Q3 2021 REPORT, HIGHLIGHTS AND FINANCIALS

16th November 2021

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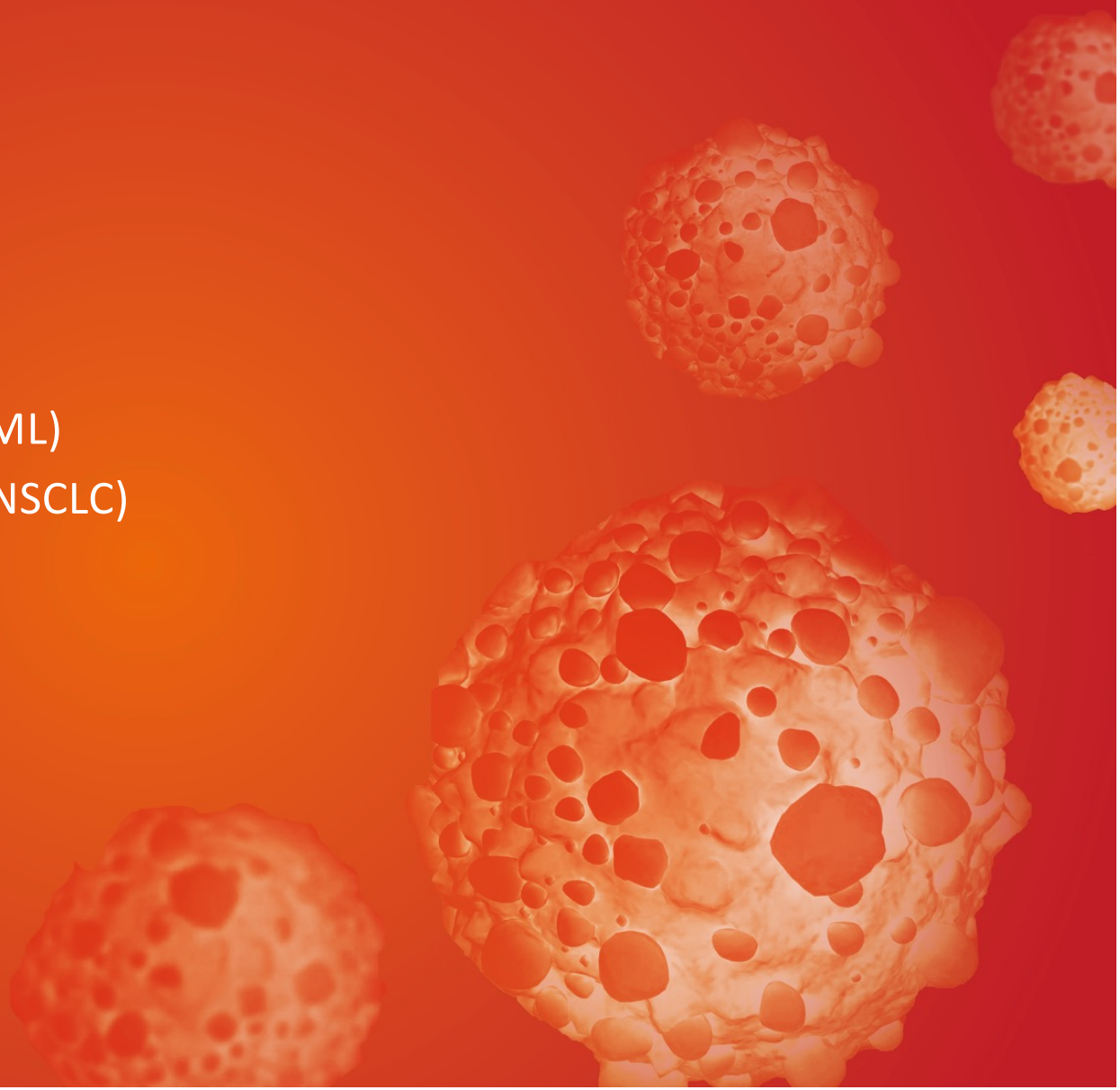
AGENDA

1. Q3 and Recent Highlights
2. AXL inhibitors
3. Bemcentinib
   - Acute Myeloid Leukaemia (AML)
   - Non-Small Cell Lung Cancer (NSCLC)
   - COVID-19
4. Tilvestamab
5. Finance Report
6. 2021 Highlights & Outlook



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Q3 and recent highlights

- Post-period end, NSCLC data presented at SITC, highlighting bemcentinib's potential in NSCLC patients harbouring STK11 mutations
- AML data presented at EHA indicate bemcentinib/LDAC combination is active and well tolerated in relapsed elderly AML patients unfit for intensive chemotherapy
- COVID-19 data in late-breaking abstract presentation at ECCMID demonstrate encouraging evidence for effect of bemcentinib in hospitalised patients receiving steroids ± remdesivir

AXL mediates aggressive disease

Very low expression under healthy physiological conditions

AXL signaling is upregulated by hostile cellular microenvironment and viral infection

Cancer
- Immune evasive
- Drug resistant
- Metastatic

Elevated AXL signaling strongly associated with cancer progression, immune evasion, drug resistance and metastasis

Viral infection
- SARS-CoV-2
- Ebola
- Zika

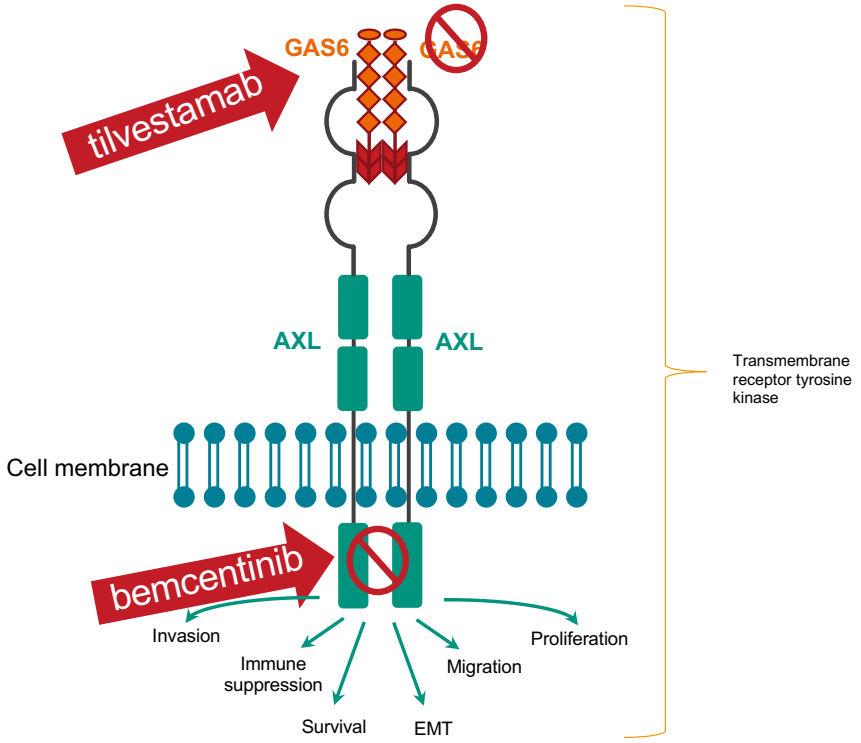
AXL mediates viral entry to cells and dampening of viral immune response

Fibrosis
- Renal
- NASH
- IPF
- MF
- COPD

Axl regulates cellular plasticity implicated in fibrotic pathologies e.g., EMT, EndMT, Macrophage polarity

First-in-class selective AXL inhibitors

Bemcentinib & Tilvestamab block AXL signaling



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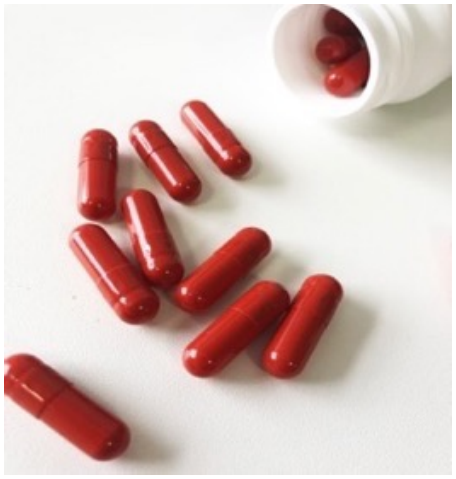
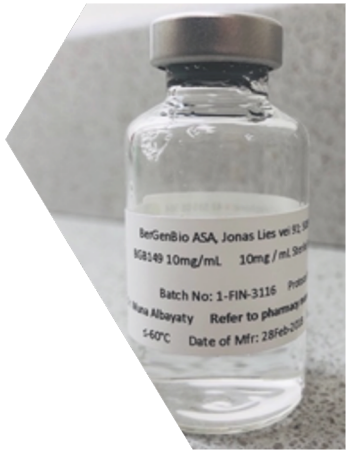
Two first-in-class, potent, highly selective AXL inhibitors in clinical development

Bemcentinib*



- Oral, once a day
- Size 0 capsule
- Favorable benefit:risk profile
- Combines well with other drugs
- In Phase II (AML/MDS, NSCLC and COVID)

Tilvestamab**

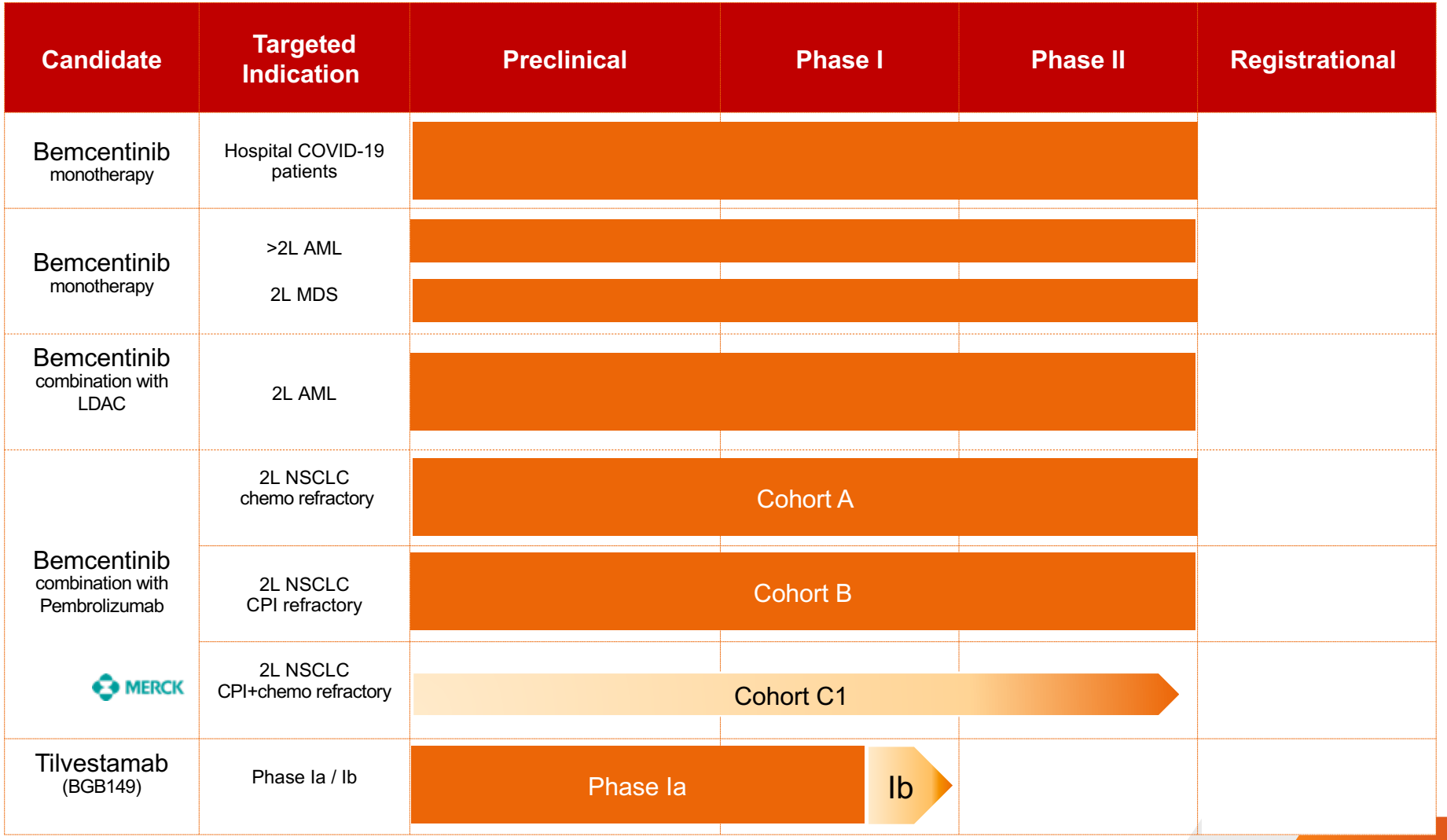


- Fully humanized mAb – displaces GAS6
- Phase Ia complete
  - No DLTs, dose proportionate PK-PD
- In Phase Ib/IIa
  - Serial biopsies to confirm PK-PD

* In licensed from Rigel Pharmaceuticals Inc, 2011 – Global development and commercialization rights

** Developed by BerGenBio, wholly owned asset

Pipeline of sponsored clinical trials



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Bemcentinib in Acute Myeloid Leukaemia (AML)

- Despite several recent treatment approvals – 2L relapsed & refractory represents a high unmet need
- Encouraging early data (BGBC003 trial now fully enrolled) in relapsed patients unfit for intensive chemotherapy
- FDA granted Orphan Drug Designation and Fast Track
- Next step is a confirmatory randomized placebo-controlled trial in relapsed 2L AML (H2 2022)

Despite recent drug launches – high unmet medical need remains, particularly for patients progressing after 1L therapy

AML 8MM incidence ~72k 2019

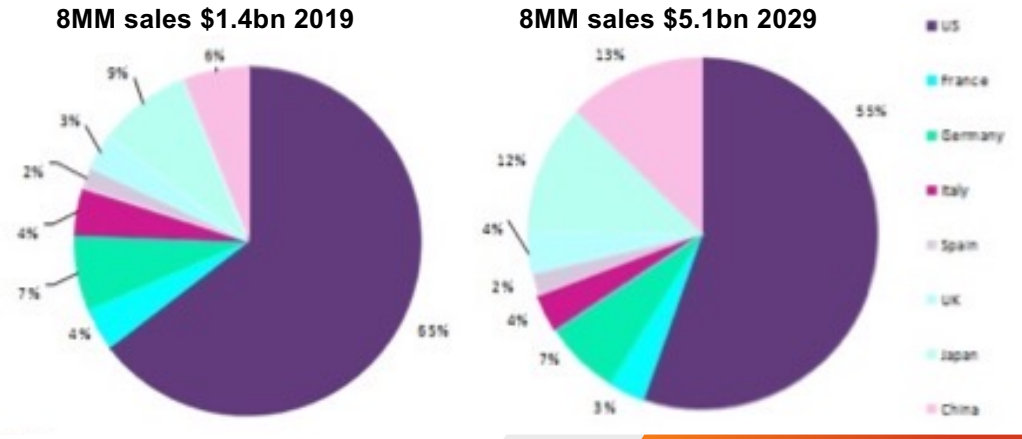
- Older population disease- >80% patients over 60
- Management dictated by suitability for intensive therapy
- Improved remission rates with new therapies have not translated to an increase in long-term survival in AML
    - 5-year OS: 28.3% all ages, 13.5% >65 and 3.4% >75

Bemcentinib opportunity in highest unmet need indication:

- Patients (all ages) who are relapsed or are refractory to previous treatments - limited market competition

AML 8MM sales $1.4bn 2019 rising to $ 5.1bn 2029

- US 65% of global sales
- Adoption of new premium priced novel therapies, particularly Venclexta® will drive significant sales growth

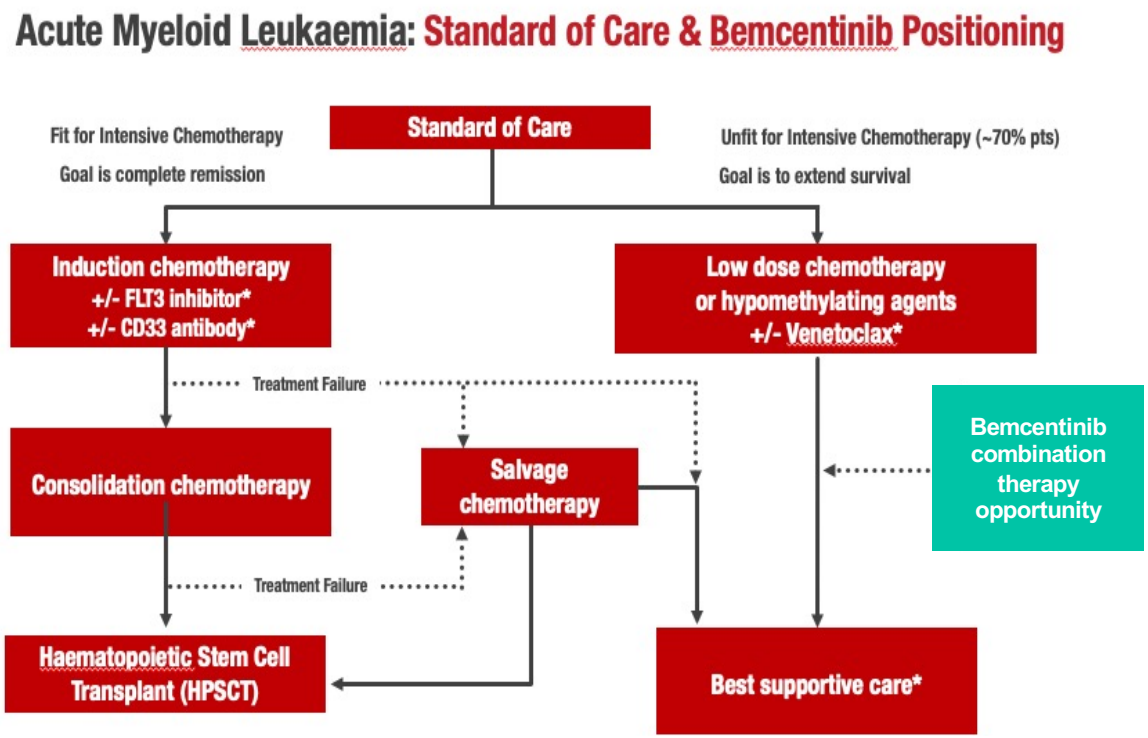


Source Global Data, UpToDate

Current treatment landscape and unmet medical need in AML

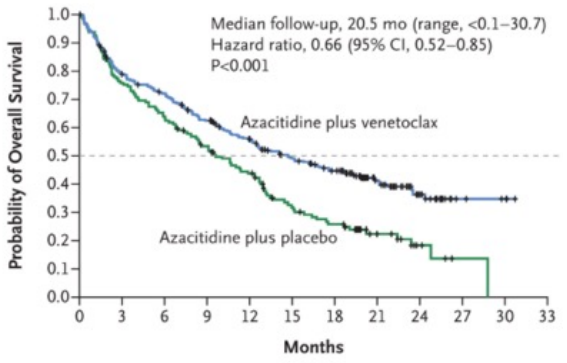
R/R patients unfit to receive intensive chemotherapy – poor outcome…

26,700 new AML diagnoses in pts unfit for IC/year across US, 5EU, Japan, China with 22,300 pts reaching 2L and 3L treatment



First Line Treatment

- Evolved to include **venetoclax in combination with HMA** (preferred) or LDAC +/- Venetoclax or Glasdegib
- **CR/CRi 65%** rate and mOS of 14.7mo[1]
- Relapsed patients **mOS 4.7mo[2]**



1.VIALE-A NCT02993523
2.2 Leukemia Research Volume 90, March 2020, 106314

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Phase I/II study in elderly AML patients unfit for intensive chemo and transplant

Phase 1 n=36

Single agent bemcentinib dose-finding in r/r AML/MDS

Established safety and recommended Phase 2 dose

Translational research confirmed immuno-therapy mechanism of action

Phase 2 Expansion Cohorts

Cohort B1 n=14

Monotherapy AML

Cohort B2 n=16

Combination with LDAC in newly diagnosed or relapsed AML

Cohort B5 expansion

Combination with LDAC relapsed AML (ongoing)

Cohort B3 n=14

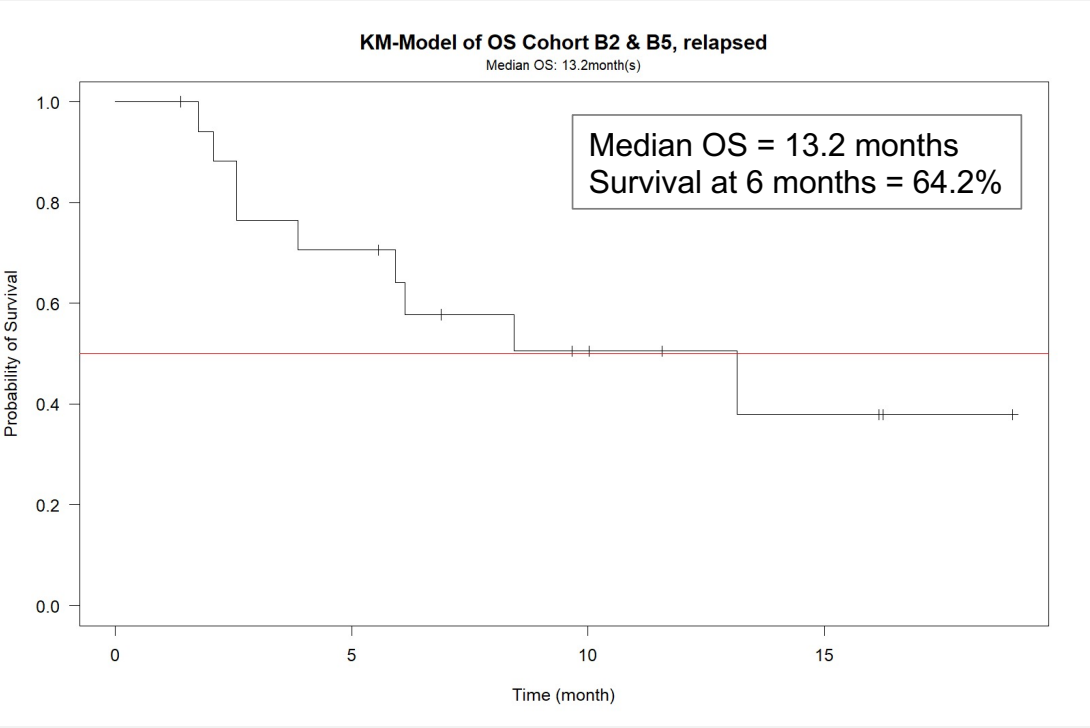
Combination with decitabine in ND or relapsed AML

Cohort B4 n=14

Monotherapy MDS

LDAC = Low Dose Cytarabine
AML = Acute Myeloid Leukaemia
MDS = Myelodysplastic syndromes

Combination of bemcentinib and LDAC (cohort B2 & B5) shows encouraging non-matured median overall survival benefits in relapsed patients

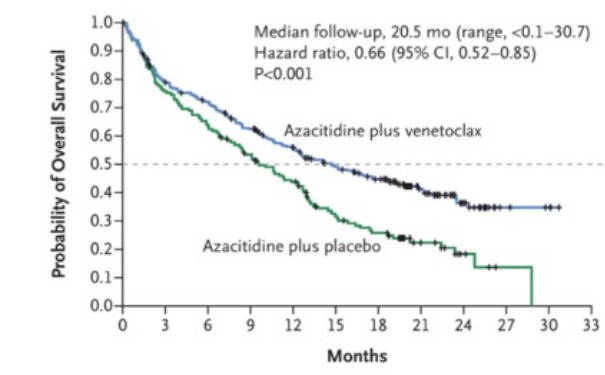


Cut off as of 28th Oct 2021

Relapsed only n=18 patients (9 censored and 9 dead)

First Line Treatment

- Evolved to include **venetoclax in combination with HMA** (preferred) or LDAC +/- Venetoclax or Glasdegib
- **CR/CRi 65%** rate and mOS of 14.7mo[1]
- Relapsed patients **mOS 4.7mo[2]**



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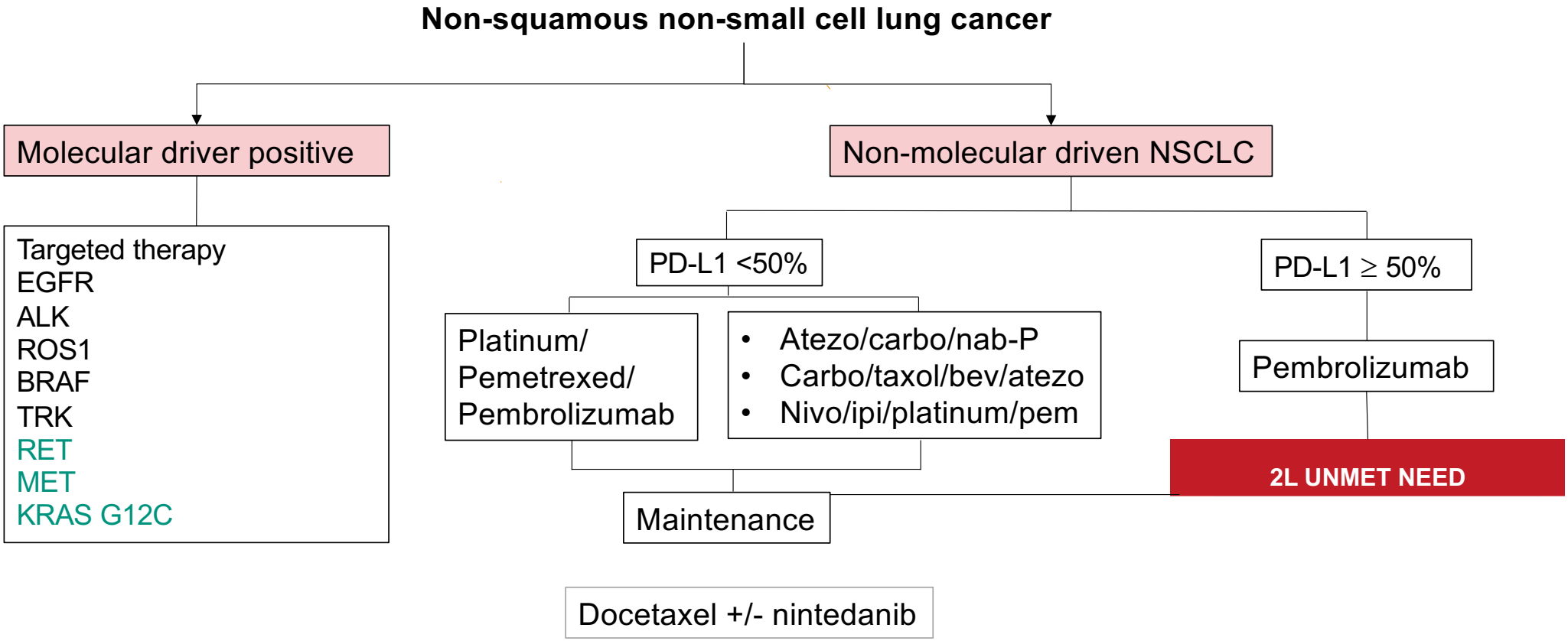
Summary of bemcentinib in AML and next steps

- High unmet medical need in relapsed and refractory 2L AML
- Bemcentinib mediates an anti-AML immune response through activation of NK and T cells
- Bemcentinib is well tolerated (mono- and combination) and accumulates in bone marrow tissue
- Encouraging non-matured mOS benefits in relapsed 2L AML patients unfit for intensive chemotherapy
- Granted Orphan Drug Designation and Fast Track by US FDA in 2L AML (patients unfit for intensive chemotherapy)
- Next step is the conduct of a confirmatory randomized and placebo-controlled trial (H2 2022)

Bemcentinib in NSCLC

- Largest oncology indication – rapidly evolving treatment landscape – unmet needs remains high
- NSCLC is composed of several mutational drivers and not just “one disease”
- BGBC008 Cohort B2 is now fully enrolled data expected in H1 2022
- STK11 mutations occurs in up to 20% of 1L NSCLC – and is reported to be a poor prognostic factor
- Bemcentinib reverses anti-PD-1/PD-L1 blockade in STK11 mutations and encouraging data from BGBC008 suggest clinical benefit in STK11 mutated patients
- Securing valuable rights through acquiring exclusive license relevant to STK11 mutations
- FDA granted Orphan Drug Designation and Fast Track
- Next step is a Phase 1b trial in 1L STK11 mutant patients (H1 2022)

Treatment landscape for NSCLC



* ESMO guidelines Sep 2020

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BGBC008

BGBC008 trial: 2L NSCLC Study with bemcentinib + pembrolizumab

Cohort A • Previously treated with a platinum containing chemotherapy • CPI-naïve • Has PD at screening	**Interim Analysis** Stage 1 N=22 patients	**Final Analysis COMPLETE** Total N=48 patients
Cohort B • Previously treated with a mono therapy PD-L1 or PD-1 inhibitor • Must have had disease control on most recent treatment • Has PD at screening	**Interim Analysis** Stage 1 N=16 patients	**Recruitment Complete** Total N=29 patients
Cohort C • Previously treated 1st line with a combination of checkpoint inhibitor + platinum-containing chemotherapy • Must have had disease control on 1st line therapy • Has PD at screening	**Interim Analysis** Stage 1 N=13 patients	**Pending** Total N=29 patients

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Pre-clinical data indicate bemcentinib restores PD-1 blockade sensitivity of STK11/LKB1 mutant NSCLC through expansion of TCF1+ CD8 T cells….

AXL targeting restores PD-1 blockade sensitivity of STK11/LKB1 mutant NSCLC through expansion of TCF1+ CD8 T cells

UT Southwestern Medical Center

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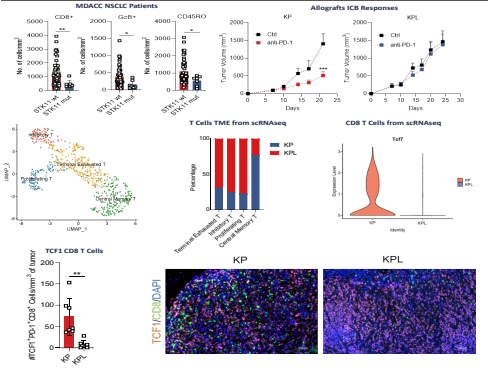
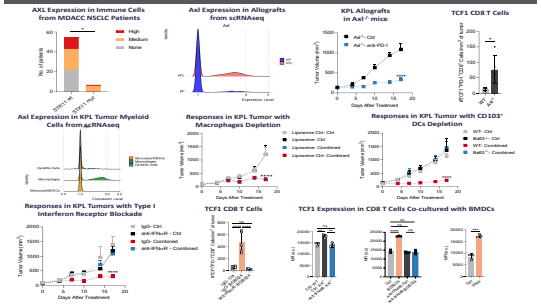
Abstract

Mutations in the tumor suppressor STK11/LKB1 are associated with negative predictive and prognostic impact in non-small cell lung cancer patients receiving immune checkpoint blockade in several published cohorts, although there have been some conflicting reports on the association of such mutations with patient outcomes in this setting [1-9]. We found that introduction of a Stk11/Lkb1 (L) mutation into murine lung adenocarcinomas driven by mutant Kras and Trp53 loss (KP) resulted in a syngeneic KPL tumor model that recapitulated the responses and tumor microenvironment of human STK11/LKB1 mutant NSCLCs. Mechanistically, KPL mutant NSCLCs lacked TCF1-expressing CD8 T cells to respond to ICB treatment. Systemic inhibition of AXL with the small molecule inhibitor bemcentinib/BGB324 results in increased type I interferon secretion from dendritic cells that expands tumor-associated TCF1+ PD-1+ CD8 T cells, restoring therapeutic response to PD-1 ICB for KPL tumors. This effect was observed in syngeneic immunocompetent mouse models and in humanized mice bearing STK11/LKB1 mutant NSCLC human tumor xenografts. Anecdotally, 3 of 3 evaluable NSCLC patients with identified STK11/LKB1 mutations receiving bemcentinib and pembrolizumab demonstrated objective clinical response to combination therapy. We conclude that in these models AXL is a critical targetable driver of immune suppression in STK11/LKB1 mutant NSCLC.

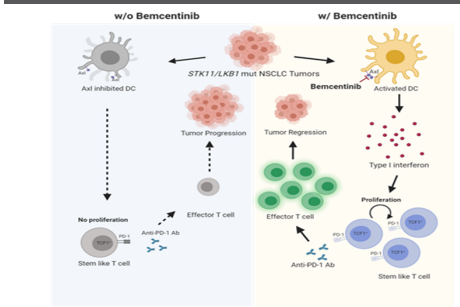
STK11 Mutated Tumors Lack TCF1 CD8 T Cells



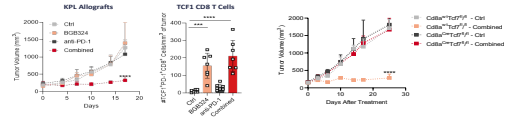
Axl Inhibition in Dendritic Cells Restores TCF1 CD8 T Cells



Graphic Abstract



Bemcentinib Sensitizes STK11 Mutant tumors to ICB Therapy



Therapeutic Effects in NSCLC Xenografts & Patients

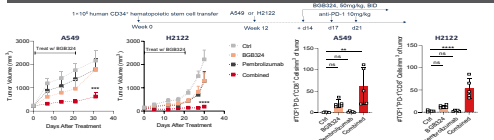


Table 1: NCT03184571, BerGenBio ASA and Merck & Co., Inc.

Age/Gender	79 / Male	73 / Male	51 / Male
Previous therapy	Carboplatin / Paclitaxel	Pembrolizumab	Alezolizumab
STK11 mutation	Moderate LD140PY	Moderate D115V	High S271fs
KRAS mutation	Not detected	Not detected	Not detected
TP53 mutation	High (multiple variants)	Moderate R337L	High R110P
PD-L1 TPS	0	15	0
AXL Expression	Tumor and Immune weak pos.	Immune strong pos.	Immune pos.
Target Lesions	1 Lung, 1 Adrenal	1 lymph node, 1 chest wall	
Sum Longest Diam.	79 mm	85 mm	129 mm
PFS on study	10.1 months	3.5 months	6.2 months
Overall survival	>33 months (ongoing)	10 months	10 months
Best response	Partial Response	Stable Disease	Stable Disease

Conclusion / Summary

Lack of TCF1-expressing CD8 T cells prevents ICB efficacy in *KPL* tumors. Systemic inhibition of AXL increased type I interferon secretion from dendritic cells that expanded tumor-associated TCF1+ PD-1+ CD8 T cells and restored anti-PD-1 efficacy in *STK11/LKB1* mutant tumors. Anecdotally, NSCLC patients with identified STK11/LKB1 mutations receiving bemcentinib and pembrolizumab demonstrated objective clinical response to combination therapy. These results show that AXL is a critical targetable driver of immune suppression in *STK11/LKB1* mutant NSCLC.

Funding Resources / Acknowledgements

This work was supported by: CPRIT training grant RP210041(to HL); RCN industrial PhD studentship 311397 (to AR); BerGenBio ASA and NIH grants R01 CA243577 and U54 CA210181 (to RAB); NIH SPORE P50 CA070907, U54 CA224065, and CPRIT RP160652 (to JDM); RP150072 and RP180725 (Y-XF); NIH P30 CA142543 (RAB, JDM, Y-XF). We also thank the ARC, Whole Brain Microscopy Facility and Flow Cytometry Facility cores at UTSW for assistance and we acknowledge NIH P01 HD087150 for cord blood collection.

References: [1]Gu M, Xu T, et al. Ther Adv Med Oncol. 2021;13:17588359211006950. [2]Cho BC, et al. Cancer Res. 2020;80(16 Supplement):CT084. [3]Aredo JV, et al. Lung Cancer. 2019;133:144-150. [4]Kwack WG, et al. Oncol Targets Ther. 2020;13:8901–8905. [5]Shire NJ, et al. PLoS One. 2020;15(9):e0238358. [6]Skoulidis F, et al. Cancer Discov. 2018;8(7):822-835. [7]Wang H, et al. 2020;84:106574. [8]Kitajima S, et al. Cancer Discov. 2019;9(1):34-45. [9]Mograbi B, et al. Diagnostics (Basel). 2021;11(2):196

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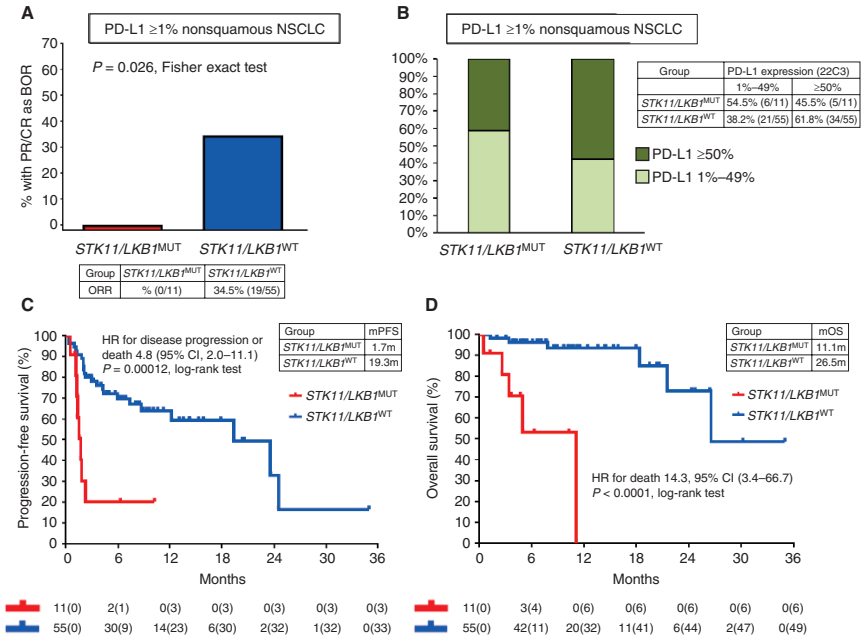
...and clinical evidence suggests that STK11/LKB1 mutations are associated with shorter mPFS and mOS with PD-1/PD-L1 blockade and reduced response….

- 66 NSCLC pts treated with nivolumab 0/11 *STK11*-mutant pts responded (Skoulidis *et al* 2018)
- 75 NSCLC pts treated with ipi-nivo 0/7 STK11-mutant pts responded (Hellman et al 2018)
- 161 NSCLC pts treated with durvalumab 1/21 STK11-mutant pts responded (Kunkel et al 2018)
- 97 NSCLC patients treated with durvalumab + tremelimumab 1/23 STK11 mutant pts responded (Kunkel et al 2018)
- **Overall response rate in CPI treated STK11 mutant patients (without chemotherapy) 3% (2/62)**



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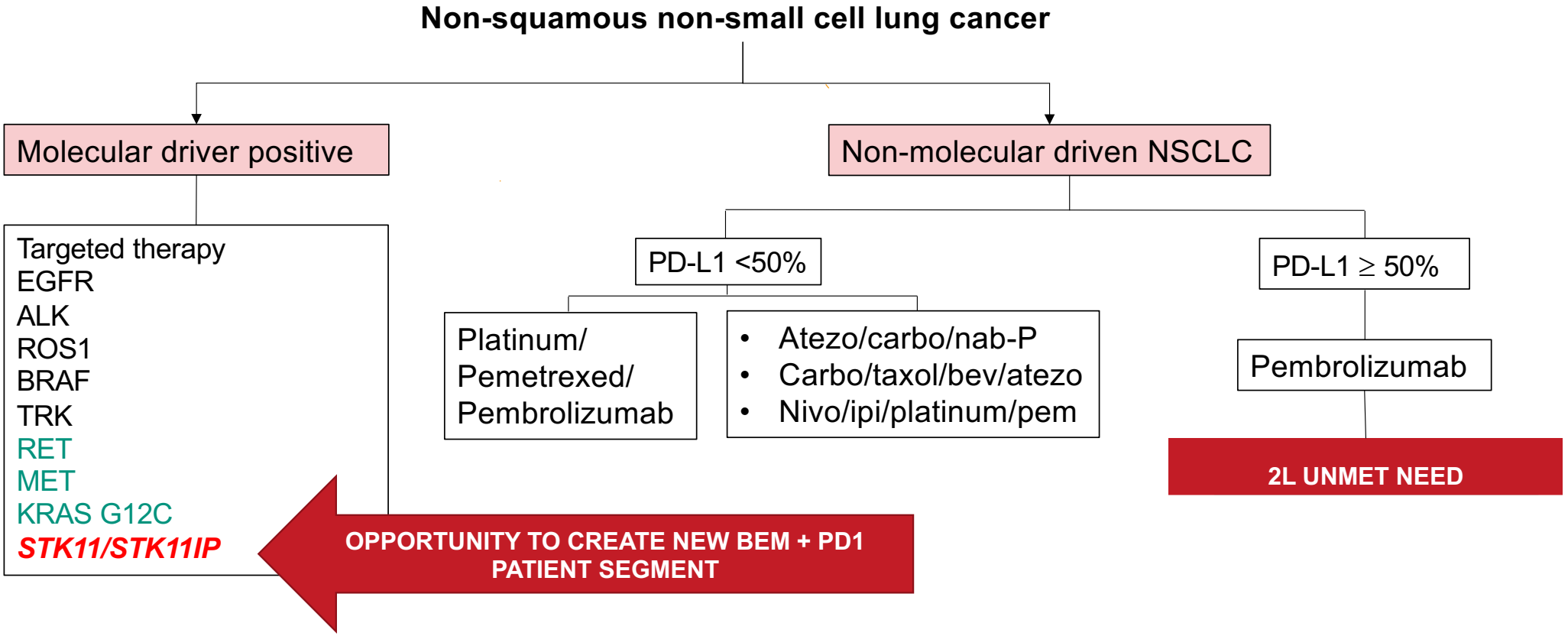
There is also evidence to suggest that STK11 mutations do not benefit from pembrolizumab + platinum doublet chemotherapy (CP) in NSCLC

- 377 NSCLC pts treated with pembrolizumab + platinum doublet chemotherapy (CP)
- Comparing STK11 mutation patients (N=102) with STK11-wt patients (N=275): patients had significantly reduced :
  - ORR (32.6 vs 44.7%),
  - mPFS (4.8 vs 7.3mo)
  - mOS (10.6 vs 16.7mo)

For STK11m patients, addition of pembrolizumab to platinum doublet chemotherapy did not improve mPFS (4.8 vs 4.3mo) or mOS (10.6 vs 10.3mo) vs chemotherapy alone

Treatment landscape for NSCLC



* ESMO guidelines Sep 2020

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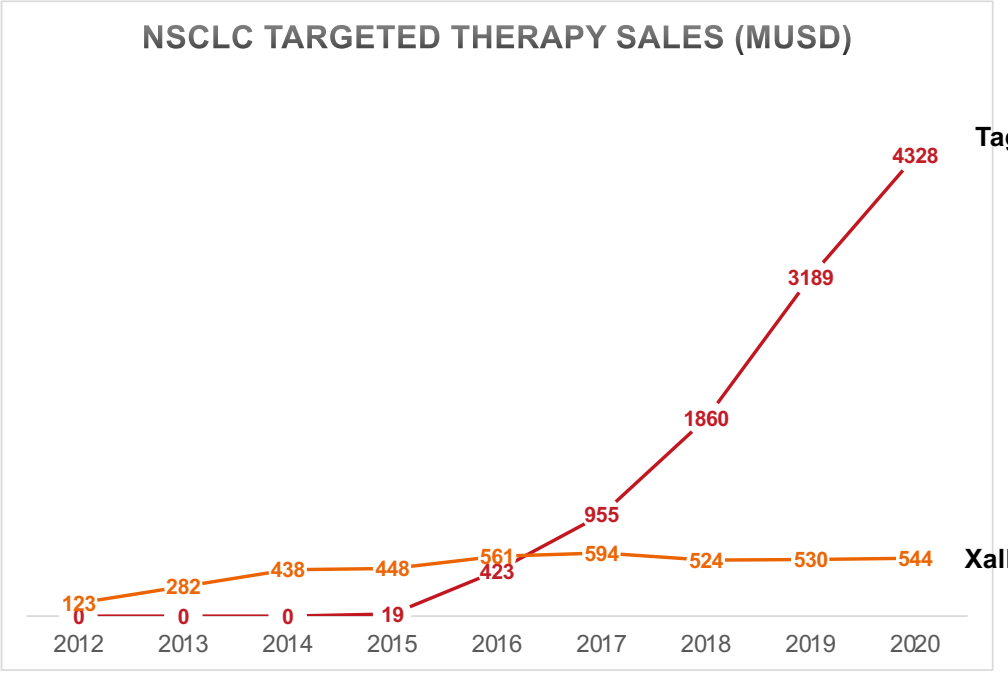
Opportunity in 1L NSCLC is large for targeted therapies including potentially STK11 mutation

- STK11 mutation is present in *up to* 20% of NSCLC
- Tagriso targeting EGFR mutation (*ca* 15-20% of NSCLC) generates *ca* $4.3B in sales
- Xalkori targeting ALK mutation (*ca* 5% of NSCLC) generates *ca* $544M in sales



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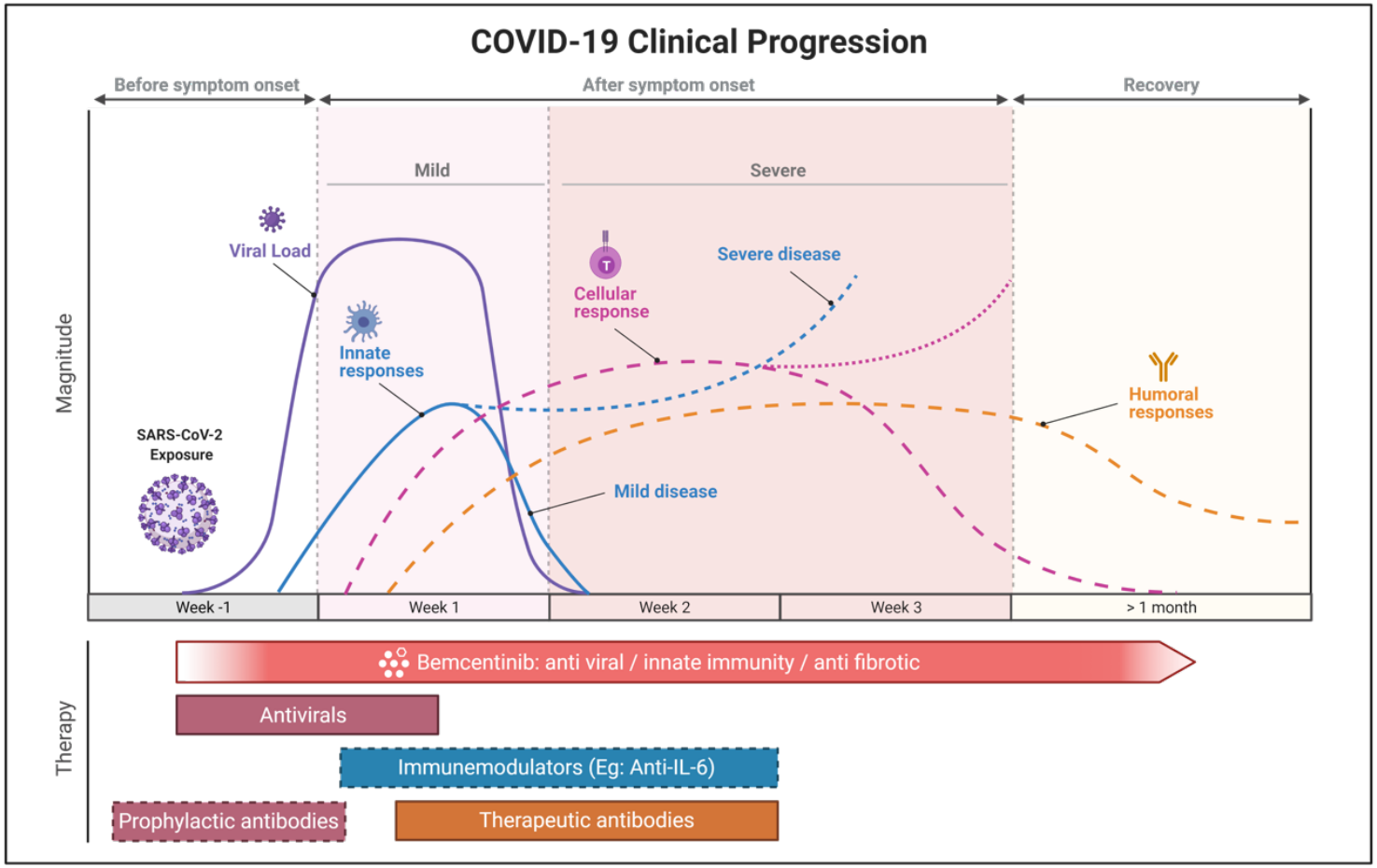
Summary of bemcentinib in NSCLC and next steps

- Unmet medical need in 2L (non-molecular) and 1L (molecular)
- Data from BGBC008 in 2L not yet matured – expected in H1 2022
- Bemcentinib expand TFC1+ and CD8 T cells and potentially restores PD1-blockade sensitivity of STK11 mutations combined with encouraging clinical benefit in STK11 mutated patients from BGBC008 trial (3 out of 3 evaluable patients)
- 1L STK11 NSCLC represents a significant opportunity for bemcentinib in combination with anti-PD-1/PDL-1 therapies
- Granted Orphan Drug Designation and 2X Fast Track by US FDA in NSCLC for nonactionable mutations
- Next step is (i) data analysis on BGBC008 trial and (ii) and commence a Phase 1b trial in 1L NSCLC STK11 mutated patients (H1 2022)

BEMCENTINIB IN COVID-19

- Despite rapidly evolving landscape the unmet medical need for hospitalised patients requiring oxygen remains
- Bemcentinib's modulatory effect (immune system, inflammation, viral entry) provides strong rationale in respiratory infections like COVID-19
- Clinical data (in 179 patients) validate potential role of bemcentinib for hospitalised patients
- Next step is a confirmatory randomized placebo-controlled trial conducted through a sponsored platform at significant reduced cost

Clinical progression – COVID-19



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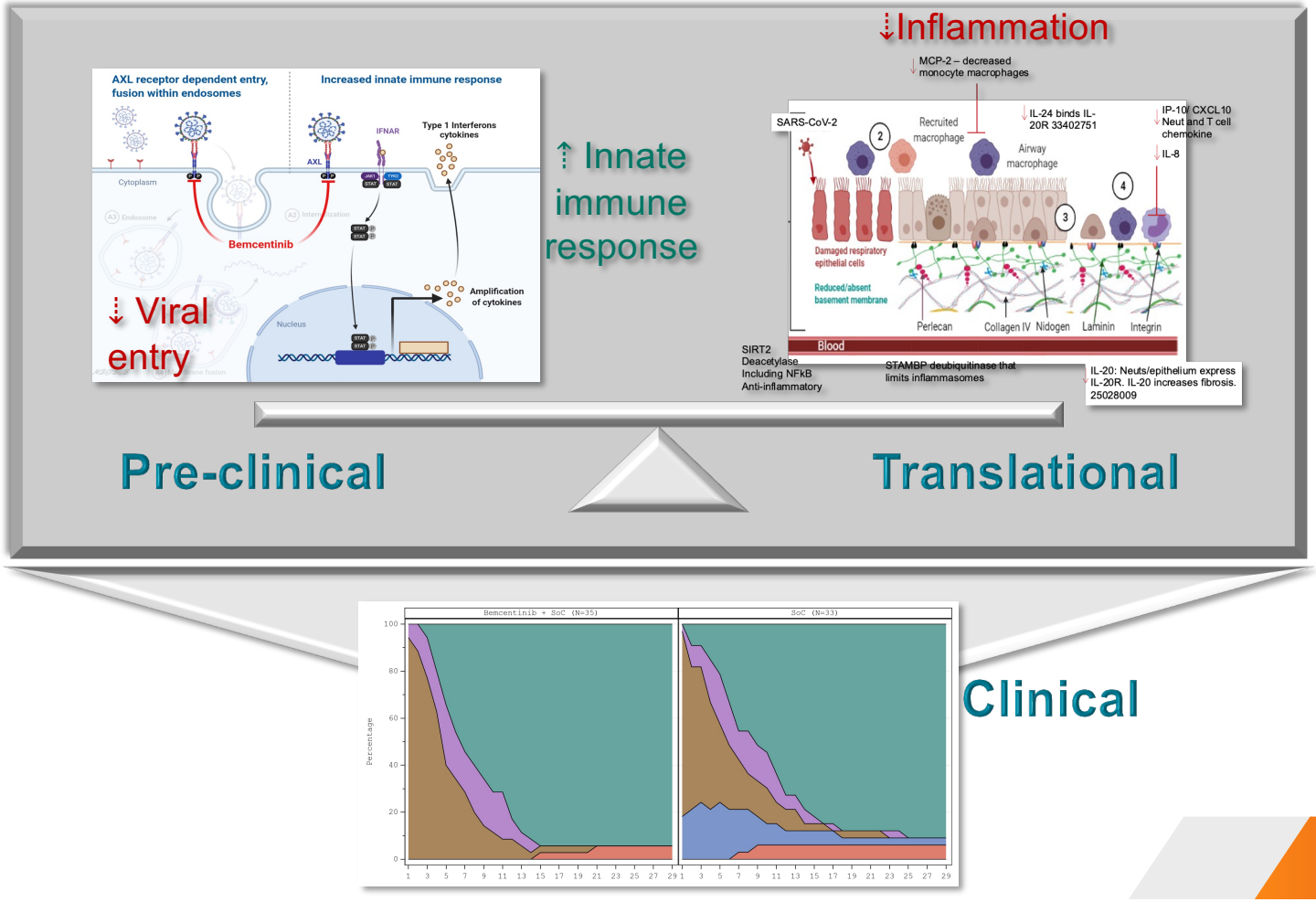
AXL inhibition with bemcentinib

multiple mechanisms responsible for clinical efficacy in severe COVID19



Clinical

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Summary of bemcentinib in COVID-19 and next steps

- Despite recent approvals a high unmet medical remains in the prevention of hospitalised patients requiring oxygen progressing to ventilation
- Strong scientific and clinical rationale for utility of bemcentinib is severe respiratory infections including COVID-19
- Next step is a confirmatory randomized placebo-controlled trial utilising sponsored platform setup allowing BGB to confirm encouraging clinical data at significantly reduced cost (H1 2022)

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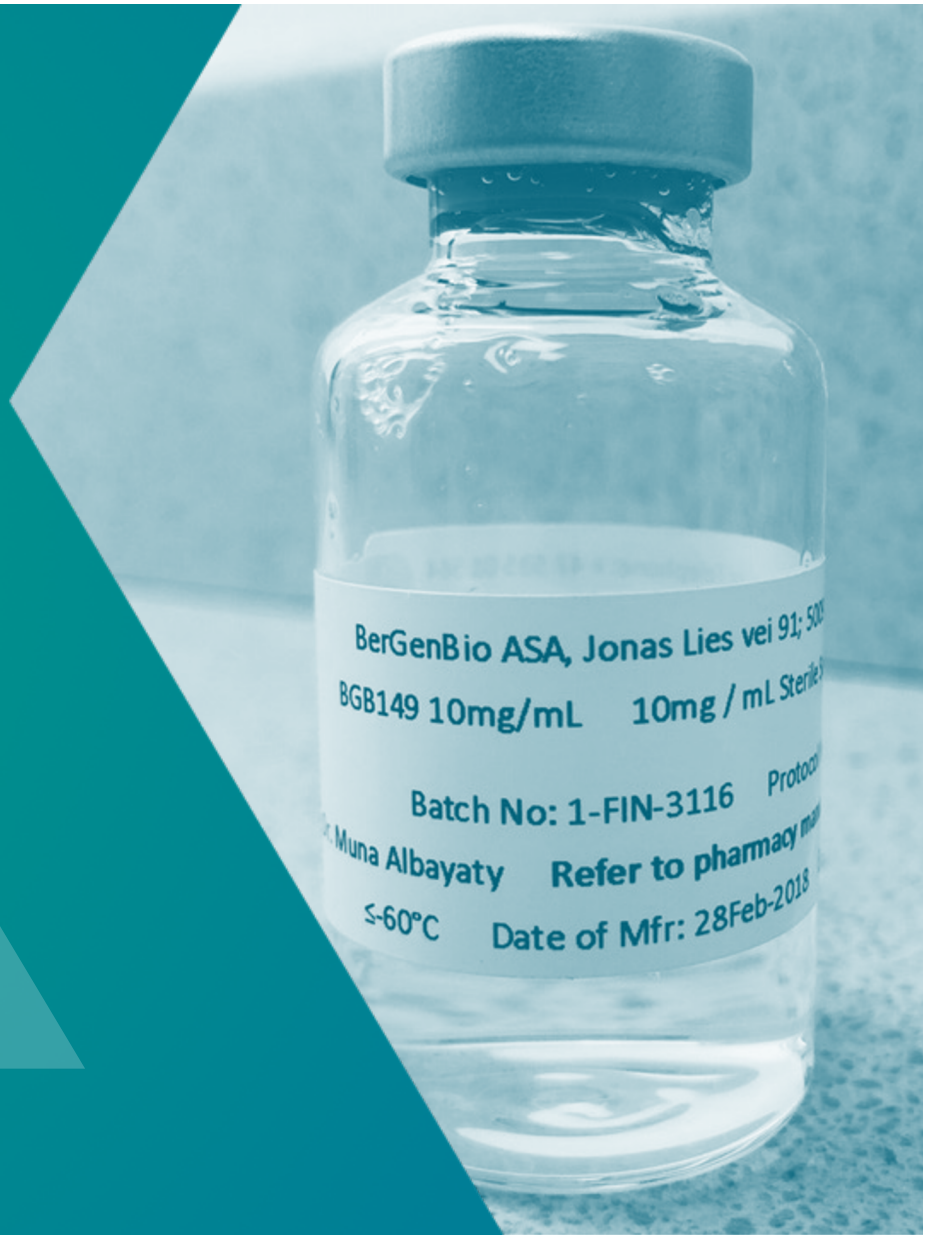
Tilvestamab (BGB149)
anti-AXL monoclonal antibody



Ref. BGB149-101 / NCT03795142

TILVESTAMAB: Anti-AXL monoclonal antibody

Functional blocking fully-humanised IgG1 monoclonal antibody

Binds human AXL, blocks AXL signalling

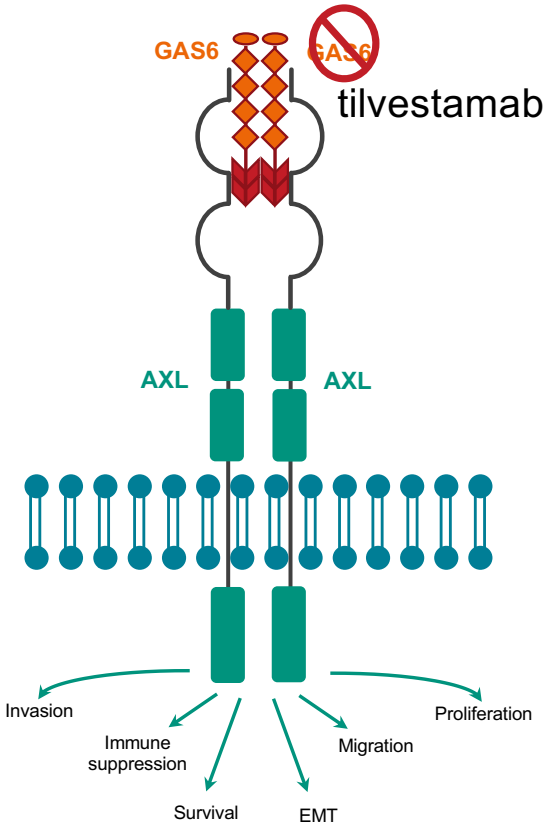
High affinity (KD: 500pM), displaces GAS6
Anti-tumour efficacy demonstrated *in vivo*

Robust manufacturing process established, 18 months stability

Phase Ia healthy volunteer SAD study complete

Safety – no dose limiting toxicity seen up to 3mg/kg dose
Pharmacokinetics - exposure predictable with dose proportional Cmax increase
Confirmatory evidence of *in* vivo target engagement with sAXL -- stabilisation in circulation

Phase I SAD trial complete
Phase Ib/IIa MAD ongoing



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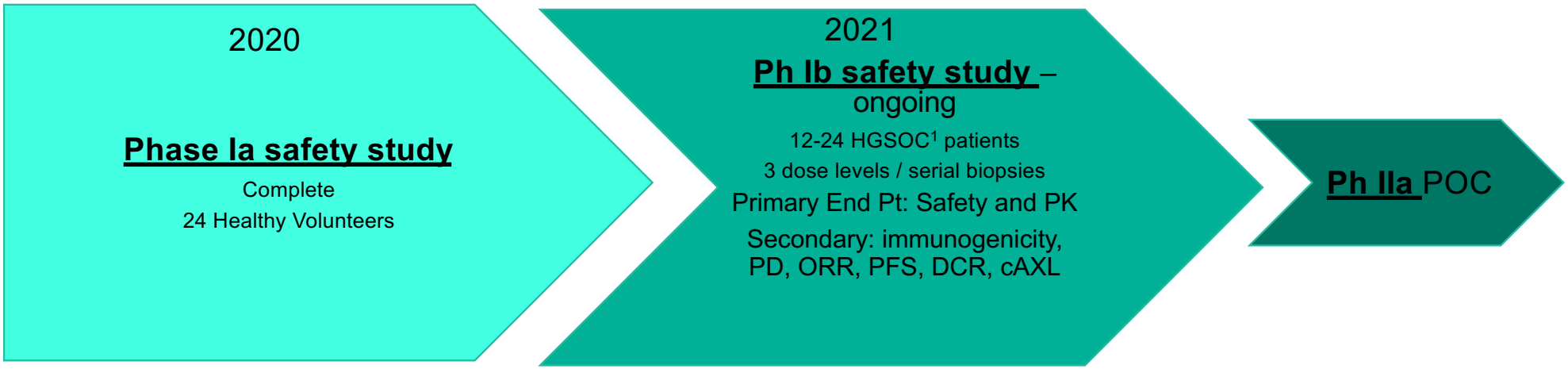
Tilvestamab development plan



Safety – no dose limiting toxicity seen up to 3mg/kg dose
Pharmacokinetics - exposure predictable with dose proportional Cmax increase
Confirmatory evidence of *in* vivo target engagement with sAXL -- stabilisation in circulation

1. High Grade Serous Ovarian Cancer

Summary of tilvestamab and next steps

- Phase 1b on track – 5mg/kg with no DLT's
- Biopsies to be evaluated for clinical response
- Next step is continued pre-clinical evaluation and completion of on-going Phase 1b trial

Finance Report – Key Financial Q3 2021

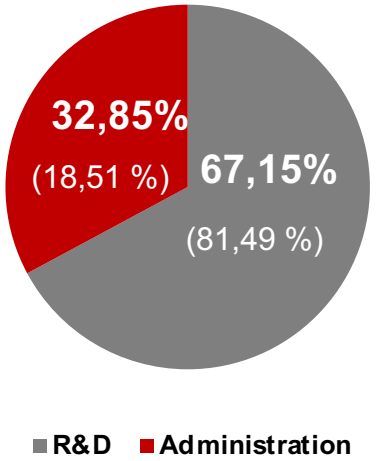
CFO Rune Skeie

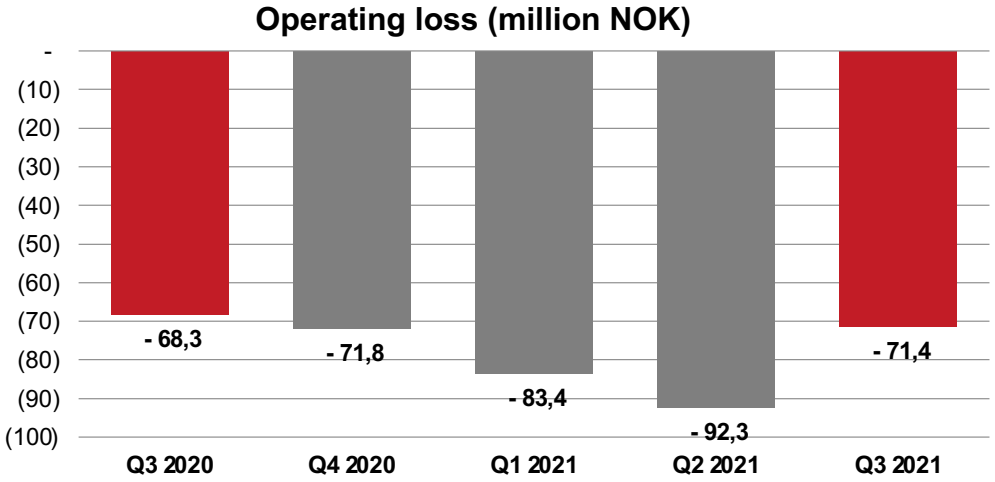
BerGenBio

Key financial figures

(NOK million)	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Operating revenues	0,0	0,0	0,0	0,0	0,6
Operating expenses	71,4	68,3	247,1	189,3	261,7
Operating profit (-loss)	-71,4	-68,3	-247,1	-189,3	-261,1
Profit (-loss) after tax	-70,5	-67,3	-240,6	-183,2	-257,0
Basic and diluted earnings (loss) per share (NOK)	-0.80	-0.77	-2.74	-2.51	-3.43
Net cash flow in the period	-61,7	-49,4	-208,2	521,8	468,8
Cash position end of period	509,4	777,9	509,4	777,9	721,6

Operating expenses Q3 2021 (YTD 2021)





- Operating cost decreased to an average level after peak patient recruitment in Q1-Q2, mostly related to COVID-19 clinical trial.
- Organisational development continuing with increased headcount compared to Q3 2020.
- Well managed overhead costs. 67 % of operating expenses in Q3 2021 (YTD 81%) is attributable to Research & Development activities. Decrease in the quarter is related to complete recruitment of several clinical trials in 2021 and decreased program cost in addition to one-time cost due to management change.

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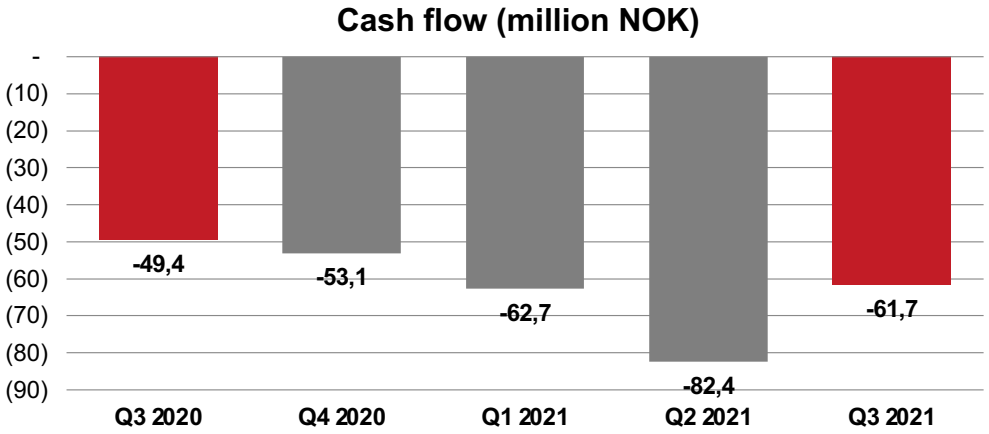
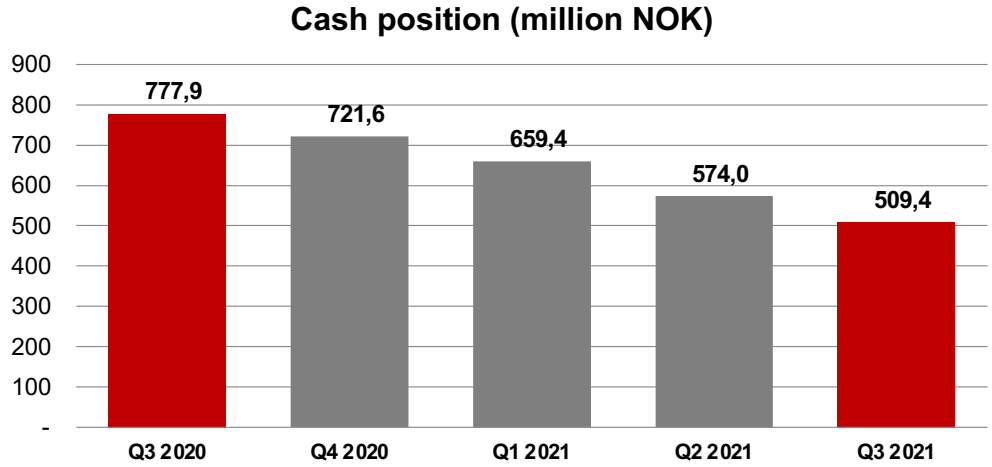
Cash flow and cash position





Cash burn operating activities Q3 2021

67.2 / 7.7

NOK million / USD million

Quarterly average cash burn (Q3 2020-Q3 2021)

61.9 / 7.1

NOK million / USD million

Cash position Q3 2021

509.4 / 58.0

NOK million / USD million

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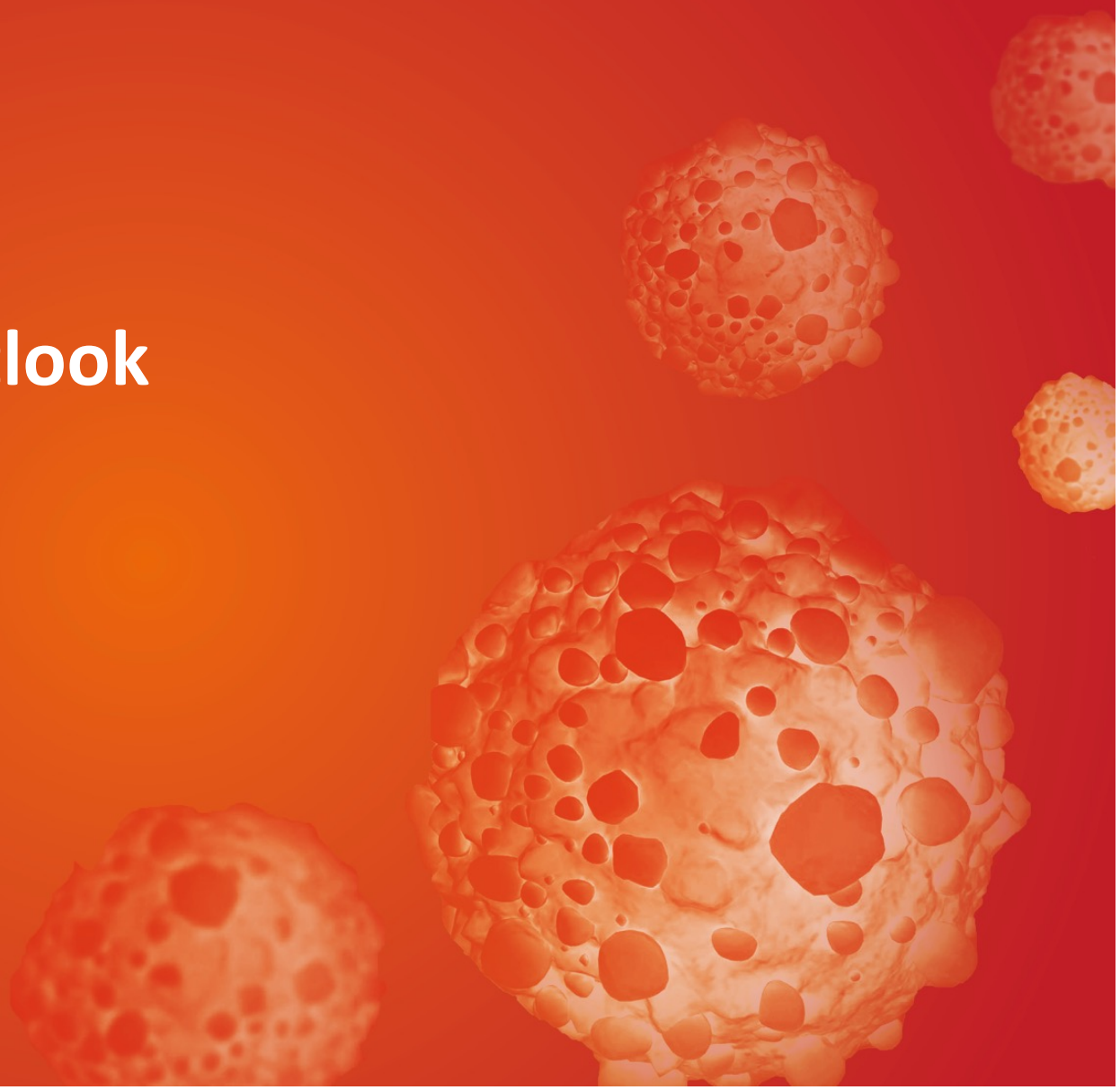
Financial Calendar 2021

16 November 2021: Quarterly Report Q3 2021

16 February 2022: Quarterly Report Q4 2021

2021 Highlights & outlook



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Positioning BerGenBio for success

AML

- Encouraging early data in relapsed 2L AML patients with high unmet medical need
- Orphan Drug Designation and Fast Track by US FDA
- Position for confirmatory randomized placebo-controlled trial in H2 2022

NSCLC

- Phase II trial (BGB008) cohort B now fully enrolled – data to mature in H1 2022
- Identified large 1L line opportunity – STK11 mutations
- Orphan Drug Designation and Fast Track by US FDA for STK11
- Position for Phase 1b trial in 1L STK11 mutations in H1 2022

COVID-19

- Encouraging Phase II data
- Positioned for confirmatory randomized placebo-controlled trial through sponsored platform in H1 2022

BerGenBio – investment highlights

Pioneering biology

World leaders in understanding AXL biology, as a mediator of aggressive cancer, fibrosis and viral infections

Two first in class selective AXL inhibitors

Bemcentinib - oral once-a-day capsule

Tilvestamab – functionally blocking mAb

Diversified late stage pipeline

AML (Orphan/FT)

NSCLC (Orphan/FT)

COVID-19

Potential to unlock significant value

2nd line AML

1st line NSCLC STK11

Hospitalised COVID-19

Strong balance sheet and fit-for-purpose organisation

Experienced R&D team

Industry & academic partnership and collaborations

AML – Acute Myeloid Leukaemia
MDS – Myelodysplastic Syndrome
NSCLC – Non-Small Cell Lung Cancer
IST – Investigator Sponsored Trial
AXL – Receptor Tyrosine Kinase AXL