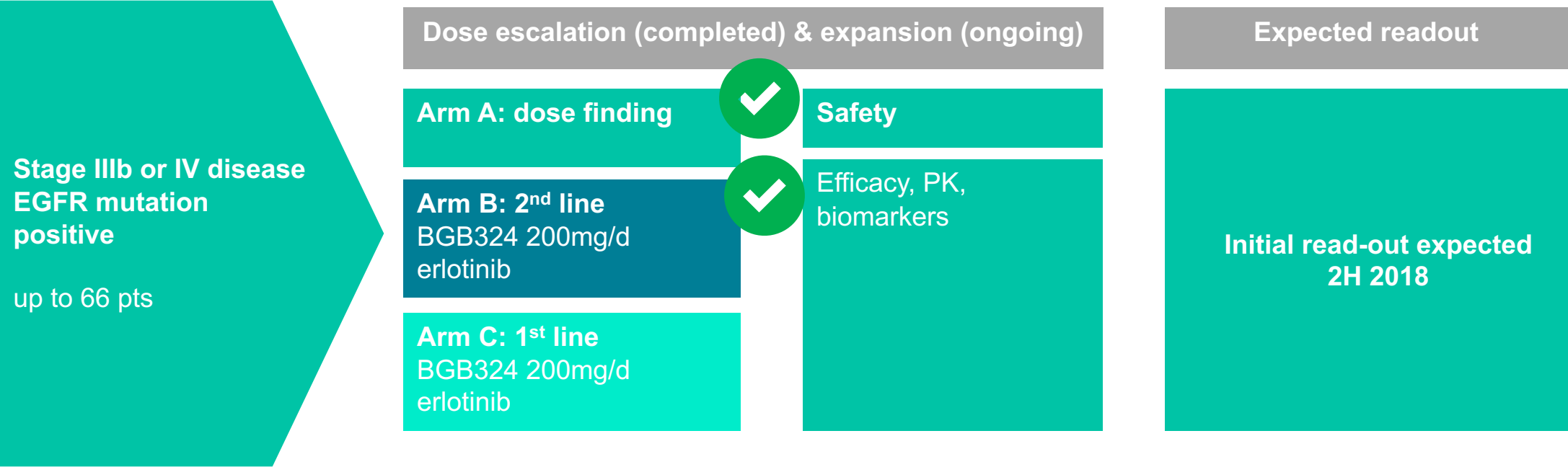
- **Reverse** and / or
- **Prevent** resistance to EGFRm targeted therapies

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



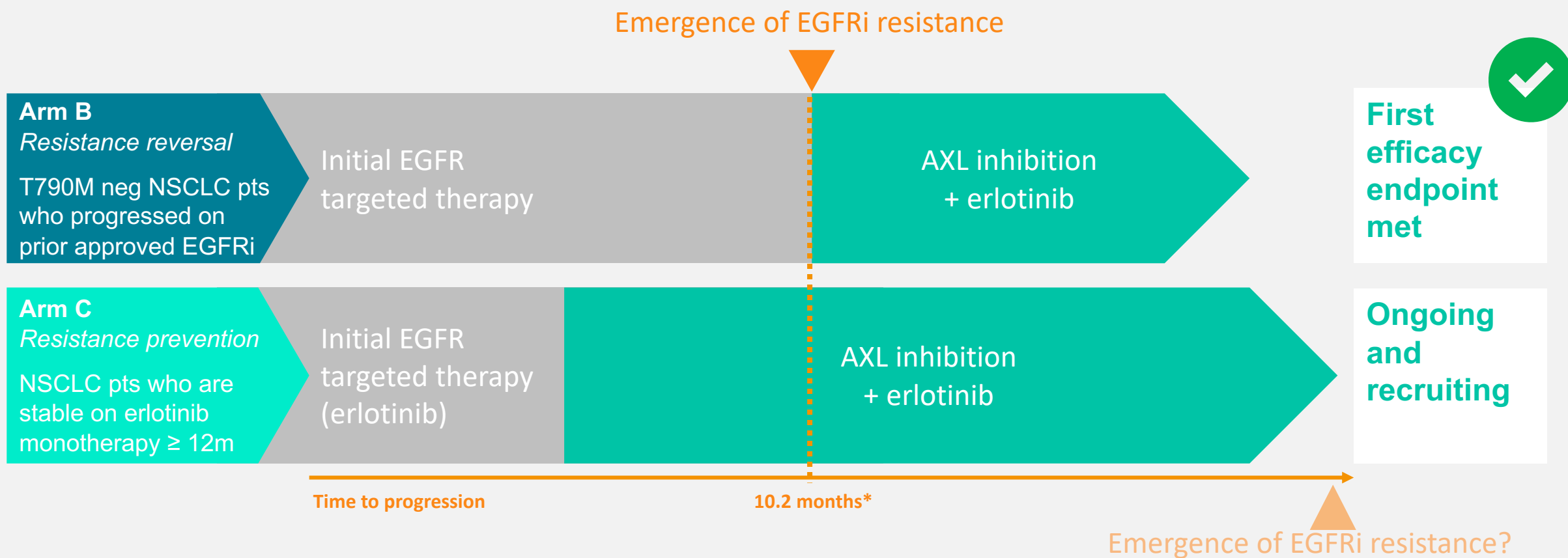
BGBC004: Proof-of-concept Phase II trial in NSCLC of bemcentinib with TARCEVA (erlotinib)

BGBC004 Phase II – NSCLC EGFR-mutation driven

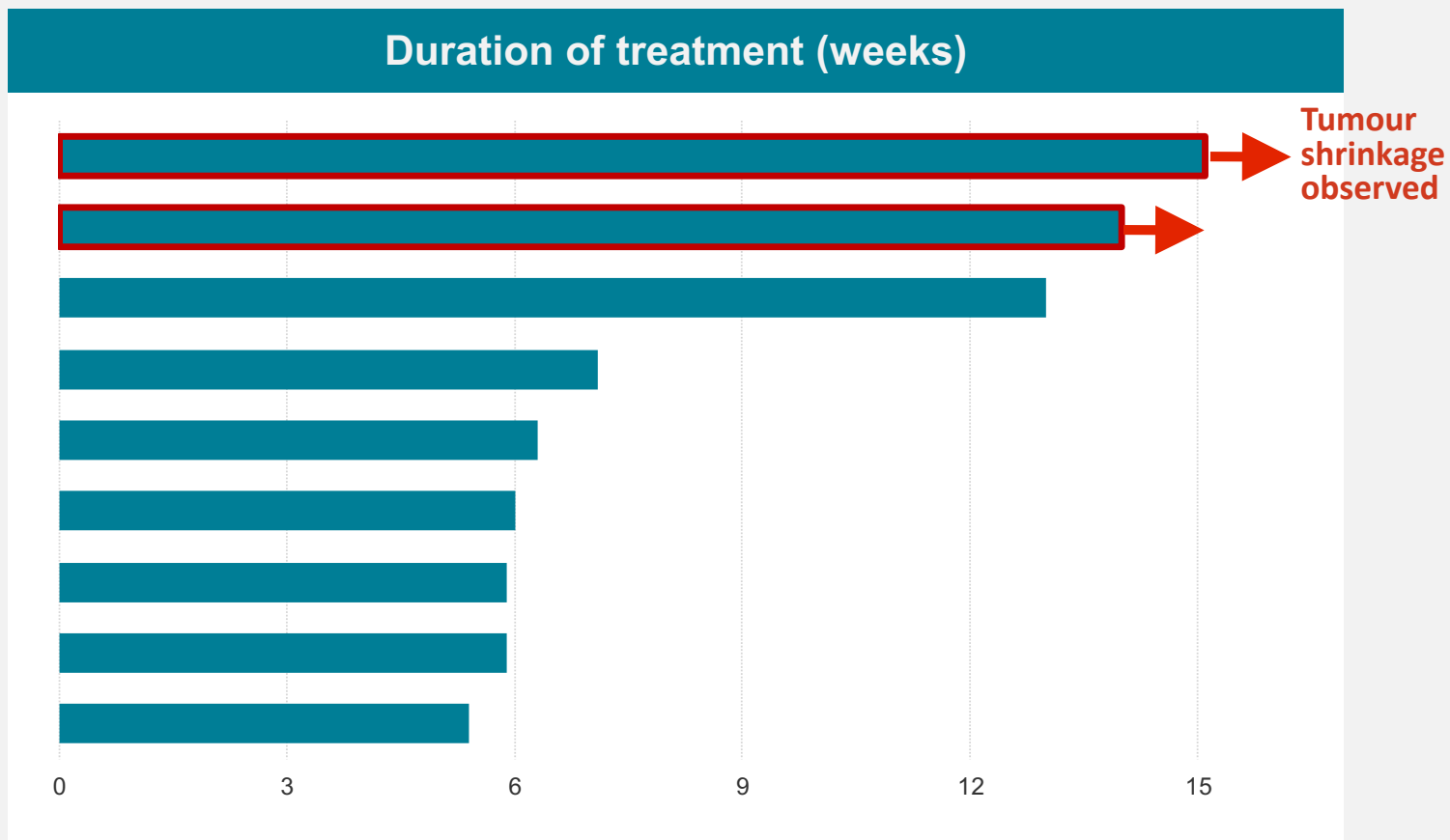


Designed to evaluate the potential of bemcentinib to reverse and prevent acquired resistance to EGFR targeted therapy:

Reversal setting (Arm B) successfully completed proof of concept stage



Arm B, resistance reversal Proof-of-concept Phase II patient data



Clinical benefit

- 2 SD > 4 cycles
- 3 SD at 6 wks

Status January 2018

Clinical Efficacy

- **33% disease control**
→ Reverse resistance to erlotinib
- **2 pts ongoing beyond 4 months**

Arm B patient population

- **Progressed on 1st line approved EGFR TKI therapy** (erlotinib, afatinib, gefitinib)
- **Median 3 lines** prior therapy
- **T790M negative**

Clinical trial regulatory update

- BerGenBio received all the required approvals from the **US Food & Drug Administration (FDA)** and from the **ethics committees at the participating US hospitals prior to starting this study.**
- In November 2017, BerGenBio informed that the Company is in discussions with the Regional Ethics Committee (REK) in Bergen and the Norwegian Board of Health regarding the BGBC004 study.

BGBC008 trial in NSCLC

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

The BGBC008 trial is designed to test the hypothesis whether AXL inhibition with bemcentinib can

- **Enhance** responses to immunotherapy

when given in combination with pembrolizumab in previously treated, immunotherapy-naïve NSCLC patients.

Clinical collaboration with Merck & Co. (MSD)



BGBC008: Phase II trial in NSCLC of bemcentinib in combination with KEYTRUDA

Patient recruitment on track



BGBC008 Phase 2 – NSCLC Adenocarcinoma of the lung

Previously treated,
unresectable
adenocarcinoma of the
lung

up to 48 pts
any PD-L1 expression
any AXL expression
no prior IO

Simon two stage (interim after 22 pts)

Single arm

BGB324 200mg/d
Keytruda 200mg/3w

ORR

Safety, DoR, TtP, OS
at 12 mo, response by
biomarker expression

Expected readout

Initial read-out expected
2H 2018



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3. Bemcentinib in Lung Cancer – compelling clinical data presented
4. **Other clinical trial data**
 - **Encouraging safety reported for combination of bemcentinib & Keytruda (Oct '17 & Jan '18)**
 - **Encouraging efficacy reported for bemcentinib monotherapy in R/R AML & MDS (Dec '17)**
 - **Immune activation reported in R/R AML & MDS (Dec '17 & Jan '18)**
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BGBC007 trial in TNBC

KEYTRUDA monotherapy showed 4% response rate in previously treated TNBC patients.

The BGBC007 trial is designed to test the hypothesis whether AXL inhibition with bemcentinib can

- **Enhance responses** to immunotherapy

when given in combination with pembrolizumab in previously treated, immunotherapy-naïve TNBC patients.

Clinical collaboration with Merck & Co. (MSD)

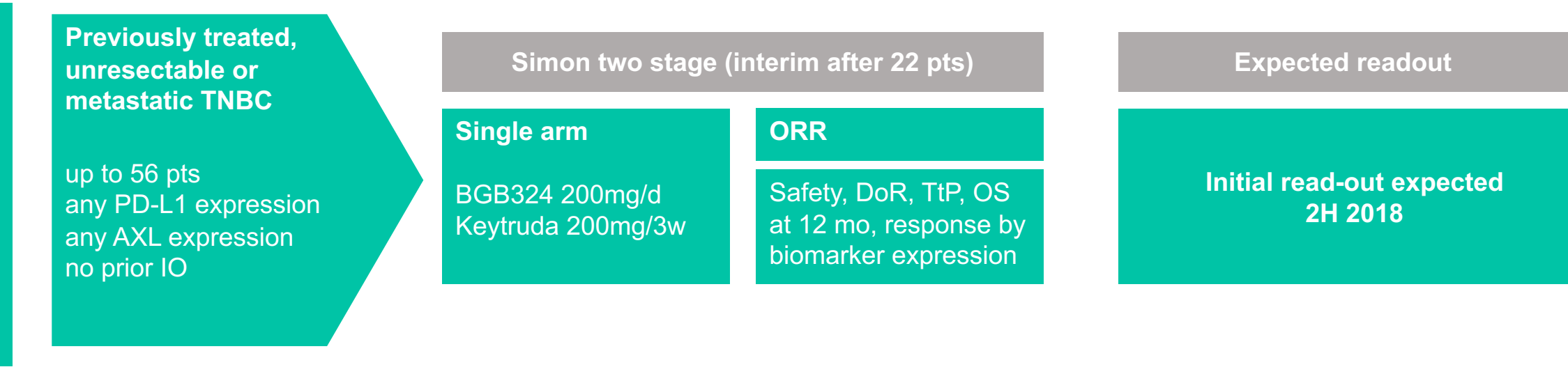


BGBC007: Phase II trial in TNBC of bemcentinib in combination with KEYTRUDA

Patient recruitment on track



BGBC007 Phase 2 – TNBC



ASCO-SITC Clinical IO Symposium 2018: Bemcentinib + KEYTRUDA well tolerated



- Serious adverse event profile across three combination trials with bemcentinib/pembrolizumab presented at ASCO-SITC Clinical Immuno-Oncology Symposium (Jan 2018)
- Data available for n = 34 pts across TNBC, NSCLC and melanoma
- Rash & pyrexia most commonly observed

- ✓ **Bemcentinib/ pembrolizumab combination is well tolerated across three cancer indications**
- ✓ **Serious adverse event profile similar to that reported for pembrolizumab alone**

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 chemotherapy

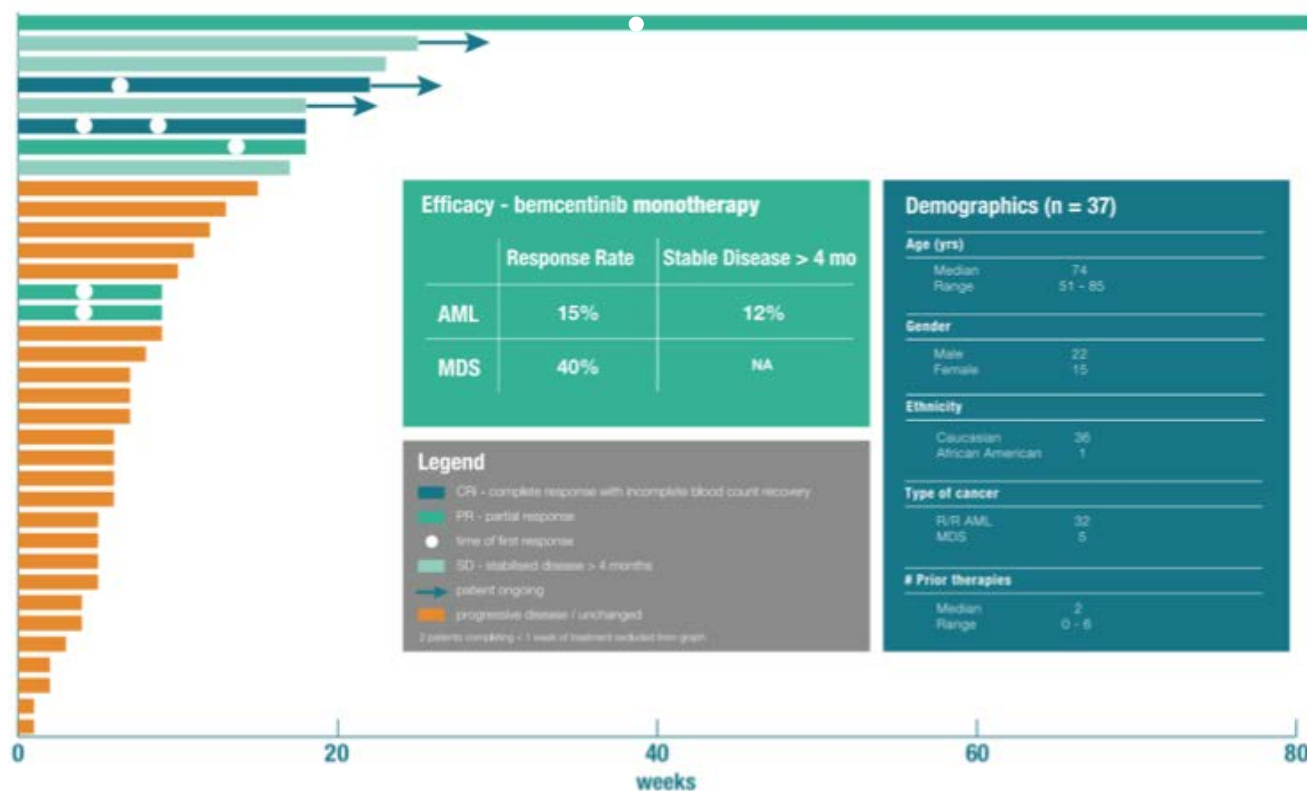
when given as a single agent in relapsed / refractory AML and high risk MDS or in combination with azacitidine or decitabine in treatment naïve AML patients



Superior monotherapy efficacy with favourable safety in R/R AML & high risk MDS reported at ASH 2017



Duration of treatment (weeks)



19% Response Rate (CRi + PR)

- 2 CRi
- 5 PRs

An additional 7 patients were stable > 4 months

Well tolerated

Correlation with predictive biomarker candidates

Clinical Trial data for R/R AML patients from ASH December 2017



American Society of Hematology
Helping hematologists conquer blood diseases worldwide

	Study	Intervention	ORR
Single agent	BerGenBio 37 patients	BGB324 all comers, elderly R/R patients	19%
	Pratz <i>et al</i> ¹ 31 patients	TAK-659 investigational FLT-3 and SYK inhibitor	9%
	Daver <i>et al</i> ⁴ 51 patients	FLX925 Dual FLT3 and CDK4/6	0%
	Dawson <i>et al</i> ⁶ 46 patients	GSK525762 BET inhibitor	11%
	DiNardo <i>et al</i> ⁵ 258 patients – selected for mIDH1 mutation	Ivosidenib (AG-120) mutant IDH1 (mIDH1) inhibitor	30%
Combination	Goldberg <i>et al</i> ² 24 patients	Venetoclax* + hypomethylating agent (HMA) or low dose cytarabine (LDAC)	28%
	Rausch <i>et al</i> ³ 27 patients	Venetoclax + HMA or LDAC	22%



*Venetoclax + LDAC received breakthrough designation in 1st line AML (July 2017)

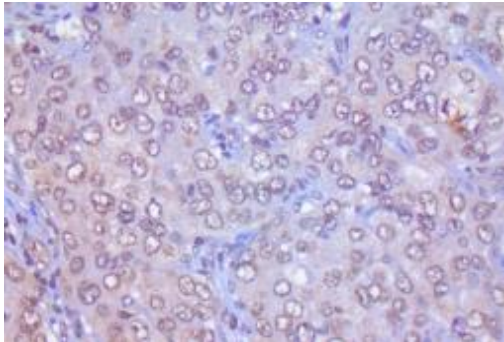
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5. **Companion Diagnostic development**
 - **Predictive biomarker candidates identified – soluble and cellular (Dec '17)**
 - **AXL IHC established and rolled out for BGBC007 and BGBC008 (Jan '18)**
6. BGB149 – solid progress towards starting clinical trials
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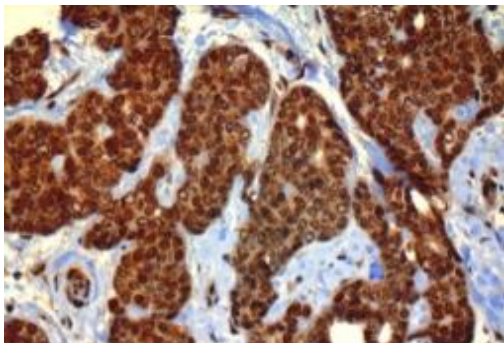
Companion diagnostic for personalised medicine

High AXL expression correlates to poor prognosis

Low AXL expression¹



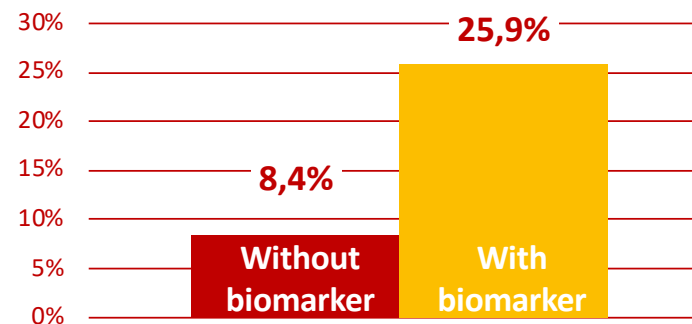
High AXL expression¹



Benefits of CDx

- Selecting patients most likely to benefit from treatment
- Improving probability of approval
- Increase reimbursement rates

Likelihood of success (Phase I to approval)



Parallel CDx development becoming standard practice

Tumour markers

PD-L1, total & phospho AXL

Tumour mutational burden

mRNA expression

Microsatellite instability

Tumour immune infiltrate

PD-L1, PD-1, CTLA-4, CD8 and CD45RO expression phenotypes

Circulation

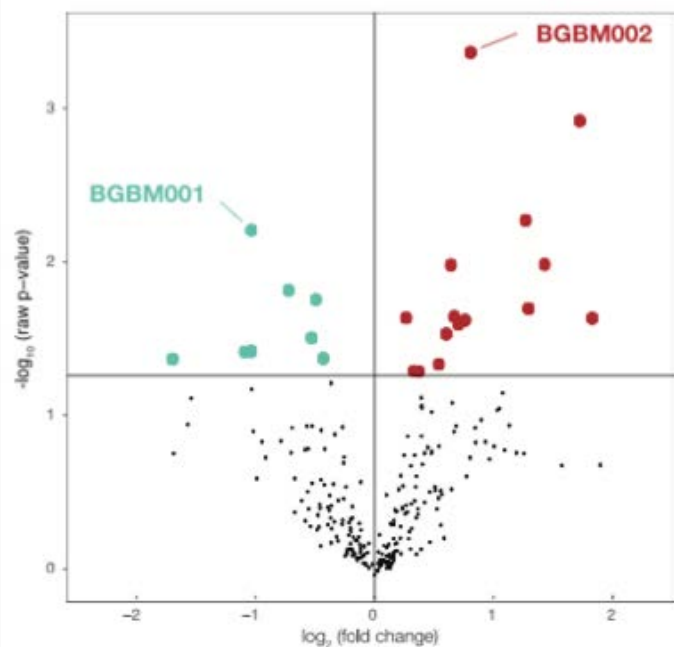
Cell mediated immune system
T-cells, dendritic cells, and other cell types

Circulating factors

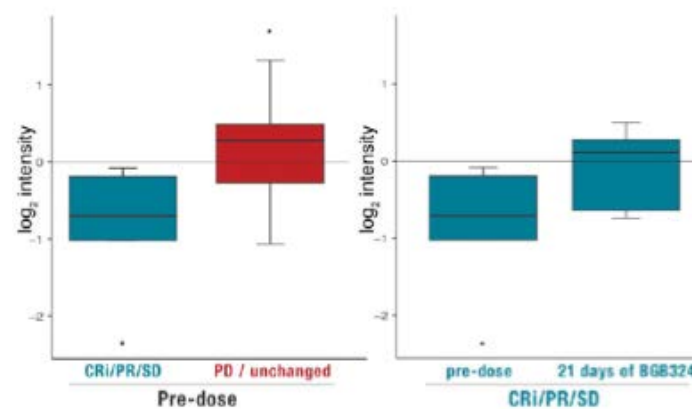
- Soluble AXL & Cytokines
- Cell counts

BerGenBio AML blood-based biomarkers predict patients benefitting from bemcentinib therapy

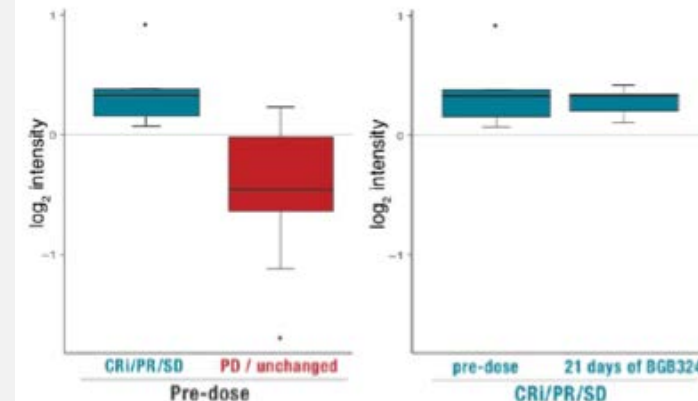
Liquid biopsy in blood plasma:
BGBM001 & BGBM002



BGBM001 in blood plasma



BGBM002 in blood plasma



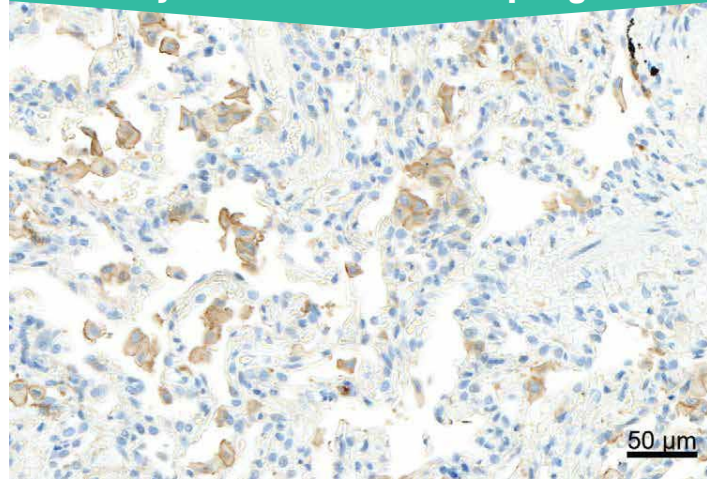
BerGenBio AXL immunohistochemistry (IHC) assay developed and validated

AXL can be detected in patient tumour and immune cells

AXL expression in NSCLC patient tumour sample



AXL expression in tumour adjacent alveolar macrophages

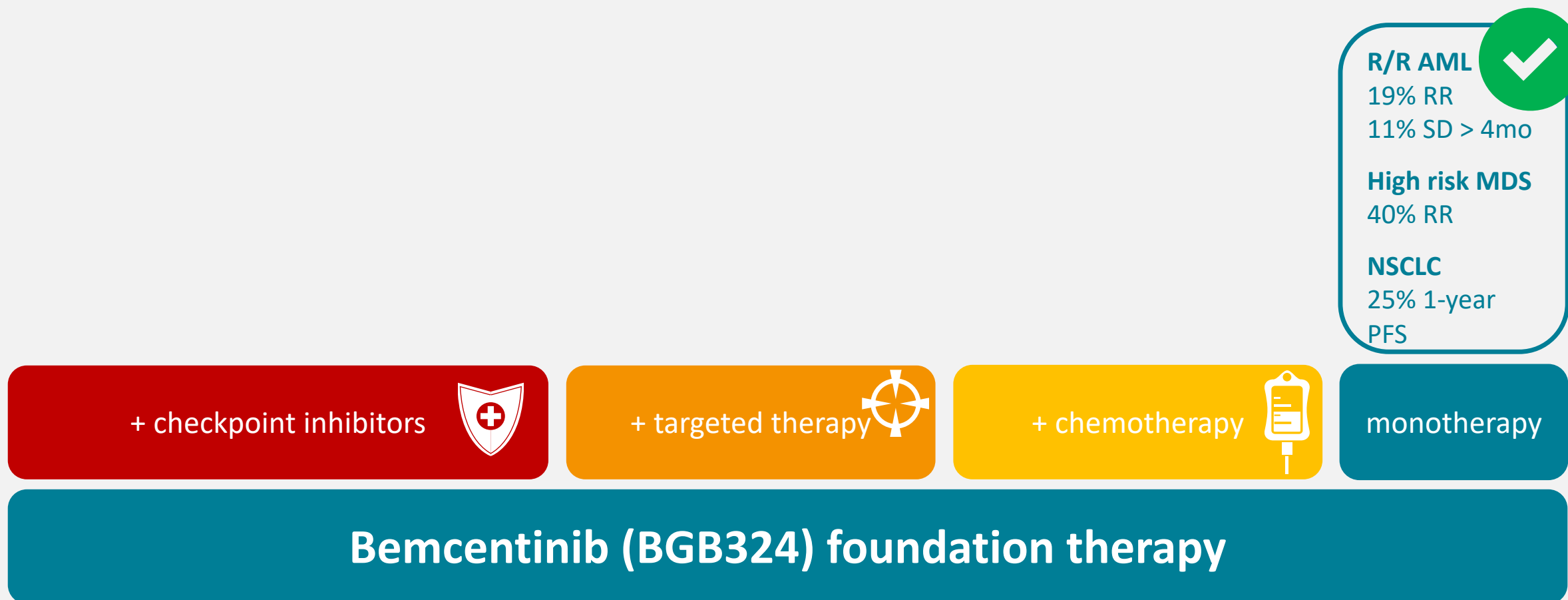


Shown are squamous cell carcinoma FFPE patient samples stained for AXL (brown) as per BerGenBio's proprietary AXL IHC assay

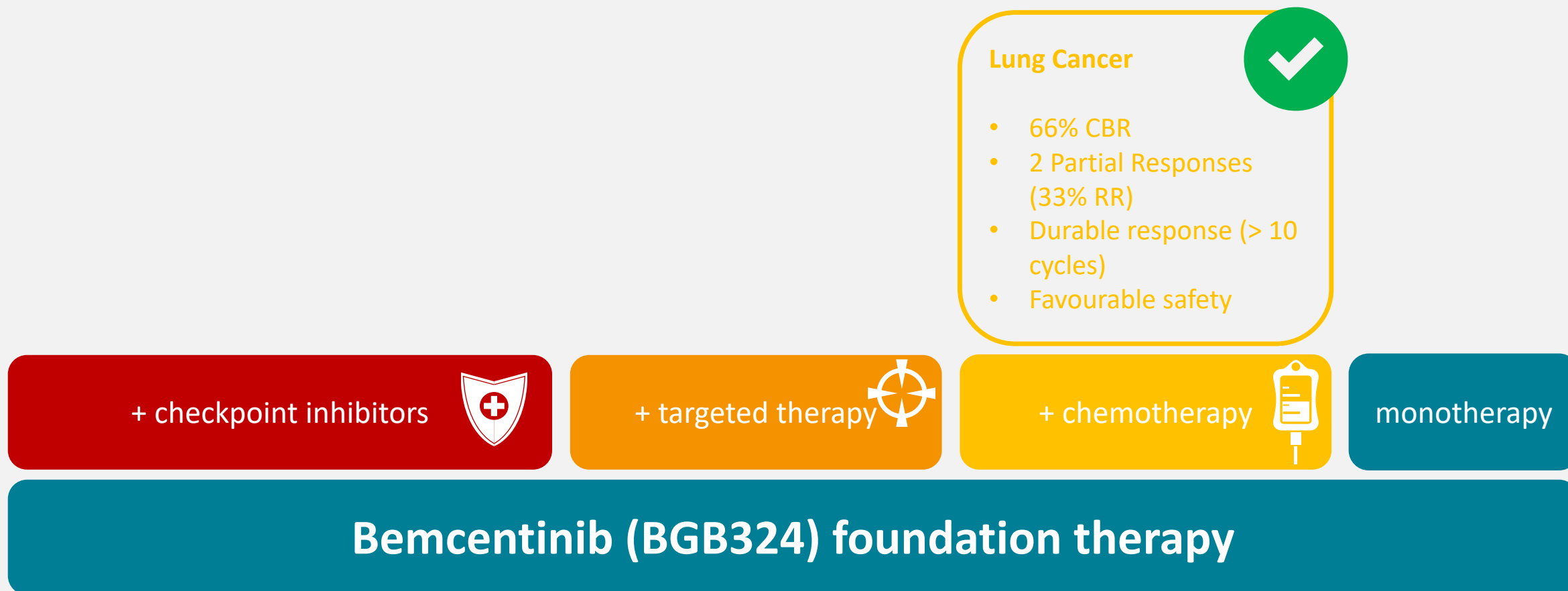
IHC assays:

- ✓ Widely used diagnostic method
- ✓ Standard for PD-1 directed and other targeted therapies
- ✓ Provide spatial information

Bemcentinib clinical development strategy: AXL inhibition as cornerstone for cancer therapy



Bemcentinib (BGB324) clinical development strategy: AXL inhibition as cornerstone for cancer therapy



Bemcentinib (BGB324) clinical development strategy: AXL inhibition as cornerstone for cancer therapy

EGFR+ Lung Cancer

- Arm A: 50% CBR + 1 PR
- Arm B: 33% CBR in T790M negative pts
- Arm A + B: Three patients ongoing (ca 2 years + 2x > 4 months)

+ checkpoint inhibitors



+ targeted therapy



+ chemotherapy



monotherapy

Bemcentinib (BGB324) foundation therapy

Bemcentinib (BGB324) clinical development strategy: AXL inhibition as cornerstone for cancer therapy

First line metastatic melanoma, second line TNBC and NSCLC:

- Combination well tolerated

+ checkpoint inhibitors



+ targeted therapy



+ chemotherapy



monotherapy

Bemcentinib (BGB324) foundation therapy

Bemcentinib ongoing clinical trials

Reporting interim response & safety data on a regular basis

BGBC008: NSCLC

OPEN & RECRUITING
ASCO-SITC '18

BGBC007: TNBC

OPEN & RECRUITING
ASCO-SITC '18

BGBC004: NSCLC

OPEN & RECRUITING
WORLD LUNG '17

BGBIL005: NSCLC

OPEN & RECRUITING
WORLD LUNG '17

BGBIL006: Melanoma

OPEN & RECRUITING
WORLD MELANOMA '17

BGBIL006: Melanoma

OPEN & RECRUITING
WORLD MELANOMA '17

BGBC003: AML

OPEN & RECRUITING

BGBC003:

AML/MDS

ASCO-SITC '18

+ checkpoint inhibitors



+ targeted therapy



+ chemotherapy



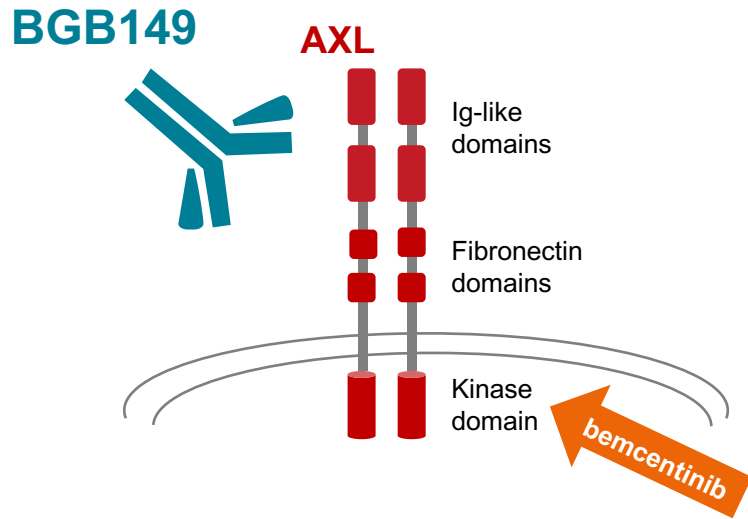
monotherapy

Bemcentinib foundation therapy

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BGB149: AXL function blocking antibody programme



Series of AXL functionally blocking antibodies – lead and back-ups

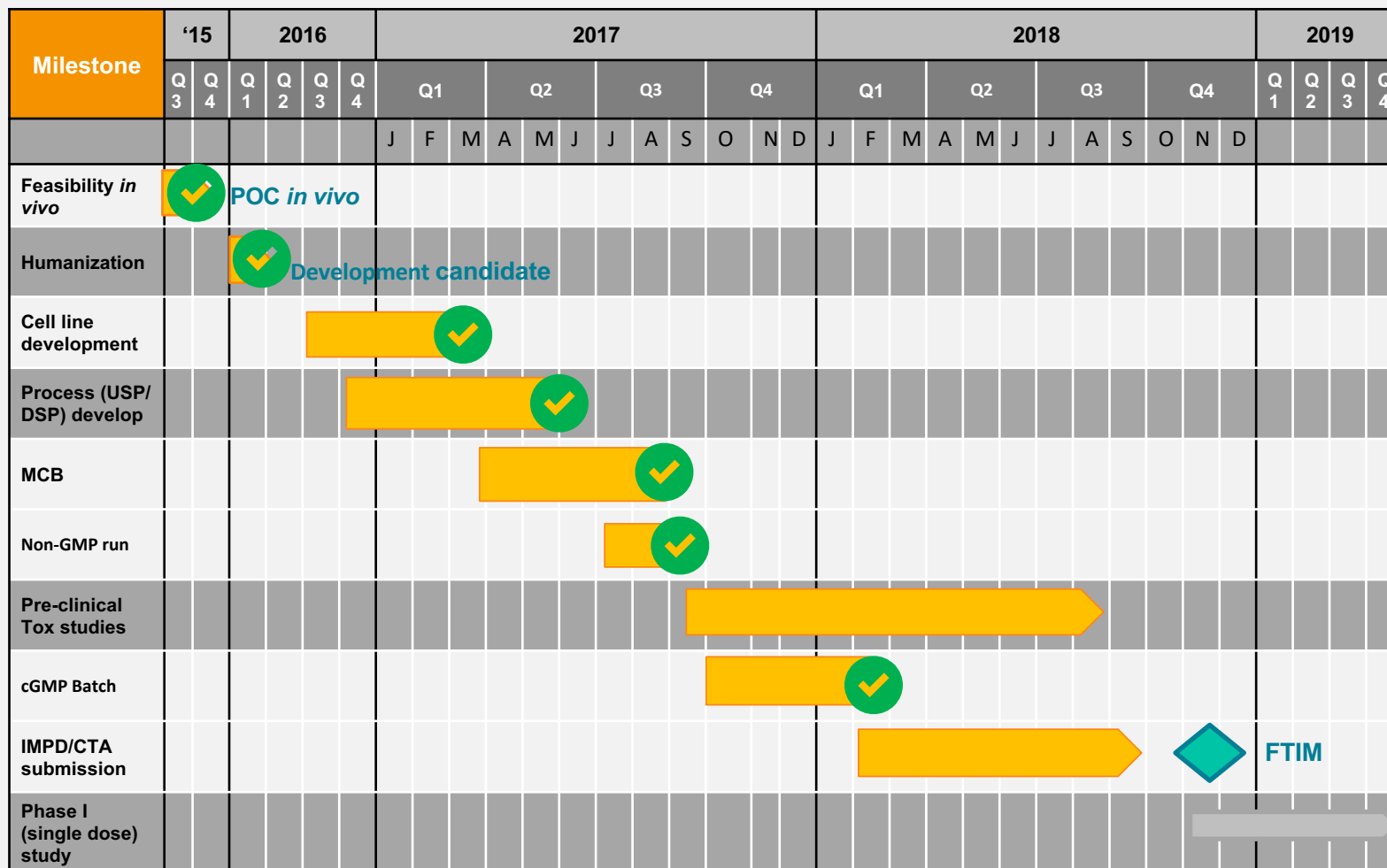
Highly selective to human AXL

High affinity (K_D : 500pM)

Patent position on CDR sequences

Anti-tumour MoA and efficacy demonstrated (AML, NSCLC, pancreatic)

Development timeline – FiM 2H 2018



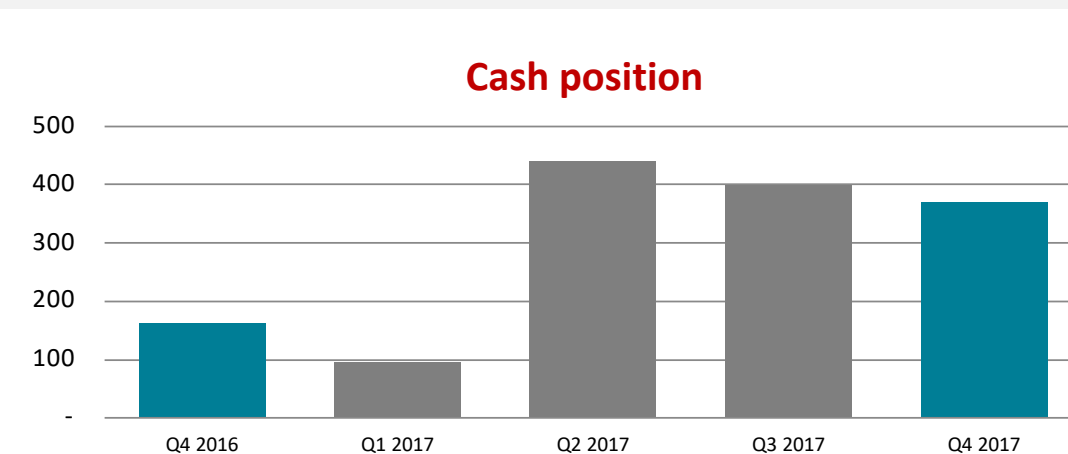
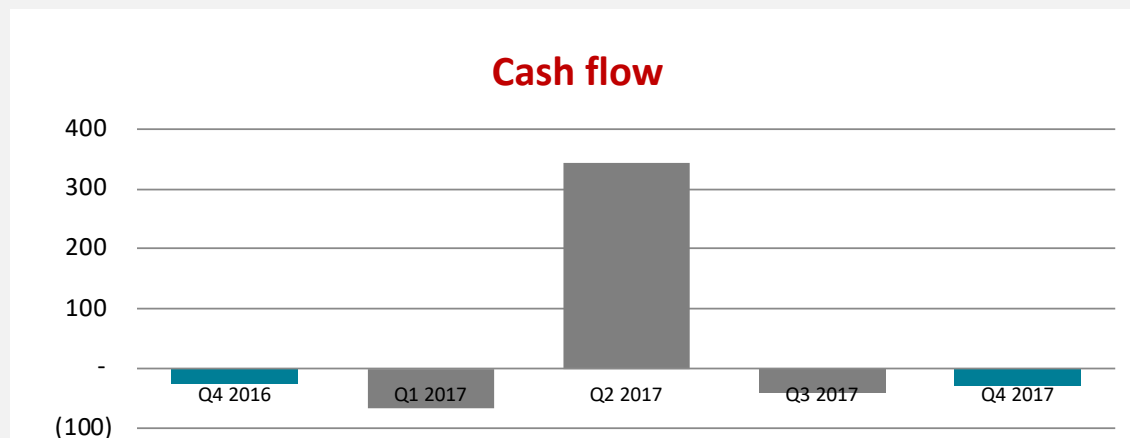
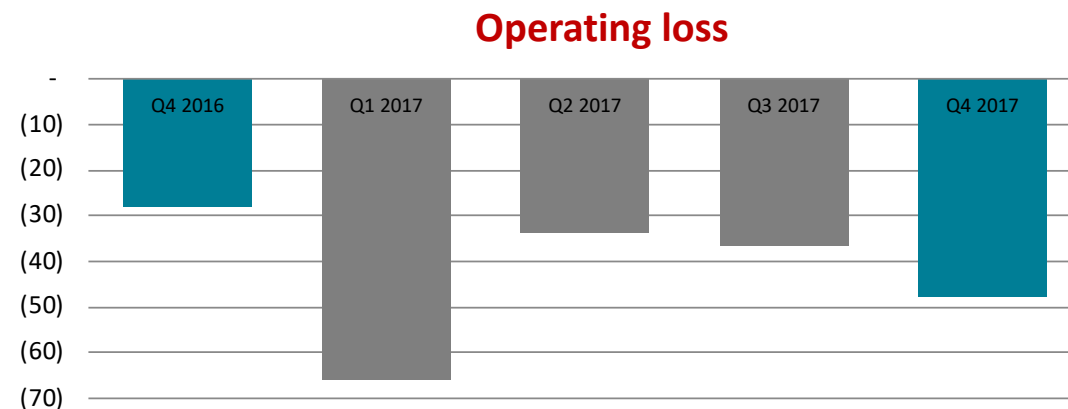
- ✓ Clinical candidate selected
- ✓ Scale-up successfully completed
- ✓ Toxicology studies on track for first in human trials in H2 2018

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Key financials

Key Figures (NOK million)	Q4 2017	Q4 2016	FY2017	FY2016
Operating revenues	-	-	-	-
Operating expenses	47.5	28.0	183.7	131.6
Operating profit (loss)	-47.5	-28.0	-183.7	-131.6
Profit (loss) after tax	-47.6	-27.9	-182.2	-129.8
Basic and diluted earnings (loss) per share (NOK)	-0.96	-82.81	-4.01	-419.68
Net cash flow in the period	-28.8	-25.4	208.5	87.8
Cash position end of period	370.3	161.8	370.3	161.8

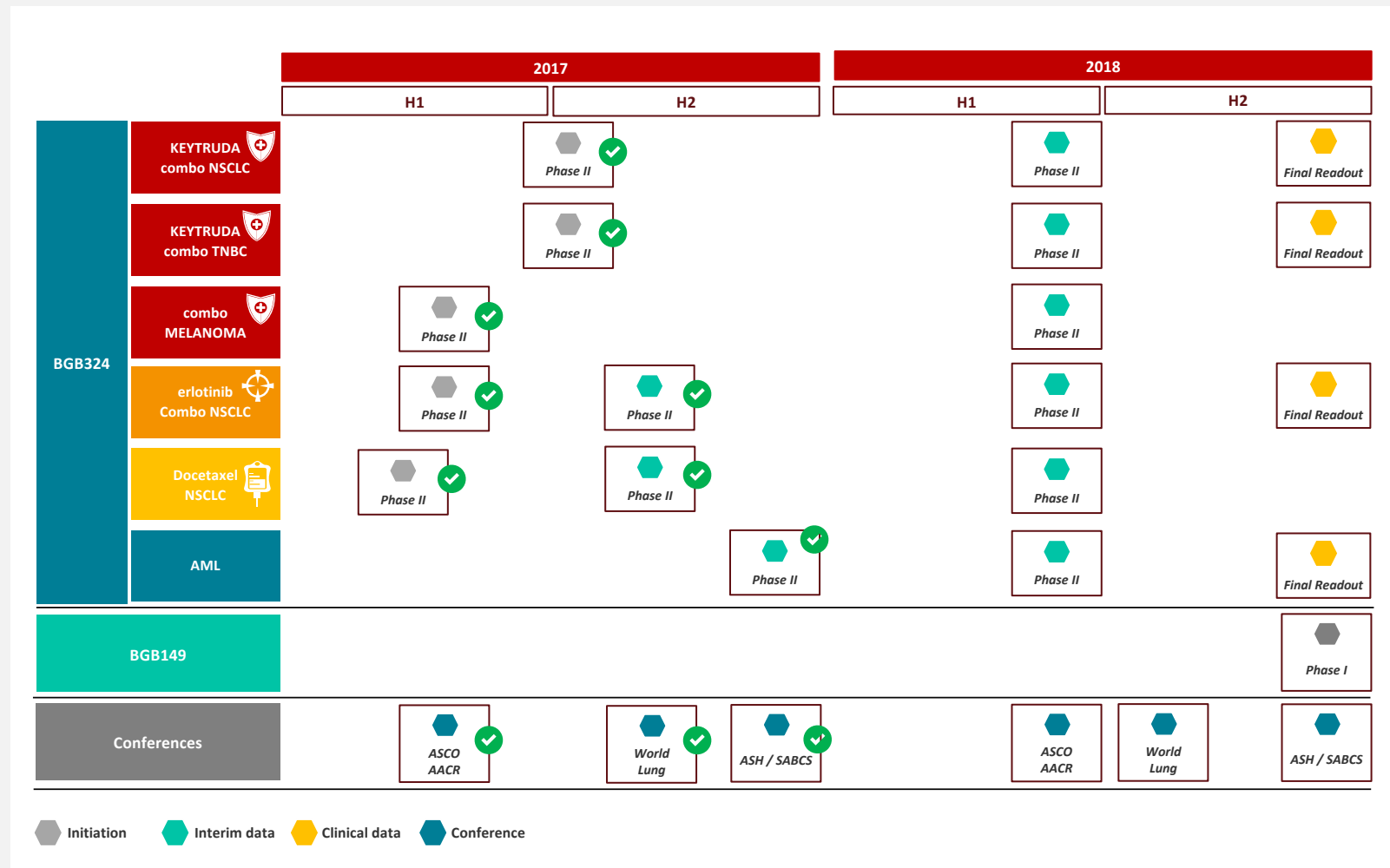


- OPEX sequentially increased as recruitment to our clinical studies is ramping up which triggers milestone payments
- Net cash flow is NOK 18.8 million below operating loss due to non dilutive cash grants and favourable working capital development
- Robust cash position gives runway to deliver key clinical read outs on our ongoing clinical studies.

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Milestones 2017 & 2018



Significant value drivers expected over the next 12 months:

- ✓ **Interim clinical data** from 6 ph II trials **H1'18**
- ✓ **Final readout** from 4 phase 2 trials in **H2**
- ✓ **Initiation of AXL antibody BGB149** clinical trials in **H2**

BGBIO Investment case

Bemcentinib, potential first-in-class, selective AXL inhibitor for multiple cancers with addressable market in excess of \$20bn

Axl mechanism now widely accepted by Pharma industry as a 'hot' target of great interest

Promising preliminary Phase II proof-of-concept data for bemcentinib already reported – additional data anticipated June 2018

Clear strategy to develop and commercialise assets

- Deliver key clinical data from ongoing Phase II studies, develop CDx in parallel, and advance pipeline candidates
- High value, first-in-class drug candidates are attractive targets for strategic partnering and M&A
- Select go-to market possibilities in enriched patient populations

Well funded & experienced organisation to deliver milestones that create shareholder value

Thank you.

For further information please visit
www.bergenbio.com

Developing first-in-class Axl inhibitors to treat
aggressive cancer



Appendix

Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited

	Note	Q4 2017	Q4 2016	FY 2017	FY 2016
Revenue		-	-	-	-
Cost					
Employee benefit expenses	3	10 302	6 242	28 827	20 561
Depreciation		41	58	193	207
Other operating expenses	6	37 168	21 734	154 687	110 802
Total operating expenses		47 511	28 034	183 708	131 570
Operating profit		-47 511	-28 034	-183 708	-131 570
Finance income		912	801	4 168	3 031
Finance expense		1 035	667	2 668	1 260
Financial items, net		- 122	134	1 500	1 771
Profit before tax		-47 633	-27 900	-182 208	-129 799
Income tax expense			-	-	-
Profit after tax		-47 633	-27 900	-182 208	-129 799
Other comprehensive income					
<i>Items which will not be reclassified over profit and loss</i>					
Actuarial gains and losses on defined benefit pension plans		-	-1 089	-	-1 089
Total comprehensive income for the period		-47 633	-28 989	-182 208	-130 888
Earnings per share:					
- Basic and diluted per share	7	-0.96	-82.81	-4.01	-419.68

Condensed consolidated statement of financial position

<i>(NOK 1000) Unaudited</i>	Note	31 Dec 2017	31 Dec 2016
ASSETS			
Non-current assets			
Property, plant and equipment		557	410
Total non-current assets		557	410
Current assets			
Other current assets	8	13 430	12 302
Cash and cash equivalents		370 350	161 825
Total current assets		383 780	174 126
TOTAL ASSETS		384 336	174 536
EQUITY AND LIABILITIES			
Equity			
Paid in capital			
Share capital	9	4 992	3 369
Share premium	9	325 018	131 875
Other paid in capital	4, 9	20 340	18 026
Paid in, not registered capital raise	9	-	-
Total paid in capital		350 350	153 270
Total equity		350 350	153 270
Non-current liabilities			
Pension liability	10	-	-
Total non-current liabilities		0	0
Current liabilities			
Accounts payable		21 575	10 703
Other current liabilities		9 391	5 721
Provisions		3 020	4 843
Total current liabilities		33 986	21 266
Total liabilities		33 986	21 266
TOTAL EQUITY AND LIABILITIES		384 336	174 536

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited

	Note	FY 2017	FY 2016
Cash flow from operating activities			
Loss before tax		-182 208	-129 799
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		193	207
Calculated interest element on convertible loan		-	19
Share-based payment expense	3, 4	2 314	5 702
Movement in provisions and pensions		-1 823	-2 099
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		-1 128	-4 263
Increase in trade and other payables		14 543	5 919
Net cash flow from operating activities		-168 109	-124 314
Cash flows from investing activities			
Purchase of property, plant and equipment		- 340	- 255
Net cash flow used in investing activities		- 340	- 255
Cash flows from financing activities			
Proceeds from issue of share capital	9	376 974	212 220
Paid in, not registered capital increase	9	-	-
Proceeds from borrowings, convertible loan		-	-1 307
Conversion of loan by issue of share capital		-	1 489
Net cash flow from financing activities		376 974	212 402
Net increase/(decrease) in cash and cash equivalents		208 525	87 832
Cash and cash equivalents at beginning of period		161 825	73 993
Cash and cash equivalents at end of period		370 350	161 825