



# BerGenBio

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**Unlocking the potential of AXL inhibition as  
a transformative treatment modality for  
severe diseases**

## Q1 2022 REPORT, HIGHLIGHTS AND FINANCIALS

[www.bergenbio.com](http://www.bergenbio.com)



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**Unlocking the potential of  
AXL inhibition as a  
transformative treatment  
modality for severe diseases**

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**BerGenBio is a world leader in exploring AXL as a transformative treatment modality for severe diseases**

**Development focus on lead program, bemcentinib, dosed in > 600 patients (~400 in oncology and ~200 in COVID) in two significant indications:**

- 1L STK11 mutated (STK11m) NSCLC
- Hospitalized COVID-19 patients

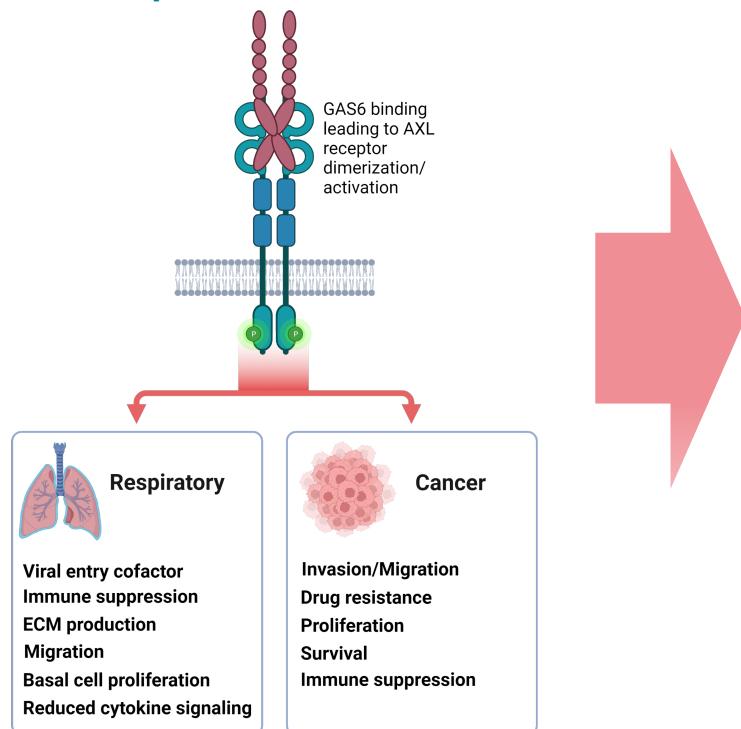
**We apply a laser-focused approach to unlock clear value drivers within 18-24 months**

**BerGenBio retains all rights to its candidates providing flexibility to generate maximum value**



# Broad potential for bemcentinib, extensively explored with indications of clinical efficacy

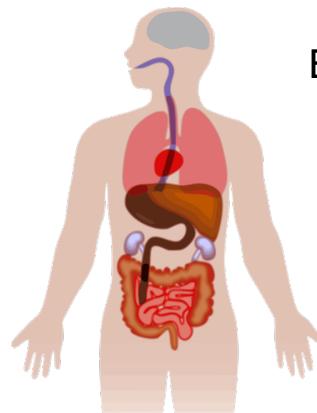
## Bemcentinib blocks AXL Activation in Multiple, Serious Diseases



Bemcentinib Phase II Studies		
Patient Population	# of Patients Studied	Clinical Activity Observed
COVID-19	179	✓
AML	122	✓
NSCLC	78	✓
Melanoma	66	✓
MDS	45	✓
Mesothelioma	17	✓
Pancreatic cancer	9	
Glioblastoma	7	

# Bemcentinib characteristics support clinical advancement in selected indications

## PRIMARY AREAS OF BEMCENTINIB ACCUMULATION



Brain – 26 fold\*

Lungs – 48 fold\*

## POTENTIAL THERAPEUTIC IMPLICATIONS

- Bemcentinib crosses the blood brain barrier
- May be particularly important to treat metastases
- Relevant to both lung cancer and respiratory infections

## BEMCENTINIB DOSING/PATIENT SELECTION

- Detailed analysis of target engagement, interaction with food conducted

## POTENTIAL THERAPEUTIC IMPLICATIONS

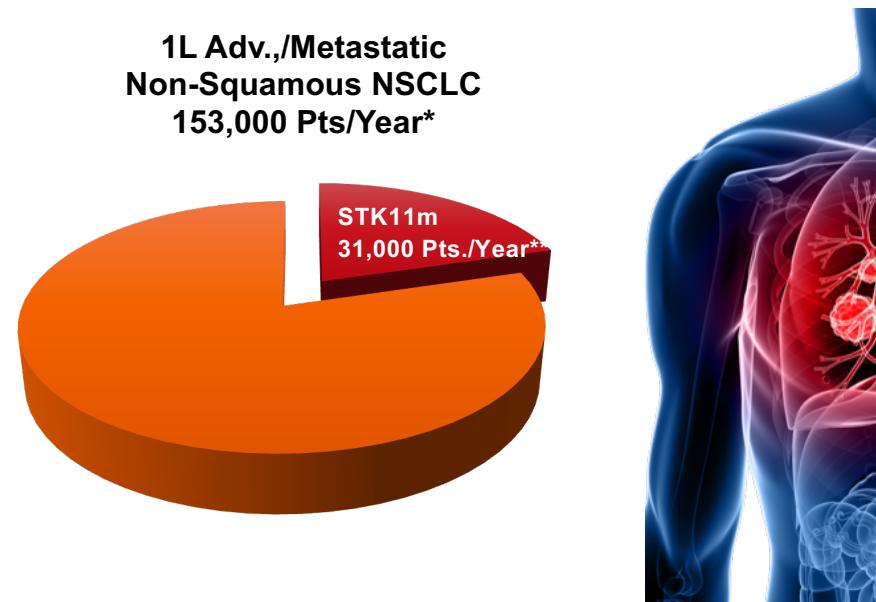
- Expect to attain sufficient blood levels to achieve efficacy in future studies
- Doses selected based on FDA “Project Optimus” providing improved therapeutic index and expected regulatory acceptability

# Compelling rationale for bemcentinib in 1L STK11m NSCLC – a significant opportunity

## KEY DEVELOPMENT/COMMERCIALIZATION ADVANTAGES

- Significant patient population ~ 30,000 pts with limited response to Immune Checkpoint inhibitors (ICIs)
- Bemcentinib restores activity of ICIs
- Bemcentinib is the only selective AXL inhibitor in development for STK11m patients, along with a strong proprietary position
- Granted FDA Fast Track status
- Potential for accelerated approval pathway

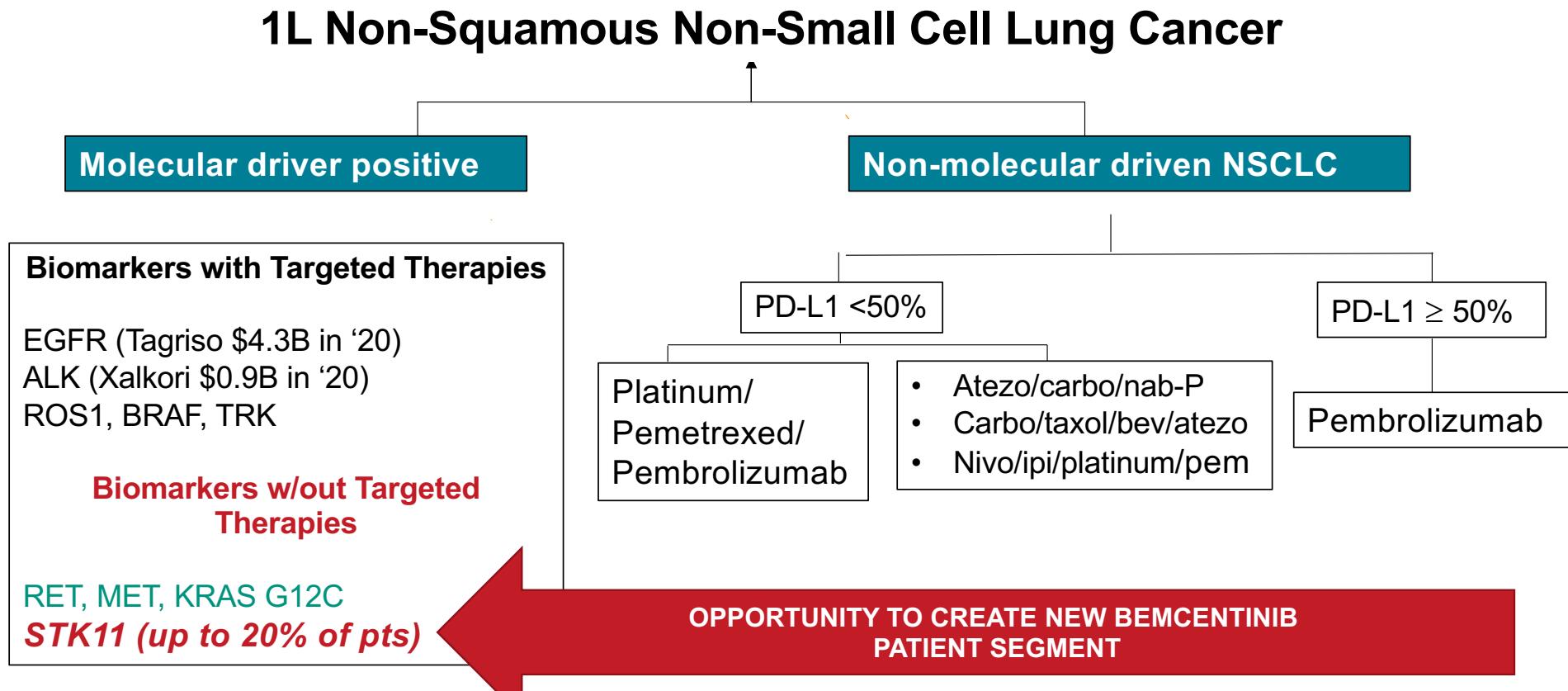
## LARGE, UNSERVED PATIENT POPULATION



\*Source: Global Data estimate in US, UK, Fr, Gr, Sp, It

\*\*Per literature

# STK11m NSCLC patients lack targeted therapies



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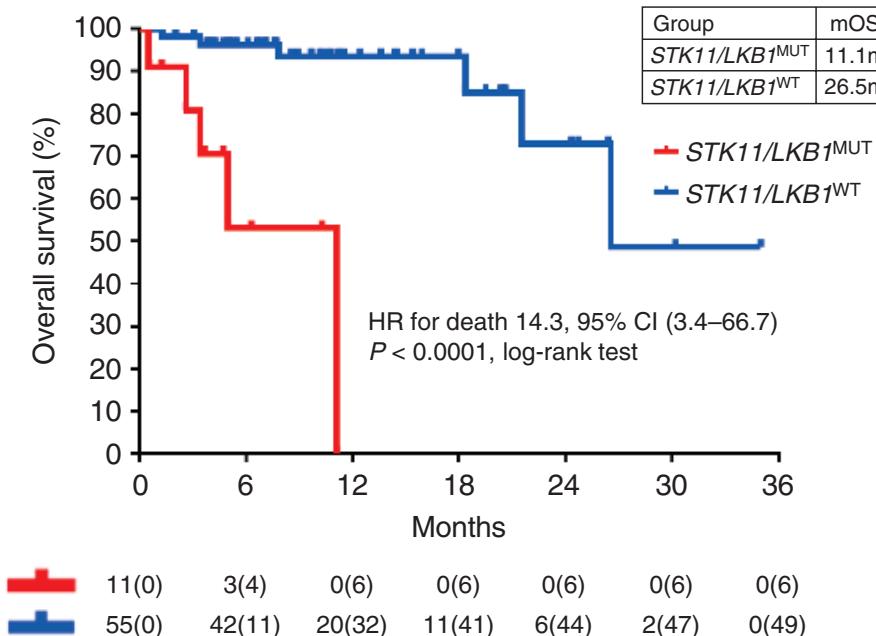
\* Adapted from ESMO guidelines Sep 2020; note prior to entry of new PD1/L1 agents into market

# STK11m are associated with low response rates and shortened mOS with ICI treatment

~3% response rate with ICIs in STK11m pts

Immune Checkpoint Treatment	# of STK11 pts Responding/ # Treated
Nivolumab	0/11 <sup>1</sup>
Ipi-Nivo	0/7 <sup>2</sup>
Durvalumab	1/21 <sup>3</sup>
Durvalumab+ tremelimumab	1/23 <sup>3</sup>

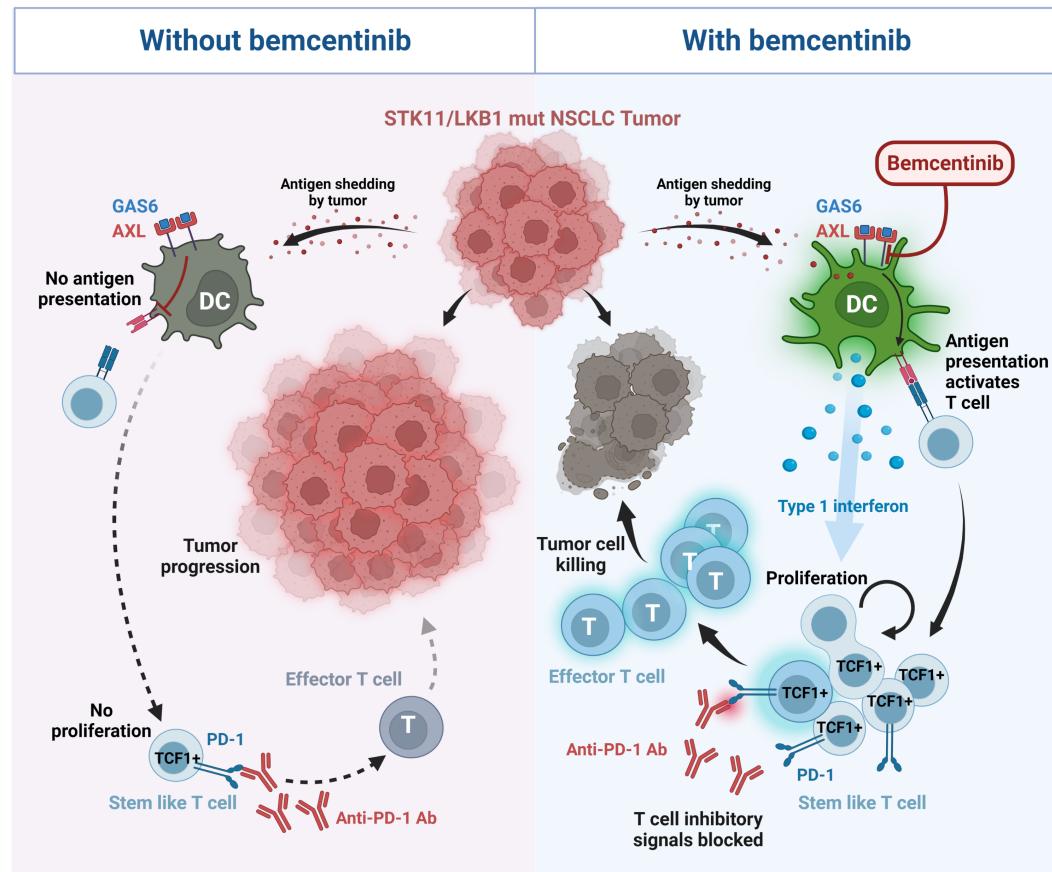
Significantly shorter median overall survival



<sup>1</sup>Skoulidis et al 2018 - <sup>2</sup>Hellman et al 2018 - <sup>3</sup>Kunkel et al 2018

Skoulidis et al J Clin Oncol. 2019;37(15\_suppl):102–102

# Bemcentinib increases ICI sensitivity in STK11m NSCLC

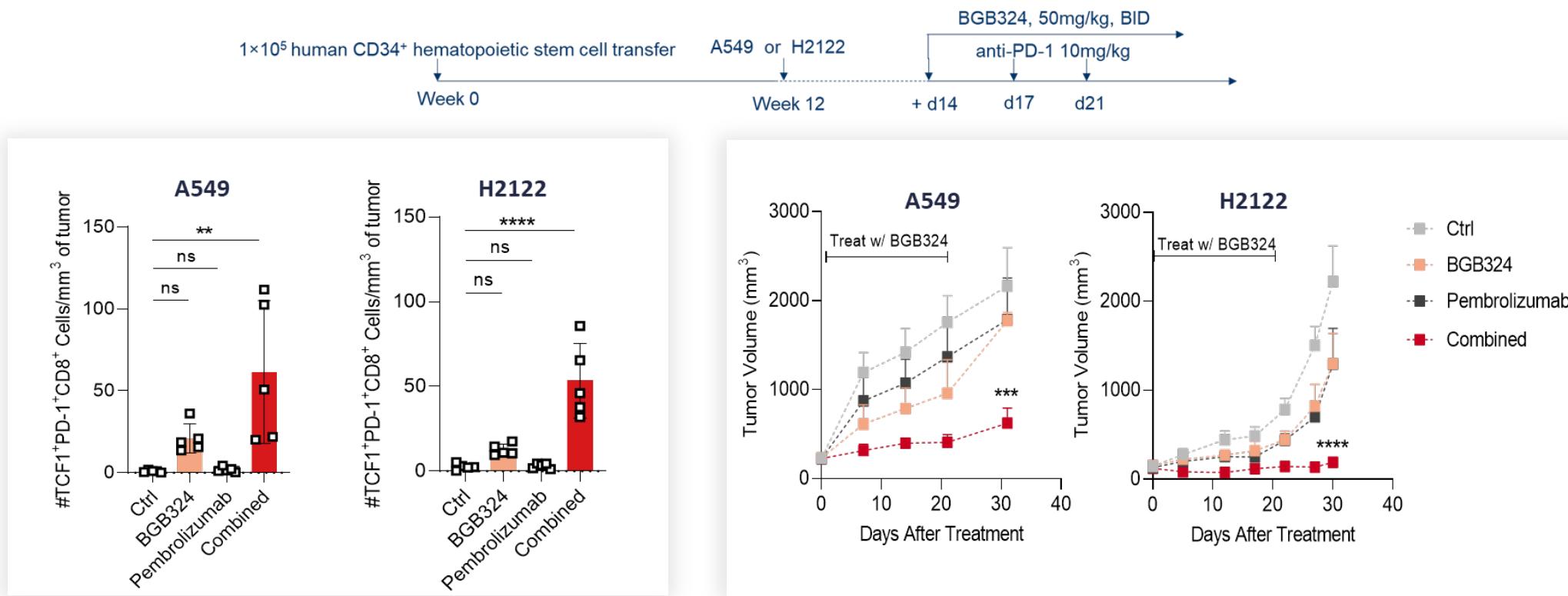


## Bemcentinib has a novel MOA to generate new tumor specific CD8 T cells

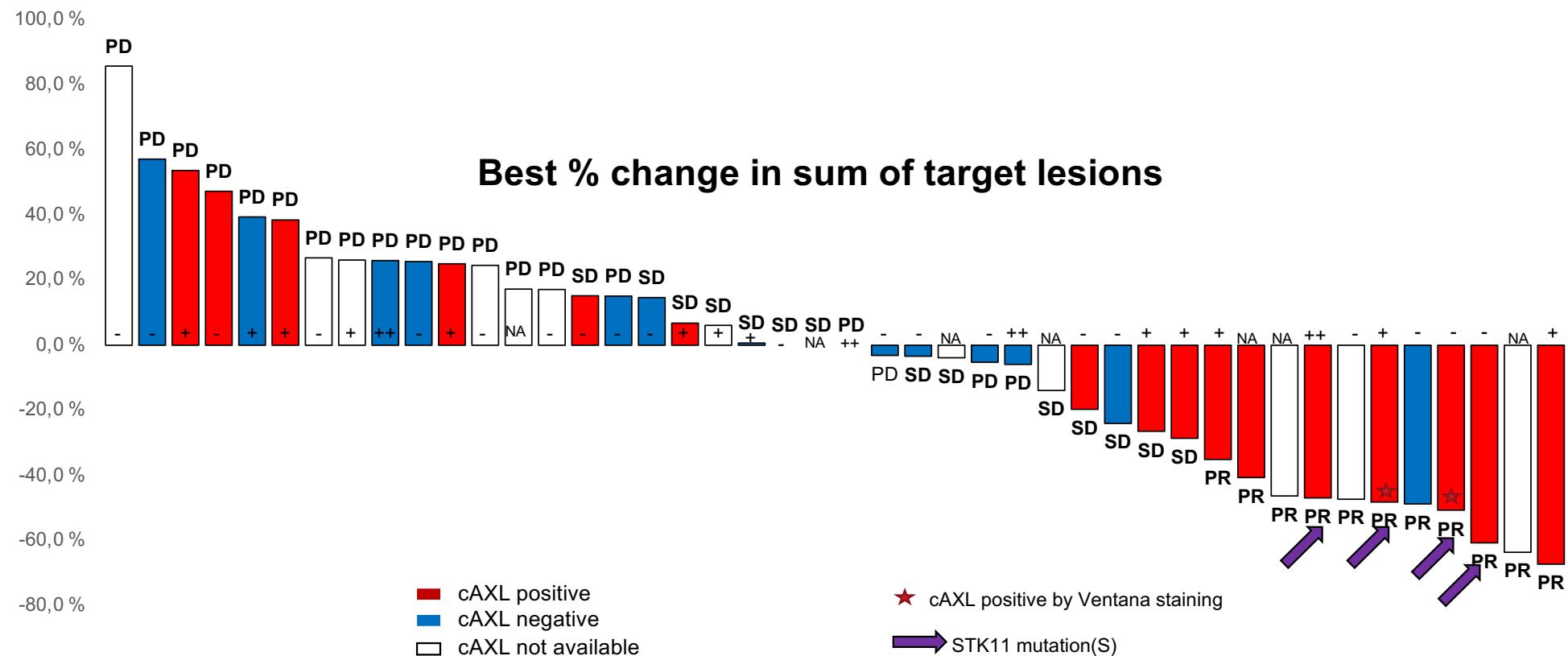
- CD8+ T cells are key populations that respond to PD-1/L1 blockade
- Bemcentinib has a unique MOA that increases Type I interferon secretion from dendritic cells that drives the generation of **new** tumor-specific CD8 T cells, restoring therapeutic response to PD-1
- Bemcentinib MOA potentiates a targeted therapy approach in STK11m population

# 2022 Cell Reports Medicine: compelling activity of bemcentinib in STK11m

## THERAPEUTIC EFFECTS IN NSCLC XENOGRAFTS & PATIENTS



## Data from on-going 2L NSCLC trial (BGBC008) indicates anti-tumor activity of bemcentinib in STK11m patients



# Path forward in STK11 1L NSCLC



**Key opinion leader interactions indicate high level of interest, awareness of STK11m and need for new therapeutics**



**Initiate ph Ib/Ila (US & EU) STK11m 1L NSCLC study in H2 2022**



**Further expansion of pre-clinical understanding including MoA and co-mutational efficacy**



# Strong rationale for hospitalized COVID-19

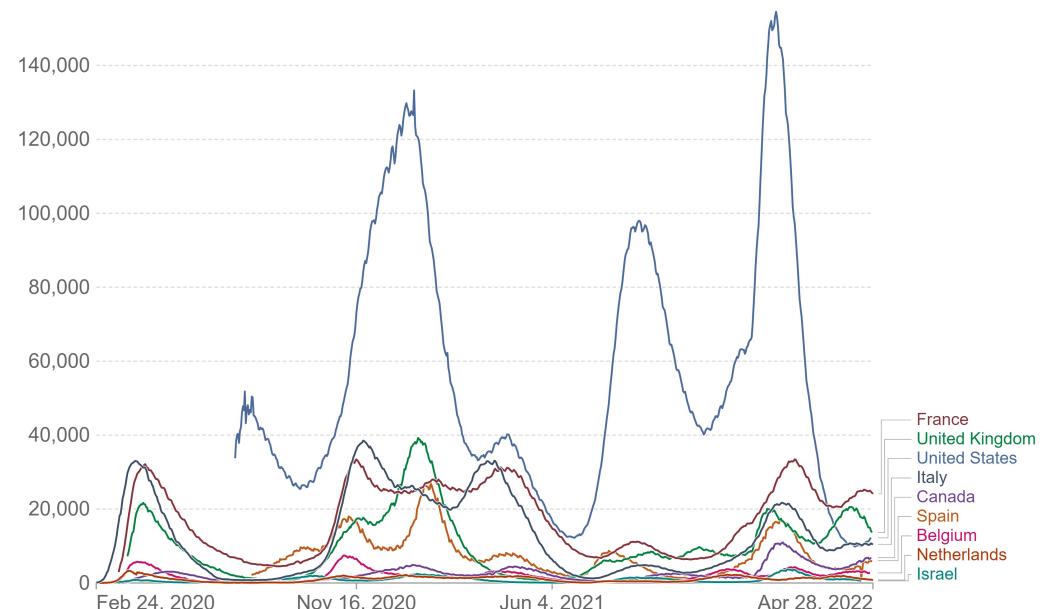
## KEY DEVELOPMENT/COMMERCIALIZATION ADVANTAGES

- Despite recent approvals medical need in hospitalized patients remains
- Preclinical data indicate potential for broad variant coverage
- Profound efficacy signal seen in ACCORD2 study of hospitalized COVID-19 patients
- Accepted into the EUSolidAct platform study of an expected 500 hospitalized COVID-19 patients to commence early H2 2022
- Regulatory agencies are expected to continue to grant accelerated/emergency authorizations for promising drugs

## COVID-19 HOSPITALIZATIONS CONTINUE

Number of COVID-19 patients in hospital

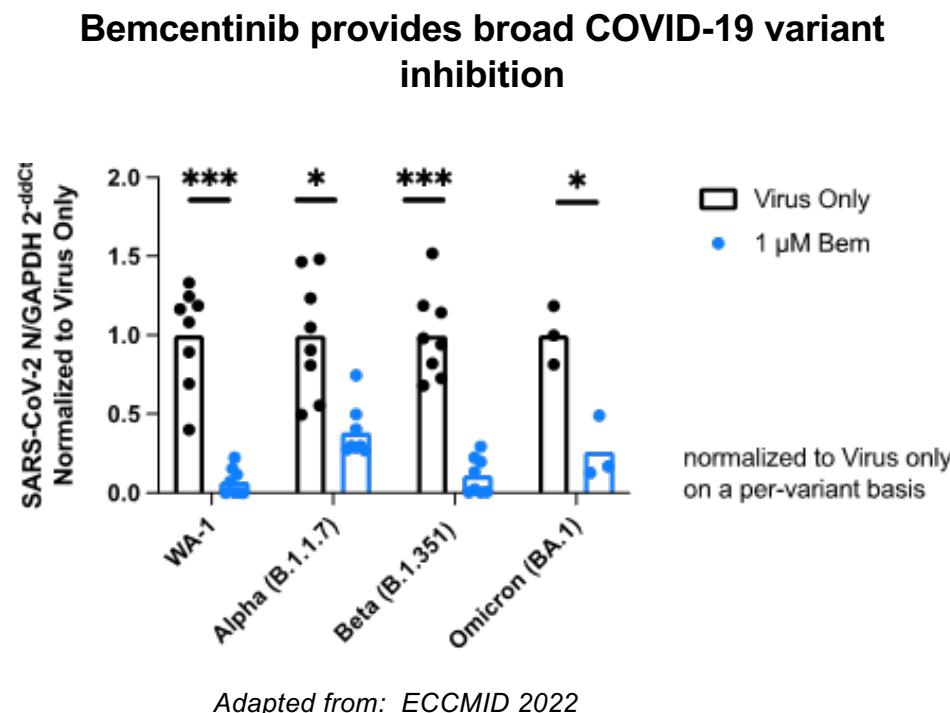
Our World  
in Data



Source: Official data collated by Our World in Data – Last updated 29 April 2022

OurWorldInData.org/coronavirus • CC BY

# Unmet needs persist and bemcentinib is likely to be effective against current and future viral variants



## New variants likely to occur

*“The one thing we all have to be appreciative of is as long as there's virus circulating around the world there's the possibility and likelihood we're going to see more variants”*

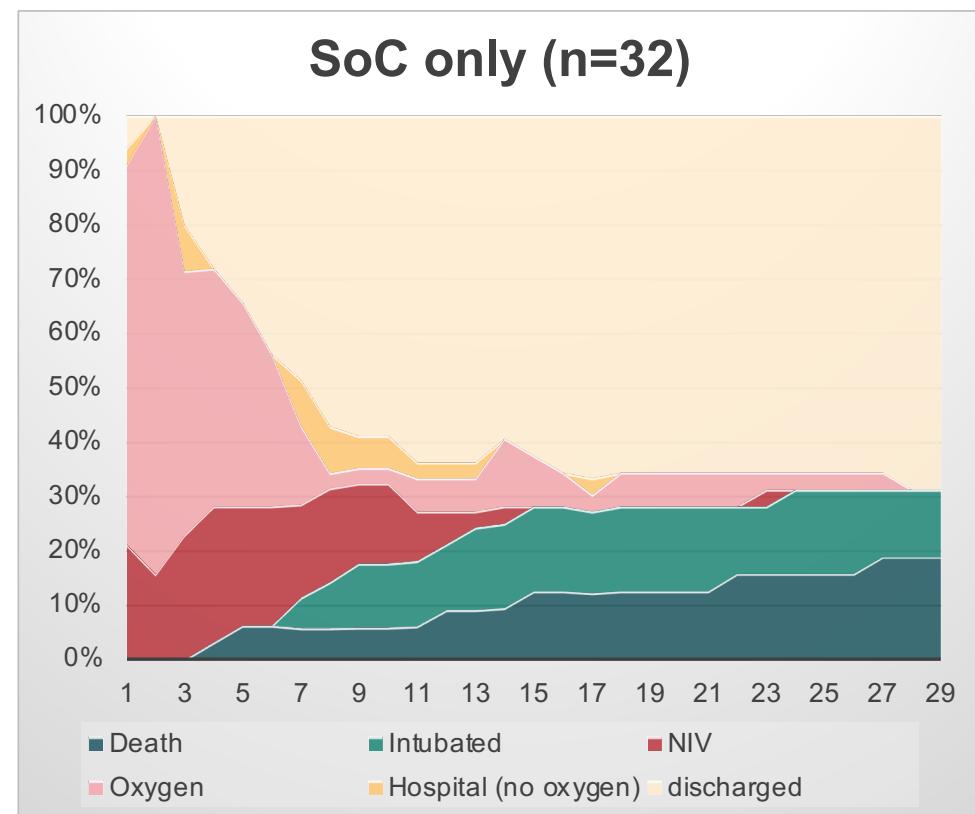
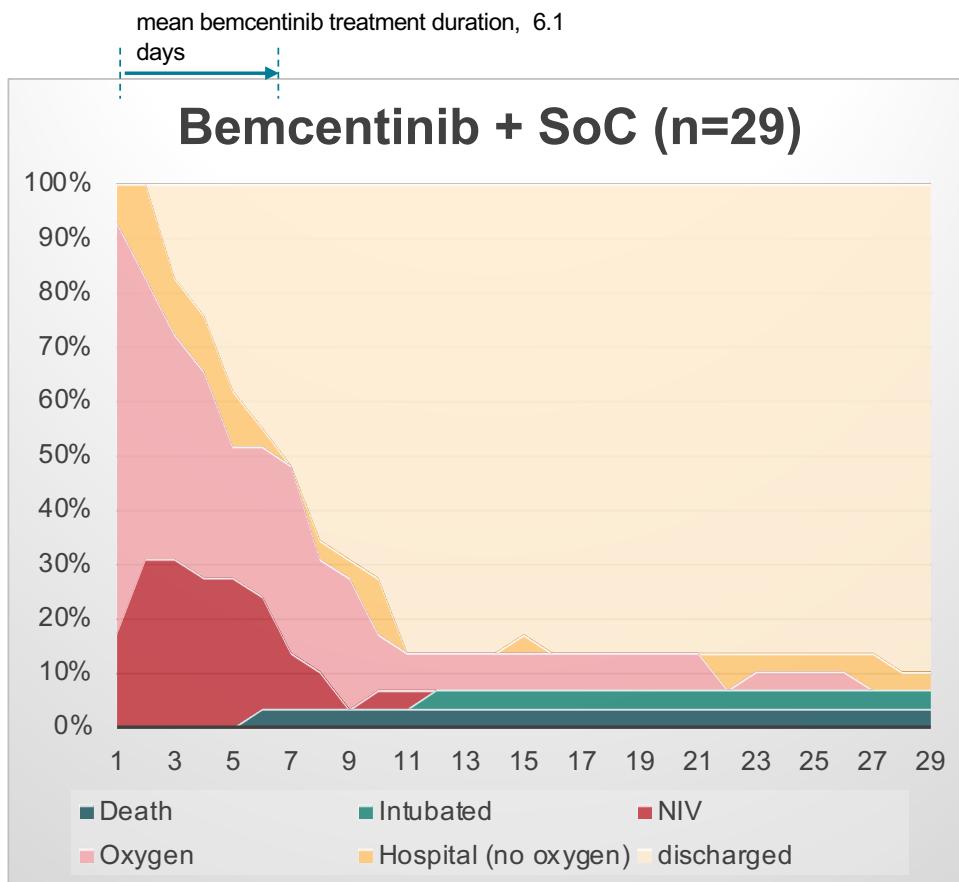
April 2022 Dr. Anthony Fauci, Head NIAID, NIH

## Level of hospitalized patients stable

*“At the end of week 15, 2022 ICU indicators remained stable over the last weeks but at a relatively high level, similar to the level observed in November 2021 ..”*

17 April 2022 European Centre for Disease Prevention & Control

# ACCORD2: bemcentinib met primary and key secondary endpoints with strong statistical significance



15 Derived from Table 14.2.1.1.1 Ordinal Scale Score over Time (full analysis set)- 29Mar2022. NIV = non-invasive ventilation or high flow nasal oxygen

# EUSolid Act: large number of sites, established capability to recruit into hospitalized COVID-19 study



- EUSolidAct has demonstrated the ability to rapidly recruit hospitalized COVID-19 patients
- Treatment with bemcentinib, or matched placebo, in addition to current SoC based on approved agents
- Study design reflects evolving nature of disease behavior due to effect of vaccines and variants
- Primary endpoint selected with consultation with EU and informed by data generated in two previous COVID-19 studies

# Path forward in COVID-19



Demonstrable efficacy in patients on top of current SOC including remdesivir and corticosteroids

EUSolid Act provides opportunity to generate data in large, multi-site study in a highly cost-effective manner

COVID-19 data could lay foundation to explore bemcentinib in other severe infections, further expanding the market opportunity

Expedited regulatory authorizations continue to be issued and may provide a route to the market

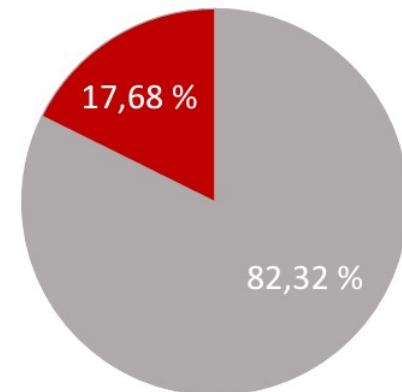
# Finance Report – Key Q1 2022 financial highlights



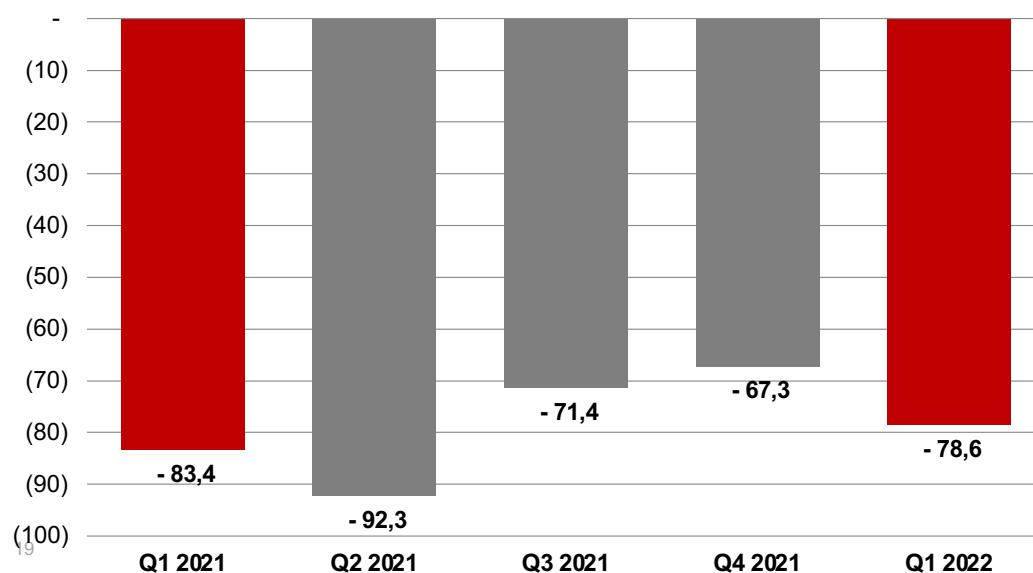
# Key financial figures

(NOK million)	Q1 2022	Q1 2021	FY 2021
Operating revenues	0.0	0.0	0.8
Operating expenses	78.6	83.4	315.2
Operating profit (-loss)	-78.6	-83.4	-314.5
Profit (-loss) after tax	-81.1	-81.2	-309.4
Basic and diluted earnings (loss) per share (NOK)	-0.92	-0.93	-3.52
Net cash flow in the period	-71.1	-62.7	-284.2
Cash position end of period	367.8	659.4	436.6

Operating expenses Q1 2022

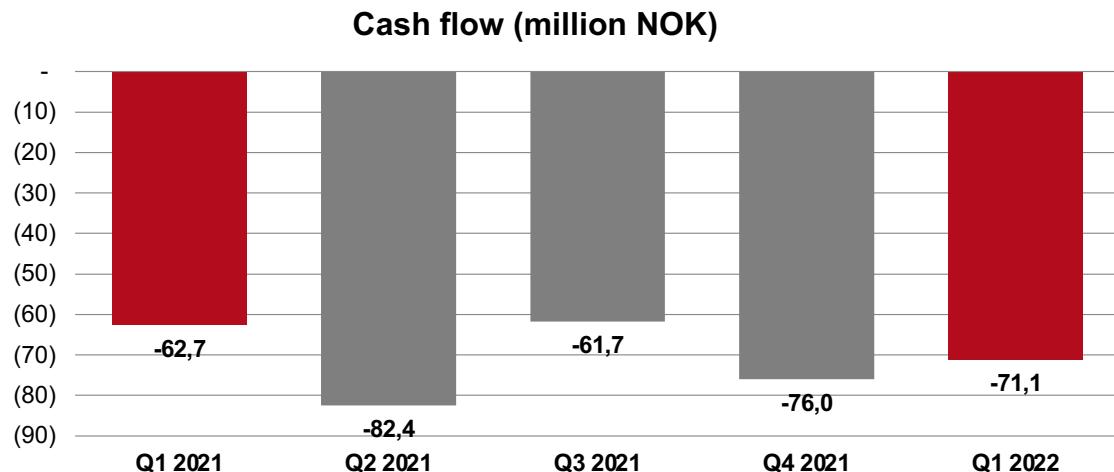


Operating loss (million NOK)



- Operating costs decreased to an average level after peak patient recruitment in Q1-Q2 2021, mainly related to the COVID-19 clinical trial
- Well managed overhead costs. 82% (Q1 2021 85%) of operating expenses in Q1 is attributable to Research & Development activities.

# Cash flow and cash position



Cash burn operating activities Q1 2022

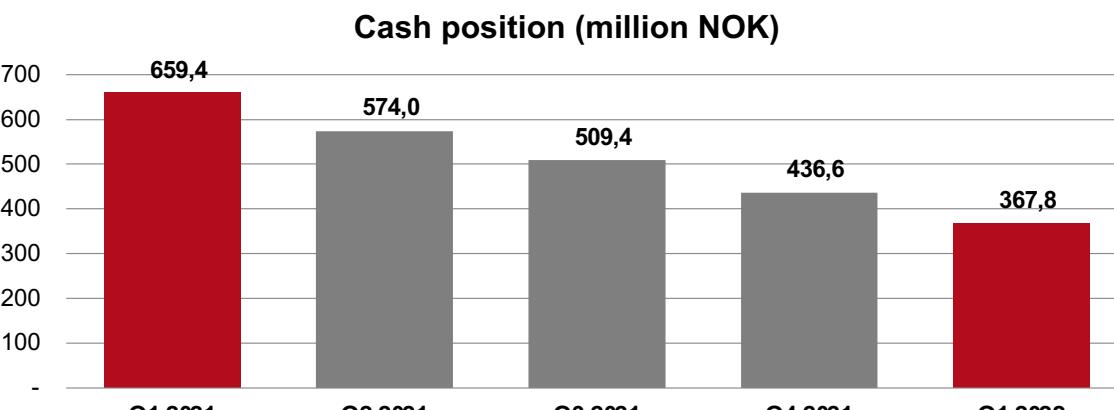
**74.2 / 8.4**

**NOK million / USD million**

Quarterly average cash burn (Q1 2021 - Q1 2022)

**72.1 / 8.3**

**NOK million / USD million**



Cash position Q1 2022

**367.8 / 42.0**

**NOK million / USD million**



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