



**Transitioning a strong scientific foundation  
toward the market and significant value  
generation**

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# Forward Looking Statements

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# About BerGenBio

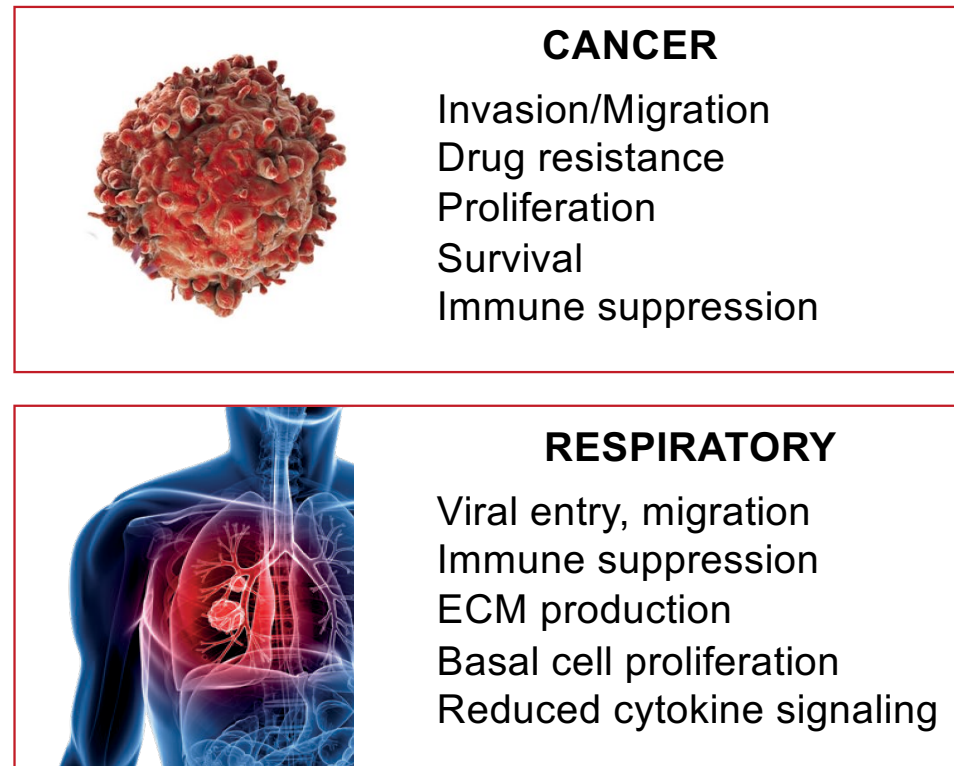
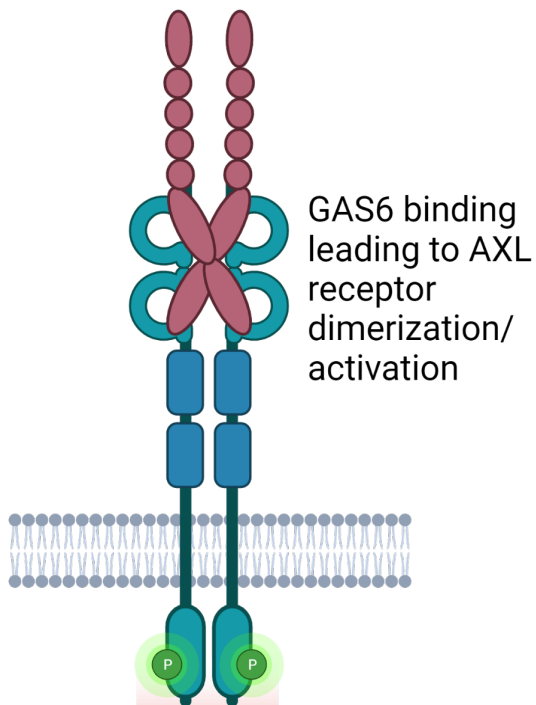
- We are focused entirely on the development of **selective AXL inhibitors**
- Our lead compound **bemcentinib** is an oral, potent and **highly selective inhibitor** of the receptor tyrosine kinase AXL
- **Bemcentinib** is currently being advanced in two significant opportunities:
  - **1<sup>st</sup> line NSCLC STK11m - Ph 1b/2a**
  - **Hospitalized COVID-19 - Ph 2b**
- We are laser-focused to **deliver clear value drivers** within next 12 -18 months

## Q2 2022 Highlights

- ✓ Announcement of focused strategy – development of *bemcentinib* in two significant indications: 1L STK11m NSCLC and hospitalized COVID-19 patients
- ✓ Phase 2 trial of *bemcentinib* in hospitalized COVID-19 patients (ACCORD2) met the primary endpoint of improved clinical response and key secondary endpoints, including a reduction in death and clinical deterioration
- ✓ Post period the Phase 2b trial under the EU-SolidAct platform enrolling up to 500 hospitalized COVID-19 patients is open for enrollment
- ✓ Preparations for the initiation a Phase 1b/2a trial evaluating *bemcentinib* in 1L STK11m NSCLC patients in the second half of 2022 - post period IND filed
- ✓ ADC Therapeutics dosed the first patient in a Ph 1 trial evaluating *mipasetamab uzoptirine*, which contains an AXL-targeting mAb licensed from BerGenBio
- ✓ Strengthened leadership team with the addition of Cristina Oliva, M.D., as Chief Medical Officer



# AXL activation results in several deleterious effects in both cancer and severe respiratory infections





# Bemcentinib: A significant potential in two major lung diseases



- **Bemcentinib inhibits AXL activation** to prevent the progression of serious disease through the modulation of resistance mechanisms and the adaptive immune system
- Bemcentinib mechanisms of action in **lead indications**:
  - **STK11m NSCLC** – Bemcentinib aims to unlock the immunosuppressive environment caused by AXL activation and drive the proliferation of immune cells to restore the effect of checkpoint inhibitors
  - **Hospitalized COVID-19** – Bemcentinib blocks viral entry, stimulates the innate immune system and promotes tissue repair regardless of variant or mutations
- Bemcentinib's mechanisms of action and **accumulation in the lung** (up to 40x) enhance its potential in severe lung diseases
- **Bemcentinib has an attractive clinical profile** with good safety profile and promising clinical activity demonstrated in previous trials of 179 COVID-19 and 159 NSCLC patients

\* Bemcentinib concentration in target organ versus normal tissues; BGB data

## BerGenBio Clinical Pipeline as of August 2022

	Candidate	Targeted Indication	Preclinical	Phase I	Phase II	Registrational
Oncology	Bemcentinib	1L STK11m NSCLC	Initiation of Ph1b/2a planned H2 2022			
	Bemcentinib	2L NSCLC				
	Bemcentinib	R/R AML				
	Mipasetamab uzoptirine	Solid Tumors			Fully out-licensed mAb	
Viral	Bemcentinib	COVID-19				

Note: Bemcentinib is also being studied in Investigator Led Trials in glioblastoma, 2L lung cancer, melanoma, pancreatic cancer and mesothelioma; Tilvestamab, our selective mAb AXL inhibitor, is being studied in a Phase 1b trial.

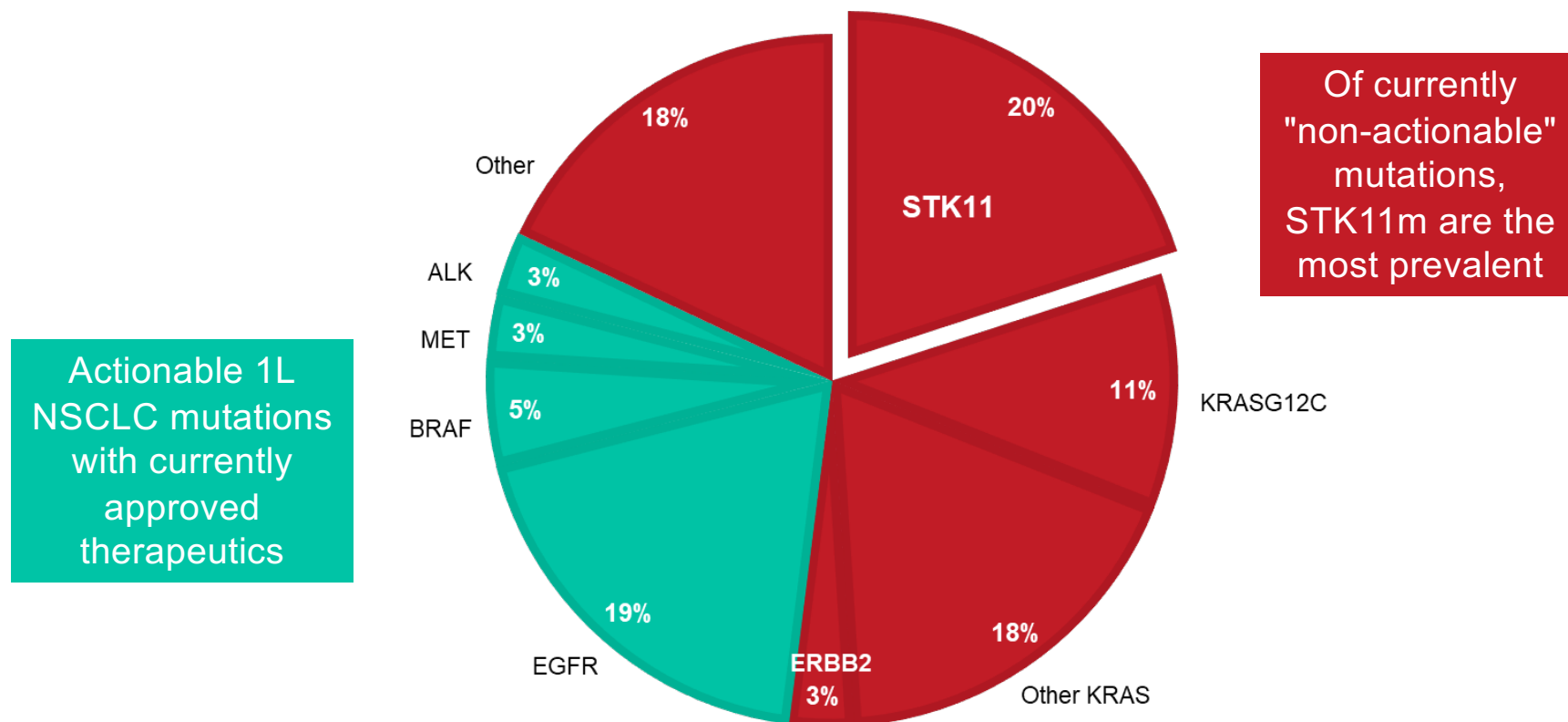
# **STK11 mutated Non-Small Cell Lung Cancer (STK11m NSCLC)**

**A significant opportunity to improve the  
lives of patients carrying a common, non-  
actionable mutation**





## 1L NSCLC treatment is based on molecular driver status; STK11 being the most common “non-actionable” mutation



\* Sources: Oncogenic driver mutations in non-small cell lung cancer: Past, present and future, *World J Clin Oncol.* 2021 Apr 24; 12(4): 217–237  
Prognostic Impact of KRAS Mutation Subtypes in Metastatic Lung Adenocarcinoma, *J.Thor.Onc.* 2015; 10(3):431-437

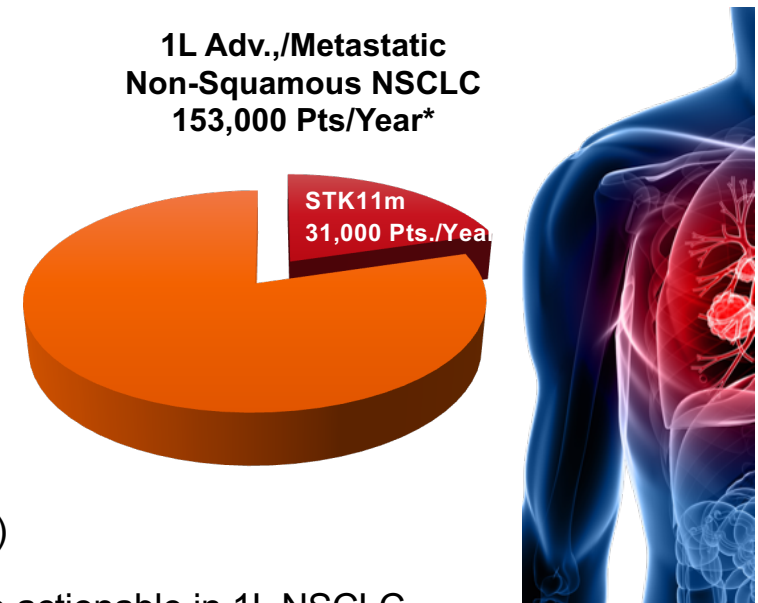
# STK11m NSCLC patients: a significant unmet need.....

## Mutations in STK11 are:

- Detected in ~20% (~31,000 per year<sup>^</sup>) of non-squamous NSCLC patients
- A recognized resistance mechanism for anti-PD-1/PD-L1 monotherapy with poor response rates and clinical efficacy
- On the panels of leading liquid biopsy providers
- Increased with immunotherapy

## STK11m patients are characterized by:

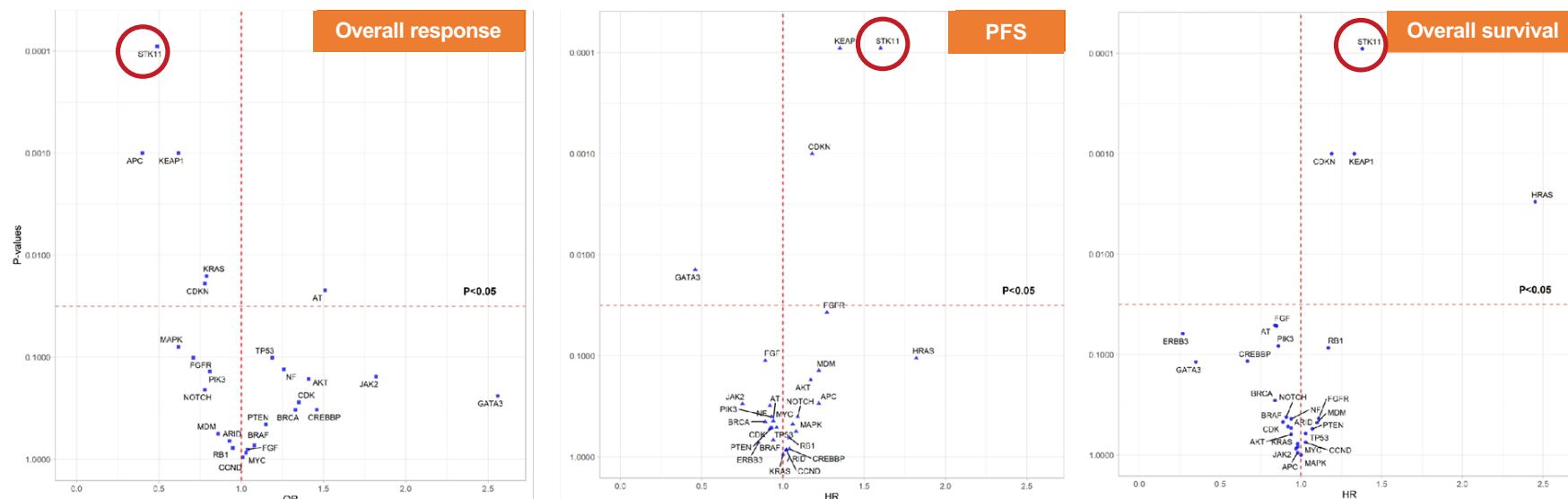
- Reduced response to CD8+/PDL1+ T cell infiltration
- Lower levels of PD-L1 expression
- Increased AXL expression on dendritic cells
- Relatively low level of actionable co-mutations (ALK, EGFR, etc.)
- Of most frequent co-mutations (KRAS, TP53, KEAP1) - none are actionable in 1L NSCLC



<sup>^</sup>Source: Global Data estimate in US, UK, Fr, Gr, Sp, It

\*ASCO 2022, Abstract 9021

# Recent ASCO "real-world" data confirms poor prognosis of STK11m patients receiving current standard of care treatment



Mutation	Overall response		
	OR [95% CI]	P-value	n
<b>STK11</b>	<b>0.49 [0.39-0.62]</b>	<b>&lt;0.0001</b>	<b>365</b>
APC	0.40 [0.23-0.69]	0.001	50
KEAP1	0.62 [0.47-0.82]	0.001	222
KRAS	0.79 [0.66-0.96]	0.016	767
CDKN2A/B	0.78 [0.64-0.96]	0.019	544
ATM/R/RX	1.51 [1.07-2.16]	0.022	147

Mutation	Progression-free survival (PFS)		
	OR [95% CI]	P-value	n
<b>STK11</b>	<b>1.6 [1.39-1.84]</b>	<b>&lt;0.0001</b>	<b>639</b>
KEAP1	1.35 [1.14-1.59]	<0.0001	391
CDKN2A/B	1.18 [1.07-1.3]	0.001	938
GATA3	0.46 [0.25-0.86]	0.014	22
FGFR	1.27 [1.01-1.59]	0.037	

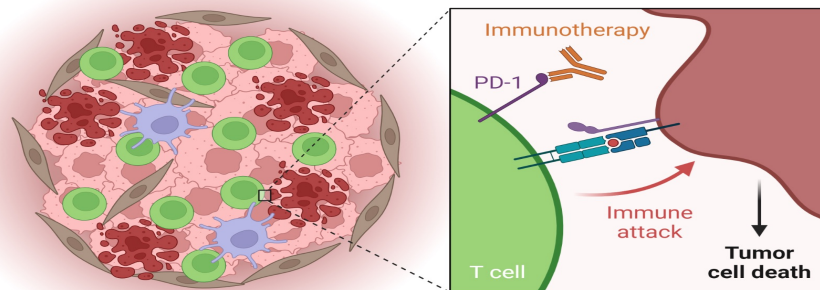
Mutation	Overall survival		
	OR [95% CI]	P-value	n
<b>STK11</b>	<b>1.38 [1.19-1.59]</b>	<b>&lt;0.0001</b>	<b>639</b>
CDKN2A/B	1.19 [1.07-1.32]	0.001	938
KEAP1	1.33 [1.13-1.58]	0.001	391
HRAS	2.45 [1.35-4.47]	0.003	14

STK11 mutations were associated with lower response rates and shorter survival

# STK11 mutations create a more immunosuppressive tumor microenvironment limiting response to checkpoint inhibition

## CHECKPOINT INHIBITION THERAPY IN NSCLC

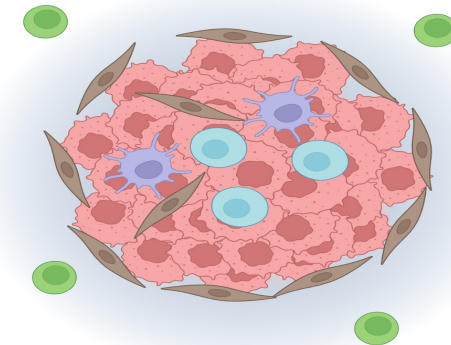
- CD8+ T cells present in tumor
- Improved prognosis and killing of tumor cells with ICI treatment



Hot tumor

## STK11/LKB1 MUTATED NSCLC

- **Exclusion of CD8+ T cells** from tumor
- **Reduced type 1 interferon** production by dendritic cells
- Poor prognosis and **limited response to immunotherapy**

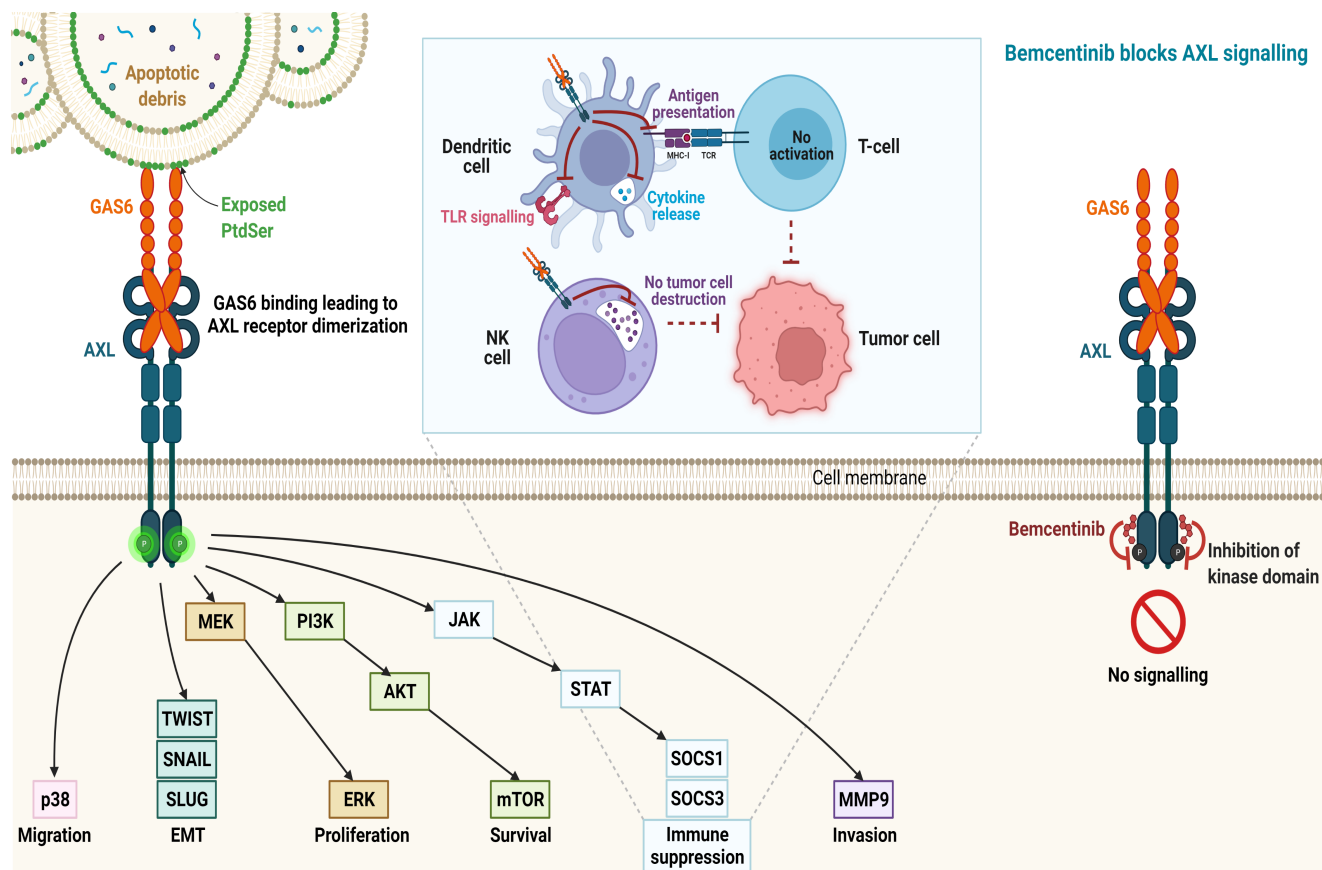


Cold tumor





# By selectively blocking AXL activation bemcentinib restore sensitivity to ICI therapy and potentiate chemotherapy

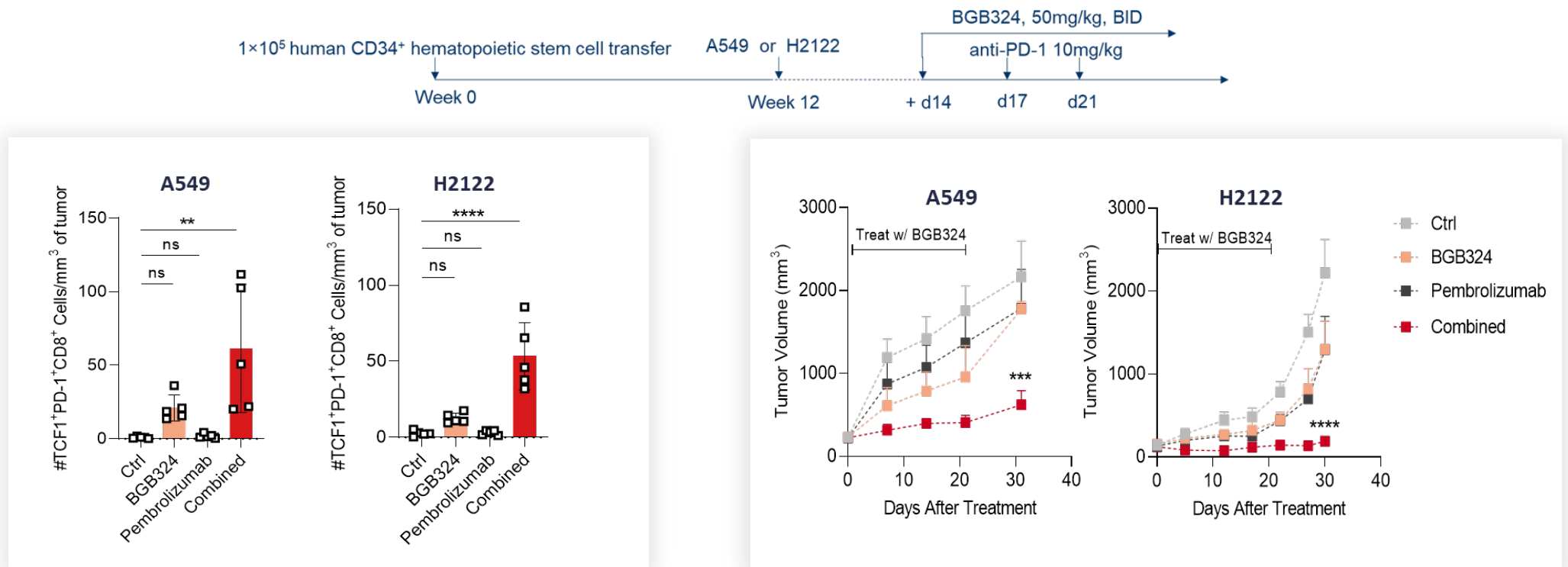


## Bemcentinib has two key MOAs relevant for STK11m NSCLC

- Bemcentinib increases Type I interferon secretion from dendritic cells driving expansion of tumor-specific CD8+ T cells, restoring therapeutic response to PD-1
- Downregulation of AXL activation in chemo-resistant cancers, delaying resistance and/or potentiating effect of chemotherapies

# Bemcentinib shown to restore sensitivity to ICI in STK11m models through the expansion of CD8+ T cells

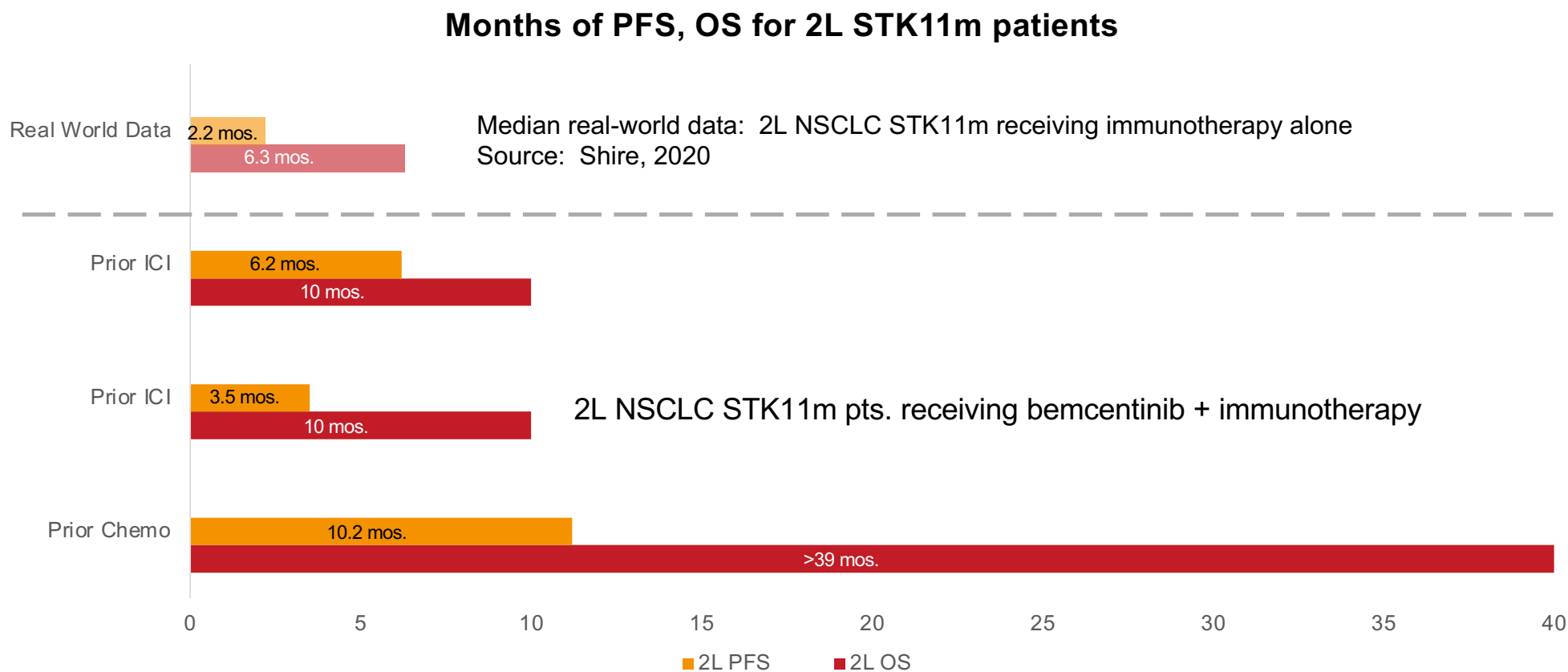
## THERAPEUTIC EFFECTS IN NSCLC XENOGRAFTS & PATIENTS



A549 cells were AXL+ KRAS/STK11 mutated and H2122 cells were AXL+ KRAS/TP53/STK11 mutated

Li et al., 2022, Cell Reports Medicine 3, 100554 March 15, 2022

# Early evidence of responses to 2L pembrolizumab + bemcentinib



## Next step: 1L NSCLC Phase 1b/2a

Phase 1b Safety & Feasibility Daily bemcentinib + SoC (pembrolizumab + doublet chemo.) n=9-30	Phase 2a Expansion of dose(s) identified in Ph 1b N=40+
<b>1L Advanced/ Metastatic Non-Squamous NSCLC pts</b>  Newly diagnosed, Any PDL1 status, no actionable mutations STK11 or AXL status not required  <b>Traditional 3+ 3 design</b>	<b>1L Advanced/ Metastatic Non-Squamous STK11m NSCLC pts</b>
<b>Endpoints</b> <b>Primary:</b> Safety/ Tolerability (DLT) <b>Secondary:</b> ORR, DCR, DOR, OS	<b>Endpoints</b> <b>Primary:</b> ORR <b>Secondary:</b> Safety, DOR, DCR, PFS, Time to Progression, OS, PK exposure
<ul style="list-style-type: none"> <li>Ph1b scheduled to start H2 2022 (in all comers)</li> <li>Bemcentinib combined with current standard of care in 1L NSCLC: pembrolizumab + doublet chemotherapy (pemetrexed + carboplatin)</li> <li>Ph 2a expansion in STK11m patients may start while last dose cohort is on-going in Ph 1b               <ul style="list-style-type: none"> <li>Primary endpoint – efficacy ; safety secondary</li> </ul> </li> <li>Data from Ph 1b expected to be available 2H23</li> </ul>	





# Hospitalized COVID-19

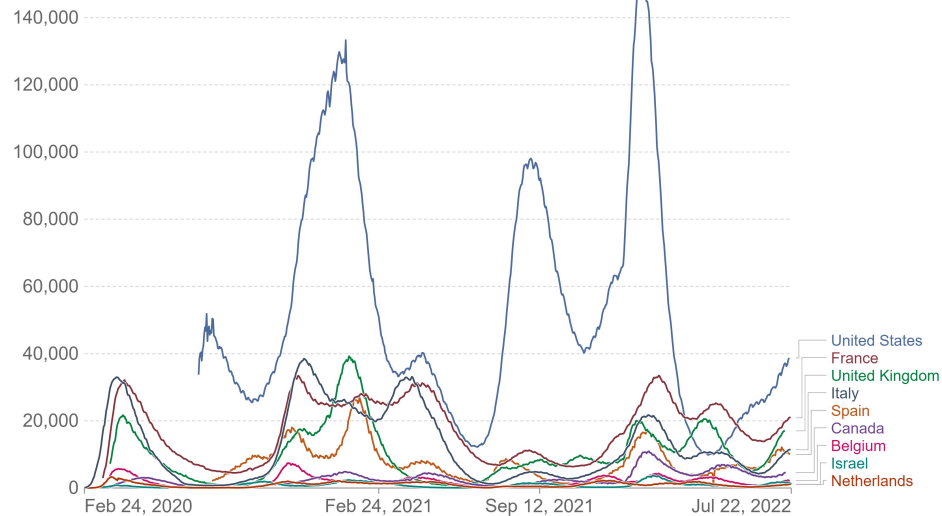
**Bemcentinib offers a novel approach to effectively treat hospitalized COVID-19 patients**



**BerGenBio**

# The need persists: hospitalizations and deaths continue even with “milder” variants

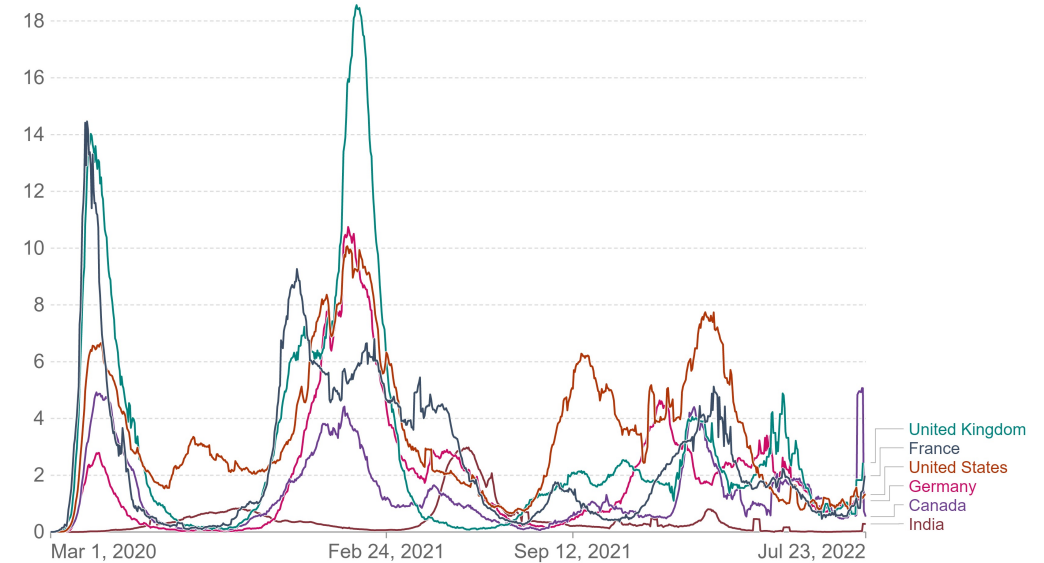
NUMBER OF COVID-19 PATIENTS IN HOSPITAL



Source: Official data collated by Our World in Data – Last updated 24 July 2022

OurWorldInData.org/coronavirus • CC BY

DAILY NEW CONFIRMED COVID-19 DEATHS PER MILLION



Source: Johns Hopkins University CSSE COVID-19 Data

CC BY

## With “endemic” COVID – three large patient populations will remain at risk for hospitalization

### Immunocompromised

- **19.7 million adults** at risk of hospitalization
- in US, EU<sup>1</sup>

### Unvaccinated

- **120 million adults** at risk of hospitalization
- in US, EU<sup>2</sup>

### Waning Immunity

- **236 million adults** without a booster shot in US, EU
- Waning immunity from prior infection
- Potential new variants may escape vaccines

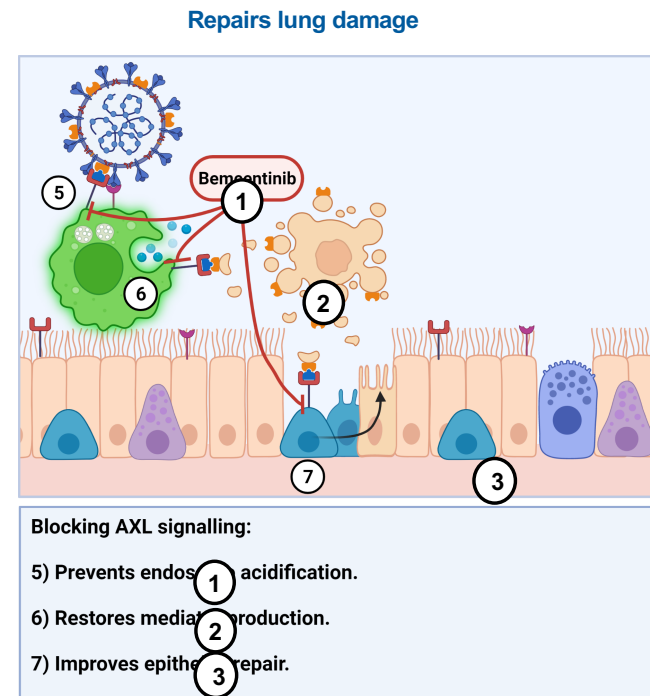
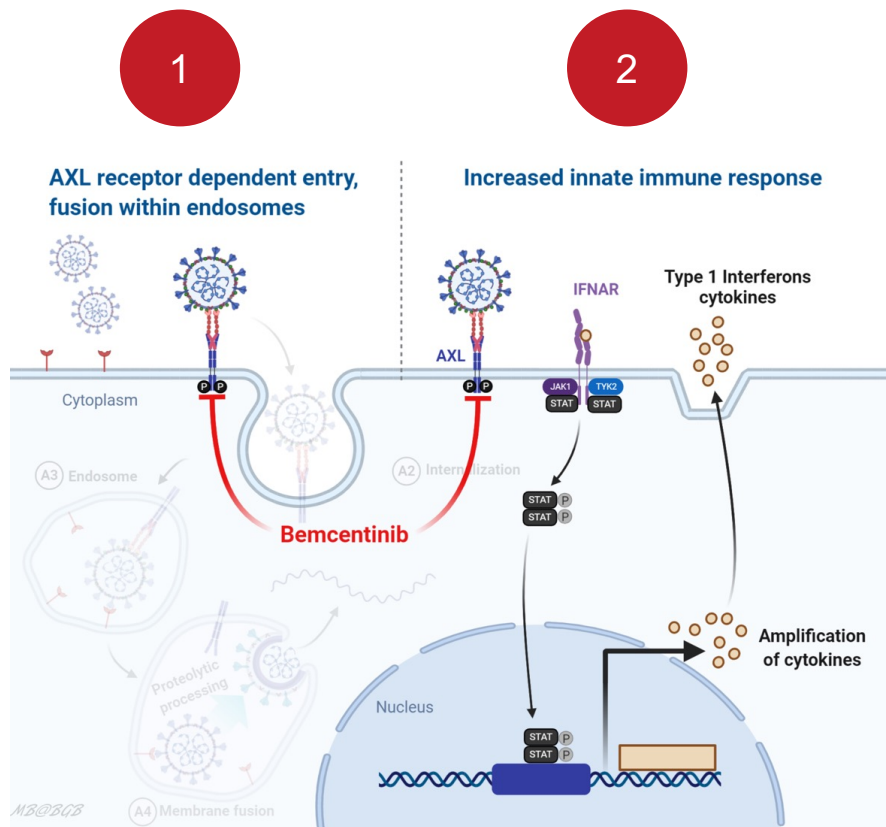
<sup>1</sup>Prevalence of Immunosuppression Among US Adults, 2013, [Rafael Harpaz, MD, MPH](#), JAMA Research Letter, December 20, 2016

<sup>2</sup>CDC, number of US adults who have received <2 vaccinations, June 2022; [ecdc.europa.eu](#) vaccination rates in EU adults >18



# Unlike other anti-virals, bemcentinib acts through 3 mechanisms

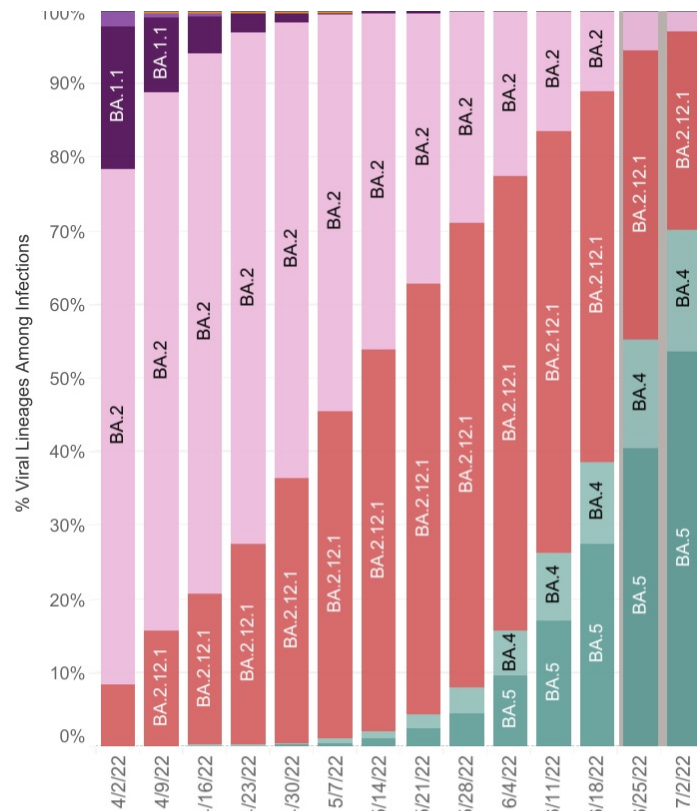
## *Prevents viral infection, promotes innate immunity and repair of damaged epithelium*



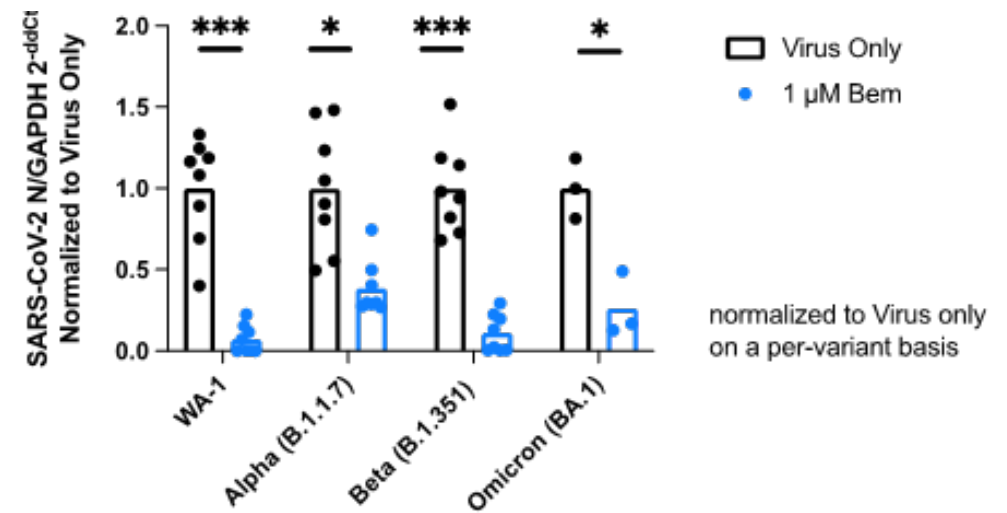


# Bemcentinib's activity is agnostic to COVID-19 variant, positioning it for future pandemics

Variant evolution in past 3 mos. in US



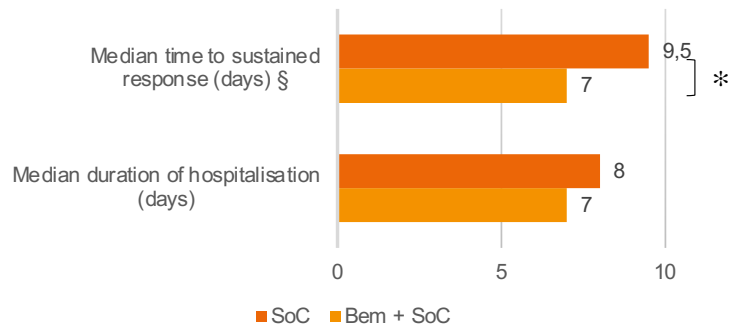
Bemcentinib broad COVID-19 variant inhibition



Adapted from: ECCMID 2022

# ACCORD2 bemcentinib + standard of care (SOC) in hospitalized COVID met primary and key secondary endpoints

## PRIMARY ENDPOINT §

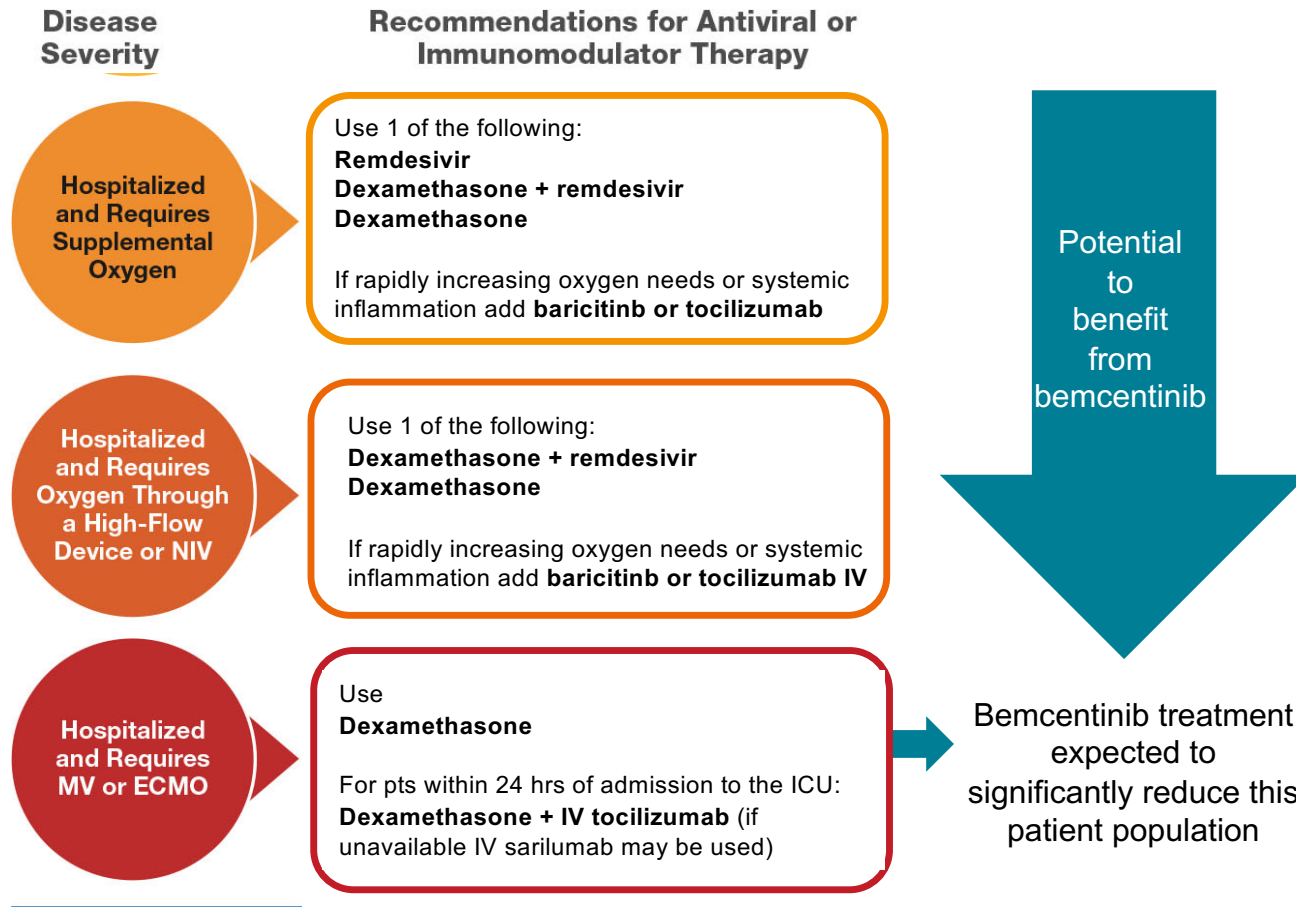


## KEY SECONDARY ENDPOINTS

Endpoint	SoC + bemcentinib	SoC alone	Statistically significant*
Alive at day 29	97%	81%	<input checked="" type="checkbox"/>
Alive at day 60	97%	75%	<input checked="" type="checkbox"/>
% w/ sustained clinical benefit	90%	69%	<input checked="" type="checkbox"/>

\*, p-value ≤0.05

# Current therapies are not positioned to treat across the spectrum of disease severity



# Phase 2b (EU-SolidAct platform) open for enrollment

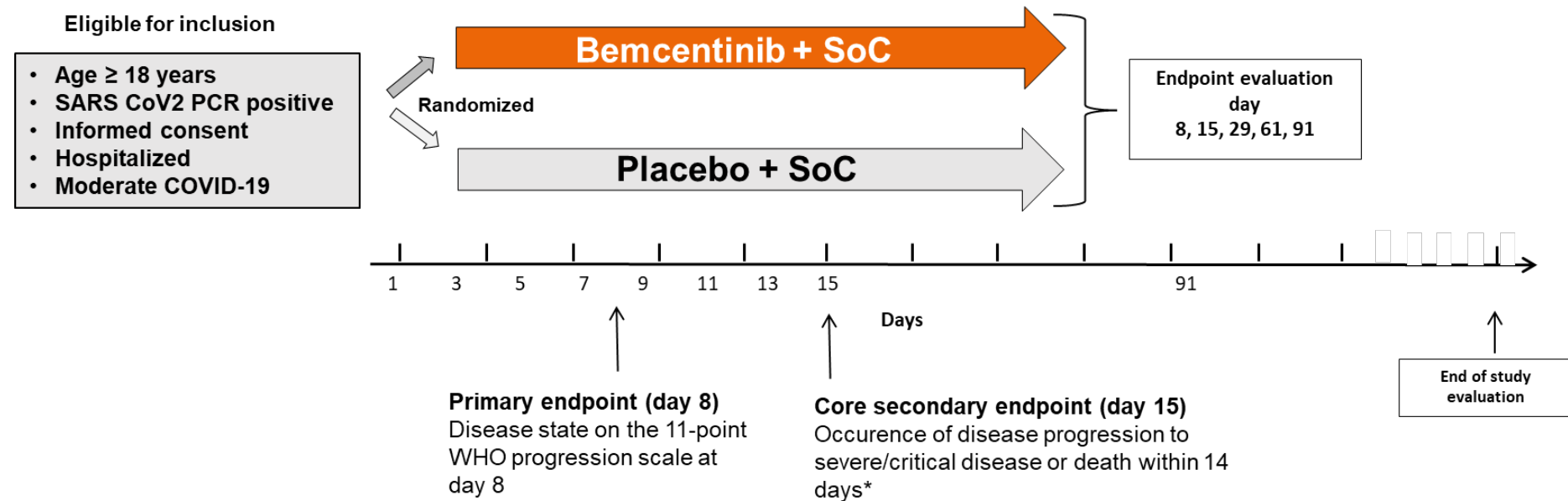
*Established capability to recruit into hospitalized COVID-19 and captive study design*

## Platform

- Demonstrated ability to rapidly recruit hospitalized COVID-19 patients
- Baricitinib recently approved in COVID-19 was studied under the platform

## Study design

- Reflects evolving nature of disease behaviour 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



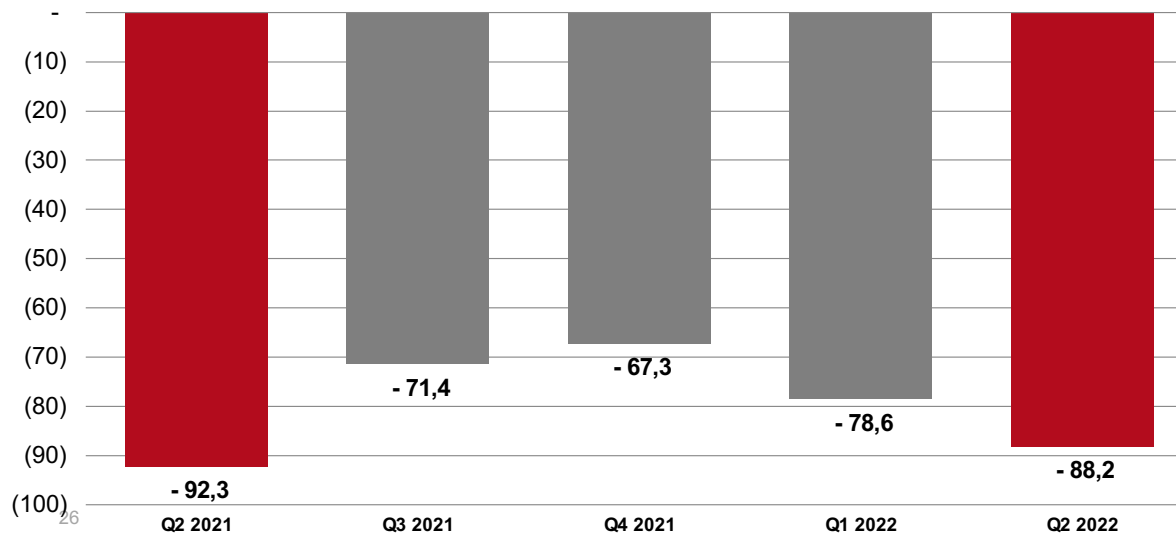
# Key Q2 2022 financials



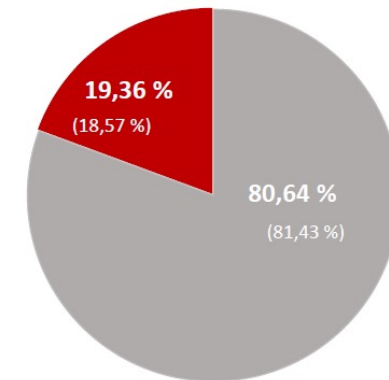
# Key financial figures

(NOK million)	Q2 2022	Q2 2021	YTD 2022	YTD 2021	FY 2021
Operating revenues	0.0	0.0	0.0	0.0	0.8
Operating expenses	88.2	92.3	166.8	175.7	315.2
Operating profit (-loss)	-88.2	-92.3	-166.8	-175.7	-314.5
Profit (-loss) after tax	-84.1	-88.9	-165.1	-170.1	-309.4
Basic and diluted earnings (loss) per share (NOK)	-0.95	-1.02	-1.86	-1.94	-3.52
Net cash flow in the period	-70.3	-82.4	-141.5	-144.2	-284.2
Cash position end of period	292.1	574.0	292.1	574.0	436.6

Operating loss (million NOK)



Operating expenses Q2 2022  
(YTD 2022)

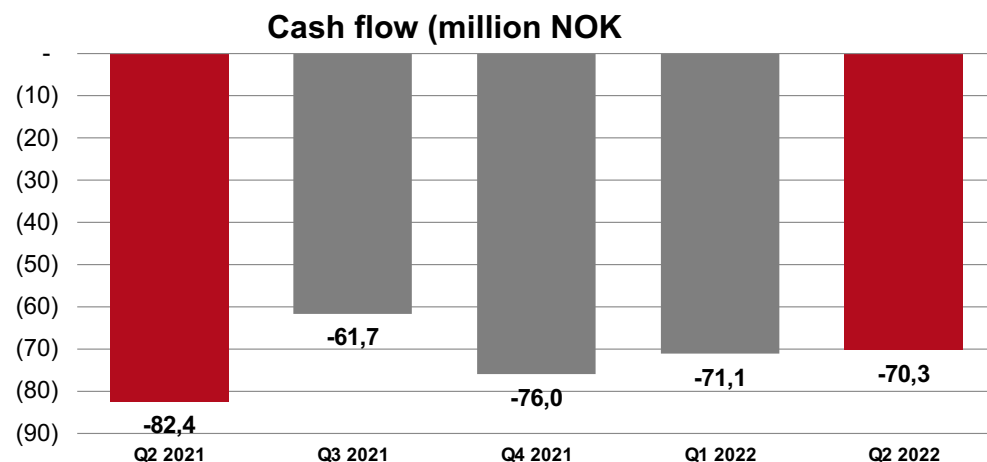


■ R&D ■ Administration

- Operating costs increased from Q1 22 to Q2, mainly caused by employee restructuring cost related to rightsizing the organisation announced in May 2022.
- Well managed overhead costs. 80% of operating expenses in Q2 and half year is attributable to Research & Development activities.



# Cash flow and cash position



Cash burn operating activities Q2 2022

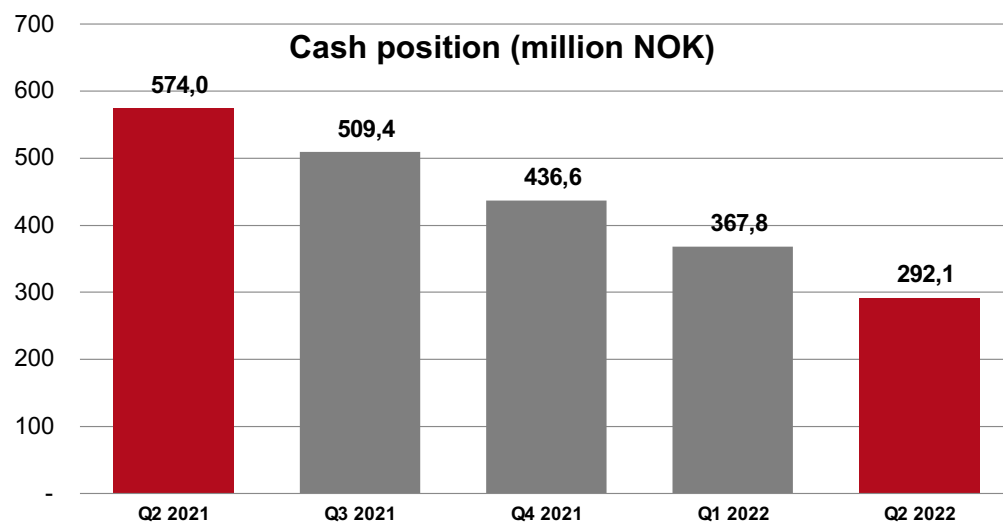
**72.3 / 8.2**

NOK million / USD million

Quarterly average net cash burn (Q2 2021 – Q2 2022)

**75.2 / 8.5**

NOK million / USD million



Cash position Q2 2022

**292.1 / 29.3**

NOK million / USD million

# Key catalysts for bemcentinib in next 12-18 months

## 1L STK11m NSCLC

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- Initiation of Ph 1b study (H2 2022)
- Additional pre-clinical data on STK11m and co-mutations (H1 2023)
- Ph 1b data (H2 2023)
- Initiation of Ph 2a study (H2 2023)

## Hospitalized COVID-19 patients

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- Phase 2b (EU-SolidAct) data (H2 2023)
- Additional data on respiratory infections (H2 2023)