BerGenBio ASA (OSE:BGBIO)
DNB Healthcare Conference 2018

12 December 2018

Richard Godfrey, CEO

BerGenBio

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Corporate Snapshot

Focussed on AXL

Leaders in developing selective AXL inhibitors: innovative drugs for aggressive diseases, including immune evasive, drug resistant and metastatic cancers

Diversified pipeline, lead drug is tested in several indications of high unmet medical need and large market potential

Promising efficacy with sustained treatment benefit and confirmed favourable safety

Companion diagnostic

Phase II POC Data:

Monotherapy efficacy

Combination therapy

Biomarker correlation

Pipeline

Bemcentinib* Phase II

First-in-class highly selective oral AXL inhibitor

BGB149

First-in-class AXL antibody

Well funded

Cash runway through to 2020

Included in the OSEBX index from 1st June 2018

Experienced Team

38 staff

Headquarters and research in Bergen, Norway

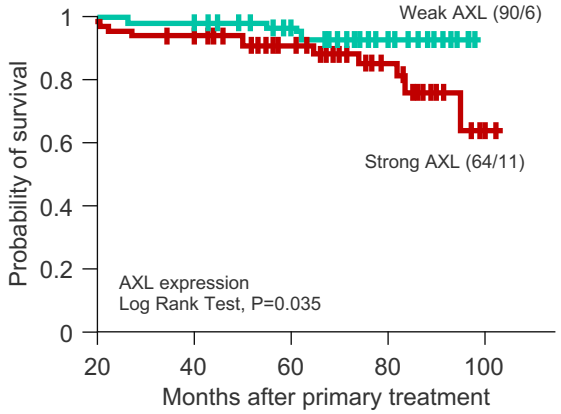
Clinical Trial Management in Oxford, UK

*formerly referred to as BGB324

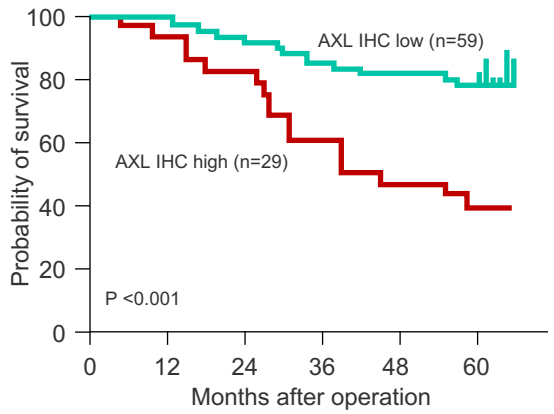
AXL expression correlates with poor patient survival rate

Aggressive cancers

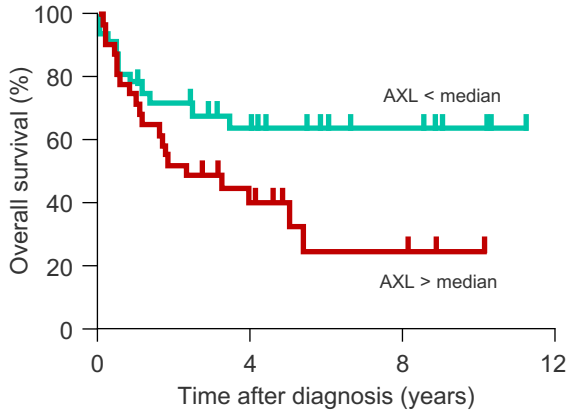
Breast carcinoma[1]



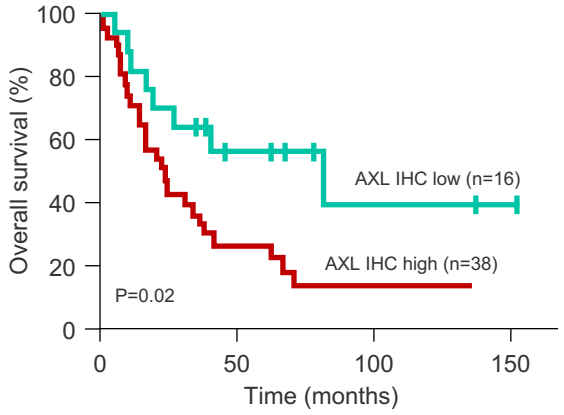
Lung adenocarcinoma (NSCLC)[2]



Acute Myeloid Leukaemia[3]



Pancreatic ductal adenocarcinoma[4]

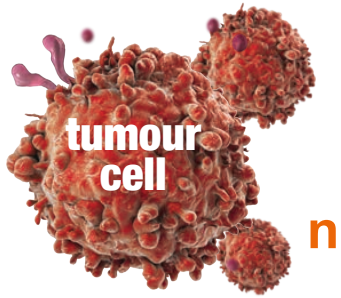


Broad evidence of AXL linked with poor prognosis[5]

Astrocytic brain tumours	Melanoma
Breast cancer	Mesothelioma
Gallbladder cancer	NSCLC
GI	Pancreatic cancer
• Colon cancer	Sarcomas
• Oesophageal cancer	• Ewing Sarcoma
• Gastric cancer	• Kaposi's sarcoma
Gynaecological	• Liposarcoma
• Ovarian cancer	• Osteosarcoma
• Uterine cancer	Skin SCC
HCC	Thyroid cancer
HNC	Urological
Haematological	• Bladder cancer
• AML	• Prostate cancer
• CLL	• RCC
• CML	

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

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

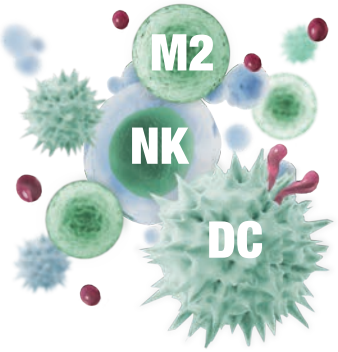


Drives tumour cell plasticity: non-genetic resistance mechanism

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**

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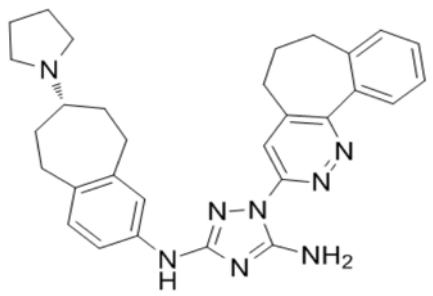
Bemcentinib, first in class highly selective AXL inhibitor



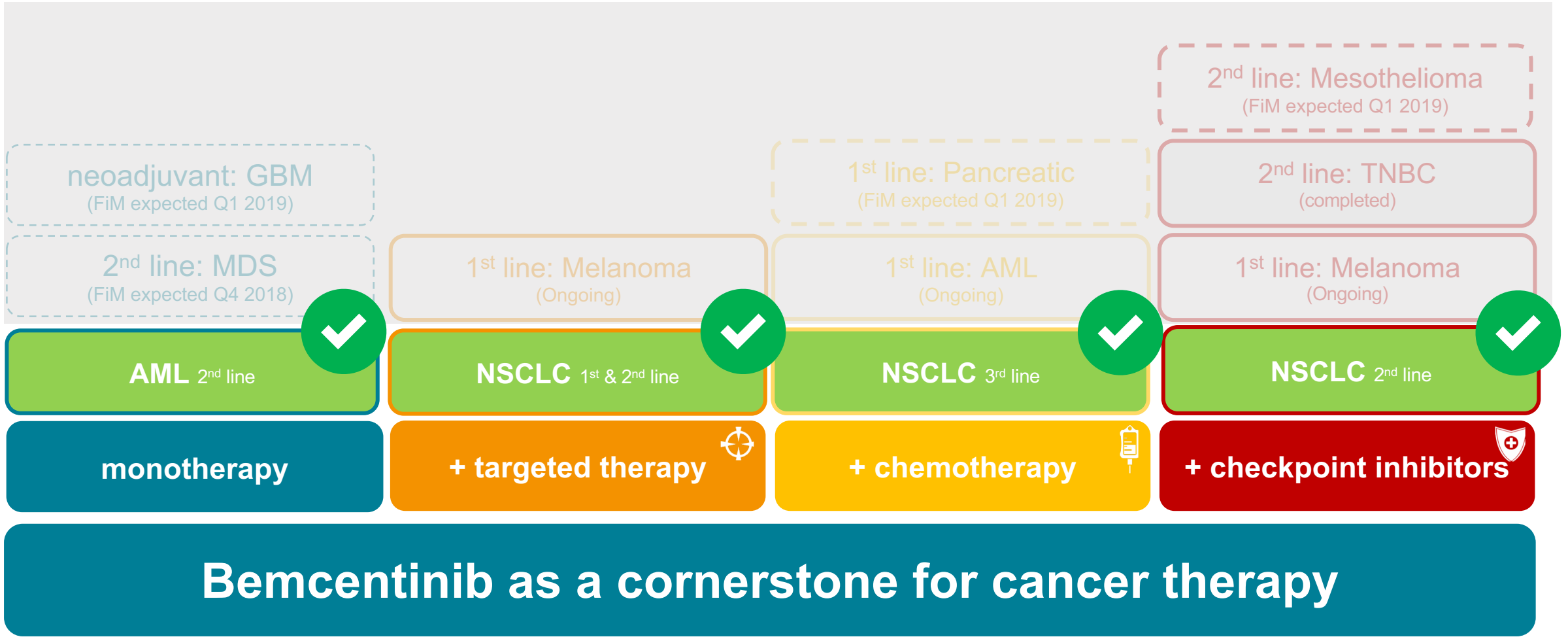
Selective, orally bioavailable, small molecule AXL kinase inhibitor

Predictable PK with once daily dosing

Well tolerated over extended periods of time

Safely combined with chemo, targeted and IO drugs

2018 Phase II proof-of-concept data confirms focus on lung cancer and leukaemia



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20 Scientific & Clinical Presentations 2018!

Presented at the top global oncology conferences.

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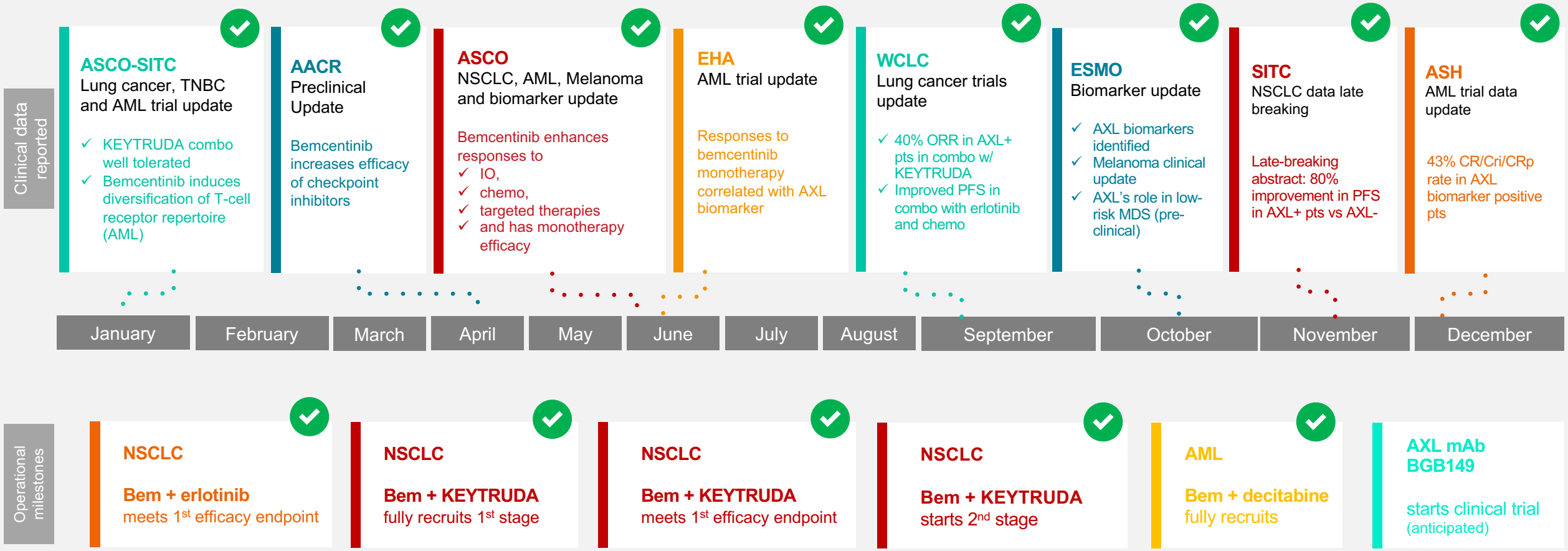
Achievements 2018: significant clinical data readouts providing PoC for bemcentinib



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

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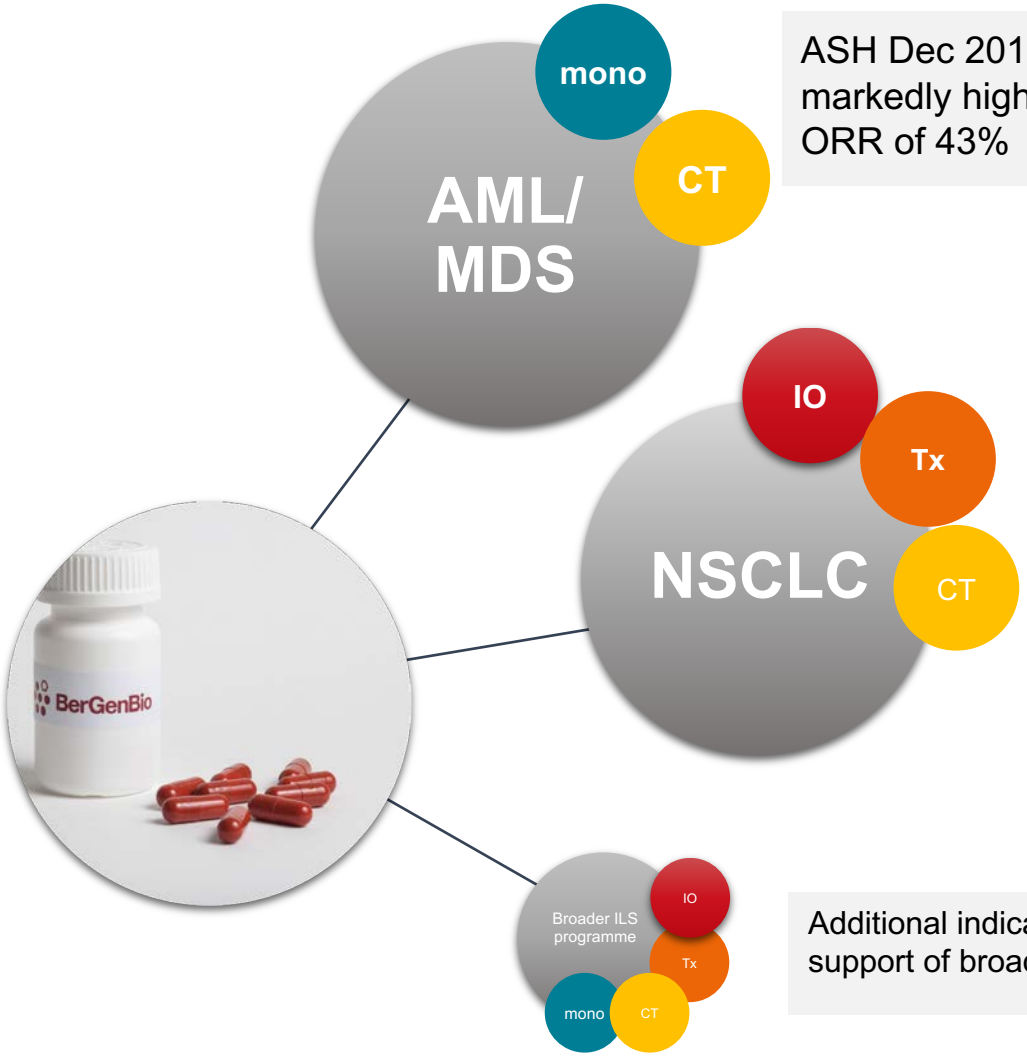
Clinical development focus: Lung Cancer & leukaemia



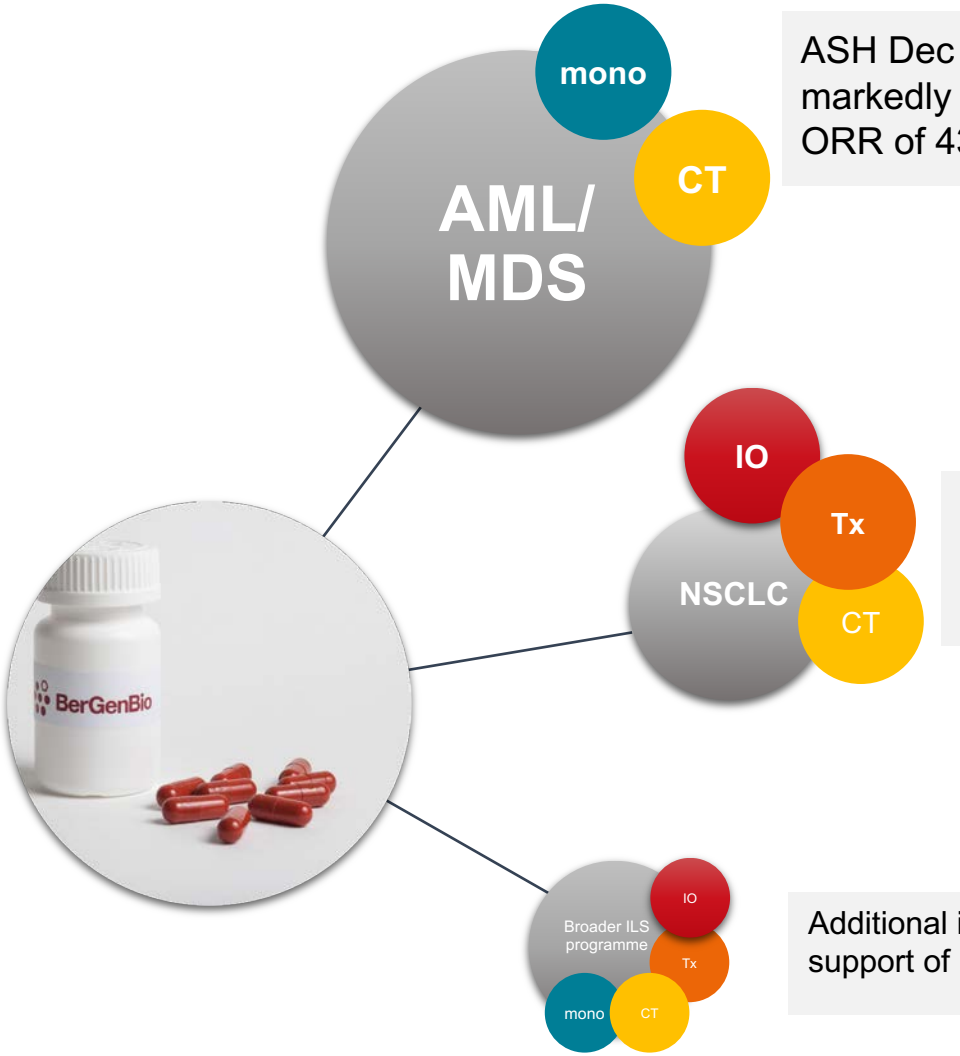
ASH Dec 2018, **bemcentinib monotherapy in R/R AML/MDS:**
markedly higher response rate in patients identified by the AXL biomarker:
ORR of 43%

SITC Nov 2018, **combination with KEYTRUDA in 2L NSCLC:**
Superior response rate and PFS in AXL positive patients – ORR of 40% and ca. 6 months PFS

Additional indications with strong rationale and KOL endorsement are being pursued through active support of broad ILS programme

PFS = Progression Free Survival ORR= Overall Response rate

Clinical development focus: Lung Cancer & leukaemia



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Acute Myeloid Leukaemia (AML) & Myelodysplastic Syndrome (MDS)

Bemcentinib is being evaluated as a monotherapy and in combination with standard of care to treat AML and high-risk MDS

MDS & AML: disease characteristics

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

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 80s[1]

MDS 40% risk of developing into AML.[4]

Acute Myeloid Leukemia (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

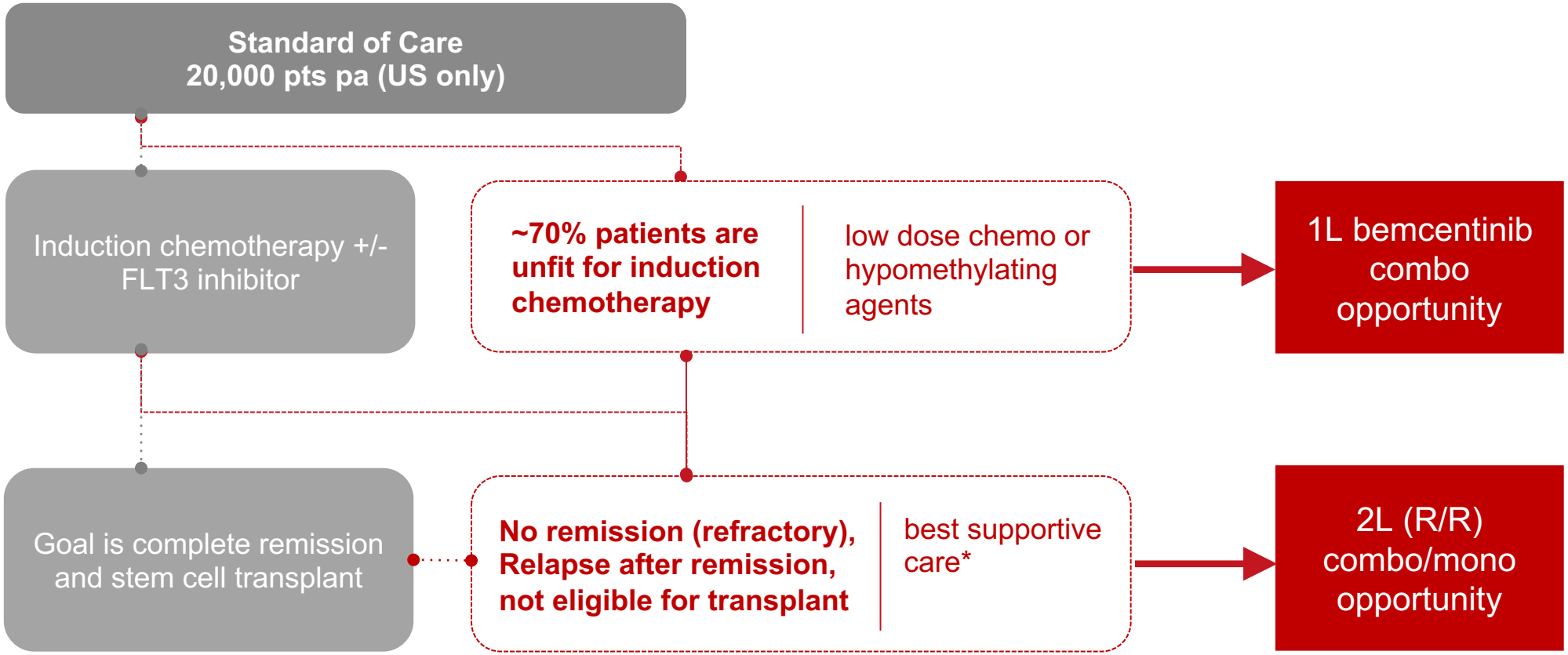
Most common type of acute leukemia in adults[1]

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

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

(1) Cancer.gov (2) SEER (3) Cogle CR, Craig BM, Rollison DE, List AF. Incidence of the myelodysplastic syndromes using a novel claims-based algorithm: high number of uncaptured cases by cancer registries. Blood. 2011;117(26):7121. Epub 2011 Apr 29. (4) AAMDS

AML & MDS – difficult to treat malignancies, predominantly elderly frail patient population.

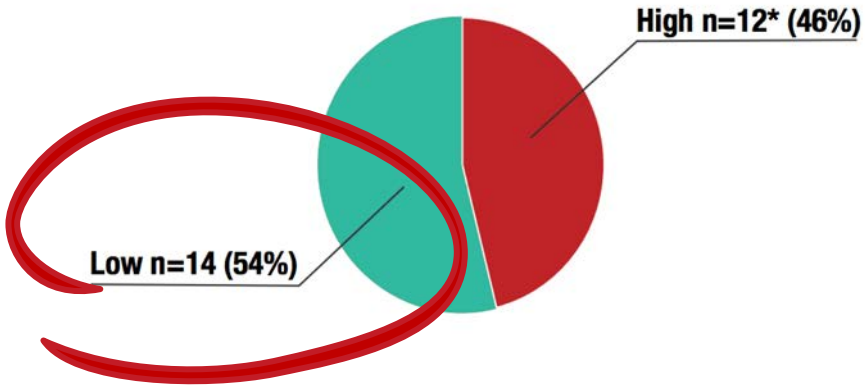


MDS: Myelodysplastic syndrome, *a small fraction of patients may be eligible for targeted therapy

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

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.

Bemcentinib reported superior efficacy in 2L R/R patients

Agent	ORR	comments
Bemcentinib in AXL biomarker pts ASH 2018	43%	Low sAXL patients
Venetoclax Konopleva et al, CancerDisc (2016)	19%	*Now approved for 1L combo with HMAs / low dose chemo
Hypomethylating agents (HMAs) Stahl et al, Blood (2018)	16%	Used off label in R/R pts
Flotetuzumab ASH 2018	19%	Bispecific CD123xCD3
Cyad-01 ASH 2018	38%	CAR-T cell therapy

Next …

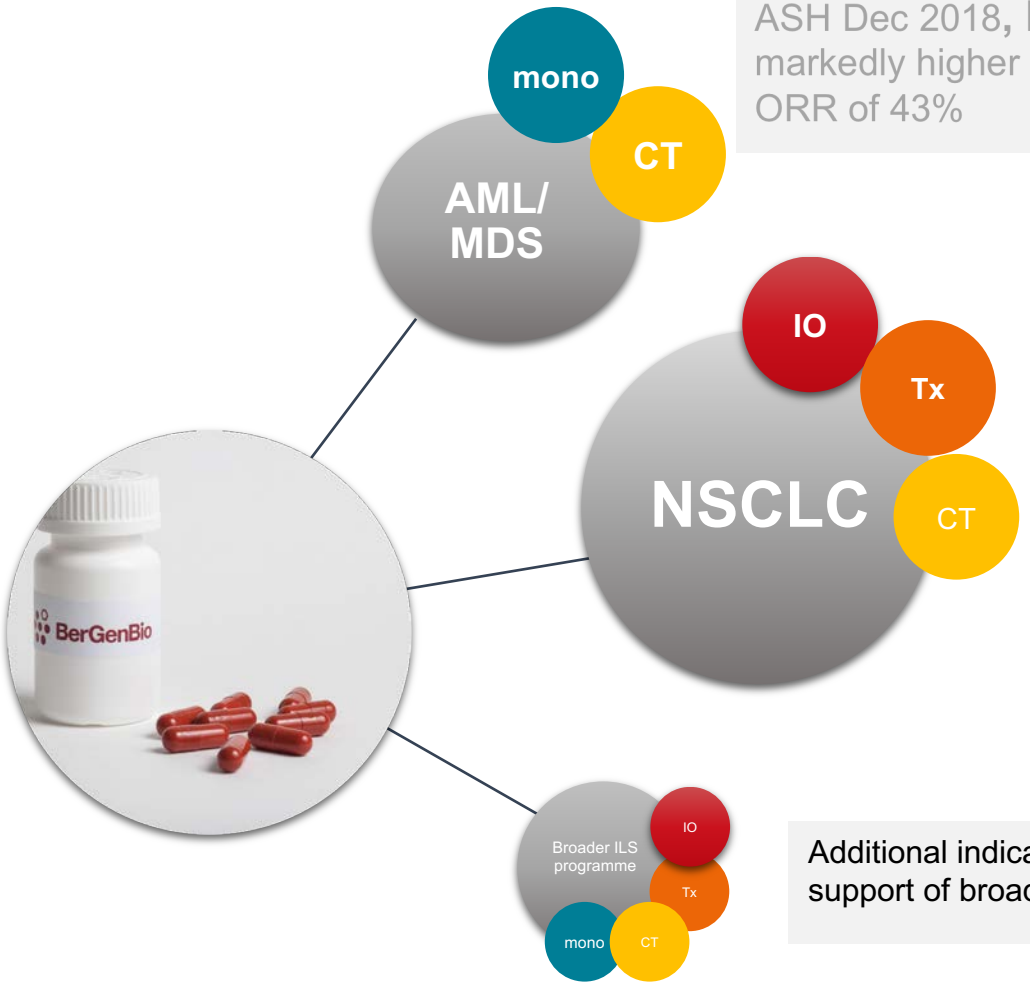
Bemcentinib now being evaluated in combo with HMAs / low dose chemo

Earlier lines of therapy

Top line combo data in Q1 2019

* 21 Nov 2018, FDA approval 1L elderly AML in combination with HMA combo ORR 54%, median time to remission 4.7month.

Clinical development focus: Lung Cancer & leukaemia



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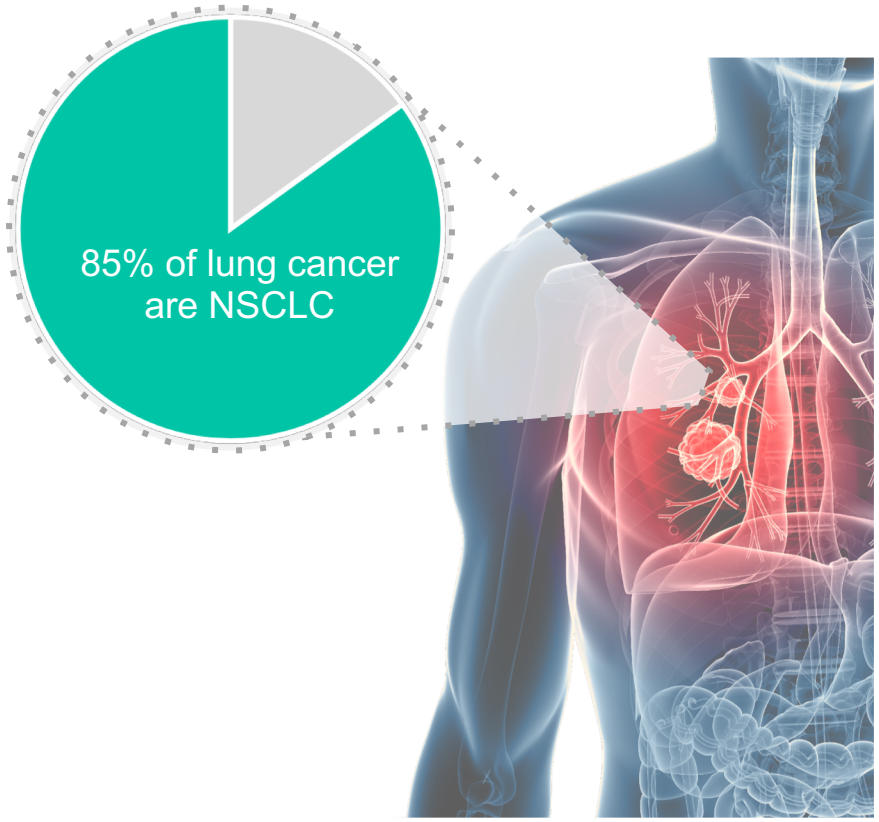
Non-small Cell Lung Cancer (NSCLC)

Bemcentinib has shown strong potential in NSCLC combining with emerging and standard of care therapies

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 cases[1]
- 1.76 million lung cancer deaths/yr worldwide[1]
- In the U.S, 5-year survival rate is approximately 18.6%, and **4.7%** in patients with distant metastases[2]

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

(1) Globocan 2018 (2) SEER

Lung Cancer: rapidly evolving standard of care… - but still lacking effective chemo free regimens

NSCLC evolving standard of care (SoC)

	No or low PD-L1 expression	High PD-L1 expression	driver mutations*
1L	Pt chemotherapy +/- anti-PD-1	Anti-PD-1 monotherapy	Targeted therapy
2L	**Docetaxel chemo therapy Increasingly used in 2L**	Pt chemo	Pt chemo

- limited by low response rate and high side effects

Opportunity for

- Effective and well tolerated 2L therapies
- Deepening 1L responses

* Mutations / rearrangements with available targeted therapies such as EGFR and ALK

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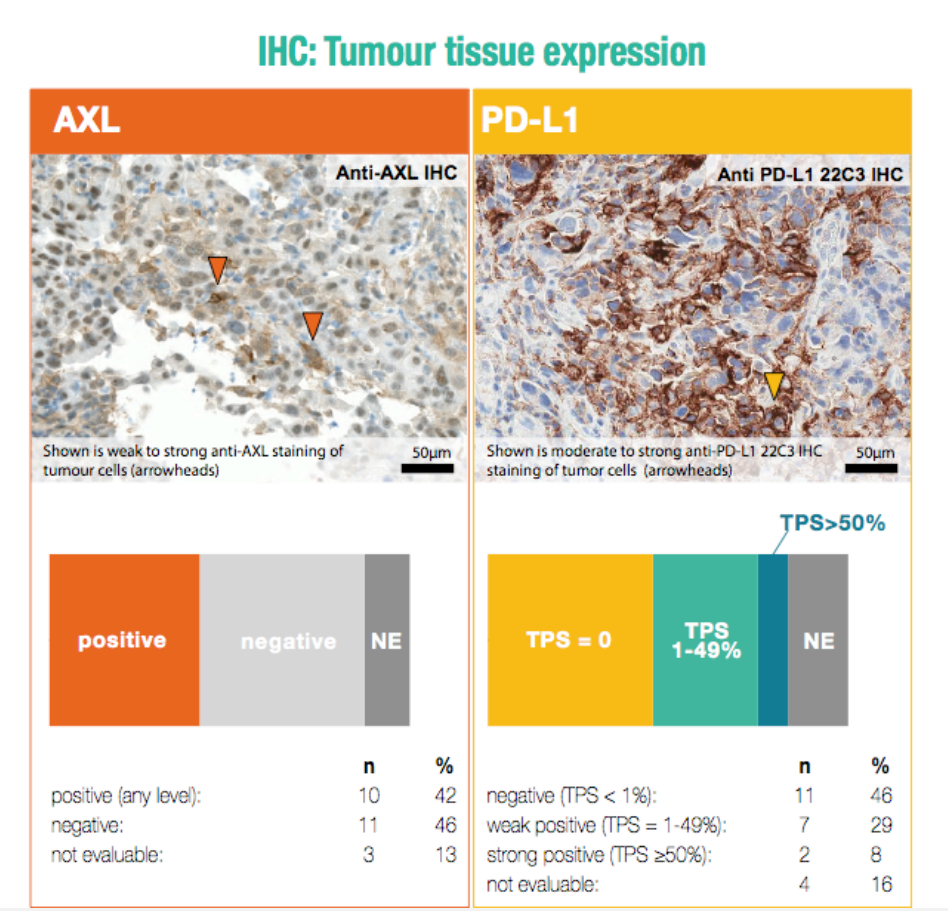
Biomarker analyses reveal predominantly PD-L1 low/negative patient population, half are AXL positive

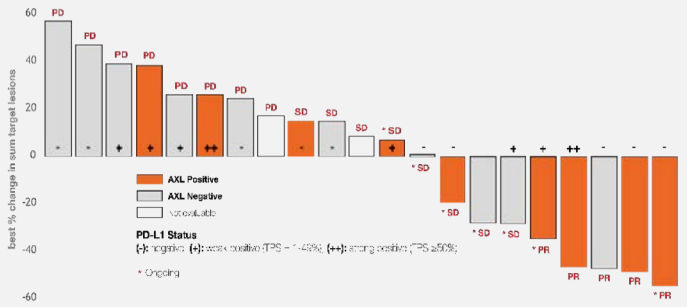


Trial has enrolled predominantly PD-L1 negative and weak-positive patients

- **Expected KEYTRUDA monotherapy ORR in these patients is 8 – 14%[2]**

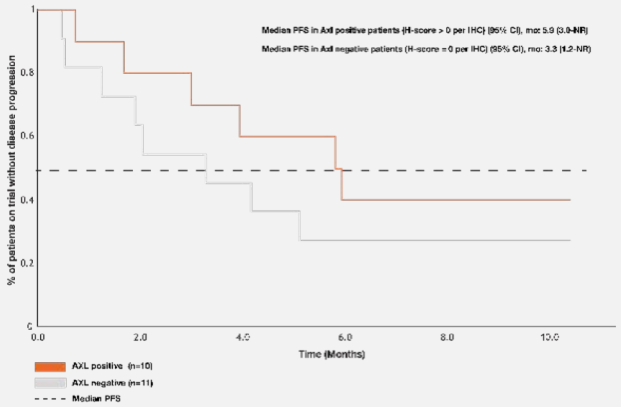
Lorens et al WCLC 2018 (2) KN-001: Garon et al. Pembrolizumab for the Treatment of Non-Small Cell Lung Cancer. N Engl J Med 2015; 372:2018-2028

In AXL positive patients, the bemcentinib + KEYTRUDA combination surpasses anti-PD1 monotherapy*



Trial	PD-L1 status		ORR (%)	PFS (months)
BGBC008	Mostly (75% of patients) 0 – 49%	AXL+	40	5.9
		AXL-	9	3.3
Keynote 001[1]	0 %		9	2.1
	1 – 49 %		14	2.3
CheckMate 057[2]	0 – 100 %		19	2.3

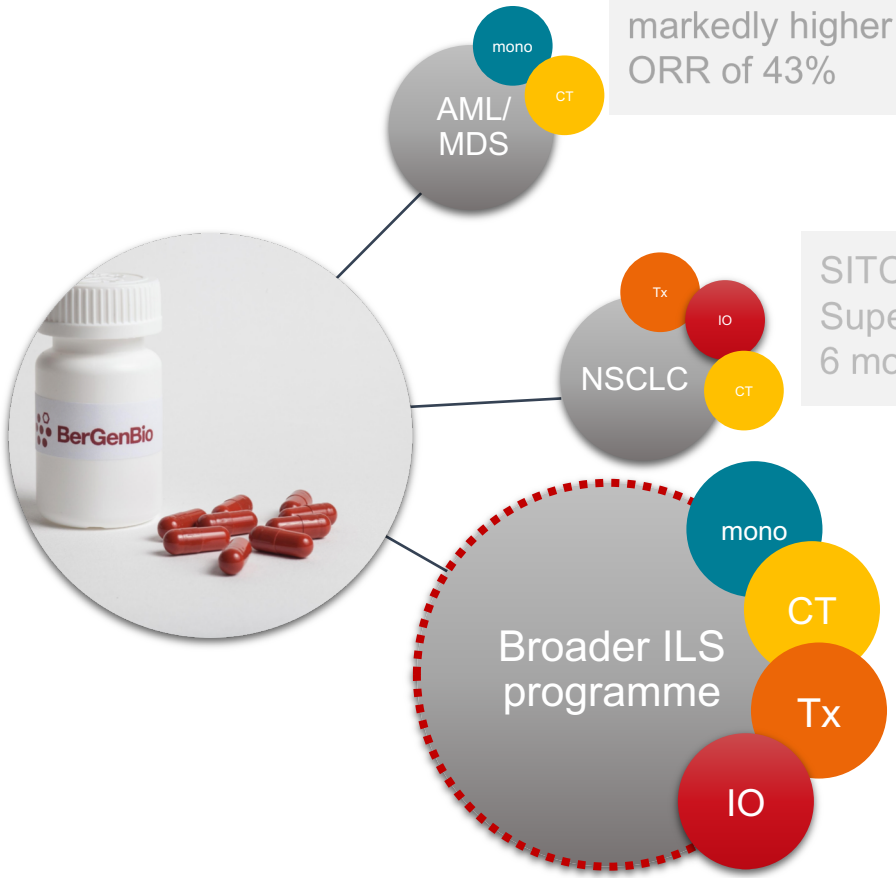
Comparison of bemcentinib combination data (BGBC008) with selected anti-PD-1 monotherapy trial results



- ✓ **40% ORR in AXL positive** patients and
- ✓ **27% ORR in PD-L1 negative** patients
- ✓ **Progression Free Survival: 5.9 months** in AXL positive
- ✓ Bemcentinib + KEYTRUDA very well tolerated

Source: Krebs et al SITC 2018 (November 2018); * comparison with historical data (see table) (1) Garon et al. Pembrolizumab for the Treatment of Non-Small Cell Lung Cancer. NEJM 2015 (2) Borghaei, Hossein, et al. Nivolumab versus Docetaxel in Advanced Nonsquamous Non–Small-Cell Lung Cancer. NEJM 2015; 373:1627-1639. DOI: 10.1056/NEJMoa1507643

Clinical development focus: Lung Cancer & leukaemia



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Bemcentinib active pipeline development programmes

			Preclinical	Phase I	Phase II	Phase III	Status
Bemcentinib – selective AXL kinase inhibitor, company sponsored trials							
NSCLC	2nd line	*Ph II KEYTRUDA combo*			previously treated advanced adenocarcinoma of the lung	MERCK (1)	Stage 1 recruited, 1st efficacy endpoint met
	1st & 2nd line	*Ph II TARCEVA combo*			advanced NSCLC with activating mutation of EGFR		Fully recruited, 1st efficacy endpoint met
AML/MDS	1st & 2nd line	*Ph II monotherapy and combo with low dose chemo*			AML or previously treated MDS unfit for intensive chemo		Part A recruited / superior RR; Part B ongoing
Bemcentinib – investigator led trials							
NSCLC	Later line	*Ph I/II docetaxel combo*			previously treated advanced NSCLC	D. Gerber, UTSW, Dallas TX	ongoing
Melanoma	1st & 2nd line	*Ph II randomised combo with KEYTRUDA or TAFINLAR/MEKINIST*			newly diagnosed unresectable melanoma	O. Straume, Haukeland, Bergen NO	ongoing
Mesothelioma	2nd line	*Ph II combo with KEYTRUDA*			Relapsed malignant mesothelioma (prior Pt containing CT)	D. Fennell, Leicester, UK	MERCK (2) FPI expected 1Q 19
Pancreatic	1st line	*Ph II randomised combo with chemo*			Metastatic or recurrent pancreatic adenocarcinoma	M. Beg / Dan v Hoff, UTSW TX ++	STAND UP TO CANCER FPI expected end of 1Q 19
Glioblastoma	adjuvant	*monotherapy*			Surgically eligible glioblastoma multiforme	B. Nabors, UoA, Birmingham, AL	FPI expected end of 1Q 19
High risk MDS	2nd line	*monotherapy*			High risk MDS (prior HMA)	U. Platzbecker, Dresden, Germany	FPI expected end of 4Q
Companion Diagnostics Pipeline				**Biomarker Discovery**	**Biomarker Verification**	**Validation**	
Tissue AXL **Soluble AXL** **Additional soluble markers**					Correlation with benefit from monotherapy, combo with targeted and immunotherapy		Correlation with efficacy reported

(1): Clinical trial collaboration, no preferential rights
(2): Merck & Co IST programme

BerGenBio sponsored study Investigator sponsored study / other

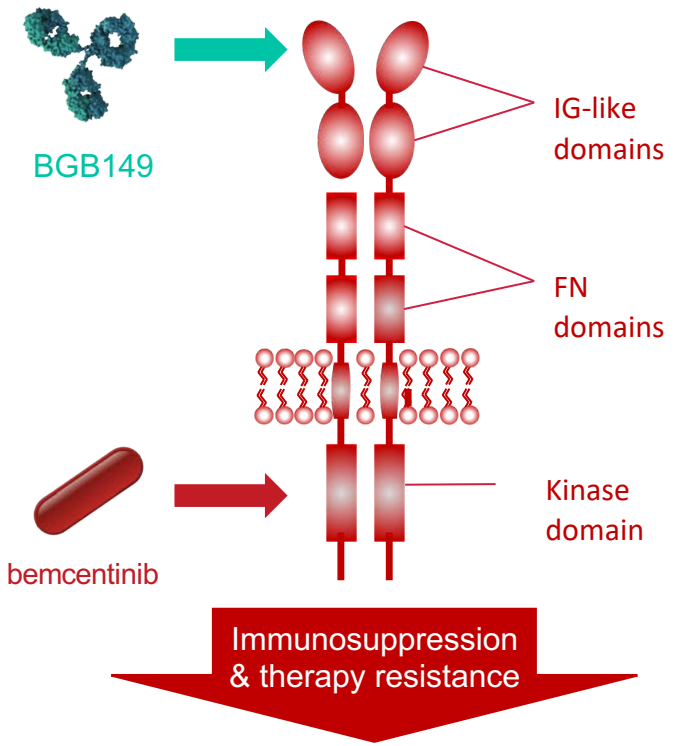
BerGenBio

BGB149

AXL mAb – clinical trials start Dec 2018

BGB149: AXL function blocking antibody programme

BGB149 & AXL receptor



Features

- AXL functionally blocking human antibody
- Highly selective to human AXL: High affinity (K_D: 500pM)
- MoA and efficacy demonstrated in pre-clinical models
- Preclinical studies demonstrate acceptable toxicology profile for planned clinical studies

Status

- Robust, scaleable manufacturing process
- Stability: current drug substance has 18 month stability at <-60 degrees C.
- Toxicity: GLP toxicity reported no major concerns
- CTA approved
- First-in-man clinical trial to be started imminently

Financial review

Good financial position and cost control

Cash position

End of Q3:
398.2MNOK

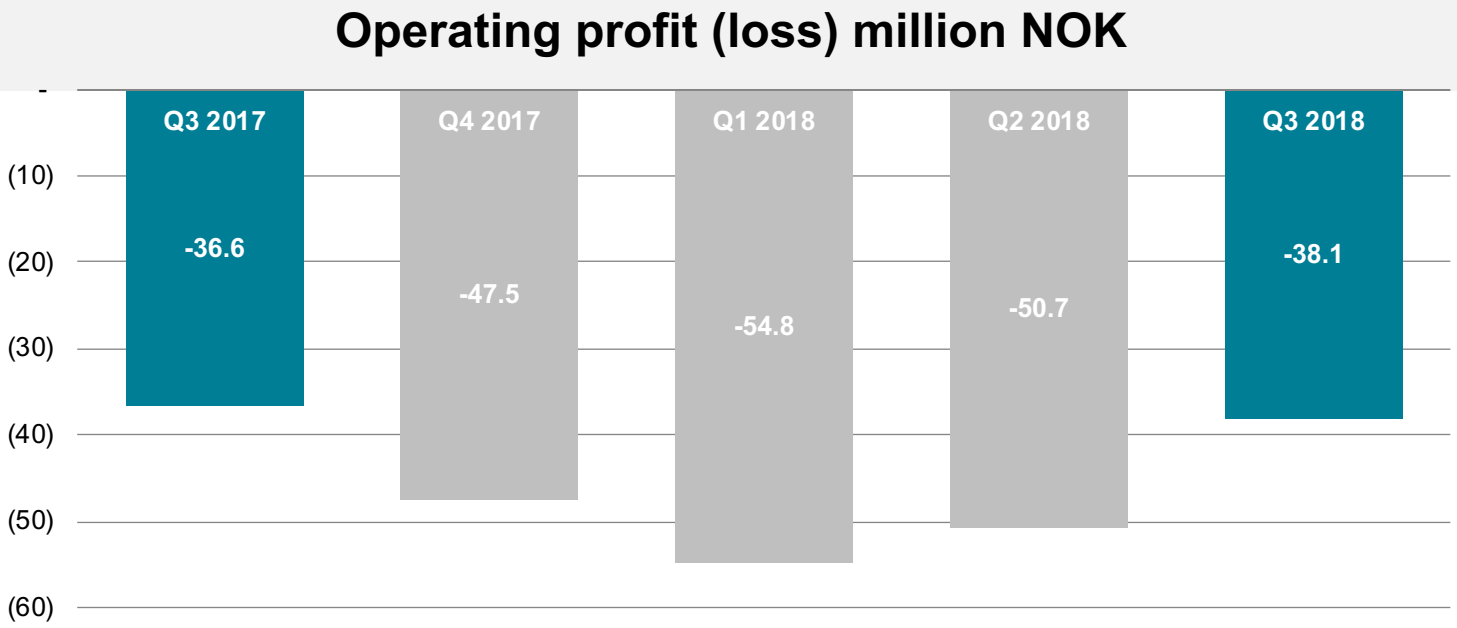
Cash burn

YTD:
149.1MNOK

Cash runway

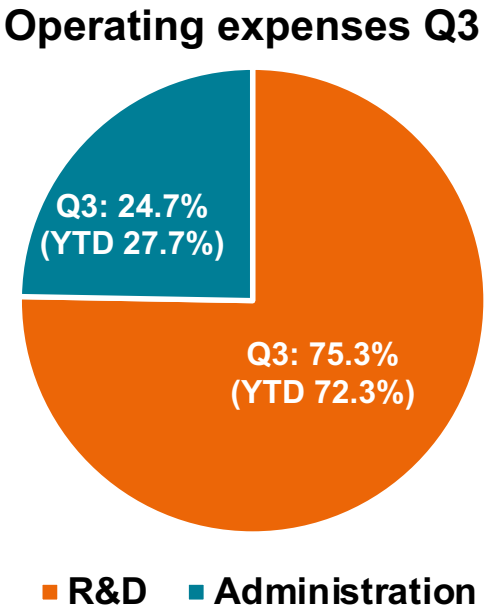
Into 2020 at current burn rate

Operating profit (loss)



- Q3'18 decrease in operating loss associated with stage 1 of NSCLC study in combination with Keytruda meeting its clinical efficacy endpoint in Q2, requiring a 12 week safety review and therefore reduced spend in Q3. Stage 2 opened in Q4.
- In addition increased cost reduction by grants:

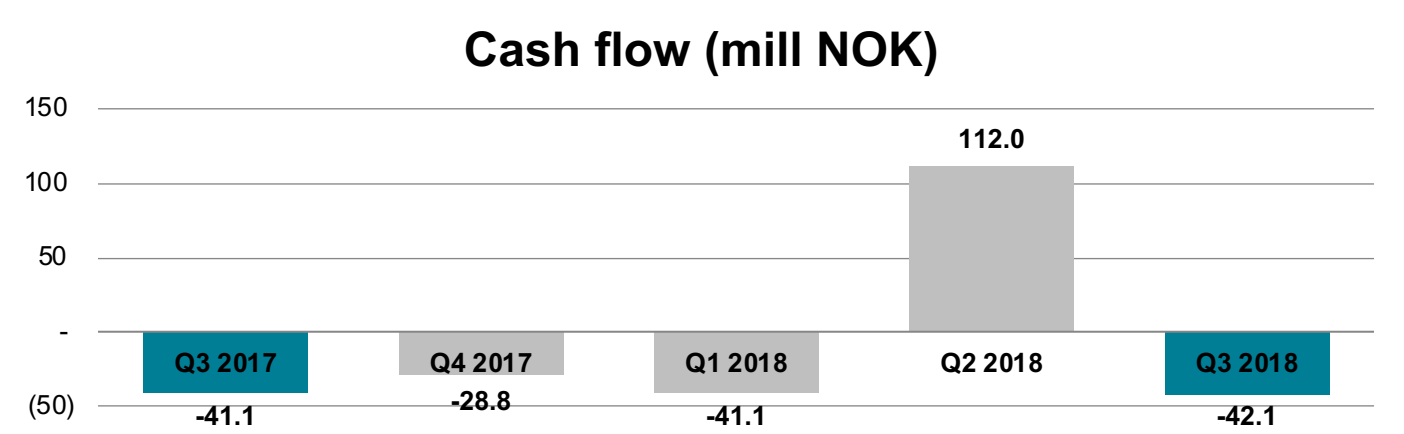
Approval tax refund (Skatte funn) cost reduction in Q3´18 NOK 5.1 mill (Q3´17 NOK 2.3 mill) Other grants Q3´18 NOK 3.3 mill (Q3´17 NOK 0.5 mill)



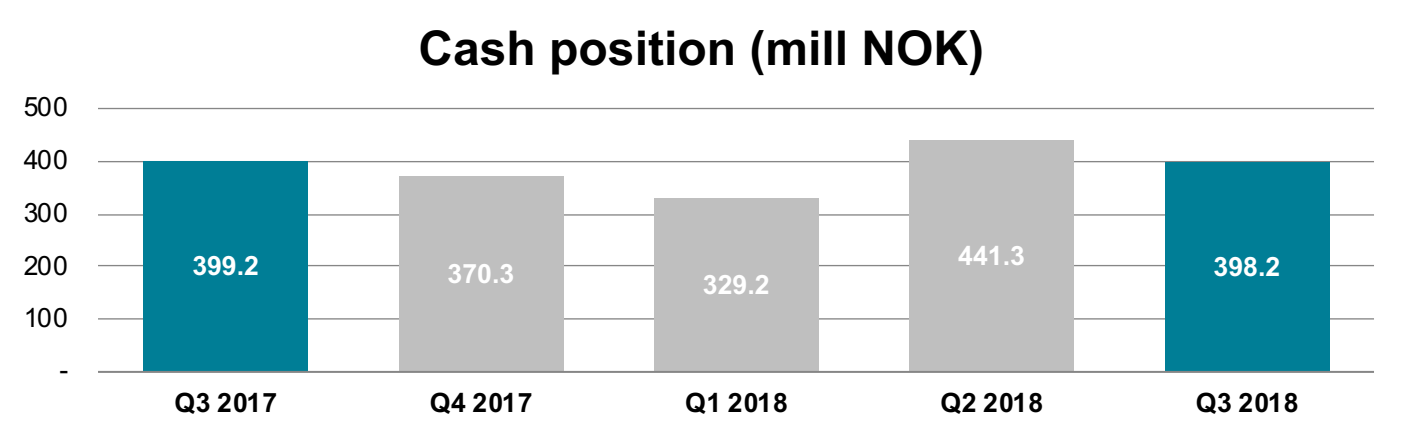
- Effective organisation
- 75.3% (YTD 72.3%) of operating expenses in Q3 2018 attributable to Research & Development activities

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

Cash flow and cash position



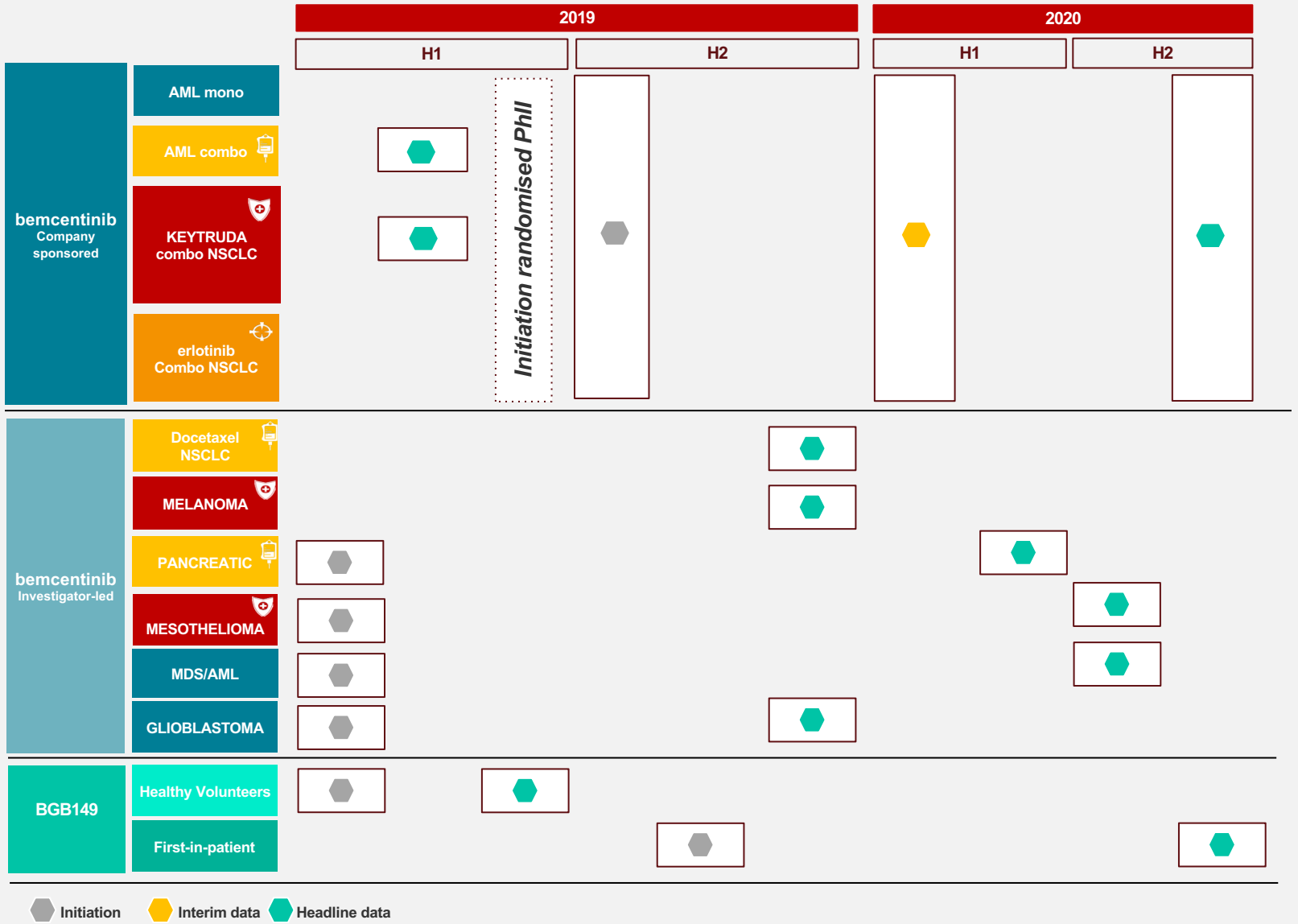
- Private placement Q2,18 strengthened cash position - gross funds raised NOK 187.5m
- Quarterly cash burn average at NOK 44.8m



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

Summary and Future Outlook

Significant milestones expected in over the coming 18 months



2019 H1 milestones

Bemcentinib

NSCLC

- ***KEYTRUDA combo from stage 2***

AML

- ***Chemo combo***

Initiation of randomised phase II studies

- ***Multiple ILS***

BGB149 (*AXL antibody*)

- ***Initiation phase I clinical trial***

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

Summary

Bemcentinib - highly selective, potent, oral AXL inhibitor

Proof-of-concept Phase II clinical data: monotherapy, combination with biomarker correlation

Bemcentinib clinical development programme to focus on Lung Cancer and Leukaemia

Anticipated cash runway into 2020, with significant milestones in the next 12 months

Thank you for your attention

Q&A

Summary results: Company sponsored Ph II studies

Study / PoC	2018 H1	2018 H2	Results	Context
KEYTRUDA combo NSCLC Increase response rate - including in PD-L1 negative	Interim data	Final Readout	• Stage 1 complete: Predominantly PD-L1 negative / low pt population • **40% ORR in AXL+ patients** • **Median PFS 5.9 months in Axl+ patients** • Stage 2: open and recruiting	• Keytruda is current SoC • KN-001 ORR in **PD-L1 neg/low pts is 8-14%, 2m PFS**[1]
erlotinib combo NSCLC Reverse (2L) and prevent resistance (1L) to EGFR targeted therapy	Interim data	Final Readout	• All arms complete • **2L: Tumour responses & disease stabilisation** observed in T790Mneg erlotinib progressors • **1L: further deepening of responses** in patients who were stable or in response to erlotinib, combined PFS exceeded that reported for erlotinib monotherapy	• Erlotinib widely used first-line in EGFR mutation+ pts • **Almost all responders develop resistance**
monotherapy/ Chemo combo AML Increase rate of remission as monotherapy and in combo with low-dose chemo	Interim data	Final Readout monotherapy	• **43% CR/CRi/CRp-rate to monotherapy in AXL biomarker positive patients** • Responses included patients with poorer prognosis • Bemcentinib + decitabine 1L cohort fully recruited	• Venetoclax, now approved in combo w/ chemo, has shown **~19% ORR in R/R AML as monotherapy**
KEYTRUDA combo TNBC Increase response rate, assess correlation with biomarkers	Interim data	Final Readout	• **14 out of 18 patients analysed were negative for AXL** • **12 out of 15 patients analysed were negative for PD-L1** • Of 18 patients analysed, 1 had significant shrinkage of target lesions	• Particularly difficult treat: KEYTRUDA monotherapy has shown only **5% ORR in TNBC**[2]

Initiation Interim data Final Readout

(1) Garon et al. Pembrolizumab for the Treatment of Non-Small Cell Lung Cancer. N Engl J Med 2015; 372:2018-2028
(2) Adams, Sylvia, et al. Phase 2 study of pembrolizumab (pembro) monotherapy for previously treated metastatic triple-negative breast cancer (mTNBC): KEYNOTE-086 cohort A. J Clin Oncol 35, 2017 (suppl; abstr 1008)

Overview results: Investigator sponsored studies

PoC / Study	2018 H1	2018 H2	Results	Context
MEKINIST/TAFINLAR or KEYTRUDA combo melanoma Increase response rate		Interim data	• Confirmed recommended phase II dose of bemcentinib in combination with MEKINIST/TAFINLAR and KEYTRUDA, **all combinations continue to be well tolerated**. • **18 out of 23 radiographically evaluated patients reporting clinical benefit including complete responses**	• Dabrafenib/trametinib & pembrolizumab are SoC • **AXL associated with resistance to these therapies**
Docetaxel combo NSCLC Increase response rate		Interim data	• **Bemcentinib + docetaxel shows promising activity in previously-treated NSCLC patients** with advanced NSCLC, including patients who failed on immunotherapy • 8 patients reported clinical benefit incl. 2 partial responses out of 11 evaluable patients	• **Docetaxel increasingly used as 2L therapy** • Docetaxel monotherapy **ORR: 8 - 14%** [1]

Initiation Interim data Clinical data

(1) Garon EB, Ciuleanu TE, Arrieta O, et al: Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV non-small-cell lung cancer after disease progression on platinum-based therapy (REVEL): a multicentre, double-blind, randomised phase 3 trial. Lancet 384:665-73, 2014