



Q3 2019 REPORT HIGHLIGHTS AND FINANCIALS

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BerGenBio – world leaders in AXL therapeutics



Bemcentinib

First-in-class AXL inhibitors for aggressive cancers

Bemcentinib targeting unmet medical need in the largest solid and blood malignancies – NSCLC and AML – ca. US\$25bn opportunity

Once-a-day bemcentinib pill – demonstrated promising efficacy and safety in > 250 patients, many with durable benefit > 2 years

Phase II LDAC combination expansion in 2L R/R AML underway, preliminary data expected 1H 2020.

Fast Track and Orphan designations granted by FDA in USA

Phase II Keytruda combination 2LNSCLC, met endpoints, and exceeded Keytuda monotherapy response and survival data by three-fold*.

Ongoing Phase II Keytruda combination 2L NSCLC studies to access large emerging patient populations, preliminary data expect 1H 2020.

BerGenBio pipeline - 3 selective AXL inhibitors in clinical development

Multiple attractive opportunities in AML and NSCLC

Candidate	Targeted Indication	Discovery	Preclinical	Phase I	Phase II	Phase III.
Bemcentinib	>2L AML	► Ph II safety and POC efficacy demonstrated in 39 patient trial				
Bemcentinib (combination with LDAC)	2L AML	► Ph Ib Safety demonstrated, efficacy POC expansion study- 28 pts.				
Bemcentinib (combination with Keytruda) 	2L NSCLC. (chemo refractory)	► Ph II safety and POC efficacy demonstrated in 50 patient trial, end points met				
	2L NSCLC (CPI refractory)	► Ph II POC study on going 29 pts				
	2L NSCLC (CPI+chemo refractory)	► Ph II POC study on going 29 pts				
Tilvestamab (BGB149)	TBA	► Ph I Healthy volunteer study ongoing				
BGB601 	Various solid tumors	► Ph I safety study ongoing				

Q3 2019 and post-period highlights

New Phase II clinical data from in NSCLC presented at ASCO, WCLC, ESMO & SITC

Bemcentinib in combination with KEYTRUDA® superior ORR, mPFS and OS data in 2L AXL positive patients*

Primary & Secondary endpoint of ORR met in Phase II 2L NSCLC (cohort A) in combination with KEYTRUDA®

Three-fold improvement over Keytruda monotherapy**

Proprietary composite AXL tumor-immune (cAXL) score developed to identify & diagnose patients that show durable benefit

Five-fold selective for ORR and three-fold mPFS improvement for cAXL +ve patients reported to date

FDA Fast Track designation received for bemcentinib in relapse AML

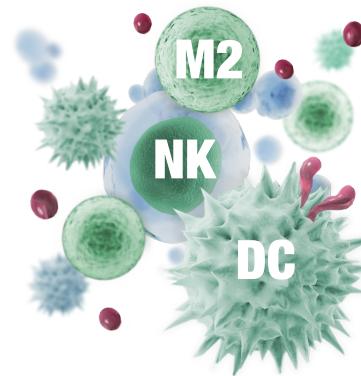
Phase Ib interim safety data in 1L Melanoma presented at ESMO

bemcentinib in combination with pembrolizumab or BRAF/MEK inhibitors was well tolerated by patients

Cash and Cash Equivalents at end of Q3 2019 NOK 289.5m

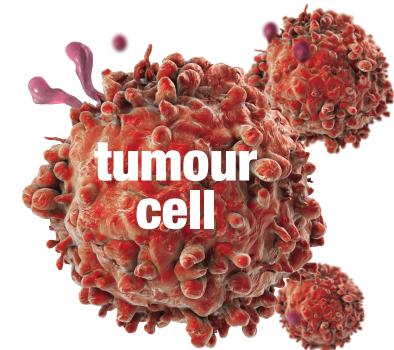
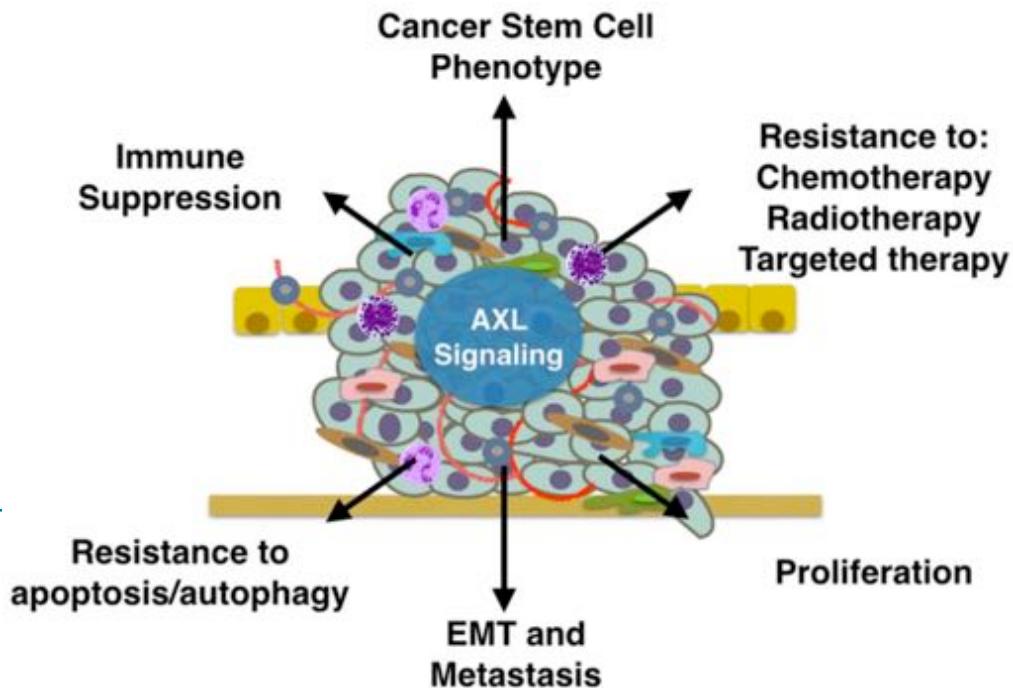
Operating loss of NOK 47.5m in Q3.

AXL is a key survival mechanism ‘hijacked’ by aggressive cancers and drives drug resistance, immune-suppression & metastasis



AXL increases on immune cells and suppresses the innate immune response

- M1 to M2 macrophage polarisation
- Decreased antigen presentation by DCs
- Prevent CD8+ T cell mediated cell death
- Activates Treg cells



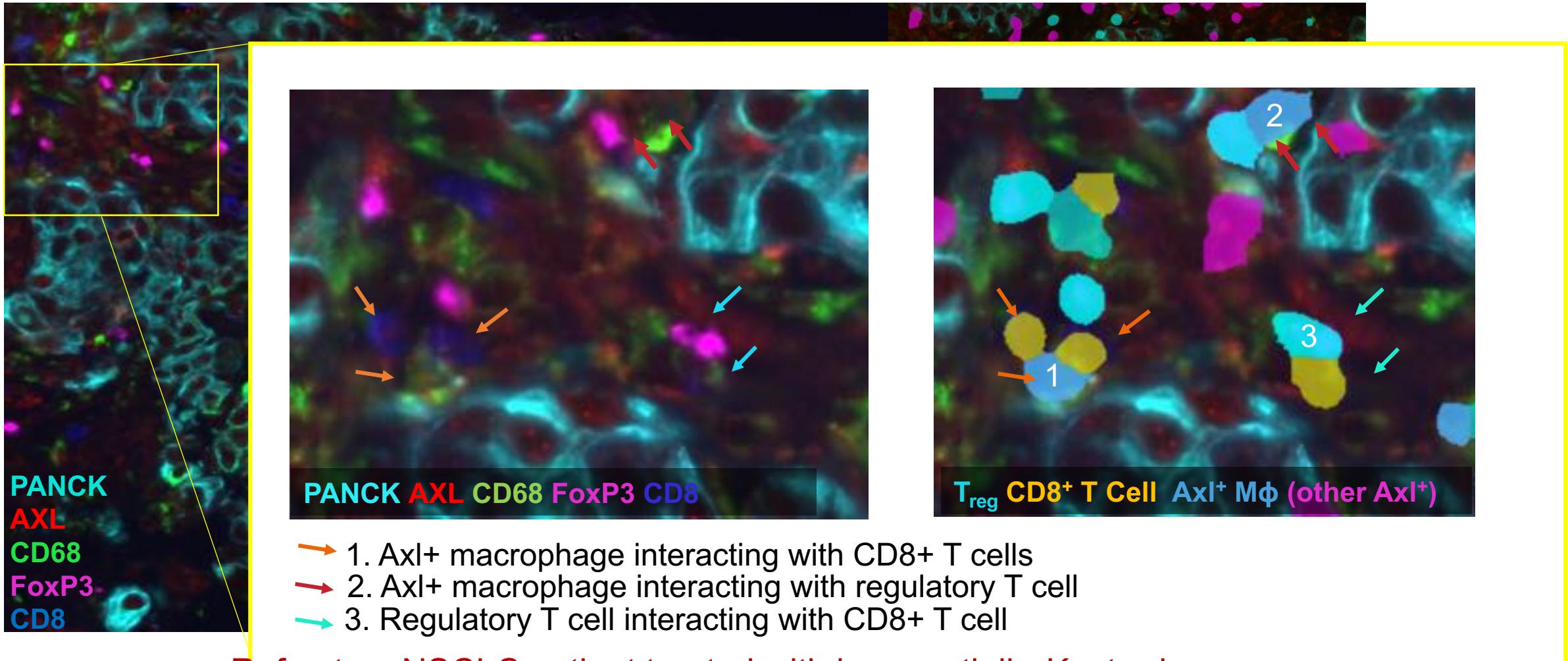
AXL increases on the tumor cell and causes cancer escape and survival

- Acquired drug resistance
- Immune cell death resistant
- Metastasis

AXL conditions the tumor micro-environment to suppress immune mediated cell death

Bemcentinib benefits patients who are not expected to respond to Keytruda

SITC 2019: Advanced multispectral imaging technology allows us to see tumor infiltrating AXL+ macrophages interact with CD8+ T cells and T_{reg}s in pre-treatment biopsy sample from a patient. The proximity of the immune cells to tumor cells would predict this patient would not respond to Keytruda.

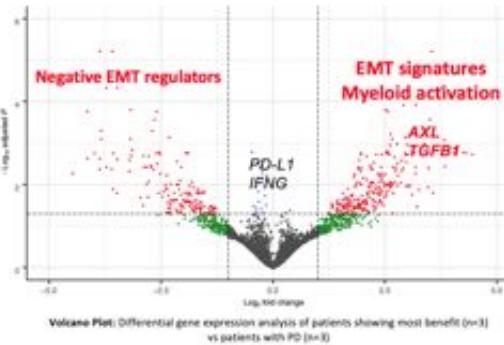


Refractory NSCLC patient treated with bemcentinib+Keytruda:
50% tumor shrinkage and ongoing response >95 weeks

BerGenBio's proprietary novel gene signature predicts patients that benefit from bemcentinib - pembrolizumab combination therapy



Novel gene signature predicts patients that benefit from bemcentinib-pembrolizumab combination therapy



- Responding patient gene expression matches signatures that predict poor outcome, lack of response to pembrolizumab, and are enriched for EMT and myeloid activation
- PD-L1 and IFNy expression do not predict response
- AXL expression in tumor and immune cells (composite score) is associated with response to combination treatment

34th Annual Meeting & Pre-Conference Programs



#SITC2019

Merck reported a gene signature from patients that did not respond to Keytruda monotherapy in many cancers, this was similar to the BerGenBio gene signature EXCEPT these patients did respond to Keytruda + bemcentinib

AXL inhibitors – emerging competitive landscape



Bemcentinib clinical development

Acute Myeloid Leukaemia (AML)

Objective: to develop a well tolerated, effective and convenient drug for this difficult to treat, elderly & frail patient population.

- ✓ Monotherapy ≥2L patients >75yrs
43% ORR in AXL +ve R/R AML
- ✓ LDAC chemo combination 2L R/R patients >60 yrs



Acute Myeloid Leukaemia (AML)

Most common type of acute leukaemia in adults¹

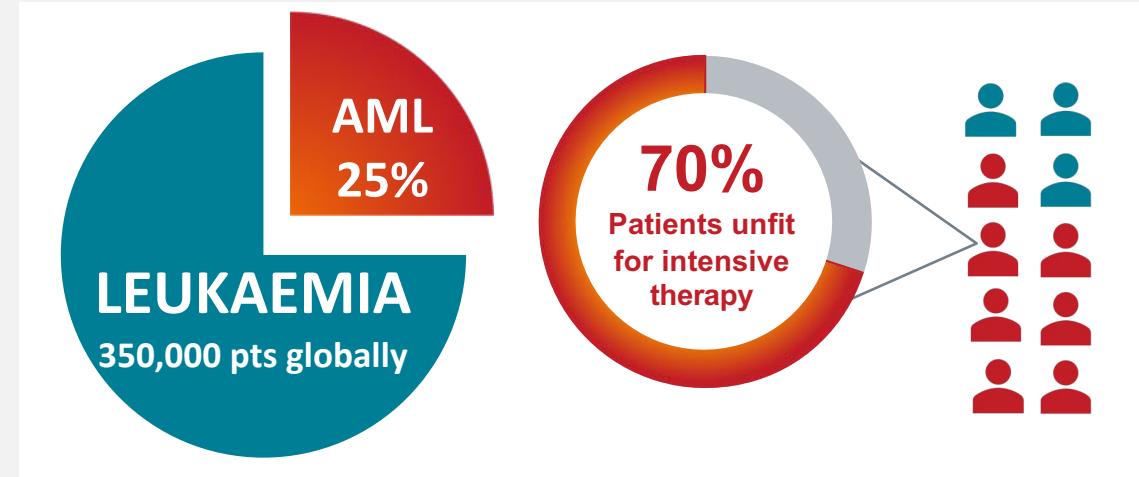
AML is a rare aggressive cancer of the blood and bone marrow characterised by difficult to treat malignancies

~ 20,000 new cases diagnosed and >10,000 deaths in the US in 2018²

AML makes up 32% of all adult leukaemia cases

Occurs in a predominantly elderly, frail patient population; 68% of patients diagnosed with AML were aged >60 years⁶

5 year survival rates of 3-8% in patients over 60 years old⁷

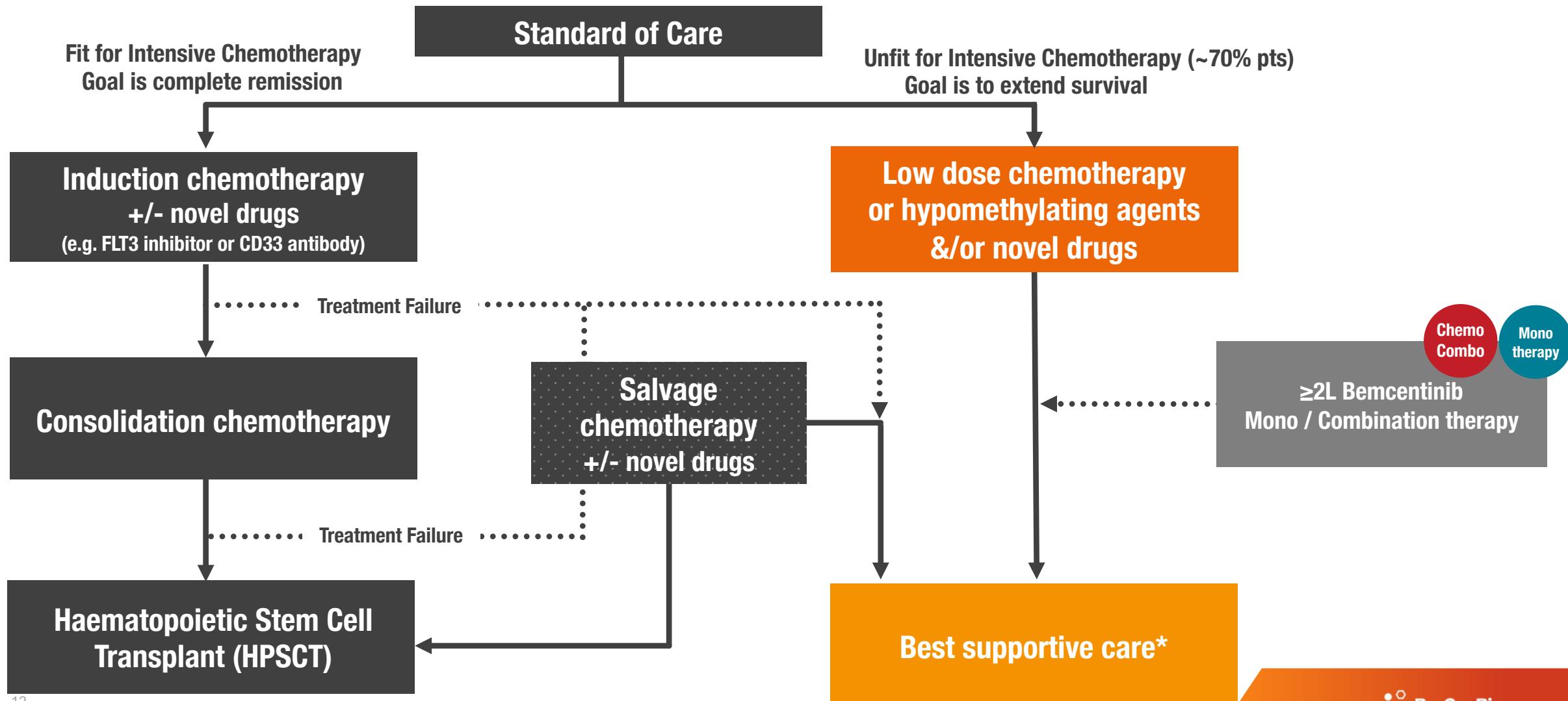


(1) Cancer.gov; (2) SEER; (3) https://www.who.int/selection_medicines/committees/expert/20/applications/AML_APL.pdf?ua=1ble

(4) <https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics> (5) <https://www.businesswire.com/news/home/20190319005442/en/> (6) <http://asheducationbook.hematologylibrary.org/content/2010/1/62.long>, (7) <https://www.ncbi.nlm.nih.gov/books/NBK65996/>

Acute myeloid leukemia (AML)

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



Clinical development to optimize bemcentinib clinical position for AML patients

FDA approved Fast Track and Orphan designation

≥2L Relapse patients >75yrs

No approved SoC

Bemcentinib Monotherapy

ASH 2018

AXL +ve* patients

14/27

52%

Stable Disease

3/14

21%

CR/Cri/CRp

6/14

43%

mDOR **3.1mo. (5.5* mo.)**

Safety profile was well tolerated

1L & 2L R/R patients >60 yrs

No approved SOC

Bemcentinib + LDAC

EHA 2019

CR/Cri/CRp

6/14

43%

mDOR **>8Mo.**

Responses occurred early, improved over time and included poor risk, previously treated patients. Bemcentinib appears well tolerated in combination with LDAC.

28 patient Ph II expansion cohort to initiate H2'19 to confirm signal in 2LR/R patient population : 2x patient population

Global randomized Ph IIb trial

U.S. Food and Drug Administration (FDA) has approved Fast Track Designation for bemcentinib

- U.S. Food and Drug Administration (FDA) has approved Fast Track Designation for bemcentinib for the treatment of elderly patients with acute myeloid leukaemia (AML) whose disease has relapsed.
- There are currently no marketed drugs specifically approved for all relapsed AML patients, representing a significant unmet medical need.
- Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
- The purpose is to get important new drugs to the patient earlier

Advantages of this designation include:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

BerGenBio has ongoing phase 2 trials in this indication and plans to seek regulatory advice from the FDA and European Medicines Agency (EMA) to determine the optimal regulatory path for bemcentinib in relapsed AML.

Thanks and acknowledgement to the entire BGB team for this achievement, especially :-

James Barnes PhD – Operations Director

Ian Thomas PhD – Associate Director Regulatory Affairs

Bemcentinib clinical development in Non Small Cell Lung Cancer (NSCLC)

Objective: to improve the effectiveness of immune check point inhibitor (CPI) (pembrolizumab/Keytruda) refractory NSCLC patients, with a well tolerated, effective, and convenient drug

Chemotherapy refractory patients

CPI refractory patients

CPI+Chemotherapy refractory patients



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

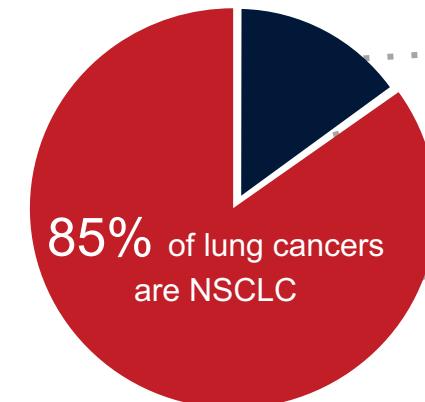
The largest cancer killer, most patients depend on drug therapy

The most common type of cancer

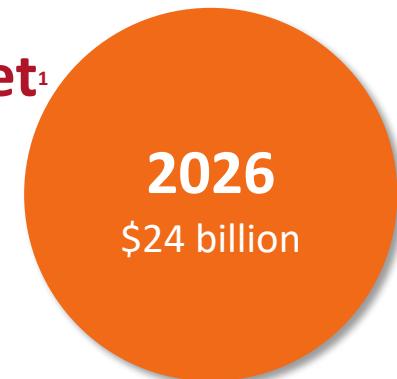
2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases¹

1.76 million lung cancer deaths/yr worldwide¹

5-year survival rate is 3.5% in patients with PD-L1 <1%, and **12.6%** in patients PD-L1 1-49%

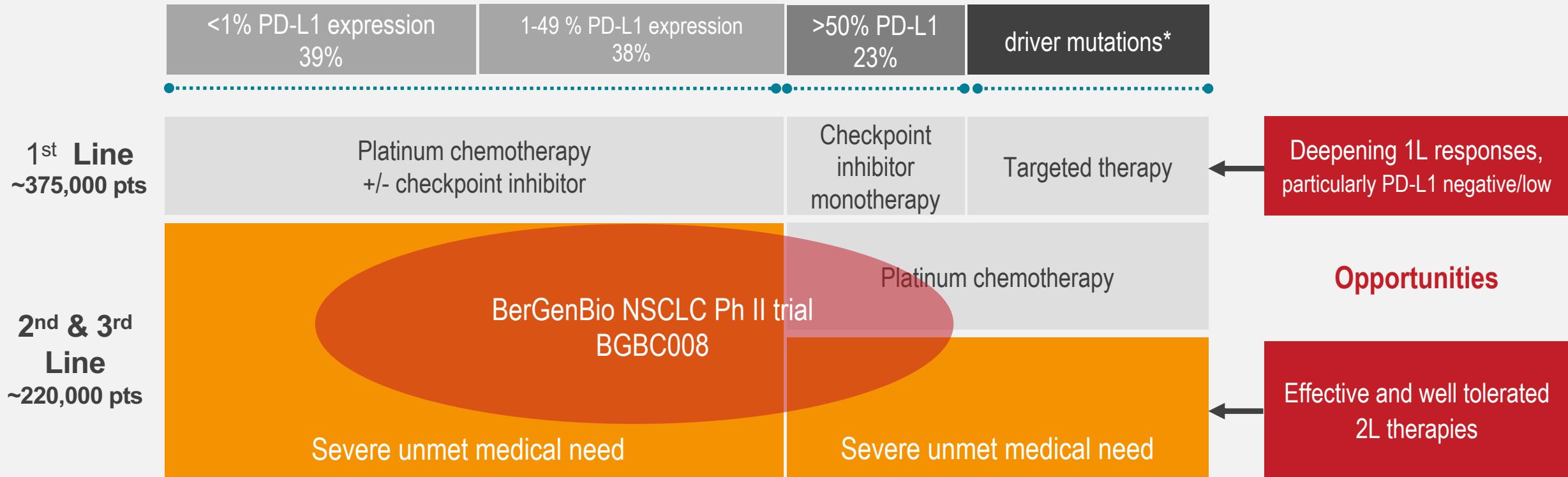


NSCLC Market¹



Non-Small Cell Lung Cancer (NSCLC)

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



Bemcentinib + KEYTRUDA in refractory NSCLC

Phase II Study Design



BGBC008
Phase II 2-stage study of
bemcentinib (BGB324) in
combination with
pembrolizumab

Inclusion criteria

- Adenocarcinoma histology
- Measurable disease
- Fresh tumor tissue
- AXL and PD-L1 All comers

Assessments

Efficacy

- Primary endpoint
 - Objective Response Rate
- Secondary endpoints
 - Duration of Response
 - Disease Control Rate
 - Time to Progression
 - Survival at 12 months
 - Response by Biomarker expression

Safety PK

Regimen

- Pembrolizumab 200mg fixed
- Bemcentinib 400mg loading dose, then 200mg OD

Cohort A

- Previously treated with a platinum containing chemotherapy
- 2nd line advanced adeno NSCLC

Interim Analysis

Stage 1

N=24 patients
(each patient has the potential for at least 24 weeks follow-up)

Stop at this stage for:
Futility (H0:15% if ≤ 3 responses)
Or unfavourable risk/benefit

Final Analysis

Stage 2

N=50 patients total
(each patient has the potential for at least 24 weeks follow-up)

Cohort B

- Previously treated with a checkpoint inhibitor (PD-L1 or PD-1 inhibitor)
- No more than 2 previous lines of treatment
- Must have had disease control for ≥ 12 weeks followed by progression
- 2nd or 3rd line advanced adeno NSCLC

Cohort C

- Previously treated 1st line with a checkpoint inhibitor- containing regimen in combination with a platinum-containing chemotherapy
- Disease control on 1st line therapy for ≥ 12 weeks followed by progression
- 2nd line advanced adeno NSCLC

Interim Analysis Cohorts B & C

Stage 1

N=13 patients/cohort

(each patient has the potential for at least 24 weeks follow-up)

Stop at this stage for
Futility (H0:15% if 0 responses)
Or unfavourable risk/benefit

Final Analysis Cohorts B & C

Stage 2

N=29 patients/cohort

(each patient has the potential for at least 24 weeks follow-up)

Cohort A Patient Disposition and Demographics*

Patient disposition	N
Screened	74
Enrolled	50
Evaluable	44
Ongoing	9

Patient demographics	N (%)
Age	Median
	39-82
ECOG at screen	0
	22 (44%)
Sex	1
	28 (56%)
Female	20 (40%)
Smoking Status	Smoker
	10 (20%)
	Ex-smoker
	29 (58%)
Never smoked	10 (20%)
Unknown	1 (2%)

Disease mutations	N (=50)
None	36 (72)
KRAS	7 (14)
TP53	2 (4)
EGFR	3 (6)
Other	4 (8)

Safety Summary

The safety profile of combination treatment is consistent with that of each individual drug

Treatment related adverse events were generally mild and reversible

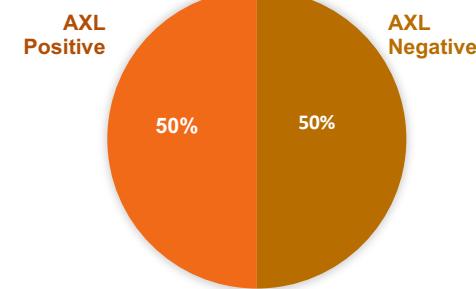
Treatment related adverse events were considered to be less severe and better tolerated than for other TKIs or CPI combinations used in NSCLC

Most frequent TRAEs ($\geq 10\%$ dosed pts)

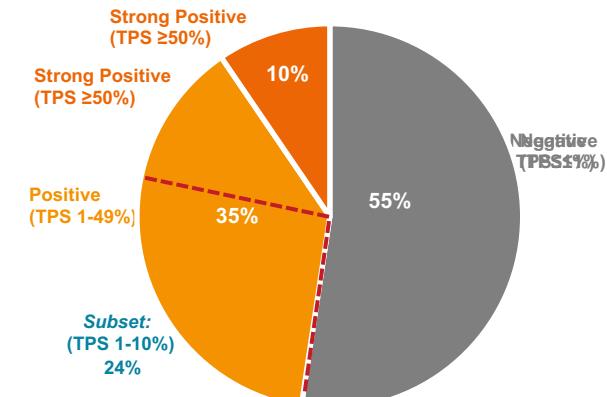
Event Terms	All Grades		Grade ≥ 3	
	n	%	n	%
Transaminase increased*	19	38 %	7	14%
Asthenia / Fatigue	15	30 %	4	8%
Diarrhoea	12	24 %	0	0%
Nausea	7	14 %	0	0%
Anaemia	6	12 %	1	2%
Blood creatinine increased	6	12 %	0	0%
Decreased appetite	6	12 %	0	0%
Pruritus	5	10 %	0	0%

Biomarker

cAXL status
n = 30



PD-L1 status
n = 37



Composite AXL tumor-immune Score (cAXL)

A proprietary diagnostic algorithm using IHC scoring AXL on tumor cells but also on immune cells

Patient A

Age:	64
Sex:	Female
Race:	white
Smoking Status:	ex-smoker (unknown)
(pack years)	
PD-L1 (TPS%)	-ve (0%)
AXL expression	
Tumour cells (H-Score)	-ve (0)
Immune Cells	Strong +ve
Stromal Cells	Weak +ve

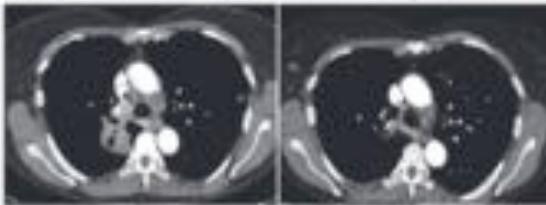


IHC evaluation of AXL:
Expression of AXL, both on cancer cells and cells in the stroma (right).

CT scan at baseline dated 31 Jan 2018



CT scan at C28 dated 30 Aug 2019



Patient A has received 4 cycles of cisplatin and pemetrexed with disease progression after 4th cycle prior to study entry. She started study treatment (pembrolizumab and bemcentinib) in Feb 2018 and her target lesions have shrunk from 57mm to 35mm with partial radiological response as per RECIST 1.1.

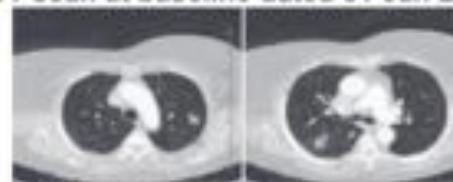
Patient B

Age:	76
Sex:	Female
Race:	white
Smoking Status:	ex-smoker (28.5)
(pack years)	
PD-L1 (TPS%)	Non-Evaluable
AXL expression	
Tumour cells (H-Score)	-ve (0)
Immune Cells	+ve
Stromal Cells	-ve

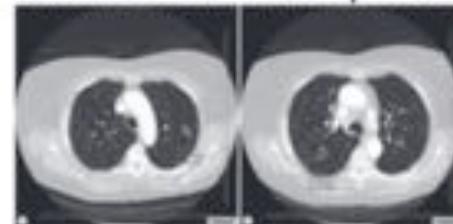


IHC evaluation of AXL:
Strong expression of AXL on alveolar macrophages (left).
cancer cells stained negative for AXL expression (right)

CT scan at baseline dated 31 Jan 2018



CT scan at C32 dated 23 Sept 2019



Prior to study entry Patient B received 6 cycles of carboplatin and pemetrexed from April 2015 to Jun 2015 with disease progression in Sep 2017. She started study treatment (pembrolizumab and bemcentinib) in Dec 2017 and her target lesions have shrunk from 32mm to 19mm with partial radiological response as per RECIST 1.1

ESMO 2019: AXL IHC staining

Patient A: RESPONDER

- AXL stained +ve on tumor cells
- 61% tumor shrinkage

Patient B: RESPONDER

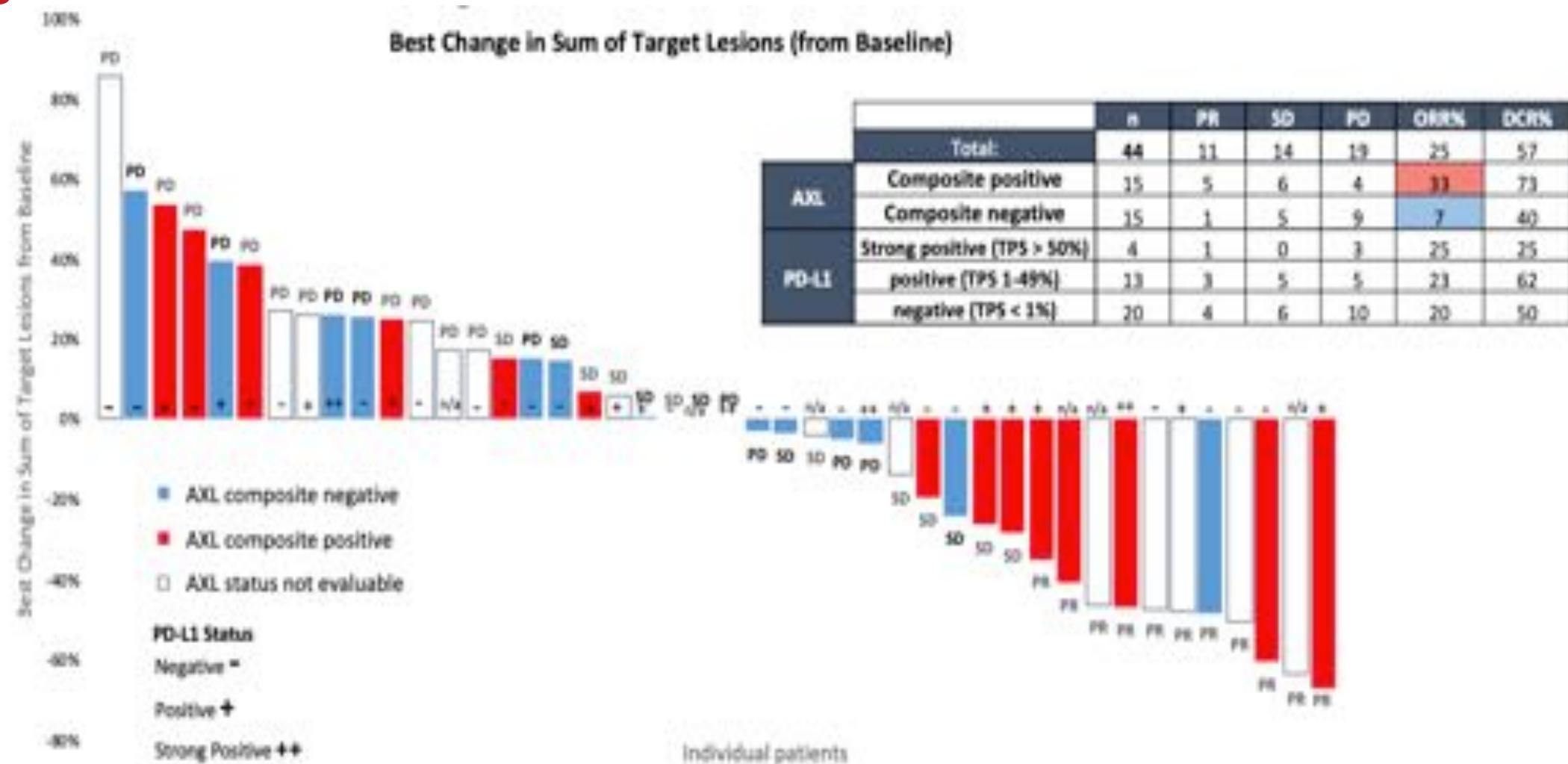
- AXL stained -ve on tumor cells
- 59% tumor shrinkage

WHY?

- We see AXL +ve staining on lung macrophages (immune suppressive cells)
- When we inhibit AXL with bemcentinib we stop the macrophages suppressing immune mediated cancer death

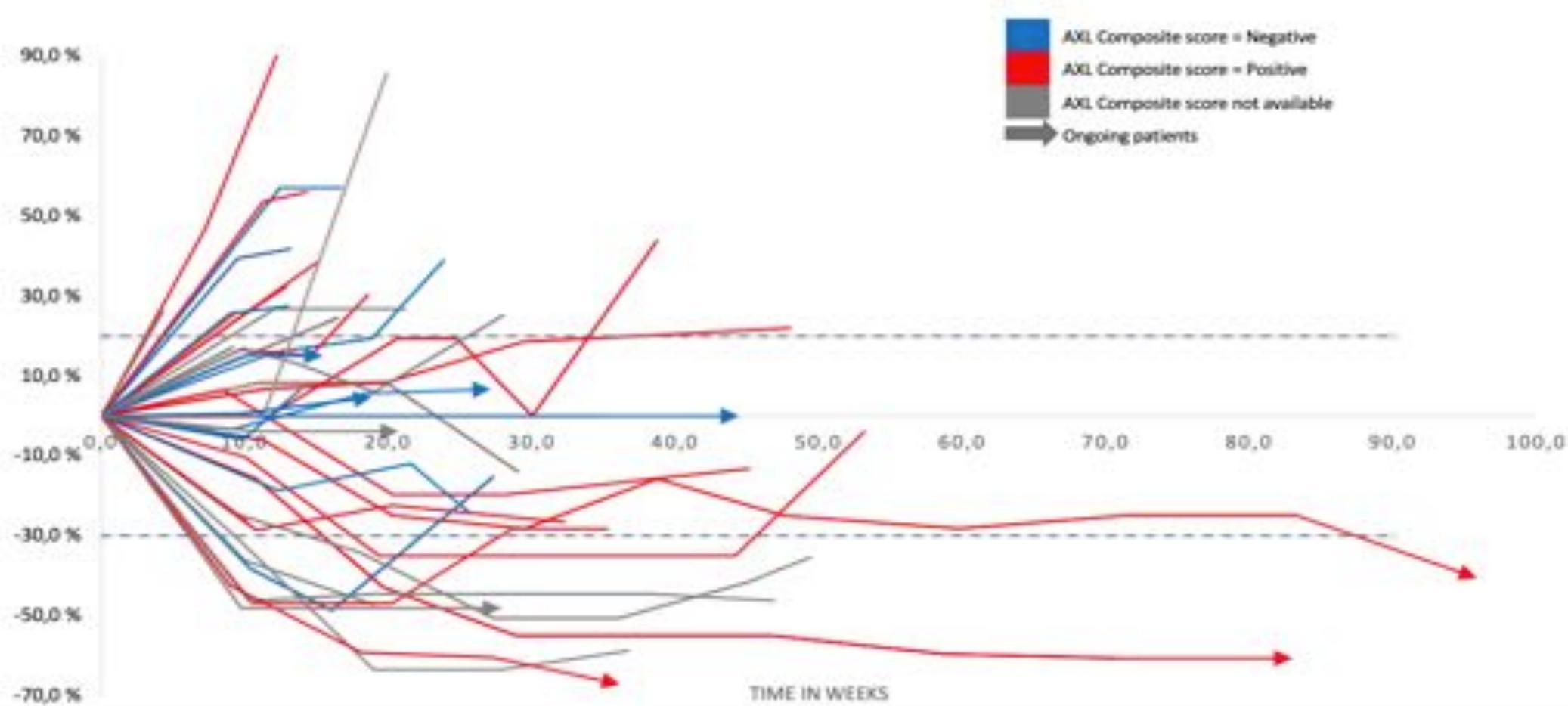
cAXL score captures AXL on tumor cells and immune cells to identify NSCLC patients that respond / benefit from bemcentinib + Keytruda

Anti-tumor activity of bemcentinib in combination with pembrolizumab: Change in tumour size from baseline by RECIST 1.1

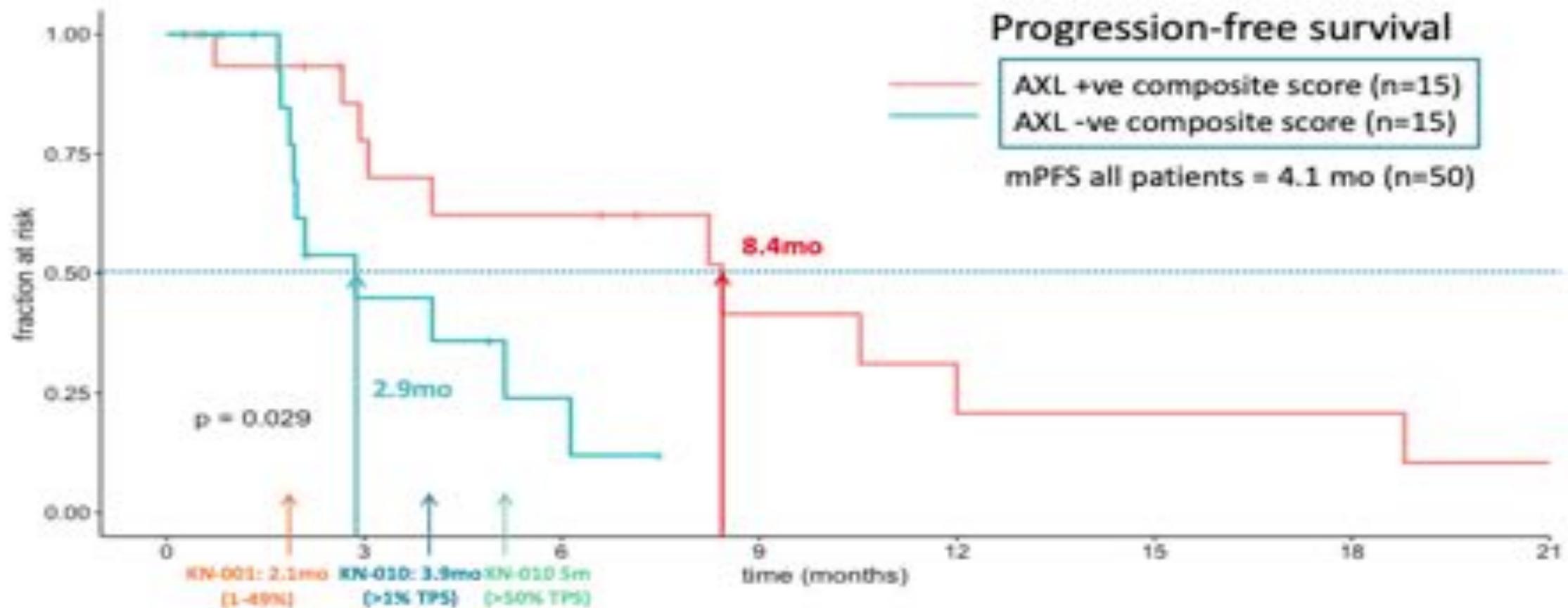


Primary endpoint met: ORR 33% in cAXL +ve, 5X > cAXL-ve. Disease Control Rate (DCR) 73%

Anti-tumor activity of bemcentinib in combination with pembrolizumab: Change in sum of target lesions over time, by patient



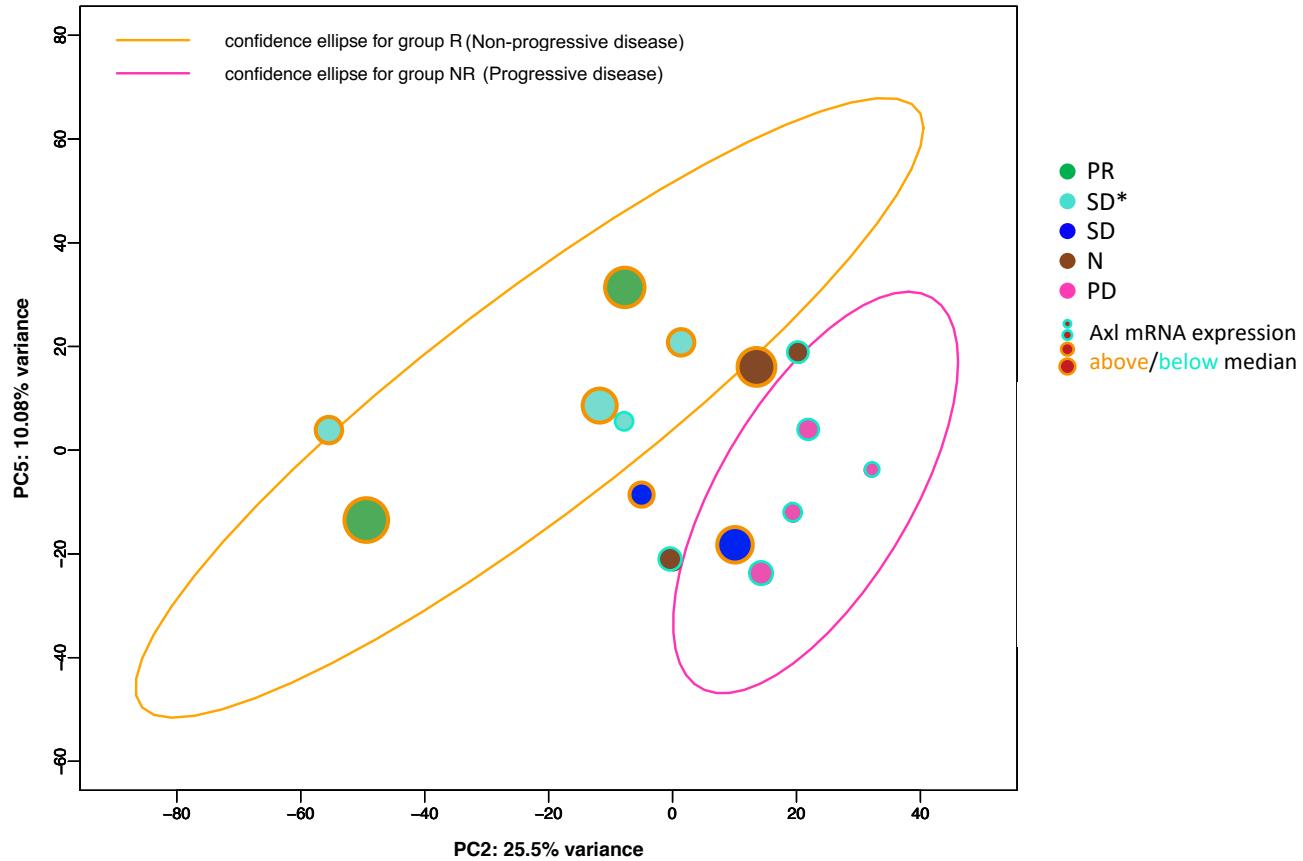
Significant mPFS improvement in cAXL +ve patients



- ✓ 3-fold improvement in cAXL +ve vs. cAXL -ve patients.
- ✓ 4-fold improvement in what might be expected in the same patient population with Keytruda monotherapy

Confirmation of predictive power of cAXL score

Clinical benefit from bemcentinib-pembrolizumab correlates with AXL expression



- Blinded (unbiased) clustering of patients based on RNAseq analysis (>16,000 genes) of pretreatment biopsy
- All 15 patients for whom sufficient biopsy material was available
- 2 Responders, 6 Stable Disease, 4 Progressive disease, 3 Not Evaluable
- Separates patients into clinical benefit and progressive disease groups

Unsupervised Principal Component Analysis

Finance Report

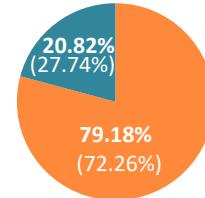
Rune Skeie - CFO



Key financial figures Q3 2019

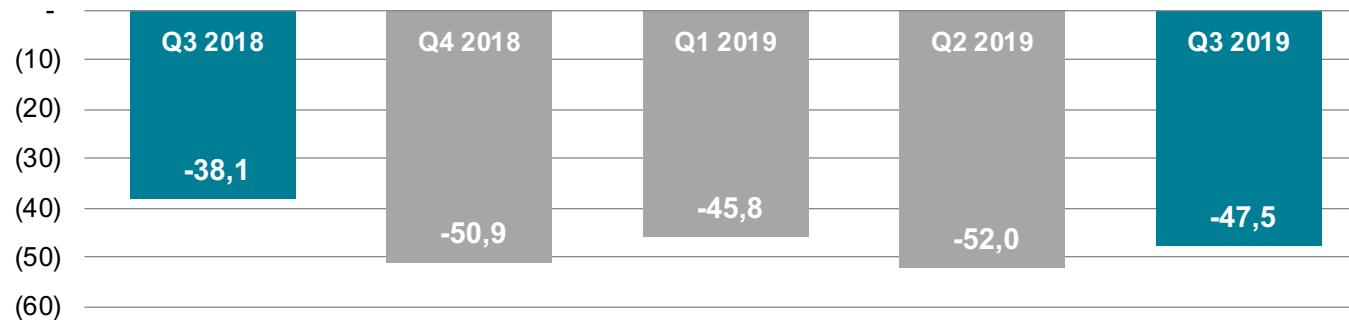
(NOK million)	Q3 2019	Q3 2018	YTD 2019	YTD 2018	FY 2018
Operating revenues	0	0	8,7	0	2,3
Operating expenses	47,5	38,1	154,0	143,6	196,9
Operating profit (-loss)	-47,5	-38,1	-145,3	-143,6	-194,5
Profit (-loss) after tax	-44,6	-37,7	-141,7	-140,7	-191,7
Basic and diluted earnings (loss) per share (NOK)	-0,73	-0,69	-2,57	-2,66	-3,60
Net cash flow in the period	-34,9	-43,1	-70,9	27,8	-9,9
Cash position end of period	289,5	398,2	289,5	398,2	360,4

Operating expenses YTD 2019 (YTD 2018)



■ R&D ■ Administration

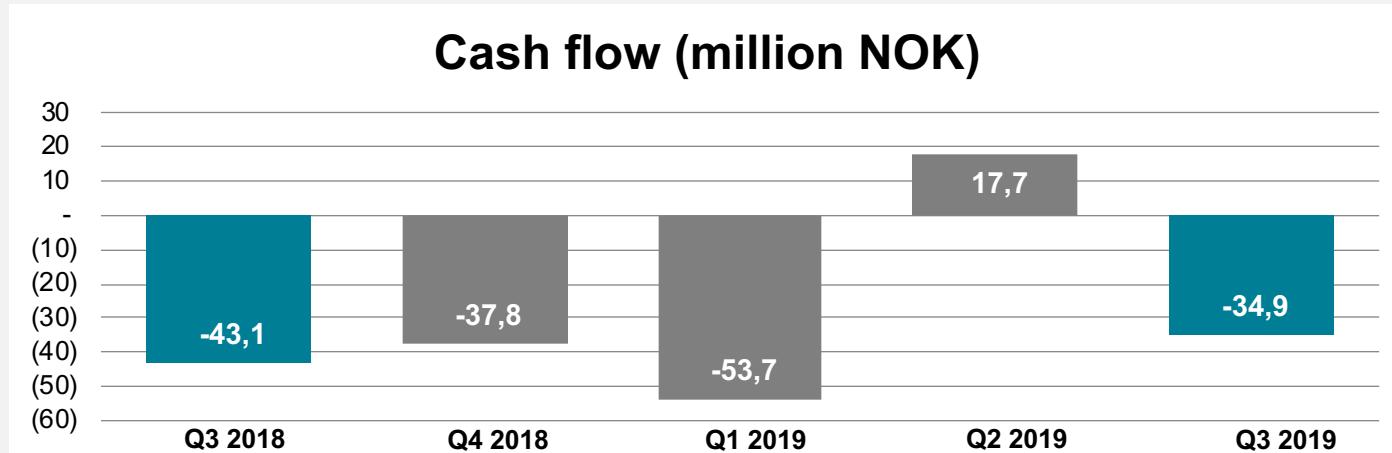
Operating profit (-loss) million NOK



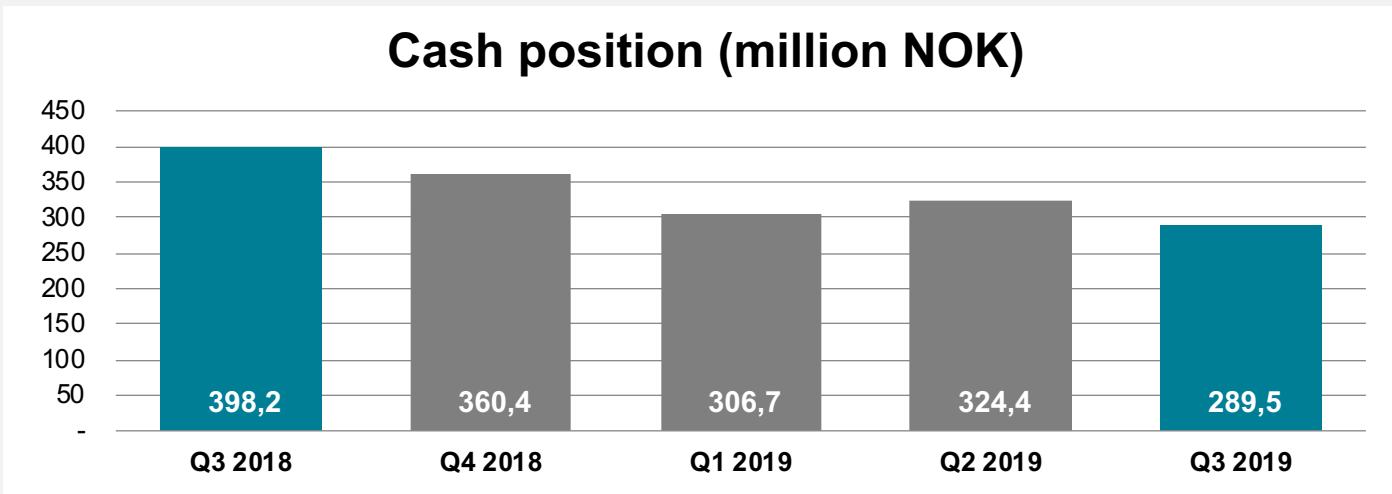
The provisions for social security tax on share options was reduced by -0.1 million (YTD 2019 -4.3 million) in the operating expenses, this has no cash effect.

- Well managed overhead costs
- 80% of operating expenses YTD 2019 (YTD 2018: 72.26%) attributable to Research & Development activities.

Cash flow and cash position



- Deviation between operating loss and cash flow in Q3'19 mainly due to cash in-flow from grants in Q3'19 of NOK 14.7 million.
- Private placement Q2 '19 strengthened cash position - gross funds raised NOK 74 million (USD 9 million)
- Quarterly cash burn average (Q318 – Q319) NOK 46.6 million (USD 5.4 million)



- Cash position Q3 2019 NOK 289.5 million (USD 31.9 million) – ca. 5 quarters of cash burn

Analyst coverage



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Link to reports from Trinity Delta:

<https://www.bergenbio.com/investors/analyst-coverage/>

Q3 Summary & Near term goals and milestones

Q3 was a period of significant progress for BerGenBio

FDA granted Fast Track Designations for 2L Acute Myeloid Leukaemia (AML)

High impact oral presentation of 2L NSCLC clinical data at SITC

Met primary and secondary end points in NSCLC Phase II clinical trial in previously treated patients post chemotherapy (cohort A)

Proprietary composite AXL Immune Score identified patients that have shown very durable response and significantly prolonged median Progression Free Survival

Proprietary gene signature selected 2L NSCLC patients that report durable benefit and is independent of PD-L1

Phase Ib/II interim clinical data with bemcentinib in combination with pembrolizumab or BRAF/MEK inhibitors in 1L Melanoma confirmed these combinations are well tolerated by patients, presented at ESMO

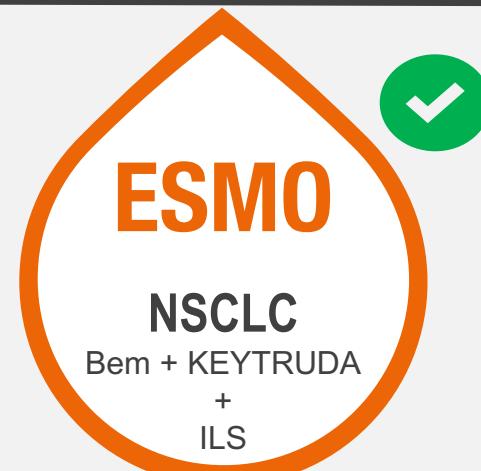
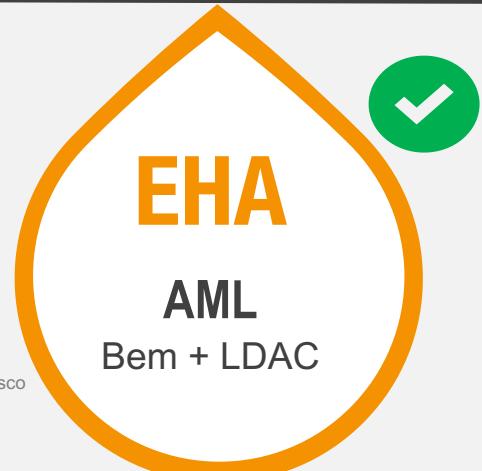
Cash and Cash equivalents at end of Q3 2019 NOK289.5m. Operating loss of NOK 47.5 million in Q3 2019 (NOK 38.1 in Q3 2018)

Expected Newsflow

2019



2019 MAY JUN JUL AUG SEP OCT NOV DEC 2020



ASCO-SITC: Clinical Immuno-Oncology symposium, San Francisco
ASCO: American Society of Clinical Oncology, Chicago
WCLC: World Conference of Lung Cancer, Toronto
ESMO: European Society of Medical Oncology, Munich
AACR: American Association for Cancer Research, Chicago
EHA: European Hematology Association, Stockholm
SITC: Society for Immunotherapy of Cancer, DC
ASH: American Society for Hematology, San Diego

Business Priorities to secure shareholder value

- Complete enrollment of bemcentinib + LDAC expansion cohort in 2L AML study to inform pivotal study design
- Advance clinical development of bemcentinib + Keytruda cohorts in 2L NSCLC
- Seek Scientific Advice from FDA and EMA
- Progress Ph Ib clinical development of Tilvestamab (BGB149) to confirm safety and determine Ph II dose.
- Develop proprietary diagnostics and biomarkers for prospective biomarker directed clinical trials
- Pursue partnership and license opportunities to enhance shareholder value
- Develop organization to meet demands of late stage development
- Diligent management of cash and quality systems

Company goals and outlook

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	✓
	H1 2020	Expanded POC in 2L AML & 2L NSCLC	
	H1 2020	Start late stage clinical programme	
	H1 2021	Interim read-out late stage clinical programme	
Develop Companion Diagnostics	H2 2018	Identify biomarkers that correlate with efficacy	✓
	H2 2020	Validate biomarkers in late stage clinical trials	
	H2 2021	Clinical assay developed	
BGB149 anti-AXL antibody programme	H2 2018	Initiate first-in-man Ph I trial	✓
	H1 2020	Initiate first-in-patient Ph Ib trial	
	H1 2021	Interim readout	
Maximise value for bemcentinib	H1 2019	Initiate pipeline opportunities for bemcentinib via IITs	✓

Questions