BerGenBio

Bemcentinib phase II clinical data update

ASCO 2019

31st May – 4th June 2019

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BGBIO – Corporate Snapshot

World leaders in understanding AXL biology

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

AXL upregulates PDL1 on dendritic cells and blocks T-cell immunity

AXL inhibitors – potential cornerstone of cancer therapy

Pipeline opportunities in multiple cancers and fibrosis

3 selective AXL inhibitors in clinical development

Bemcentinib,
AXL-antibody BGB149, AXL ADCT601*

Monotherapy and combinations with immune-, targeted and chemotherapies

Biomarker correlation across programme, parallel CDx development

Phase II Proof of Concept
AML (monotherapy), **AML** (chemo-combo)
NSCLC (KEYTRUDA combo)

Resourced to deliver significant milestones

Listed on Oslo Børs: BGBIO

Clinical trial collaborations with Merck and leading academic centres

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

Q1'19 Cash USD 35.7m

*AXL antibody out licensed to ADC Therapeutics SA

Bemcentinib Phase II POC data – ASCO 2019

Monotherapy
ACUTE MYELOID LEUKEMIA
2L elderly

Bemcentinib monotherapy

ORR
43%
AXL +ve patients

DoR
ca. 3.1 months

Early onset of response

Chemo combination
ACUTE MYELOID LEUKEMIKA
1L & 2L elderly AML

Bemcentinib + low dose chemo combination (LDAC)

ORR
46%
All comer patient population

Median DoR in CR/CRi
6.2 months (range 0.7 – 9.6)
(immature)

Early onset of response

CPI* combination
LUNG CANCER
2L chemo relapse/IO naïve ad. NSCLC

Bemcentinib + Keytruda Combination

ORR
40%
AXL +ve patients

92% pts low/zero PD-L1

mPFS
5.9mo. (AXL +ve, stage I only)

mOS
12.2mo (stage I only)

*Check point Inhibitor

Phase II data highlights: ASCO June 2019

IL/2L AML (>75yrs)

LDAC + bemcentinib

16 patients enrolled
13 patients evaluable for efficacy *
9 ongoing in treatment

* 2 patients did not complete one cycle (21 days) of treatment
1 patient has missing blast count for assessment

Preliminary efficacy Results

ORR: 46% (6/13)

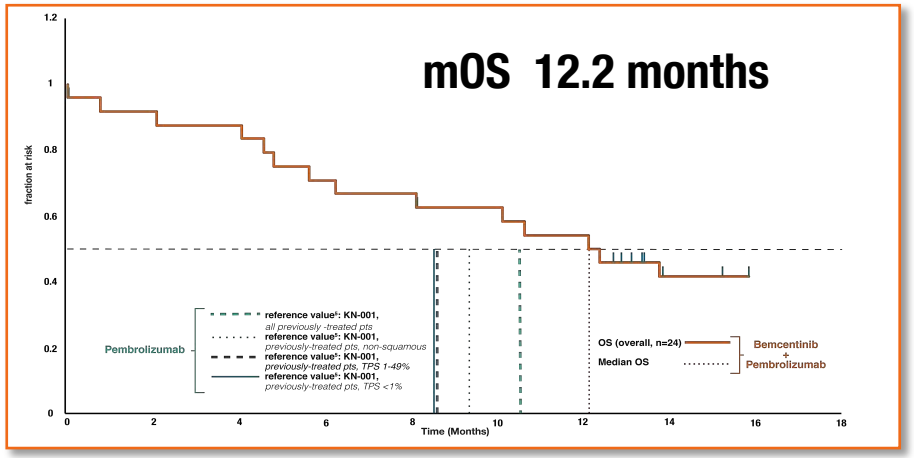
6 responses have been reported
(4 CR/CRi + 2 PR)
1 durable stable disease (≥3 months)
Current relapse-free survival in CR/CRi patients: 6.2 months
(range: 0.7 – 9.6 months)

2L NSCLC combo with CPI (46pts)

58% AXL positive

Bemcentinib + KEYTRUDA
ORR: 40%
CBR: 67%

Keytruda monotherapy*
ORR: 12%

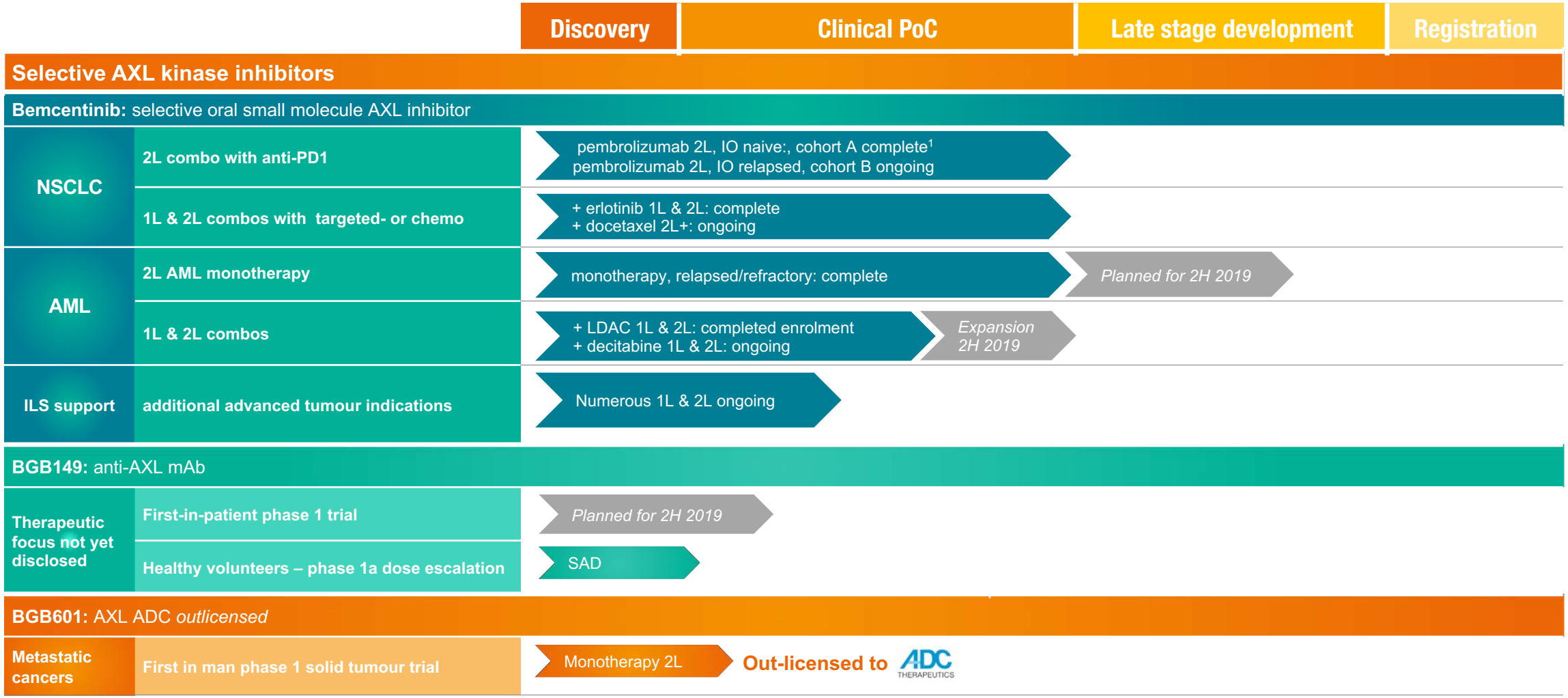


* Garon, et al. Pembrolizumab for the Treatment of Non–Small-Cell Lung Cancer. NEJM (2015).

Bemcentinib: once-a-day pill

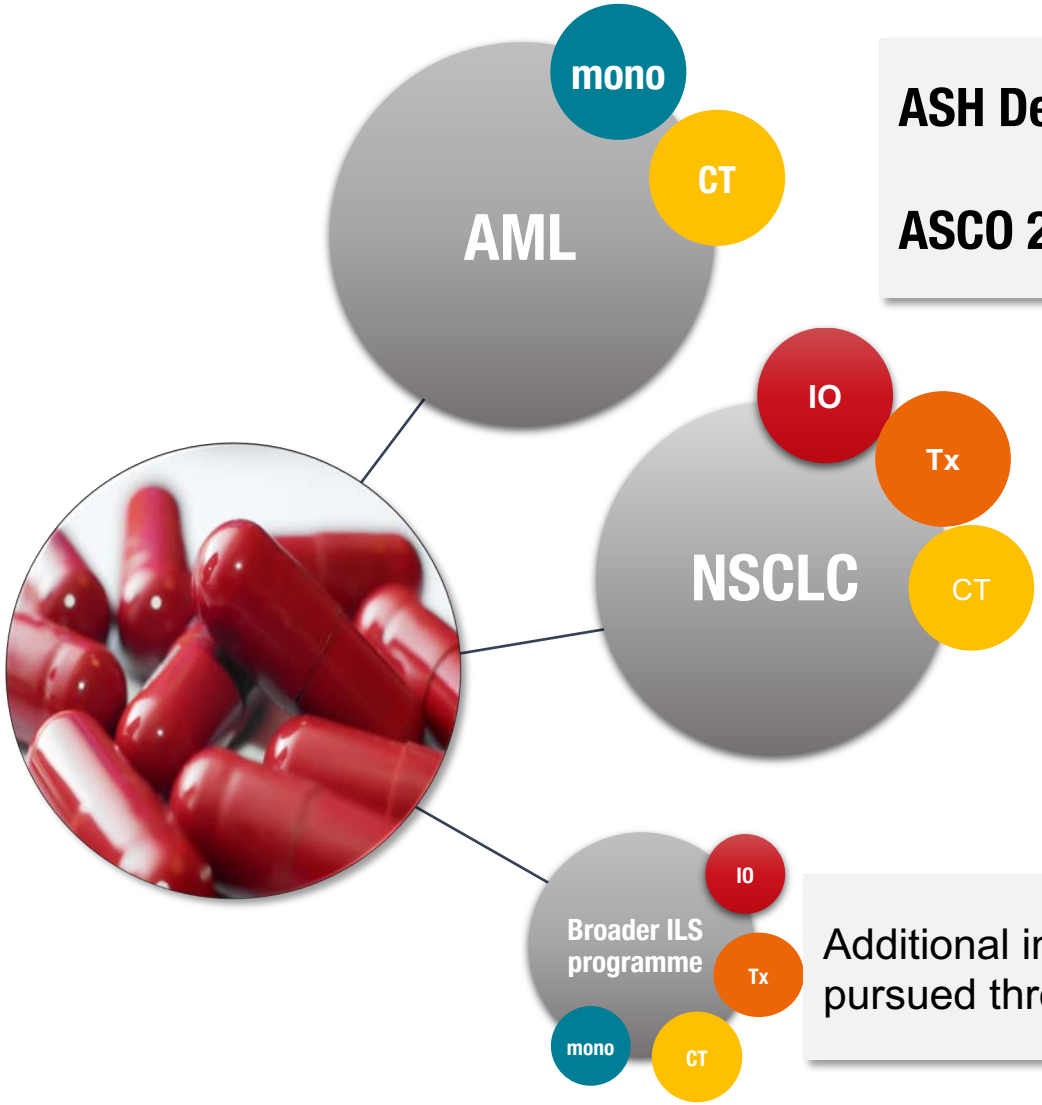
- Highly selective, potent, orally bioavailable
- Blocks AXL signalling, reverses aggressive tumour traits & counteracts immune escape
- Once-a-day administration
- Clinical PoC in AML and NSCLC as a monotherapy and in combination
- Correlation of clinical efficacy with AXL biomarkers observed
- Combines successfully with chemo, targeted and CPI drugs
- Excellent clinical safety profile: >250 subjects dosed

Portfolio of selective AXL inhibitors in clinical development



(1): Clinical trial collaboration with Merck & Co, no preferential rights (2) Investigator initiated trial programme, BerGenBio does not act a regulatory sponsor

Clinical development focus: Leukaemia & Lung Cancer



ASH Dec 2018: bemcentinib monotherapy in R/R AML: 43% ORR

ASCO 2019: bemcentinib + LDAC: 46% ORR

ASCO 2019: combination with KEYTRUDA in 2L NSCLC: ORR of 40% and mOS 12.2months.

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

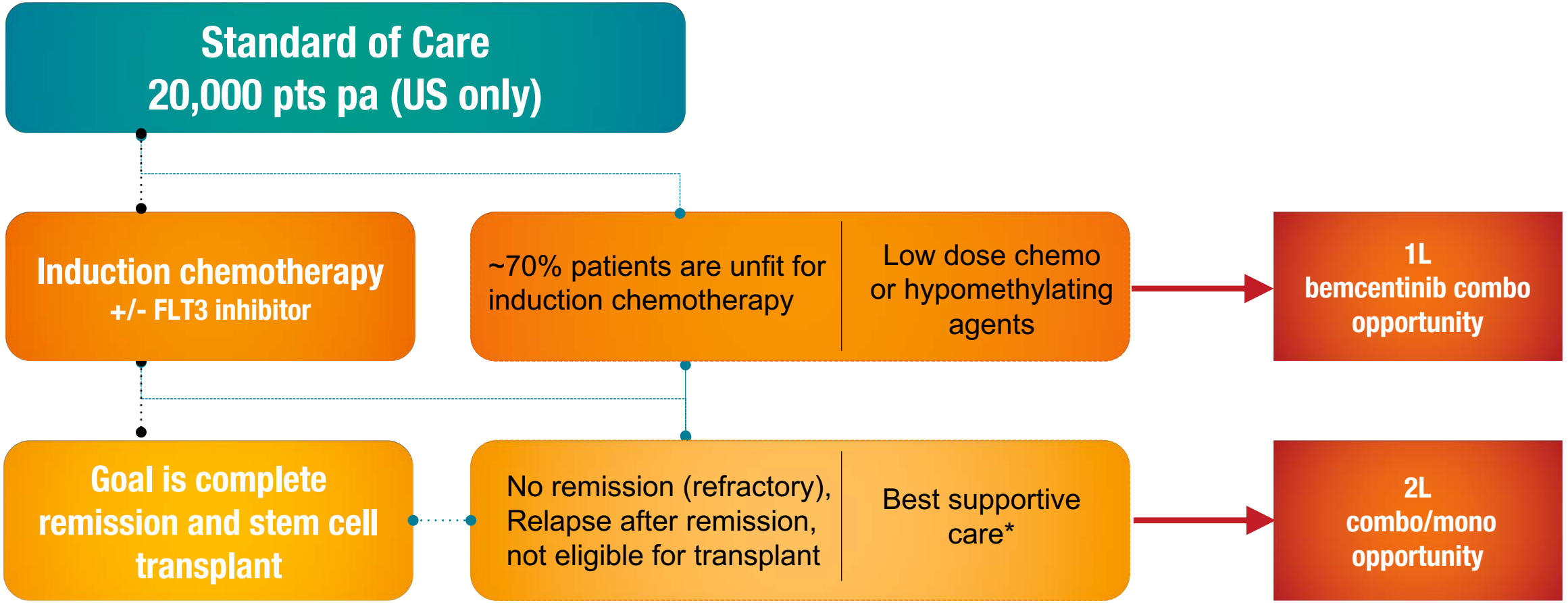
Ref. BGBC003 / NCT02488408

Acute Myeloid Leukaemia (AML)

Bemcentinib is being evaluated as a monotherapy and in combination with standard of care chemo therapy to treat AML

- ***Monotherapy 43% ORR in AXL +ve R/R AML***
- ***LDAC chemo combo 46% ORR in all comer AML***

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



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

Ref. BGBC003 / NCT02488408

Bemcentinib in AML

Monotherapy & in combination with low-dose chemotherapy

Relapsed/ refractory AML & high-risk MDS

up to 90 pts

2L Monotherapy (completed)

2L R/R AML & MDS
N = 36 pts

Combination Therapy (completed)

Decitabine combo
AML, N = 14 pts

Low-dose cytarabine (LDAC) combo
AML, N = 14 pts

Endpoints

Primary
- safety / ORR

Secondary
- RFS
- OS
- biomarkers

43%*

CR/CRi/CRp

* Ca. half of patients found to be AXL positive

Immune activation and clonal stabilisation observed

ASCO 2019

*LDCT: approved low dose chemotherapy regimens

Patient Demographics

Challenging Patient population

- **Elderly (>75yrs) patients**
- **LDAC treated patients were less healthy**
- **LDAC patients had less favorable cytogenetics**
- **LDAC patients predominantly pretreated**

Characteristic	LDAC + bemcentinib (n=16)	Decitabine + bemcentinib (n=17)
	n (%)	n (%)
Sex		
Male	11 (69%)	11 (65%)
Female	5 (31%)	6 (35%)
Age		
Mean	75.6	74.9
Median	76	76
Range	66-83	50-80
<75	5 (31%)	3 (18%)
>75	11 (69%)	14 (82%)
ECOG at screening		
0	4 (25%)	10 (59%)
1	10 (63%)	6 (35%)
2	1 (6%)	1 (6%)
Unknown	1 (6%)	0
% blasts at screening (bone marrow)		
Median	35	47.5
Range	3-96	21-95
<20%	1 (6%)	0
>20%	14 (88%)	14 (82%)
Unknown	1 (6%)	3 (18%)
WBC count at screening ($x10^9$/L)		
Median	5.0	5.3
Range	1,1-47,3	0,8-92,43

Characteristic	LDAC + bemcentinib (n=16)	Decitabine + bemcentinib (n=17)
	n (%)	n (%)
Disease diagnosis		
De novo	7 (44%)	5 (29%)
Secondary	8 (50%)	12 (71%)
Not assessed/Unknown	1 (6%)	0
FLT3 status		
Positive	1 (6%)	1 (6%)
Negative	11 (69%)	11 (65%)
Indeterminate/not tested	4 (25%)	5 (29%)
Cytogenetic risk class		
Favourable	1 (6%)	1 (6%)
Intermediate	7 (44%)	4 (24%)
Poor	5 (31%)	6 (35%)
Unknown	3 (19%)	6 (35%)
No. lines previous therapy		
Median	1	0
Range	0-8	0-3
0	7 (44%)	12 (71%)
1	3 (19%)	3 (18%)
2	2 (13%)	1 (6%)
>3	4 (25%)	1 (6%)
Disease status		
Refractory	4 (25%)	2 (12%)
Relapsed	4 (25%)	3 (18%)
First-line	8 (50%)	12 (72%)

Patient Treatment & Outcome

LDAC + bemcentinib

Preliminary efficacy Results

ORR: 46% (6/13)

6 responses have been reported
(4 CR/CRi + 2 PR)
1 durable stable disease (≥3 months)
Current relapse-free survival in CR/CRi patients: 6.2 months
(range: 0.7 – 9.6 months)

Decitabine + bemcentinib

Preliminary efficacy Results

ORR: 25% (3/12)

3 responses have been reported
(1 CRi + 2 PR)
5 durable stable disease (≥3 months)
Current relapse-free survival in CR/CRi patients: 5.0 months

Responses in evaluable patients *

	n	CR/CRi	PR	CR/CRi rate (%)	ORR (%)
LDAC + bemcentinib	13	4	2	30.8%	46.2%

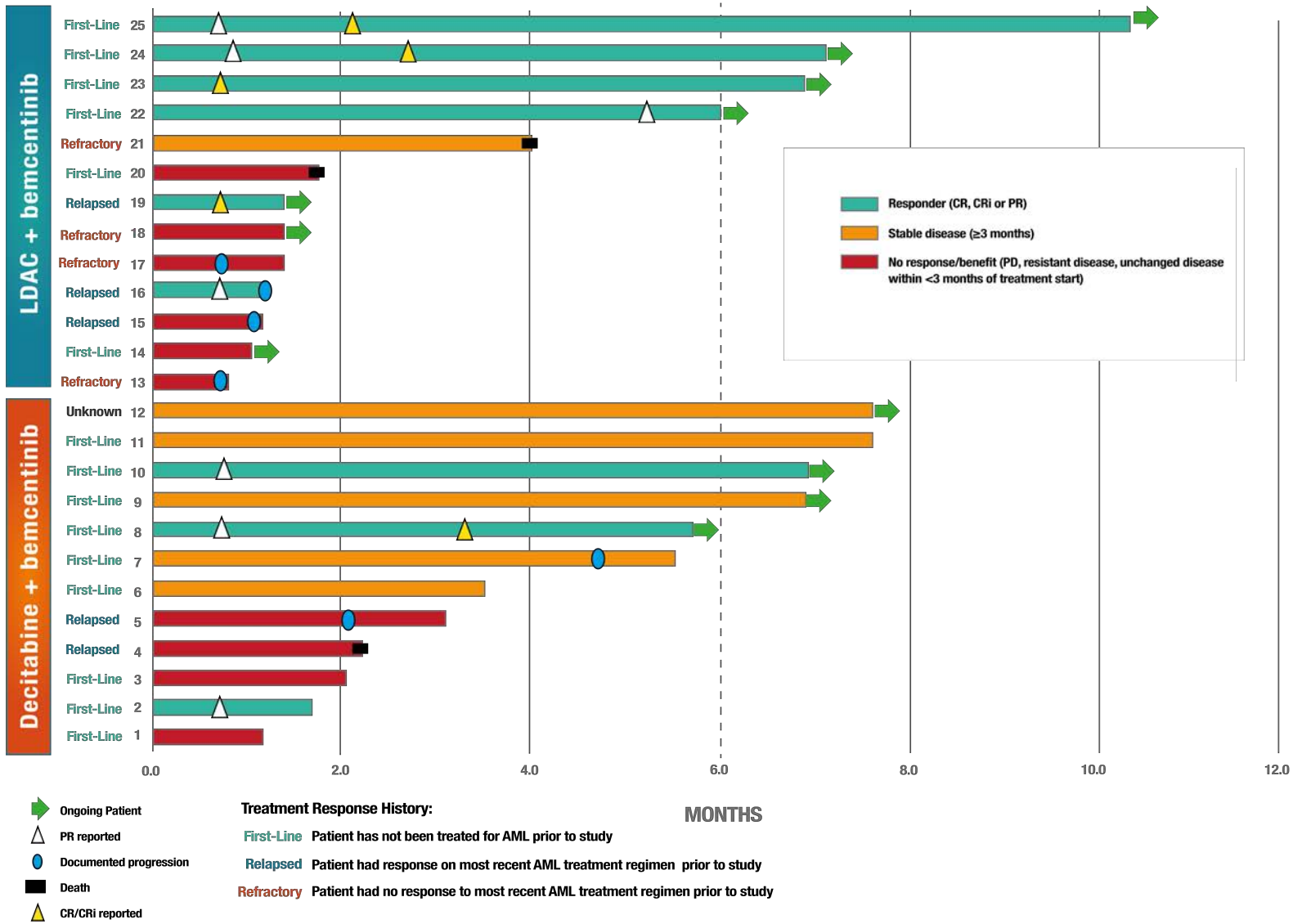
Four responses *were observed in* ***first-line*** *patients.*
Four responses *were observed in patients with* ***secondary disease***

Decitabine + bemcentinib	12	1	2	8.3%	25.0%

Three responses *were observed in* ***first-line*** *patients.*
One response *was observed in patients with* ***secondary disease.***

* **Evaluable patients are defined as those who have completed at least 1 cycle of treatment, and have at least 1 response assessment completed based on bone marrow aspiration results.**

Duration of response



Conclusions

- The LDAC+bemcentinib combination showed promising efficacy among elderly AML patient population with 80% >75 years both as first-line in untreated newly diagnosed AML patients and as 2nd - 5th line in relapsed AML patients
- Bemcentinib appears relatively safe and well tolerated in combination with both LDAC and cytarabine
- The ORR, particularly in combination with LDAC, is significantly higher than previously observed/historical benchmarks in single-agent cytarabine

Safety

- Favourable safety profile cf. other LDAC combinations approved for AML
- Treatment-related adverse events were generally considered to be less problematic than for other TKIs
- Patients did not discontinue treatment for adverse events

Adverse Events

LDAC + bemcentinib		
AEs in ≥15% of patients	**Any grade**	**Grades ≥3**
Any event, n (%)	13 (81%)	12 (75%)
Haematologic		
Anaemia	4 (25%)	4 (25%)
Neutropenia*	3 (19%)	3 (19%)
Thrombocytopenia	3 (19%)	3 (19%)
Non-haematologic		
Diarrhoea	7 (44%)	1 (6%)
Dyspnoea	3 (19%)	1 (6%)
Electrocardiogram QT prolonged	3 (19%)	2 (13%)
Epistaxis	3 (19%)	0
Mouth haemorrhage	3 (19%)	0
Oedema peripheral	3 (19%)	0

Decitabine + bemcentinib		
AEs in ≥15% pf patients	**Any grade**	**Grades ≥3**
Any event, n (%)	15 (88%)	14 (82%)
Haematologic		
Neutropenia*	4 (24%)	4 (24%)
Thrombocytopenia	3 (18%)	1 (6%)
Non-haematologic		
Electrocardiogram QT prolonged	9 (53%)	4 (24%)
Asthenia / Fatigue	5 (29%)	2 (12%)
Pyrexia	5 (29%)	0
Blood creatinine increased	4 (24%)	1 (6%)
Cough	4 (24%)	0
Diarrhoea	4 (24%)	1 (6%)
Hypokalaemia	4 (24%)	0
Constipation	3 (18%)	0
Oedema peripheral	3 (18%)	0
Pneumonia	3 (18%)	3 (18%)

Deaths, Infections & Neutropenia

		LDAC + bemcentinib (n =16)	Decitabine + bemcentinib (n =16)
Early deaths	Death ≤30 days after treatment start	1 (6%)	1 (6%)
	Death ≤60 days after treatment start	2 (13%)	3 (18%)
Infections	Any serious infection reported**	2 (13%), 3 events	3 (18%), 5 events
	Fatal infection within 60 days of starting treatment	1 (6%)	1 (6%)
Neutropenia*	Incidence of neutropenia (number of pts)	3 (19%)	5 (29%)
	Incidence of prolonged neutropenia, ≥10 days	1 (6%)	1 (6%)

* Preferred terms included: neutropenia, febrile neutropenia

** Patients affected by any SAE falling under System Organ Class "Infections and infestations" (preferred terms included: Atypical pneumonia, Sepsis, Device-related infection, Urinary tract infection enterococcal, Pseudomonas infection, Escherichia sepsis)

Conclusions

- The LDAC+bemcentinib combination showed significant promising efficacy among elderly AML patient population with 80% aged >75 years both as first-line in untreated newly diagnosed AML patients and as 2nd - 5th line in relapsed AML patients
- Bemcentinib appears relatively safe and well tolerated in combination with both LDAC and cytarabine
- The ORR, seen particularly in combination with LDAC, is significantly higher than previously observed/historical benchmarks in single-agent cytarabine

Context

Venetoclax + LDAC (1L)[1]

- Efficacy: CR/CRi rates: 54% mDOR: 8.1 months, mOS: 10.1 months,
- Safety (TEAEs, grades ≥3): Febrile neutropenia, 42%, Thrombocytopenia: 38%,

[1] Wei, Andrew et al. Journal of Clinical Oncology (2019). Venetoclax Combined With Low-Dose Cytarabine for Previously Untreated Patients With Acute Myeloid Leukemia: Results From a Phase Ib/II Study.

Clinical Development in AML

1. First to market : 2L in elderly relapse AML : Bemcentinib monotherapy

- No approved SOC for elderly (>75yrs) relapse AML patients, only treatment option is supportive palliative care
- Patient population is ca. 50% AXL +ve by BGB sAXL biomarker
- 43% ORR with DoR 2-15mo.
- Very well tolerated, no immune suppression

Clinical development strategy: All comer phase IIb > Interim Analysis > Registration cohort
Potential for breakthrough and accelerated approval

2. Bemcentinib + LDAC : 1L elderly AML

- Bemcentinib + LDAC appears well tolerated when compared to other LDAC combinations
- The ORR, observed in mixed line patient population is encouraging relative to other LDAC combinations and significantly higher than previously observed/historical benchmarks as single-agent.
- ORR of 46% was reported in an all comer AXL patient population, with mDoR exceeding that of other LDAC combinations, whilst still not mature.

Clinical development strategy: Expansion of current phase IIa, to confirm results.

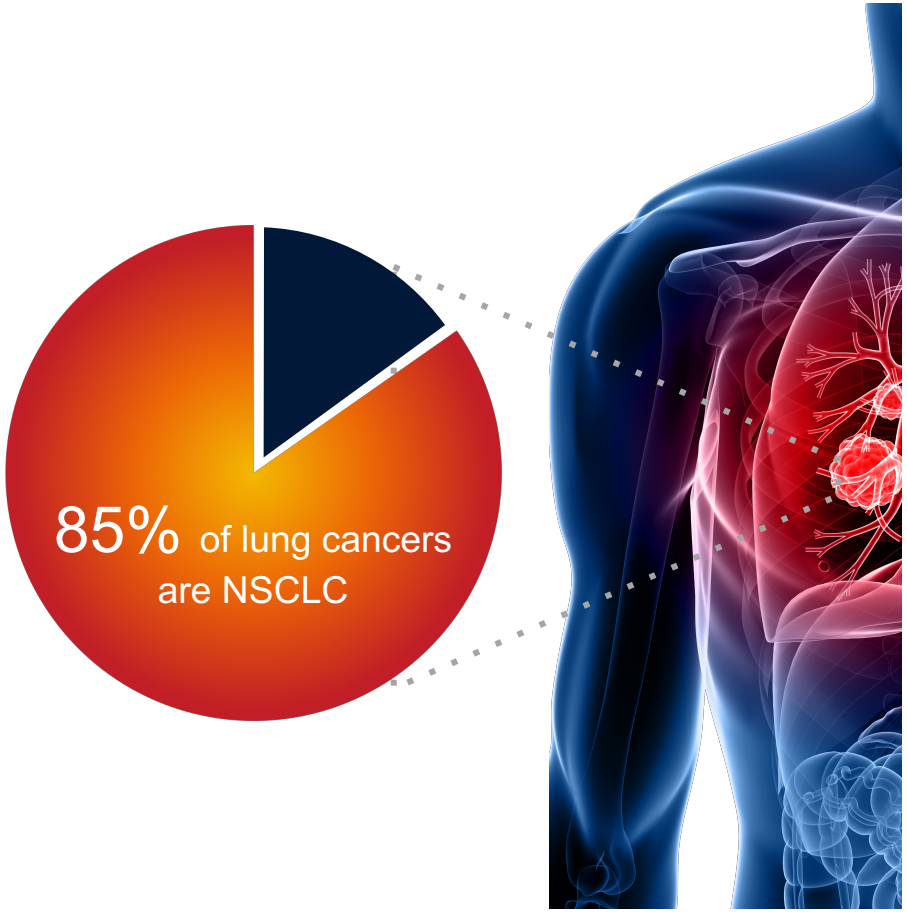
Non- Small Cell Lung Cancer (NSCLC)

NCT03184571

A phase II study of bemcentinib (BGB324), a first-in-class highly selective AXL inhibitor, with pembrolizumab in patients with advanced NSCLC: OS for stage I and preliminary stage II efficacy.

In collaboration with Merck & Co.

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



The largest cancer killer, most patients depend on drug therapy

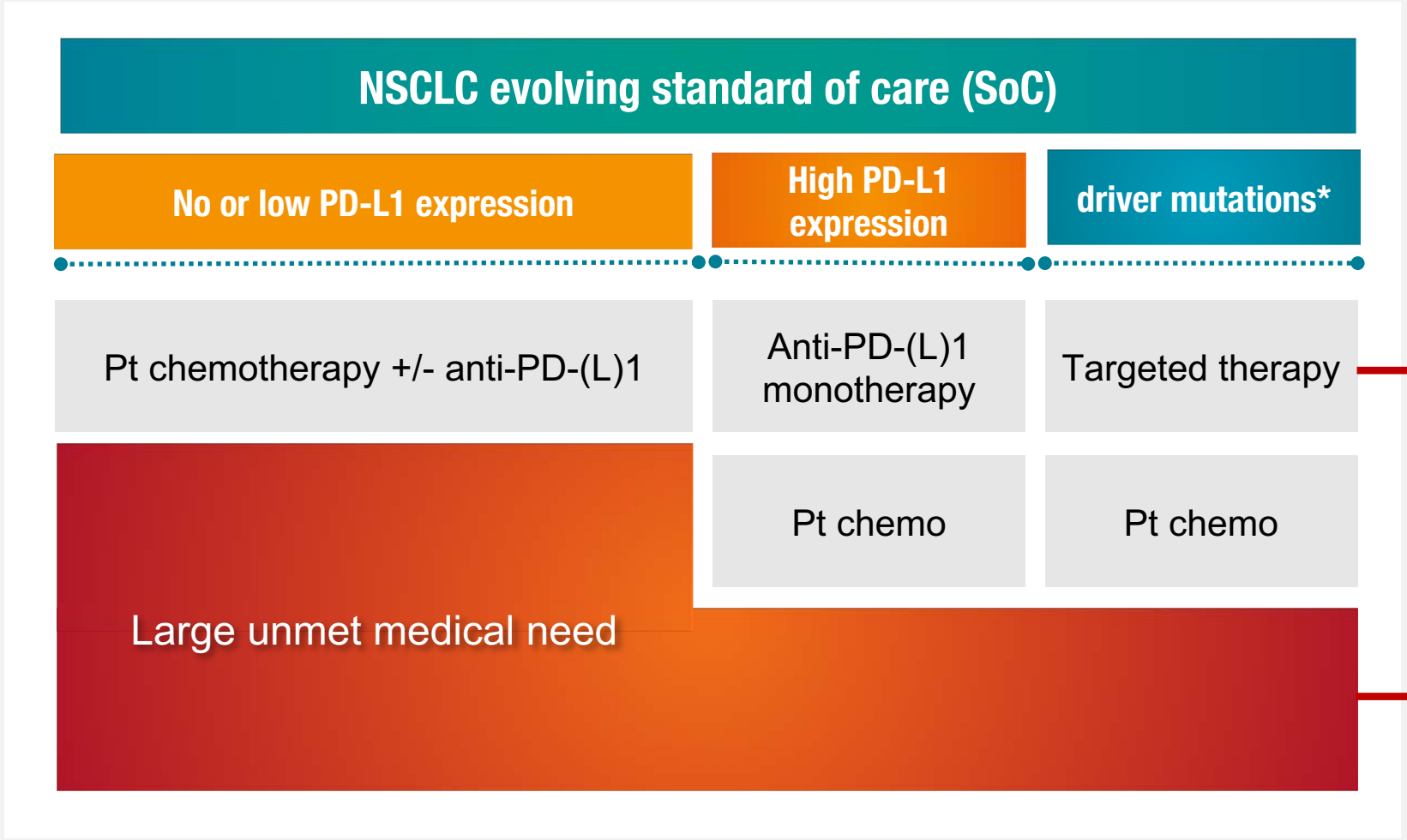
2.09 million new cases of lung cancer diagnosed/yr worldwide, making up 11.6% of all cancer cases[1]

1.76 million lung cancer deaths/yr worldwide[1]

5-year survival rate is 3.5% in patients with PD-L1 <1%, and **12.6%** in patients PD-L1 1-49%[2]

(1) Globocan 2018 (2) Garon, E.B. et al. 5-Year Long-Term Overall Survival for Patients With Advanced NSCLC Treated With Pembrolizumab: Results from KEYNOTE-001. 2019 ASCO Annual Meeting.

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



Opportunity for bemcentinib

Deepening 1 Line responses, particularly PD-L1 negative/low patients

Effective and well tolerated 2 Line therapies

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

Ref. BGBC008 / NCT03184571 – clinical trial collaboration with Merck & Co.

Bemcentinib + KEYTRUDA in Refractory NSCLC

Phase 2 Study Design

Cohort A
Previously treated, unresectable adenocarcinoma of the lung

PD-L1 / AXL all-comers

IO naïve

Cohort B

PD-L1 / AXL all-comers

IO relapse

	Stage 1		Stage 2
Cohort A	24 patients	If ≥ 4 PRs	24 patients
	COMPLETE		COMPLETE
	November 2018		**ASCO 2019**
	Efficacy & mPFS presented: Society for Immunotherapy in Cancer (SITC)		Data update
Cohort B	N = 13 pts	If ≥ 1 PRs	N = 16 pts
	RECRUITING		

Key objectives

- Evaluate safety of the combination and response to treatment with the combination
- Characterise patients by PD-L1 and AXL status
- Evaluate efficacy of patients by biomarker status, and assess predictive qualities of biomarkers
- Assess survival measures in patients by biomarker status

Patient Disposition, stages I & II

Screened: n = 74

Received at least 1 dose of combination
N=46

At least 1 radiological assessment
n=35

Progression without radiological assessment
n=3

No response assessment
n=8

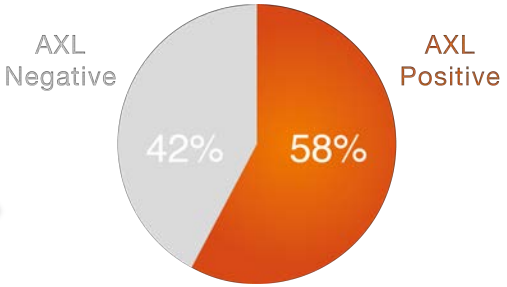
Ongoing
N=16

Discontinued
N=30

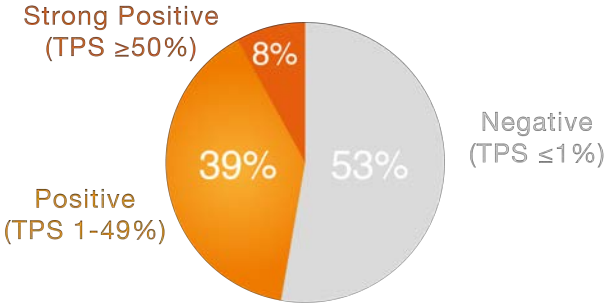
15 PD
7 AE
3 death
3 Investigator decision
2 withdrawal of consent

Biomarker evaluation

AXL Status: n = 33
28 with at least 1 radiological assessment



PD-L1 Status: n = 38
29 with at least 1 radiological assessment



Data cut off April 23'19

Patient Demographics & Disease Characteristics

Typical 2L relapse patient population, ca. 70yrs, ECOG 0&1, smokers (& -ex), non mutant.

Median Age (range)	64.5 (39-82)
ECOG at screen	
0 (%)	22 (47.8%)
1 (%)	24 (52.2%)
>2 (%)	0
Sex	
Female (%)	18 (39.1%)
Male (%)	28 (60.9%)
Ethnicity	
Hispanic or Latino (%)	9 (19.6%)
Not Hispanic or Latino (%)	37 (80.4%)

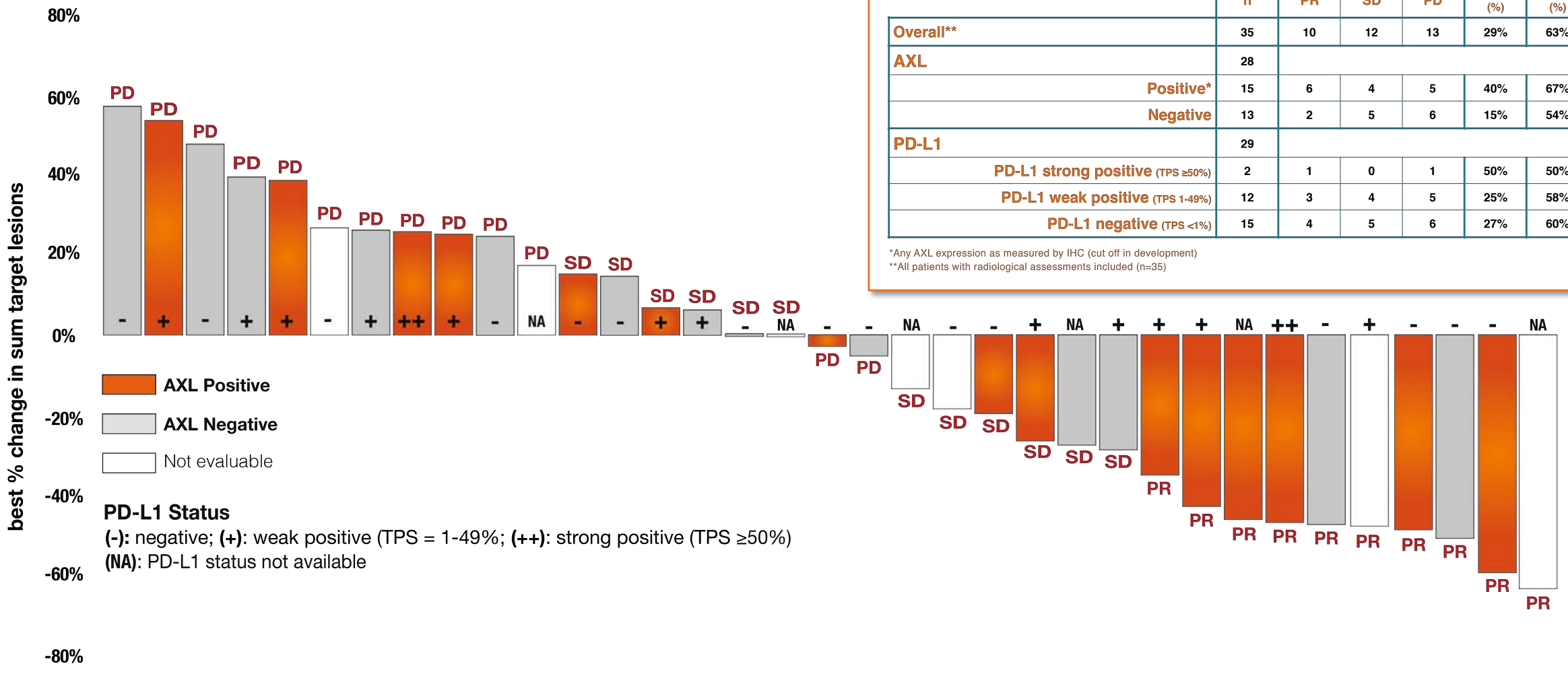
Race	
White (%)	43 (93.5%)
Asian (%)	2 (4.3%)
Other (%)	1 (2.2%)
Smoking status	
Smoker (%)	8 (17.4%)
Ex-smoker (%)	27 (58.7%)
Never smoked (%)	10 (21.7%)
Unknown (%)	1 (2.2%)
Pack years	
Median	36.5
Range	0,5-100

Mutations*	**n**	**%**
None	35	76%
KRAS	6	13%
TP53	2	4%
ERBB2	1	2%
EGFR	1	2%
Other/Unknown	2	4%
Best response to most recent treatment	**n**	**%**
CR	2	4%
PR	17	37%
SD	10	22%
PD	12	26%
Unknown	5	11%

* May be overlap between individual patients

Antitumour activity Change in tumour size from baseline (by AXL IHC)

40% ORR & 67% Clinical benefit in AXL+ve patients, irrespective of PD-L1 status.



	n	PR	SD	PD	ORR (%)	CBR (%)
Overall**	35	10	12	13	29%	63%
AXL	28					
Positive*	15	6	4	5	40%	67%
Negative	13	2	5	6	15%	54%
PD-L1	29					
PD-L1 strong positive (TPS ≥50%)	2	1	0	1	50%	50%
PD-L1 weak positive (TPS 1-49%)	12	3	4	5	25%	58%
PD-L1 negative (TPS <1%)	15	4	5	6	27%	60%

*Any AXL expression as measured by IHC (cut off in development)
**All patients with radiological assessments included (n=35)

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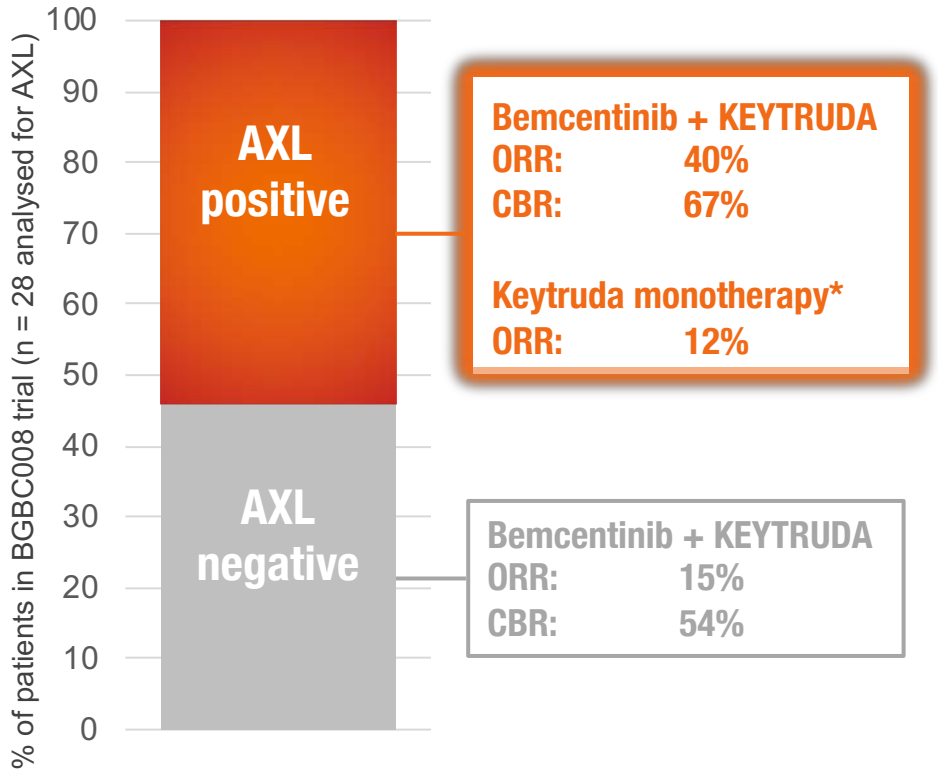
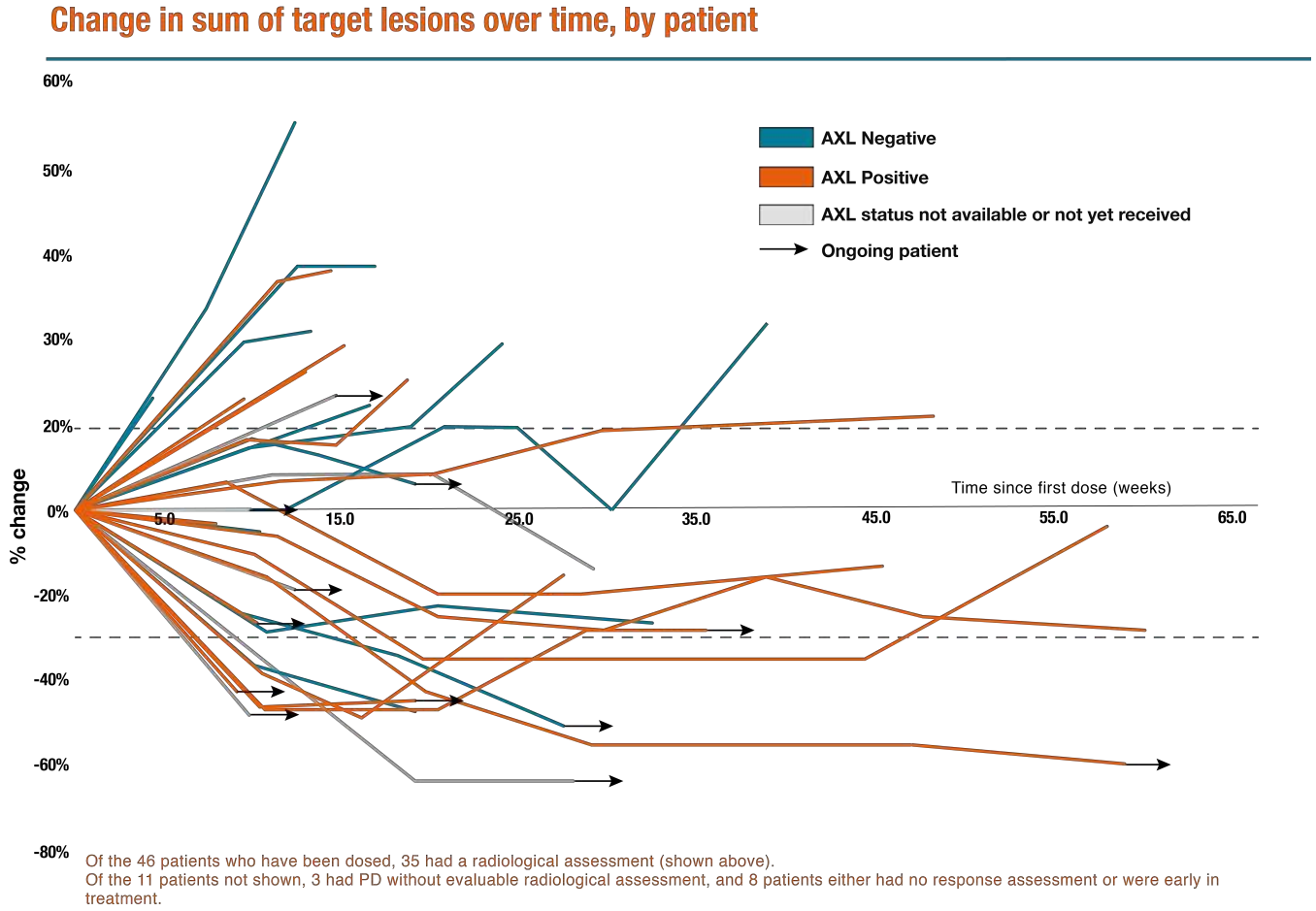
2nd Line Proof of Concept (PoC) data





* PD-L1: 0 - 49%, Garon *et al* (2015), response rates between 8% (PDL1 negative) and 12-16% (PDL1 1-49%)

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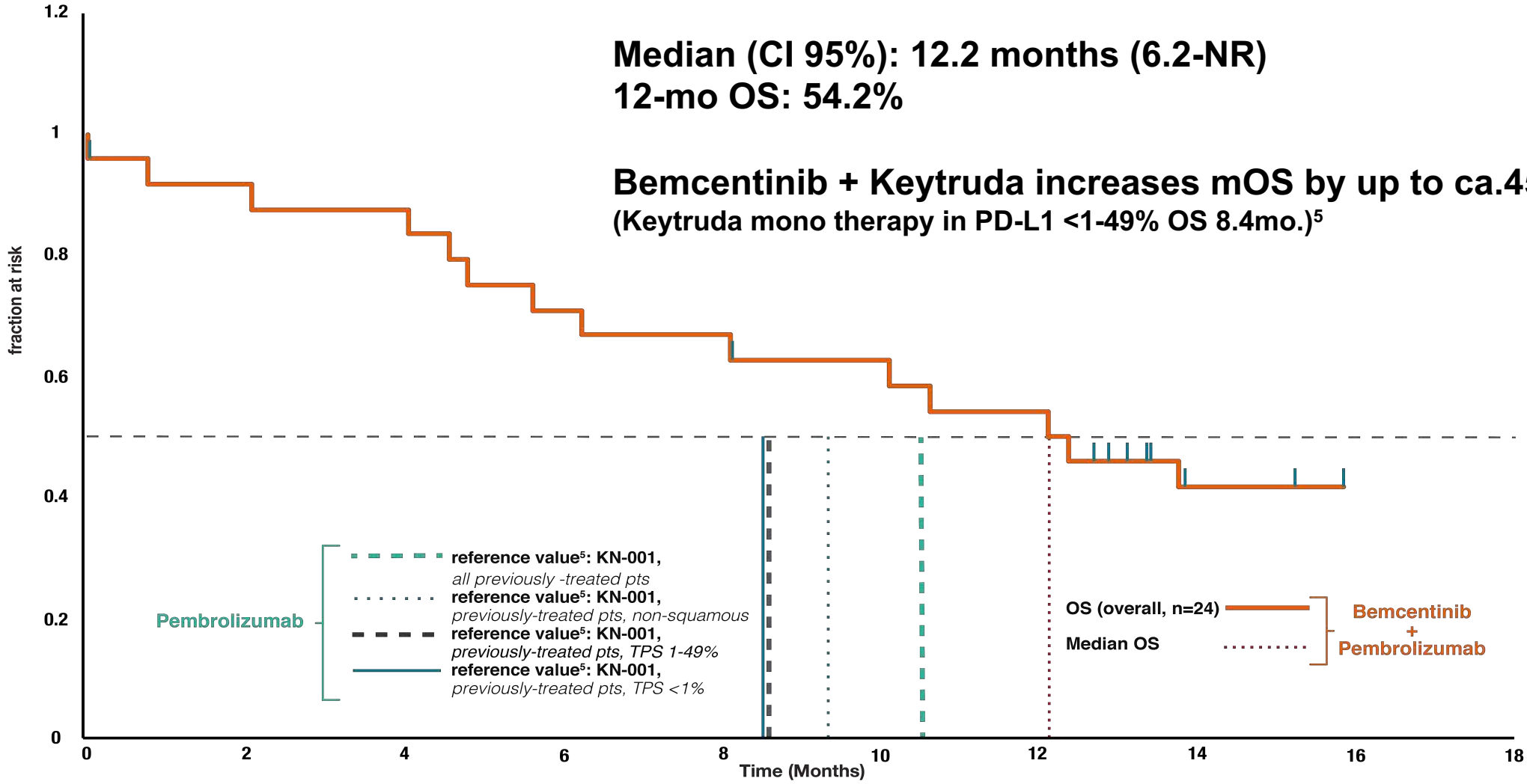
Median overall survival in stage I patients (n=24)



[5]Leighl, Natasha B. et al. Pembrolizumab in patients with advanced non-small-cell lung caner (KEYNOTE-001): 3-year results from an open-label, phase 1 study. Lancet Respir Med (2019).

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Safety

- **The safety profile 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 problematic than for other TKIs or CPI combinations used in NSCLC**

Safety

Most frequent TRAEs (occurring in >10% of dosed patients)
n = 46

Preferred term	All grades		Grades ≥3	
	n	%	n	%
Transaminase increase*	16	35%	6	13%
Asthenia / Fatigue	14	30%	2	4%
Diarrhoea	12	26%	0	0%
Nausea	6	13%	0	0%
Anaemia	5	11%	1	2%
Decreased appetite	5	11%	0	0%

* Preferred terms include: Alanine aminotransferase increased, Aspartate aminotransferase increased and Transaminases increased. All events were reversible

No grade 5 TRAEs were reported.

Conclusions

- Promising clinical activity continues to be seen overall, particularly in patients with AXL positive tumours, including those with weak or no PD-L1 expression
- The median overall survival has surpassed what has been shown historically in 2nd line treatment with PD-1 inhibitor monotherapy
- The studied population was predominantly PD-L1 negative (53%) patients who are less likely to benefit from pembrolizumab monotherapy treatment
- The studied population was predominantly AXL positive (58%) patients
- The combination of bemcentinib and pembrolizumab was well-tolerated.

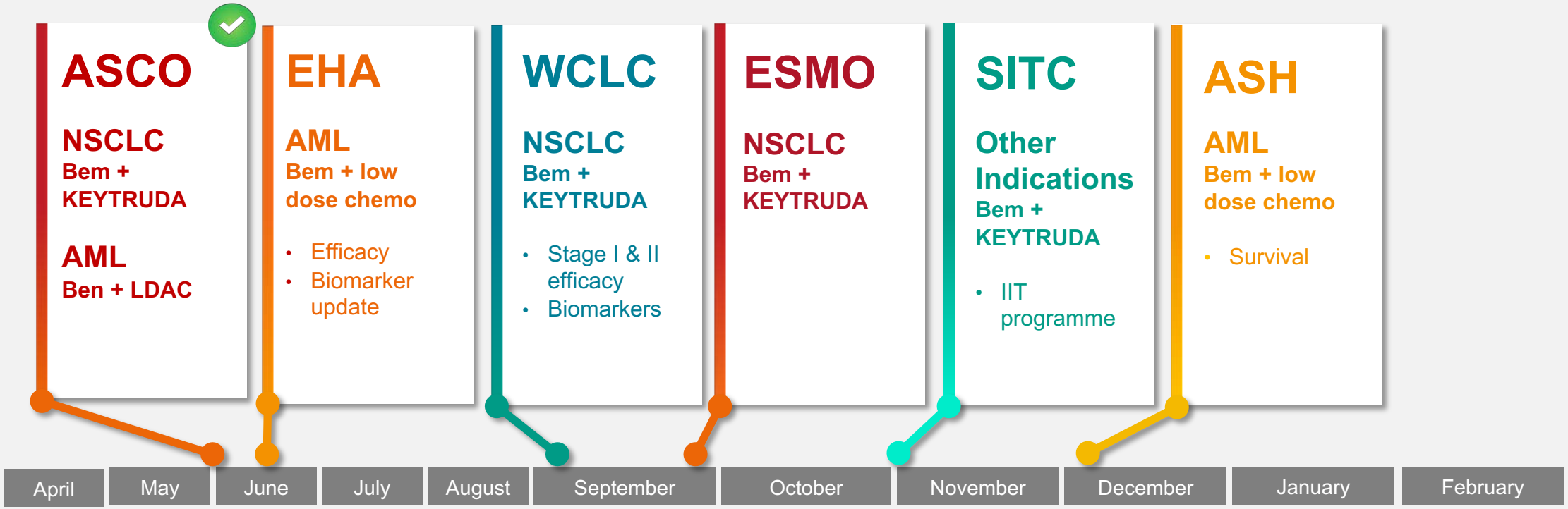
Clinical Development in NSCLC

Step 1. 2L CPI relapse

- Emerging 1L combination of KEYTRUDA + chemotherapy has left a vacuum in 2L
- KEYTRUDA + chemotherapy - ORR 48% with mPFS of 8.8mo.
- 2L standard of care is limited to docetaxel or clinical trial
- Check point inhibitor (CPI) 'salvage' represents a substantial unmet medical need

Clinical strategy: On-going cohort B IO relapse patients.
Potential for breakthrough and accelerated approval

Newsflow
H2, 2019



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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QUESTIONS?