AXL inhibitors as a cornerstone of combination cancer therapy

Corporate Update

April 2018

Richard Godfrey, CEO

BerGenBio

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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

Companion diagnostic supported by biomarker tests

Bemcentinib (BGB324)

First-in-class highly selective small molecule AXL inhibitor

Broad phase II clinical programme

Confirmed favourable safety profile

Durable responses:

- NSCLC
- AML / MDS

Pipeline

Bemcentinib

AXL antibody

AXL ADC (partnered)

Immunomodulatory small molecules

Companion Dx

Corporate

35 staff

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

OSE:BGBIO

Raised USD 50m in IPO on OSE in April ’17

USD 270m market cap (April 5th 2018)

Management
Presenting team

Richard S. Godfrey, *Chief Executive Officer*

- Pharmacist / MBA – joined BerGenBio in 2008 as CEO
- 28 years industry experience, led and managed multiple international drug development and commercialization partnerships
- Previous international executive roles with Eli Lilly, Reckitt Benckiser, Catalent, DDC and SwissCaps
- Developed and launched many drugs in different classes: Adalat, Noctura, Feldene, Imodium, Pepcid, Zyprexa Zofran, Subutex

Prof. James Lorens, *Founder and Chief Scientific Officer*

- Professor University of Bergen Medical School
- 30 years biotech research experience, academic biomedical research positions at Stanford University and University of Bergen
- Former Director Oncology R&D, Rigel Inc. (San Francisco, CA)
- The first to recognize that Axl kinase is an essential mediator of cancer development (EMT)

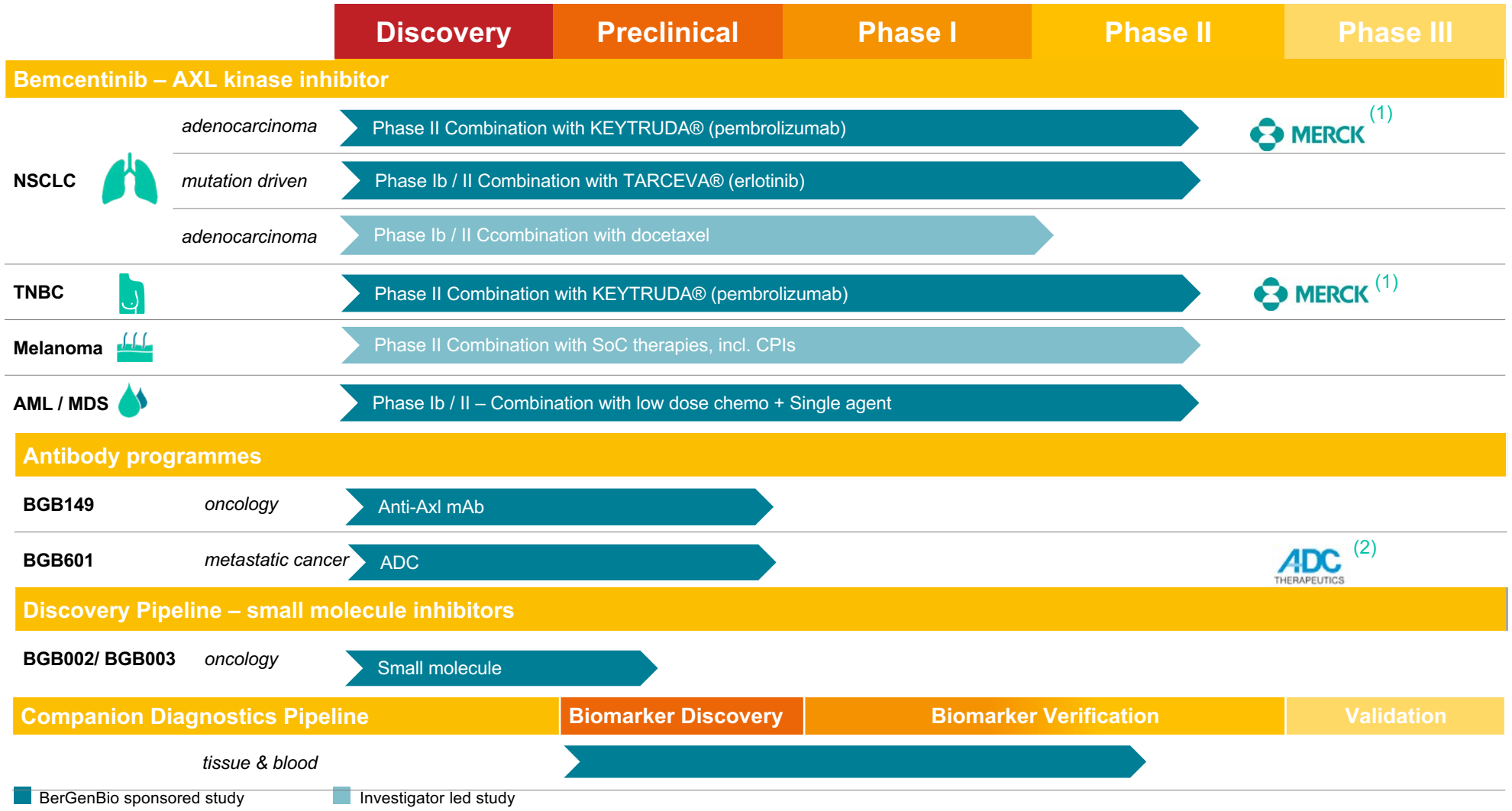
Murray Yule MD, PhD, *Clinical Development Officer*

- MD Oncologist – joined BerGenBio in 2011
- 17 years industry experience with Roche, Eisai and Astex Pharmaceuticals
- Developed and launched several cancer drugs: Velcade, Erubulin

Rune Skeie, *Chief Financial Officer*

- 20 years of financial management, corporate development, corporate governance and advisory experience across multiple industry sectors. – Joined BerGenBio in 2018
- Previously Executive Director at EY and CFO of REMA Franchise Norge AS, the multinational supermarket business.
- Registered Accountant and a State Authorized Public Accountant

Advancing a broad clinical development pipeline



Patients:
>350

Sites in Europe and North America:
50

Key read-outs:
2018

(1): Clinical trial collaboration, no preferential rights (2): outlicensed

Bemcentinib Phase II clinical trials
AXL inhibition as a cornerstone for cancer therapy

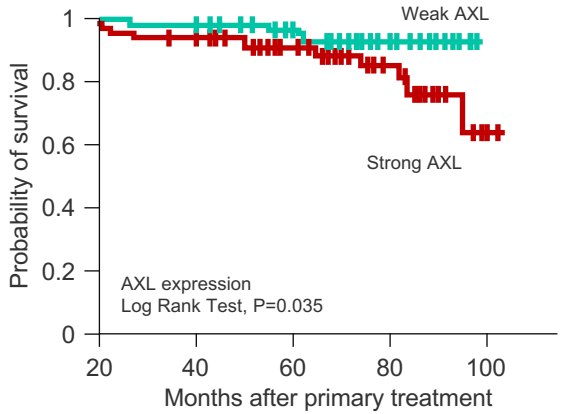
+ checkpoint inhibitors	+ targeted therapy	+ chemotherapy	monotherapy
BGBC008: **NSCLC**			
BGBC007: **TNBC**	BGBIL006: **Melanoma**	BGBIL005: **NSCLC**	
BGBIL006: **Melanoma**	BGBC004: **NSCLC**	BGBC003: **AML**	BGBC003: **AML/MDS**

Bemcentinib foundation therapy

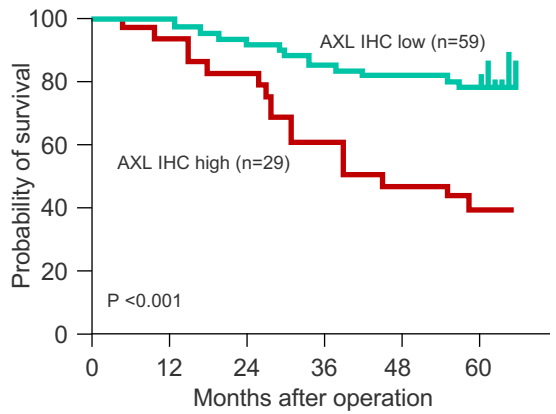
Aggressive cancers

Strong AXL expression correlates with poor survival rate

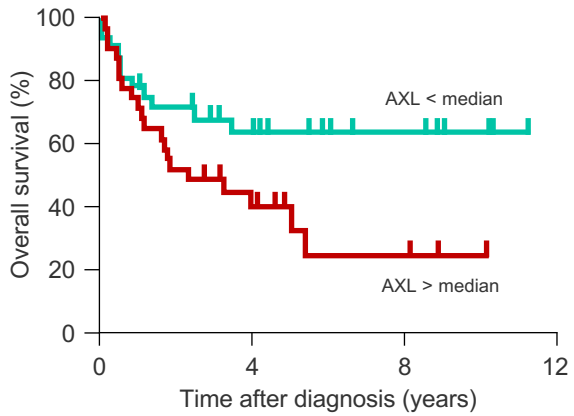
Breast carcinoma[1]



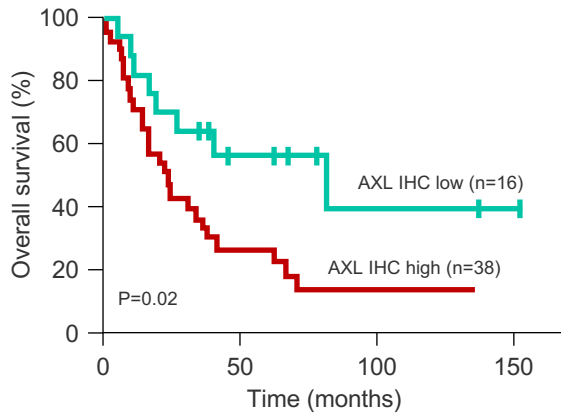
Lung adenocarcinoma (NSCLC)[2]



Acute Myeloid Leukaemia[3]



Pancreatic ductal adenocarcinoma[4]



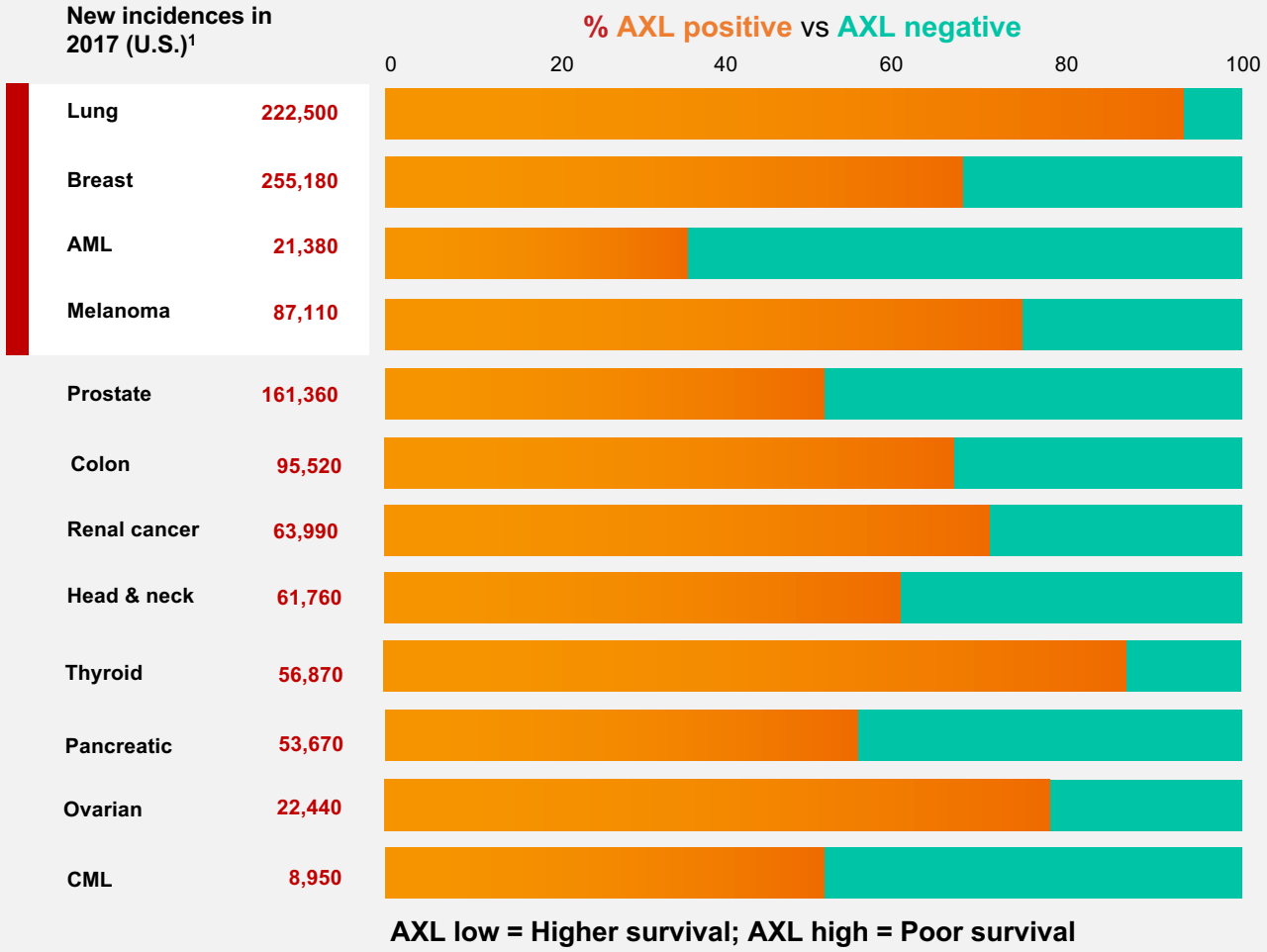
Broad evidence of AXL linked with poor prognosis[5]

- Astrocytic brain tumors
- Breast cancer
- Gallbladder cancer
- GI
  - Colon cancer
  - Esophageal cancer
  - Gastric cancer
- Gynaecological
  - Ovarian cancer
  - Uterine cancer
- HCC
- HNC
- Haematological
  - AML
  - CLL
  - CML
- Melanoma
- Mesothelioma
- NSCLC
- Pancreatic cancer
- Sarcomas
  - Ewing Sarcoma
  - Kaposis sarcoma
  - Liposarcoma
  - Osteosarcoma
- Skin SCC
- Thyroid cancer
- Urological
  - Bladder cancer
  - Prostate cancer
  - RCC

1 Gjerdrum, 2010; 2 Ishikawa, 2012; 3 Ben-Battala, 2013; 4 Song, 2010, 5 supported by > 100 publications

AXL drives majority of aggressive cancers

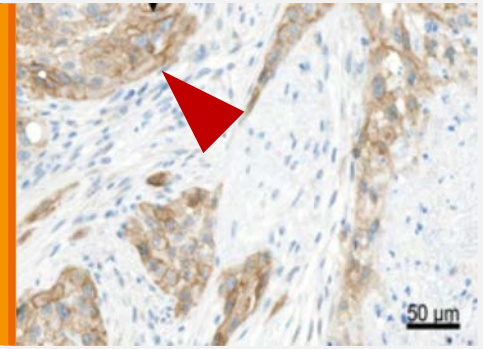
Most common tumours express high AXL levels



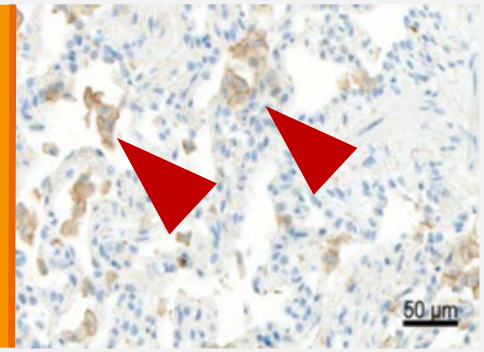
AXL low = Higher survival; AXL high = Poor survival

Companion diagnostic in development to identify AXL positive patients

AXL on tumour tissue

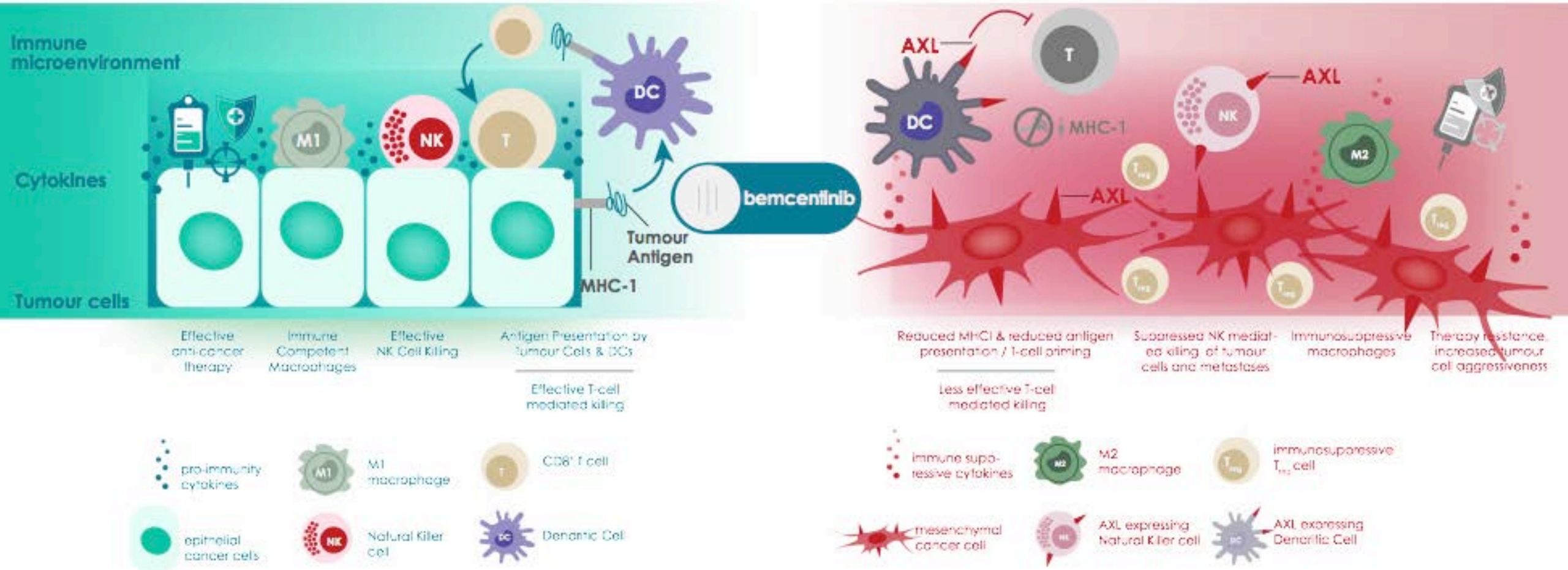


AXL on tumour adjacent immune cells



(1) SEER (2) Gjerdrum 2010

Bemcentinib, a selective AXL inhibitor, is intended to restore sensitivity to immune cell attack and therapy and prevent spread



BerGenBio

Bemcentinib, first in class highly selective AXL inhibitor

Most advanced selective, orally bioavailable, small molecule AXL kinase inhibitor in phase II clinical development

26kg API manufactured

Size 0 100mg HPMC capsules

3 years stability confirmed

Strong patent position

Once daily dosing

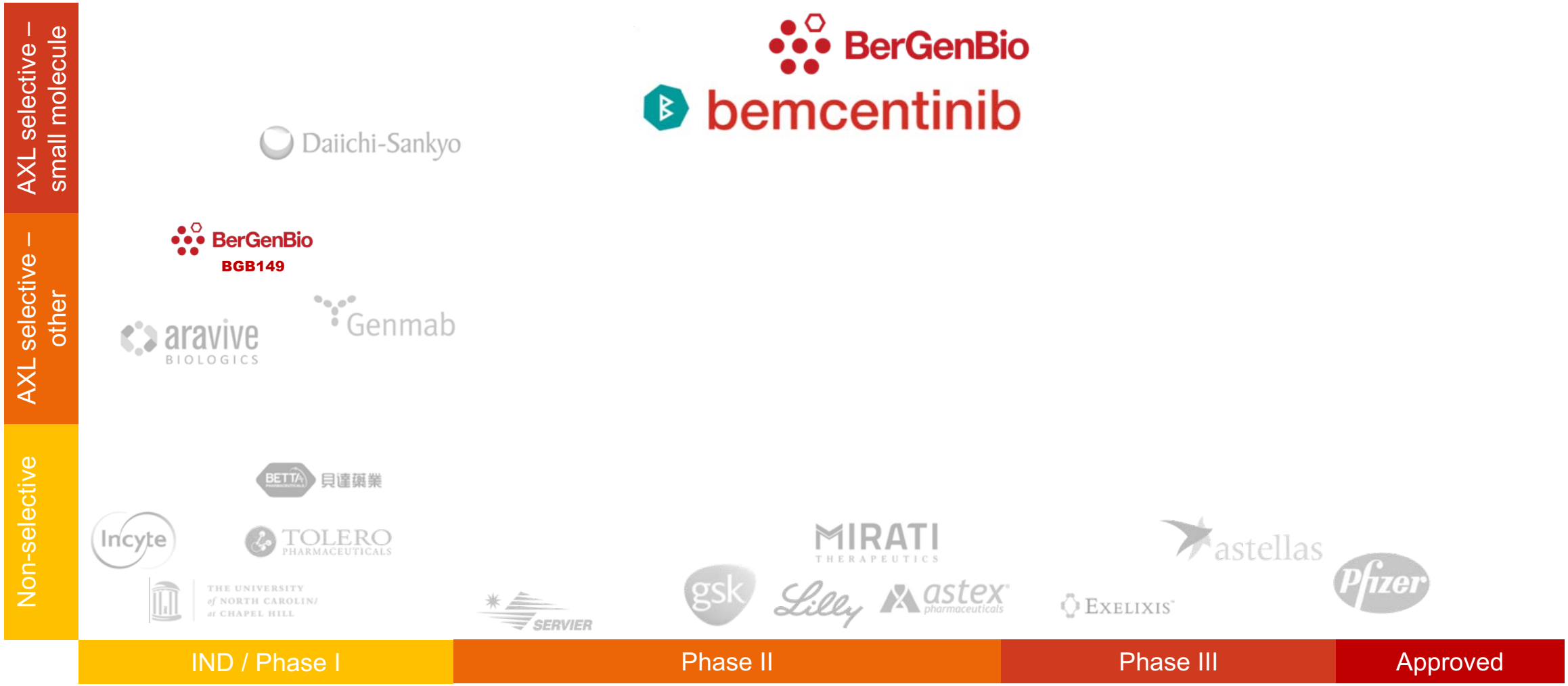
Well tolerated

Safely combined with chemo, targeted and IO drugs

IC_{50} = 14 nM

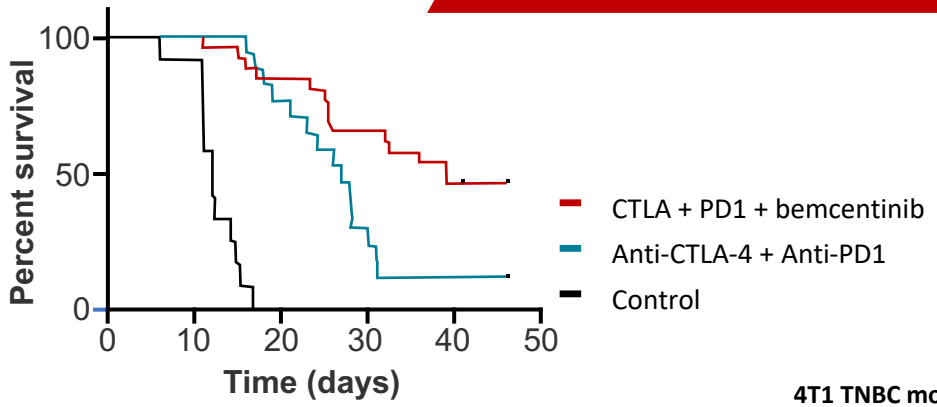
50-100 fold selective cf. TAM kinases

Axl inhibitors - competitive landscape



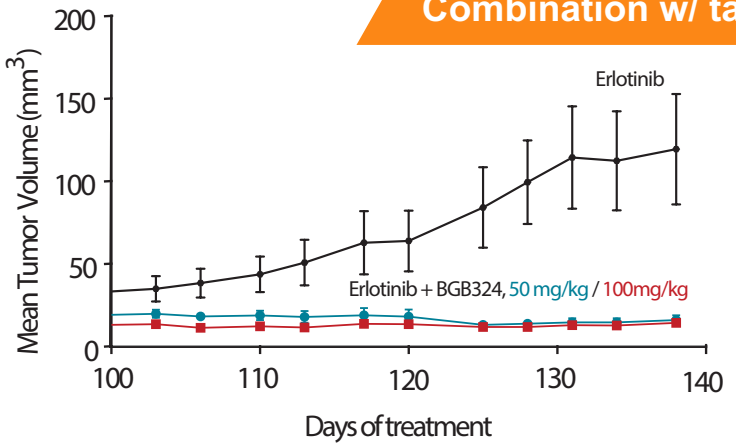
Pre-clinical data guides bemcentinib's broad clinical utility

Combination w/ CPIs



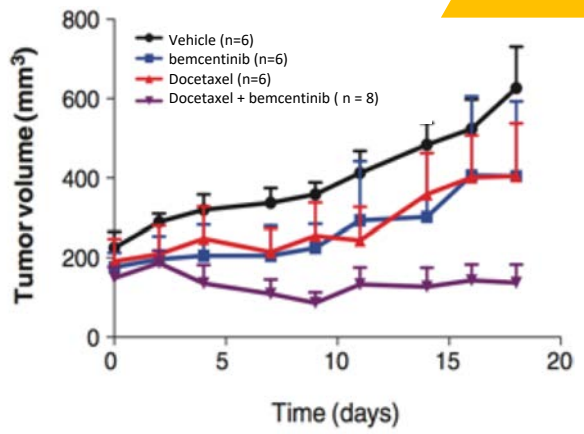
4T1 TNBC model

Combination w/ targeted therapy



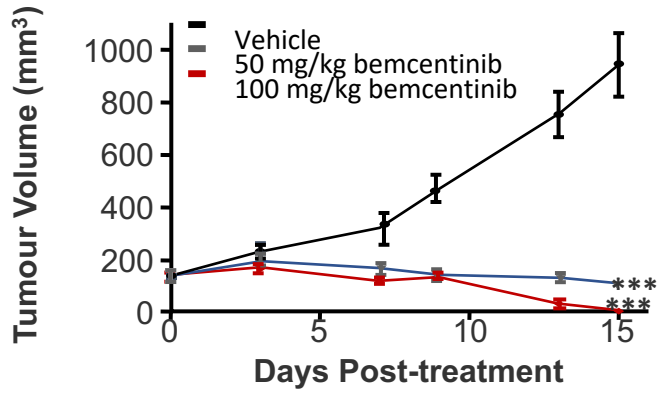
HCC827 NSCLC model

Combination w/ chemo



HeLa cervical cancer model

Single agent activity



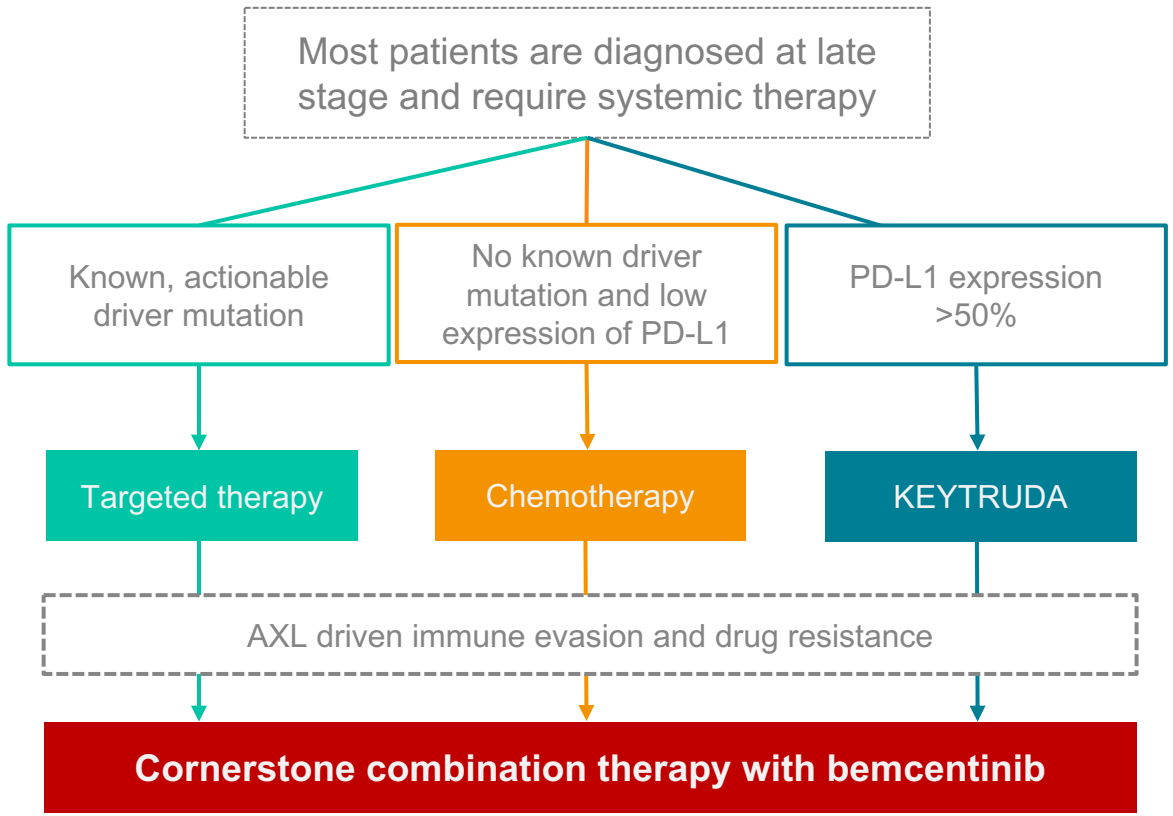
MV4-11 AML model

Source: in house and Wilson et al. Cancer Res (2014)

AXL inhibition as a cornerstone of therapy in NSCLC

BGBC004, BGBIL005, BGBC008

Potential for bemcentinib to become a cornerstone therapy for NSCLC



- Lung cancer is the most frequent cause of cancer-related death in developed countries
- More than 220,000 new cases of lung cancer will be diagnosed in the US in 2018 - 65% of NSCLCs are adenocarcinoma
- Existing treatments curtailed by acquired resistance to therapy
- Strategy to position bemcentinib as a cornerstone of treatment for NSCLC by combining with standard of care therapies

BGBC004 trial in NSCLC

NSCLC patients tend to initially respond well to targeted therapies but virtually all develop resistance over time.

The BGBC004 trial is designed to test the hypothesis whether AXL inhibition 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: Phase Ib/II trial in NSCLC of bemcentinib with TARCEVA® (erlotinib)

	Dose escalation (completed) & expansion (ongoing)		Expected readout
Stage IIIb or IV disease EGFR mutation positive 33 enrolled as of March 15th 2018	**Phase Ib** **Arm A1:** bemcentinib safety as monotherapy **Arm A2:** Dose finding in combination	**Safety** Efficacy, PK, biomarkers	**Read-out expected 2H 2018**
	Phase II **Arm B: 2nd line** *Resistance reversal* **bemcentinib 200mg daily + erlotinib daily**		
	Phase II **Arm C: 1st line** *Resistance prevention* **bemcentinib 200mg daily + erlotinib daily**		

Source: NCT02424617

BGBC004 arm A1: Phase Ib trial in NSCLC of bemcentinib as monotherapy – safety as single agent

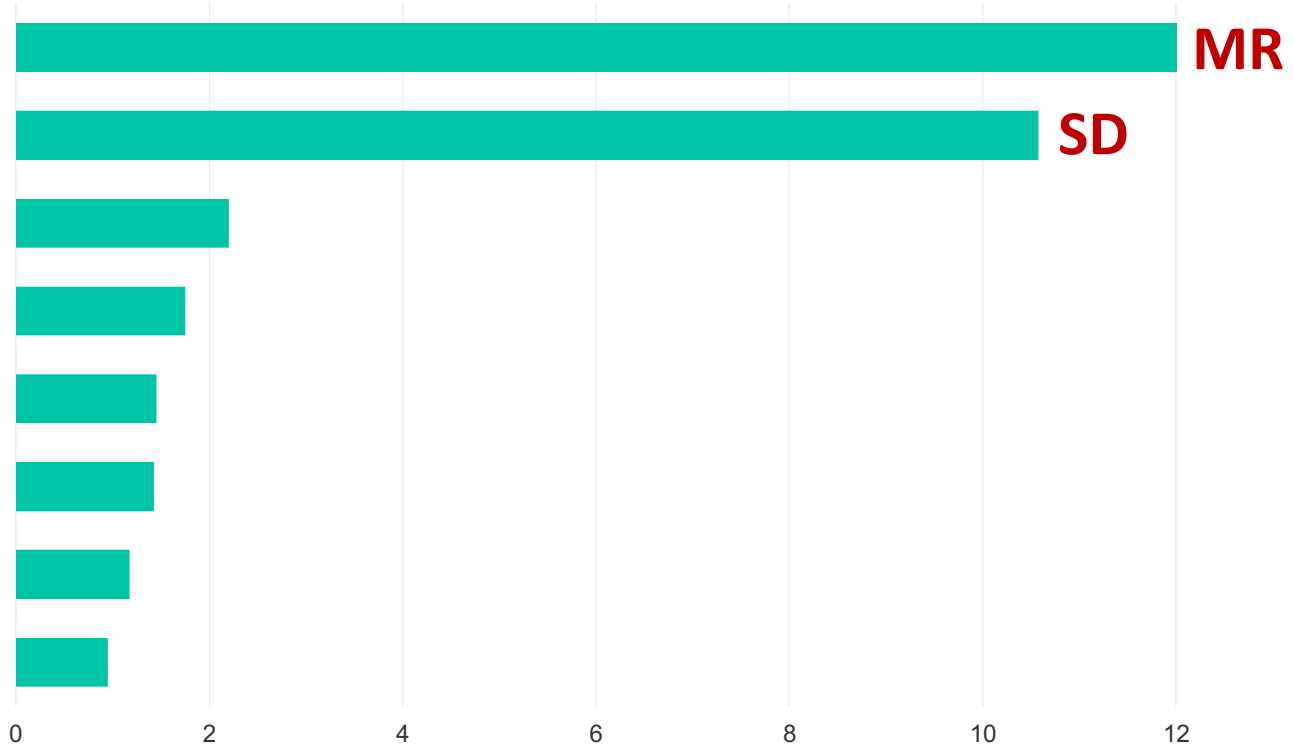
Part A1 patient population

- **All comer patient population**
- **Median 5 lines** (2 – 10) prior therapy
- **6 pts stage IV, 2 pts stage IIIB**
- **Average age:** 65 (58-77)

Outcome:

- Safety: Very well tolerated
- RP2D bemcentinib: 200 mg/d
- 2/8 patients with durable benefit

Duration of treatment (months)

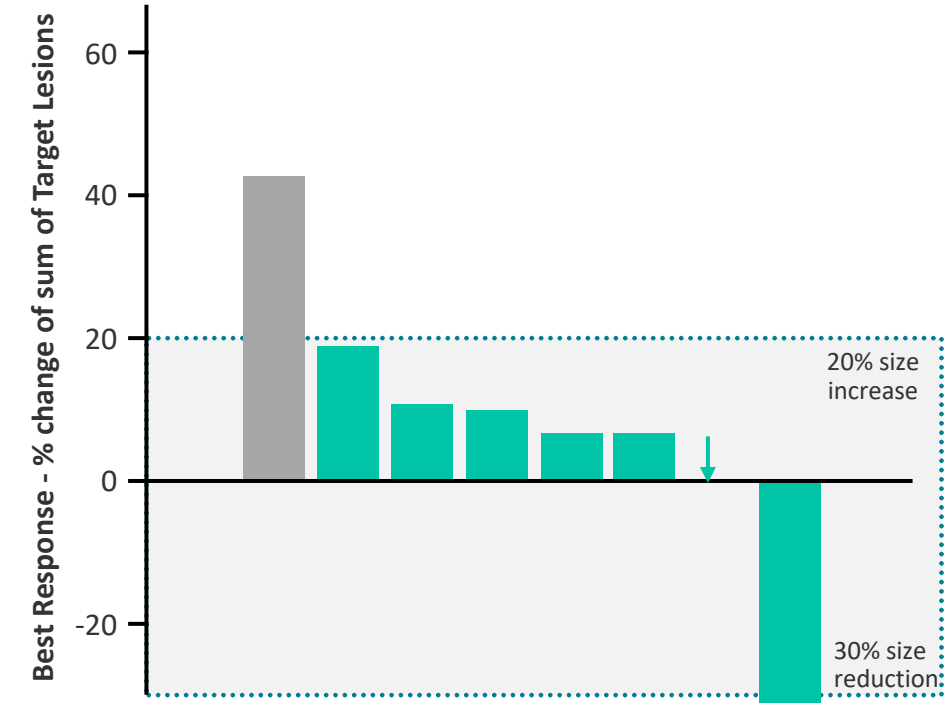


MR: minor response (19%shrinkage)

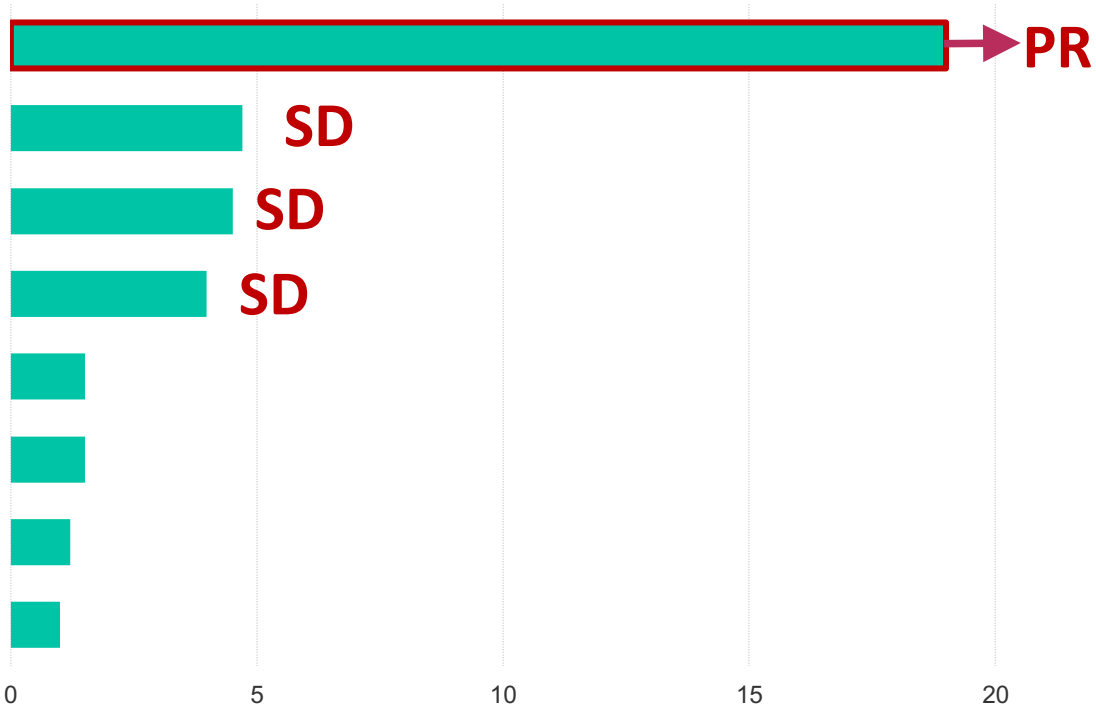
Source: Byers *et al* World Conference on Lung Cancer

BGBC004 arm A2: Phase Ib trial in NSCLC of bemcentinib with TARCEVA (erlotinib)

Waterfall plot of best response



Duration of treatment (months)



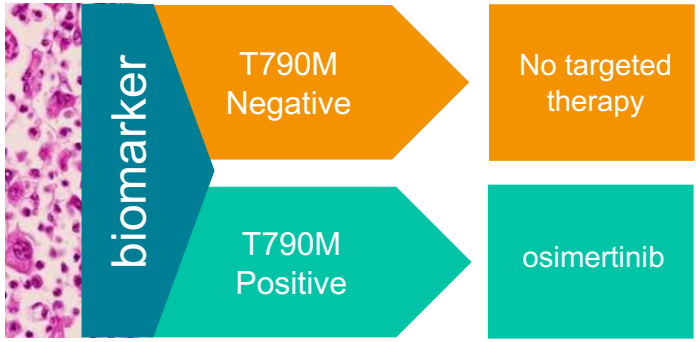
- **Full dose bemcentinib (200 mg daily) was well tolerated with 150 mg erlotinib**
- **Median # prior therapies:** 1 (1-3)

PR: Partial response SD: Stable Disease

Source: Byers *et al* World Conference on Lung Cancer

BGBC004: Phase II arm B, erlotinib resistance reversal

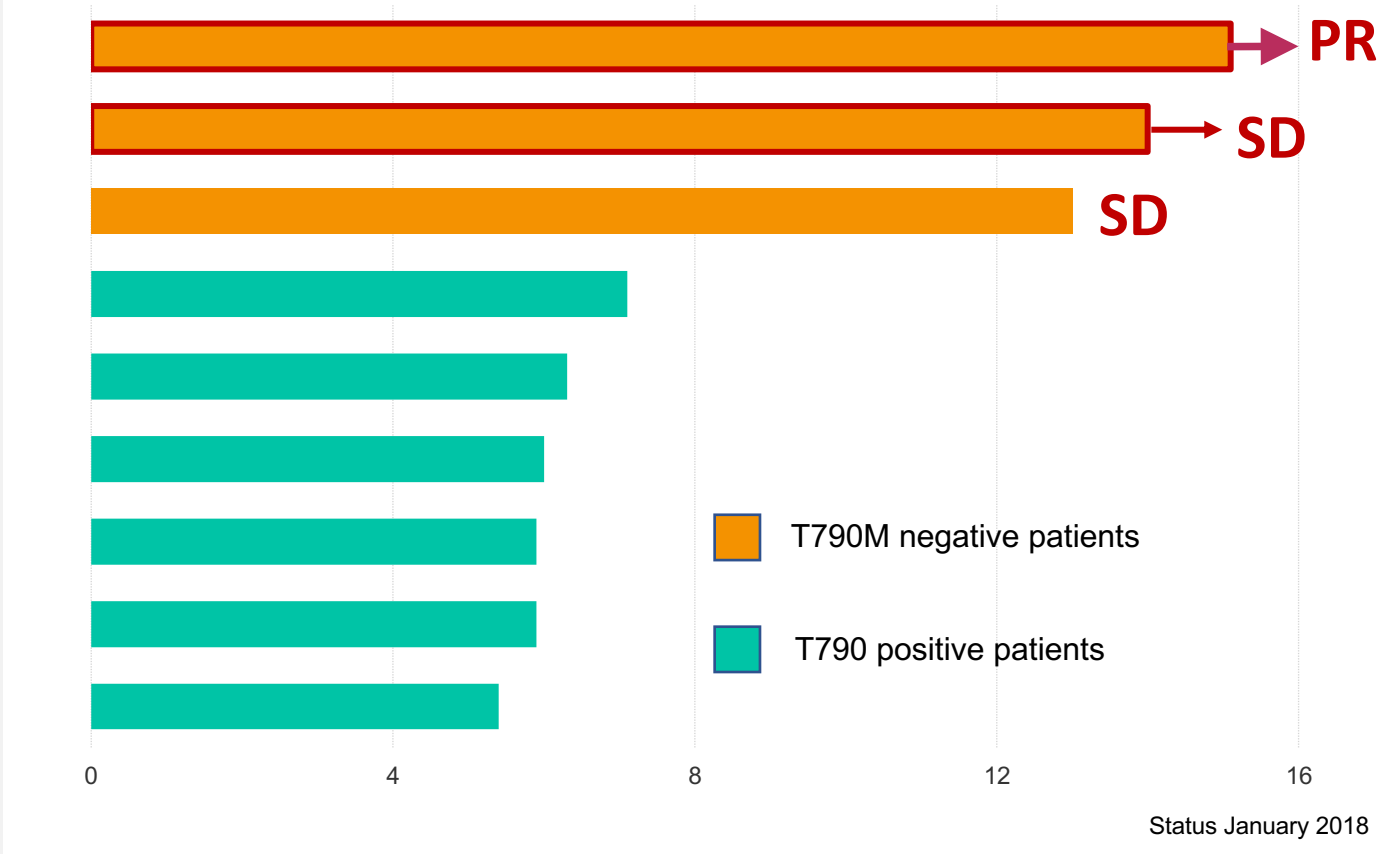
No targeted therapy available for 2nd line T790M negative patients*



Arm B patient population

- **Progressed on 1st line approved EGFR TKI therapy** (erlotinib, afatinib, gefitinib)
- **Median 3 lines (2 – 12)** prior therapy
- **Typical EGFRm population**
  - 5 of 9 pts are Asian, 6 females

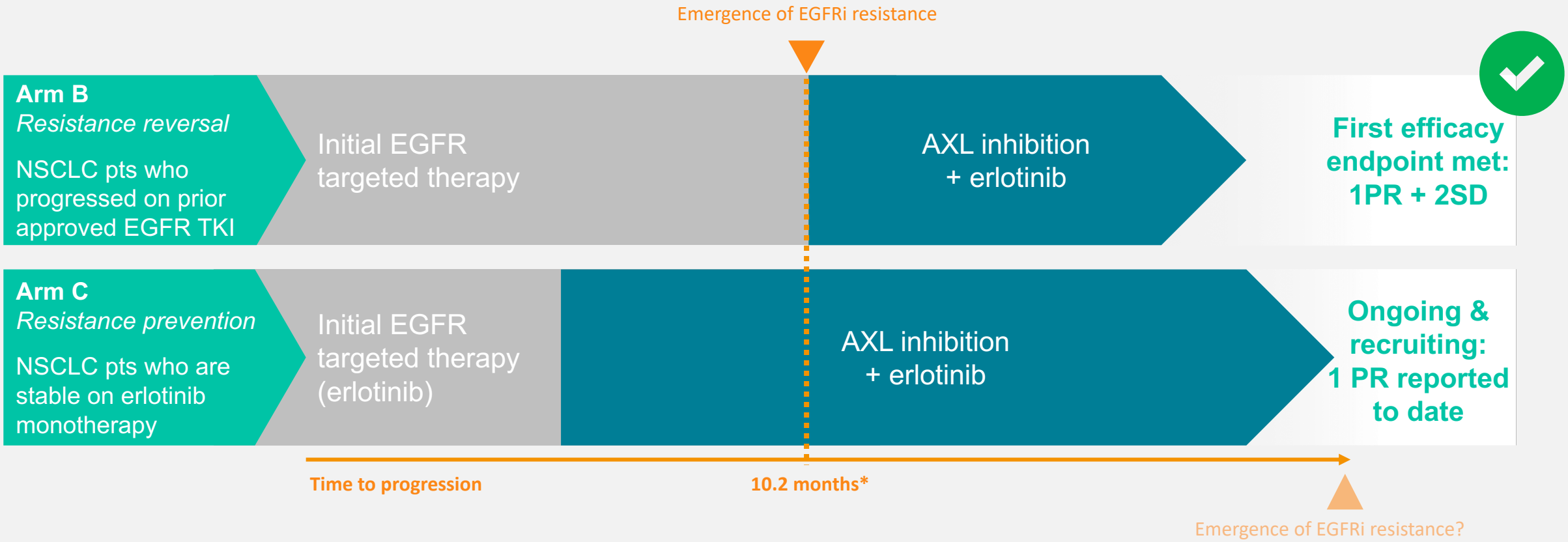
Duration of treatment (weeks)



* Astra Zeneca press release Sep 8th 2017: »Tagrisso shows potential as a new standard of care in 1st-line EGFR-mutated lung cancer at ESMO 2017 Congress»

Phase II (arm B & C): Designed to evaluate the potential of bemcentinib to reverse and prevent acquired resistance to EGFR targeted therapy:

Arm B successfully completed first stage



* FLAURA trial comparator arm, SoC erlotinib or gefitinib

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. Response rates are low and PFS short.

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

- Enhance responses to chemotherapy

when given in combination with docetaxel in previously treated (last line) NSCLC patients

Docetaxel is last line treatment option in heavily pre-treated NSCLC patients

(85,000* NSCLC patients receive docetaxel in later line therapy)

Published results in previously treated NSCLC with docetaxel
ORR 0% - 14%

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

(1) Borghaei, NEJM (2015) (2) Marinis ESMO 2017(3) Keytruda label (4) Levy, JTO 2014 (5) Ramlau JCO 2012
* company estimates – 7MM

BGBIL005: Phase I/II trial in NSCLC, bemcentinib with docetaxel –ongoing

NSCLC (2nd line – progressed/treatment-refractory disease) – *Investigator-sponsored study*

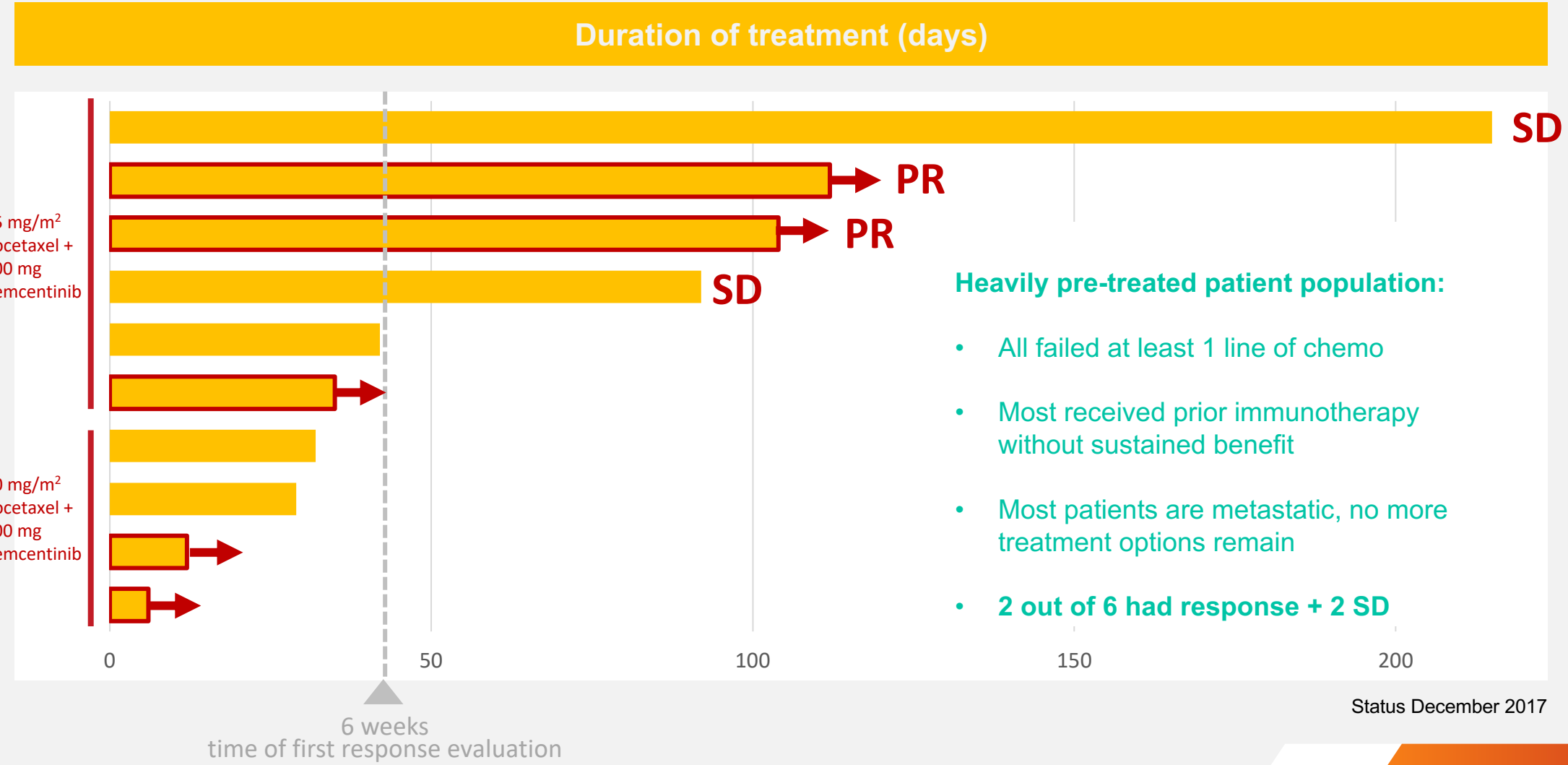
	3+3 dose escalation & expansion		Expected readout
Advanced NSCLC, exhausted all treatment options **up to 30 pts** **any prior treatment**	**Single arm** bemcentinib 100 mg/d Docetaxel 60 mg/m2	**Safety** ORR, PFS, OS, PK, biomarker assessments	**Initial read-out expected 2H 2018**

Sponsor Investigator: Dr David Gerber, UTSW Dallas

"The vast majority of my lung cancer patients progress onto chemotherapy, combining this with bemcentinib may significantly improve the performance of the chemo and could lead to meaningful disease modification in some patients."

Source: NCT02424617

BGBIL005: Phase I/II trial in NSCLC, bemcentinib with docetaxel – ongoing



Heavily pre-treated patient population:

- All failed at least 1 line of chemo
- Most received prior immunotherapy without sustained benefit
- Most patients are metastatic, no more treatment options remain
- **2 out of 6 had response + 2 SD**

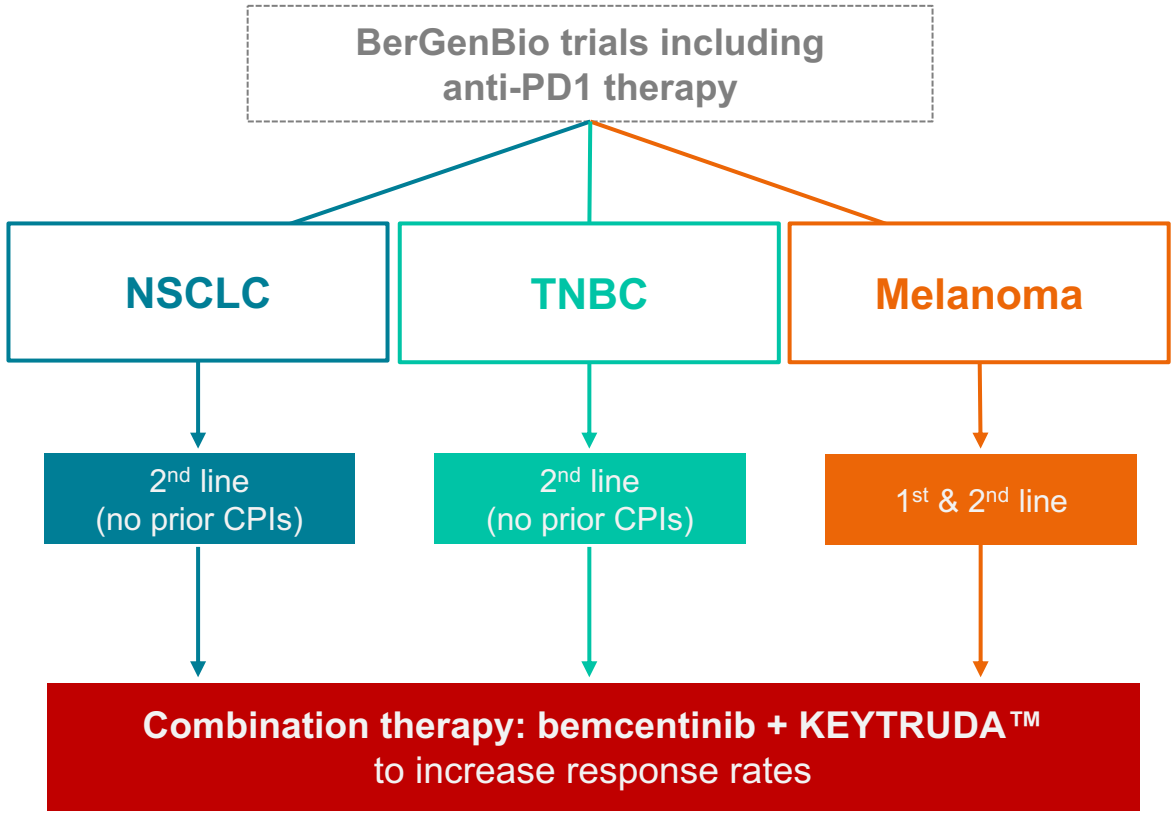
Status December 2017

PR: Partial response; SD: stable disease

AXL inhibition as a cornerstone of therapy in combination with Immune Oncology (checkpoint inhibitors)

BGBC008, BGBC007, BGBIL006

Combination with bemcentinib to increase efficacy of anti-PD1 therapy



- A significant proportion of patients do not respond to checkpoint inhibitor therapy
- Non-responders to checkpoint therapy have been shown to express AXL at higher rates
- Inhibiting AXL may increase the number of patients responding to checkpoint therapy
- Comprehensive biomarker programme analysing AXL, PD-L1 and immune signature

Source: Gay *et al* British Journal of Cancer (2017)

Favourable safety and tolerability reported for bemcentinib/KEYTRUDA combo across three indications

Nature of SAE profile of combination similar to KEYTRUDA alone

	TNBC NCT03184558	NSCLC NCT03184571	Melanoma* NCT02872259	total	
	19	9	6	34	
SOC	n	n	n	n	%
Skin and subcutaneous tissue disorders	4	0	0	4	12
General disorders and administration site conditions	3	0	1	4	12
Gastrointestinal disorders	3	0	0	3	9
Investigations	3			3	9
Blood and lymphatic system disorders	1	0	0	1	3
Cardiac disorders	1	0	0	1	3
Hepatobiliary disorders	0	1	0	1	3
Respiratory, thoracic and mediastinal disorders	1	0	0	1	3

Combo well tolerated over extended periods:

Ongoing treatment durations of over 6 months on KEYTRUDA / bemcentinib combo reported at World Melanoma (Oct 2017)

Source: Yule *et al* ASCO-SITC Clinical IO Symposium (January 2018)
* Investigator led 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 can

- **Enhance** responses to immunotherapy

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

Clinical collaboration with Merck & Co. (MSD) MERCK

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

NSCLC Adenocarcinoma of the lung

MERCK

	Simon two stage (interim after 22 pts)		Expected readout
Previously treated, unresectable adenocarcinoma of the lung up to 48 pts any PD-L1 expression any AXL expression no prior IO	**Single arm** bemcentinib 200mg/d KEYTRUDA 200mg/3w	**ORR** Safety, DoR, TtP, OS at 12 mo, response by biomarker expression	**Initial read-out expected 2H 2018**

BGBC007 trial in TNBC

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

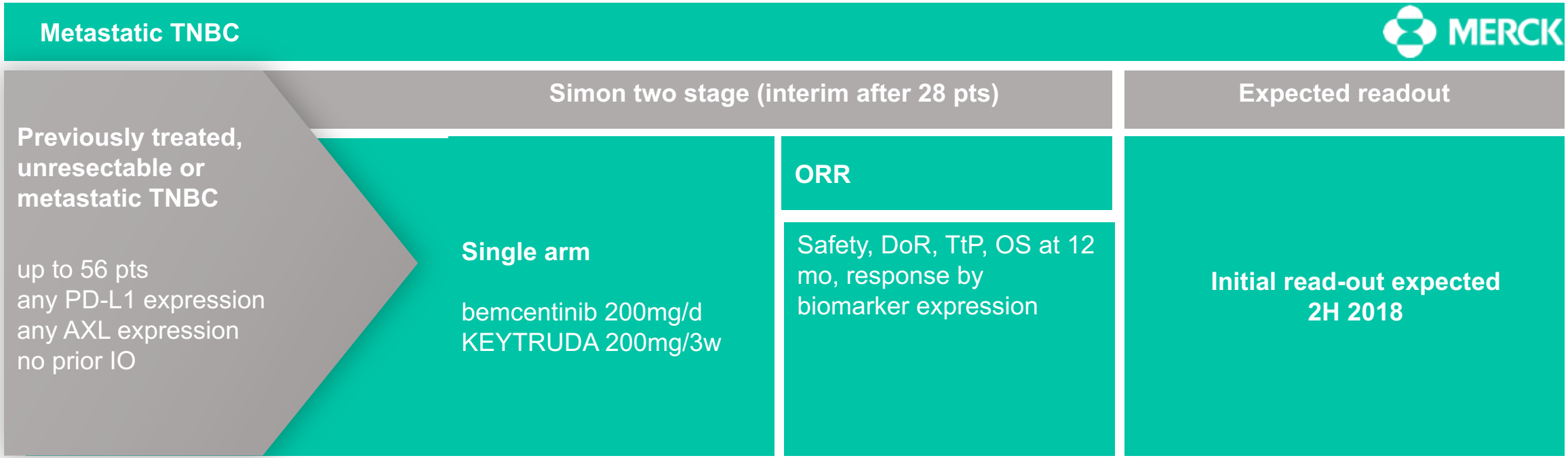
The BGBC007 trial is designed to test the hypothesis whether AXL inhibition with bemcentinib can

- **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



BGBIL006 trial in melanoma

Although responses to TKIs are rapid, resistance ultimately emerges. Monotherapy checkpoint inhibitor responses can be further improved.

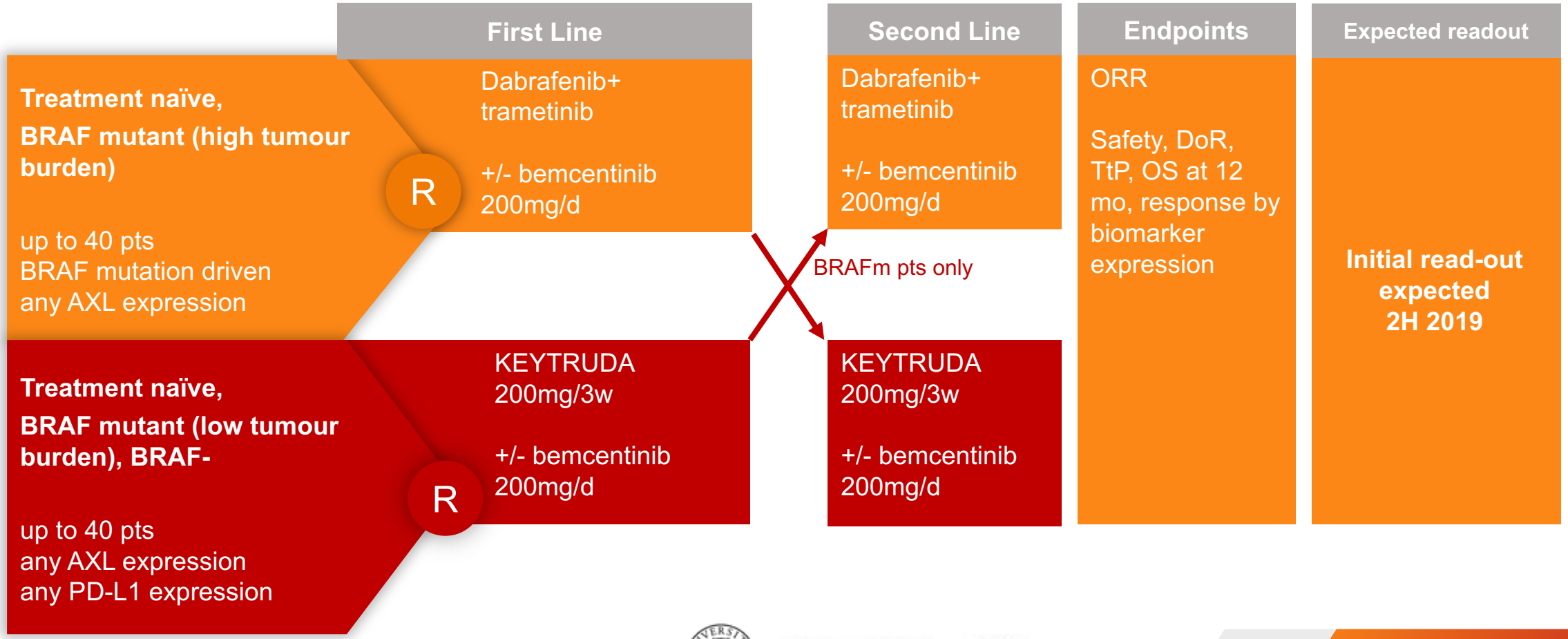
The BGBIL006 trial is designed to test the hypothesis whether AXL inhibition can

- **Enhance** responses to immunotherapy
- **Enhance** responses to targeted therapy

when given in combination with pembrolizumab or dabrafenib/trametinib in treatment naïve melanoma patients

BGBIL006: Randomised Phase II trial of bemcentinib in combination with targeted and I/O therapies in Melanoma

Melanoma, randomised SoC (KEYTRUDA or BRAF/MEKi) +/- bemcentinib



Source: Straume *et al* World Conference on Melanoma (October 2017)

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 low dose 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

R/R AML patients have no approved treatment options

Experimental agents report ORR 0-11%

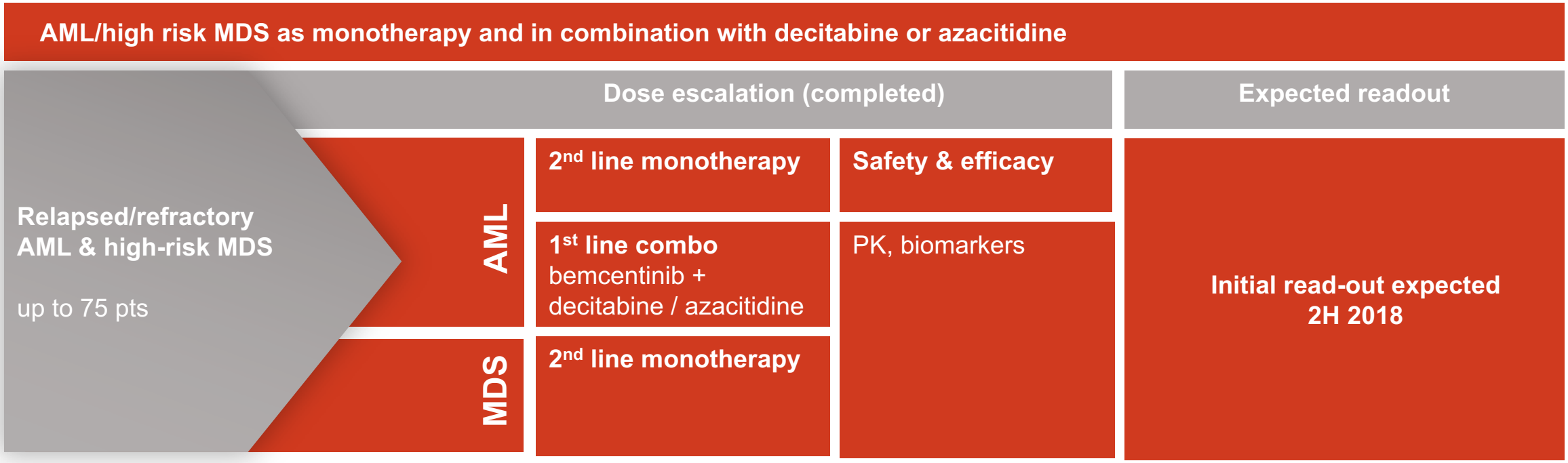
Clinical trial data for R/R AML patients from ASH December 2017

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

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

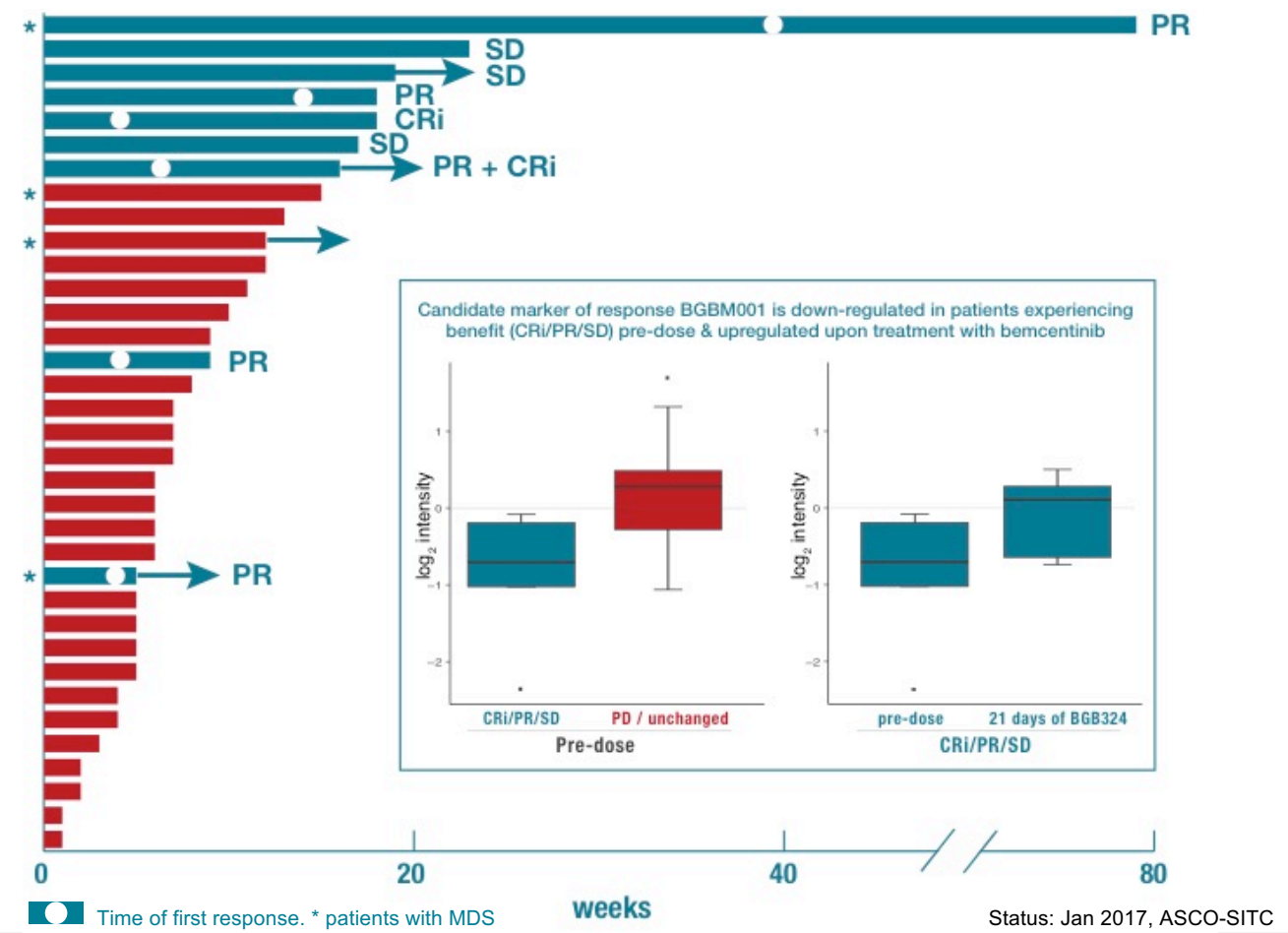
(1) ASH 2017 abstract 2622 (2) ASH 2017 abstract 1353 (3) ASH 2017 abstract 1356 (4) ASH 2017 abstract 1343 (5) ASH 2017 abstract 725 (6) ASH 2017 abstract 1377

BGBC003: Phase Ib/II trial in AML & MDS



Source: NCT02424617

Bemcentinib single agent reported 19% ORR in R/R AML & high risk MDS patients[1]



Status: Jan 2017, ASCO-SITC

Early efficacy and favourable safety

- **19% Response Rate**
- **(CRi + PR)**
  - 2 CRi
  - 5 PRs
- **Correlation with predictive biomarker candidates**
  - Proprietary predictive and PD biomarkers identified
- **Well tolerated**

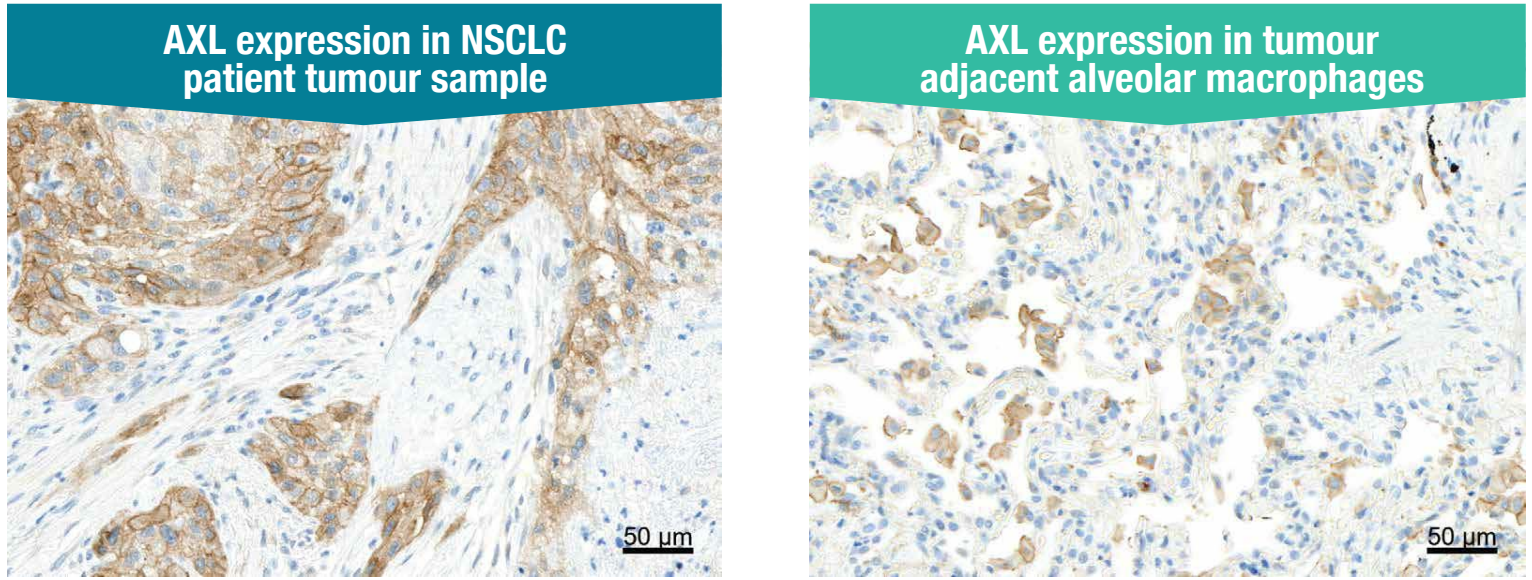
(1) Loges *et al* ASH 2017
American Society of Hematology
Helping hematologists conquer blood diseases worldwide

BerGenBio

Companion diagnostic immunohistochemistry (IHC) method developed and validated

Tumour markers & tumour immune infiltrate

AXL can be detected in patient tumour and immune cells



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

Source: Yule *et al* ASCO-SITC Clinical IO Symposium (January 2018)

Bemcentinib recently reported Proof of Concept Phase II data

BGBC008: **NSCLC**

BGBC007: **TNBC**

BGBIL006: **Melanoma**

+ checkpoint inhibitors

BGBIL006: **Melanoma**

BGBC004: NSCLC

+ targeted therapy

BGBC003: **AML**

BGBIL005: NSCLC

+ chemotherapy

BGBC003: AML/MDS

monotherapy

Bemcentinib foundation therapy

BGB149: First-in-class AXL functionally blocking antibody

- ✓ IgG1 fully humanised
- ✓ GMP manufacturing complete
- ✓ GLP tox ongoing
- ✓ FiM H2 2018

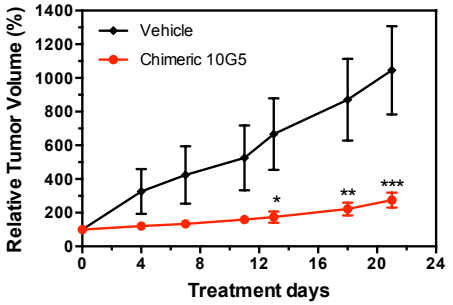
Highly selective to human AXL

High affinity (K_D: 500pM)

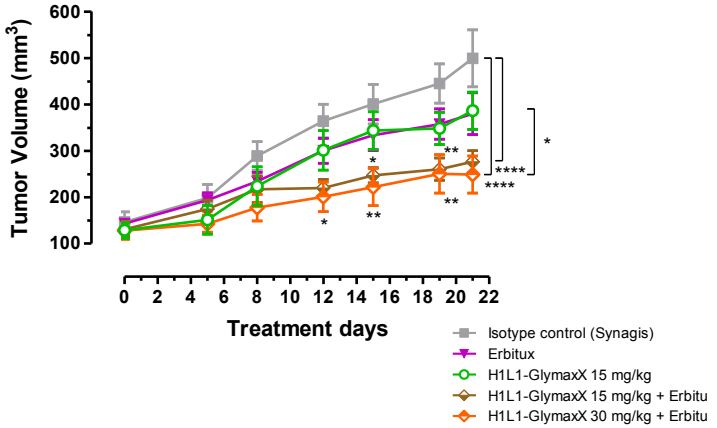
Patent position on CDR sequences

Opportunities in oncology and non-oncology

Potent anti-tumour effect *in vivo* (AML)[1]



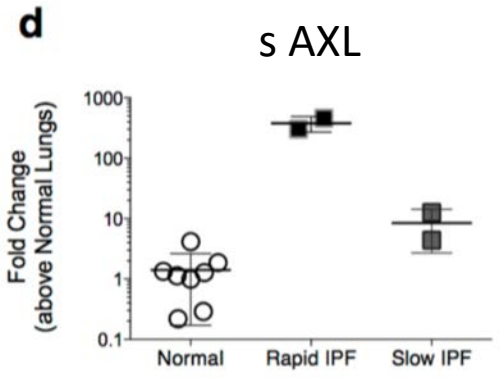
Enhances effect of erbitux *in vivo* (NSCLC)[2]

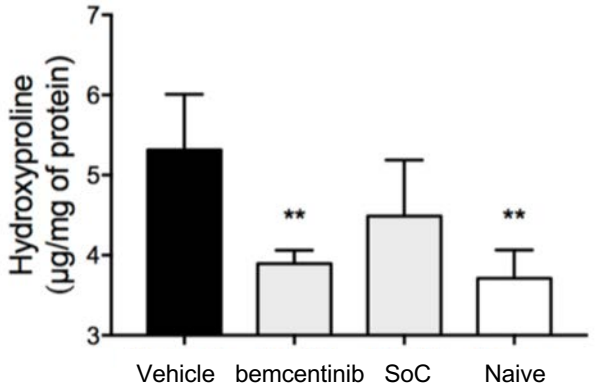


(1) MV4-11 Nude model; in house data (2) A549 Nude model; in house data

AXL inhibition as a potential therapy in fibrotic diseases

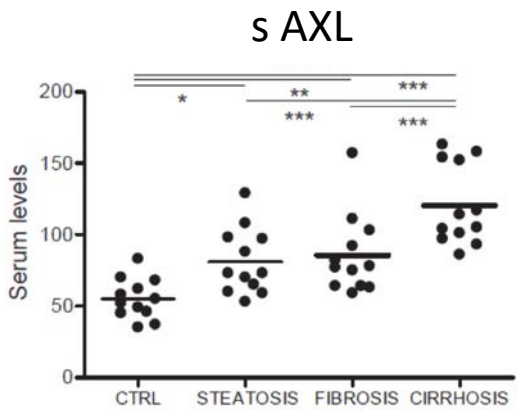
Idiopathic Pulmonary Fibrosis

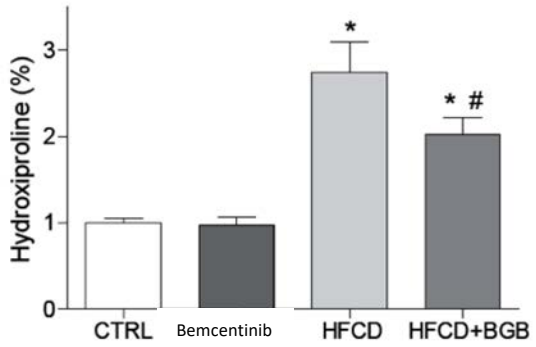




Serum AXL elevated in Idiopathic Pulmonary Fibrosis, selective AXL inhibition superior to SoC *in vivo*[1]

Non Alcoholic Steatohepatitis (NASH)



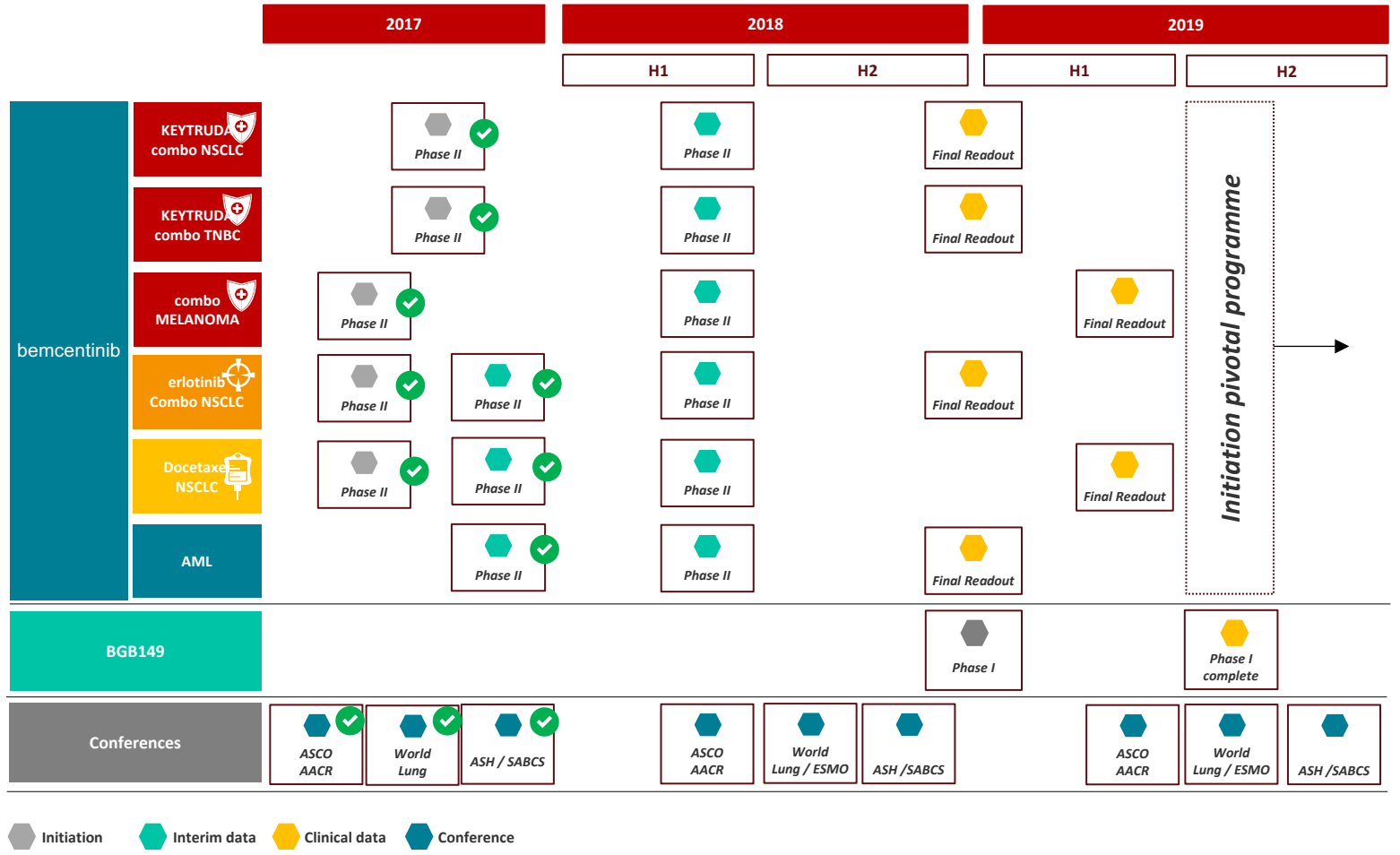


Serum AXL elevated in NASH, selective AXL inhibition active *in vivo*[2]

HFCD = high-fat, choline deficient diet
Leads to NASH in animal models

(1) Espindola, 2018 (2) Barcena EASL 2018

Significant milestones expected in 2018 & 2019



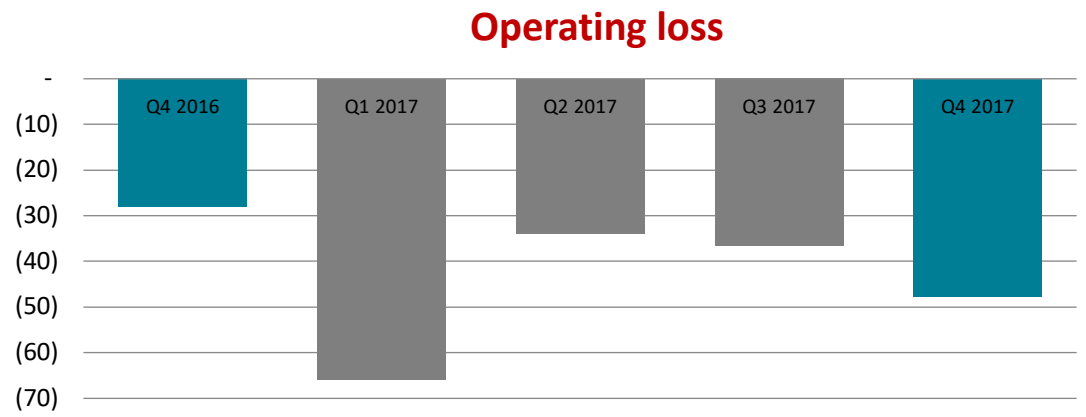
Significant milestones expected over the next 12 months:

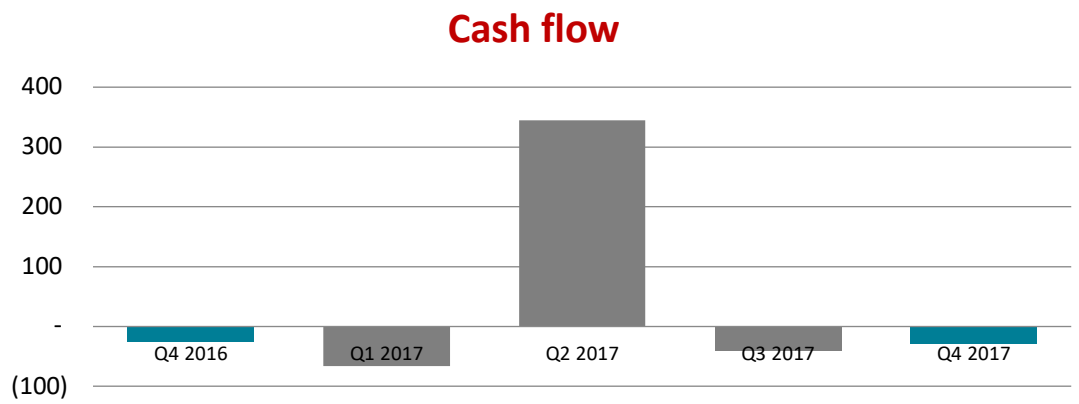
- **Interim clinical data** from 6 ph II trials **H1'18**
- **Final readout** from 4 phase 2 trials **in H2**
- **Initiation of AXL antibody** BGB149 clinical trials **in H2**

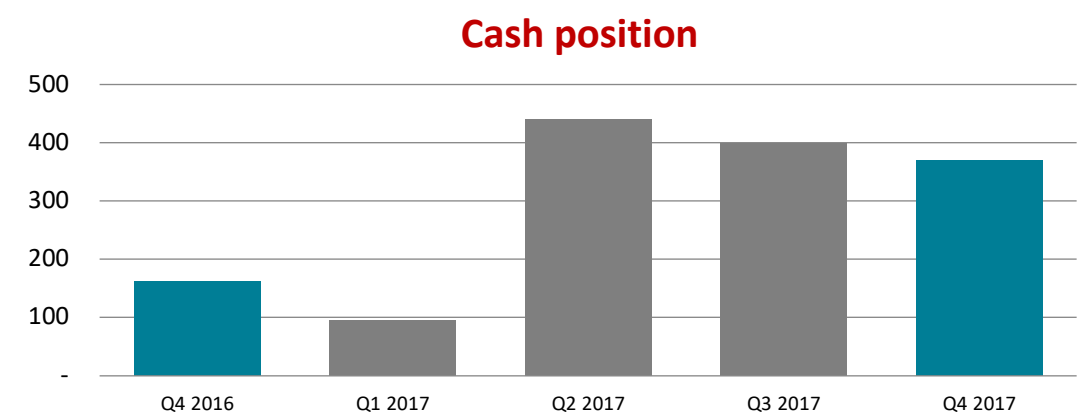
 NB: Progression of ongoing and start-up of new clinical trials are subject to customary regulatory reviews and approvals

Key financials (Q4 / YE 2017)

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.

Thank you.

For further information please visit
www.bergenbio.com

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

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