BerGenBio

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

www.bergenbio.com

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About BerGenBio

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Oslo Euronext: BGBIO

- BerGenBio is a Norwegian/UK Biotech company focusing 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 has already been studied in clinical trials in more than 600 patients**
- We are laser focused on two significant opportunities with high unmet medical need within the lung area:
  - **1st line NSCLC STK11m - Ph 1b/2a**
  - **Hospitalized COVID-19 - Ph 2b**
- **Our plan defines clear value drivers in these indications** within next 12-18 months

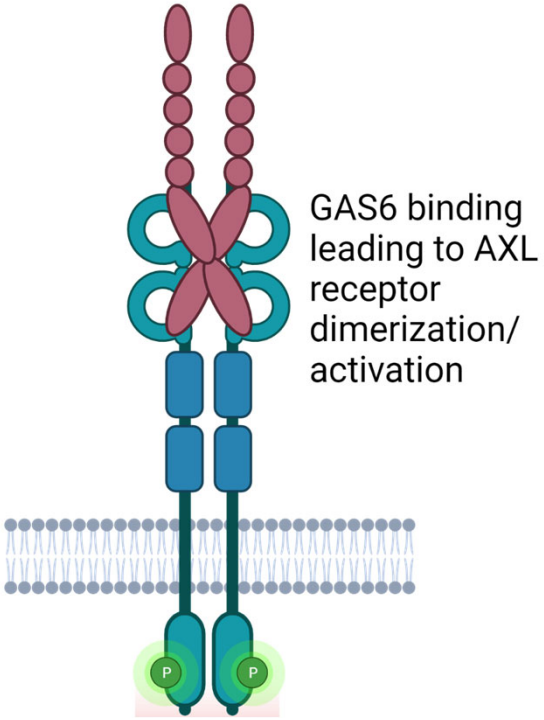
Why AXL inhibition, why bemcentinib and why lung diseases

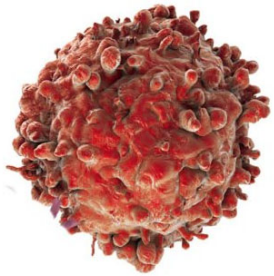
- ✓ **The receptor tyrosine kinase AXL plays an important role in efficient clearance of apoptotic material, the dampening of TLR-dependent inflammatory responses and natural killer cell activity**
- ✓ **In several severe diseases the activation and/or upregulation of AXL leads to a number deleterious effects seen in cancer and severe respiratory diseases**
- ✓ **BerGenBio is laser focused on advancing its oral, potent and highly selective AXL inhibitor, bemcentinib, administered in more than 600 patients, in two significant indications going forward: 1L NSCLC STK11 mutated patients and for hospitalized COVID-19 patients**
- ✓ **In the two selected lung diseases bemcentinib offers novel mechanisms of actions supported by pre-clinical and clinical data which is believed to potentially offer new and better treatment modalities for patients in great need**
- ✓ **The planned Phase 1b/2a trial in 1L NSCLC STK11m and the on-going Phase 2b trial in hospitalized COVID-19 patients represent true value drivers to further capitalize on the potential of bemcentinib**

Recent Highlights

- ✓ **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**
- ✓ **Opened a Phase 2b trial under the EU-SolidAct platform enrolling up to 500 hospitalized COVID-19 patients - first patient in expected imminently**
- ✓ **On schedule to initiate a Phase 1b/2a trial evaluating *bemcentinib in combination with standard of care* in 1L STK11m NSCLC**
- ✓ **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





CANCER

Invasion/Migration
Drug resistance
Proliferation
Survival
Immune suppression

RESPIRATORY

Viral entry, migration
Immune suppression
ECM production
Basal cell proliferation
Reduced cytokine signaling

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 and additionally potentiate chemotherapy
  - **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

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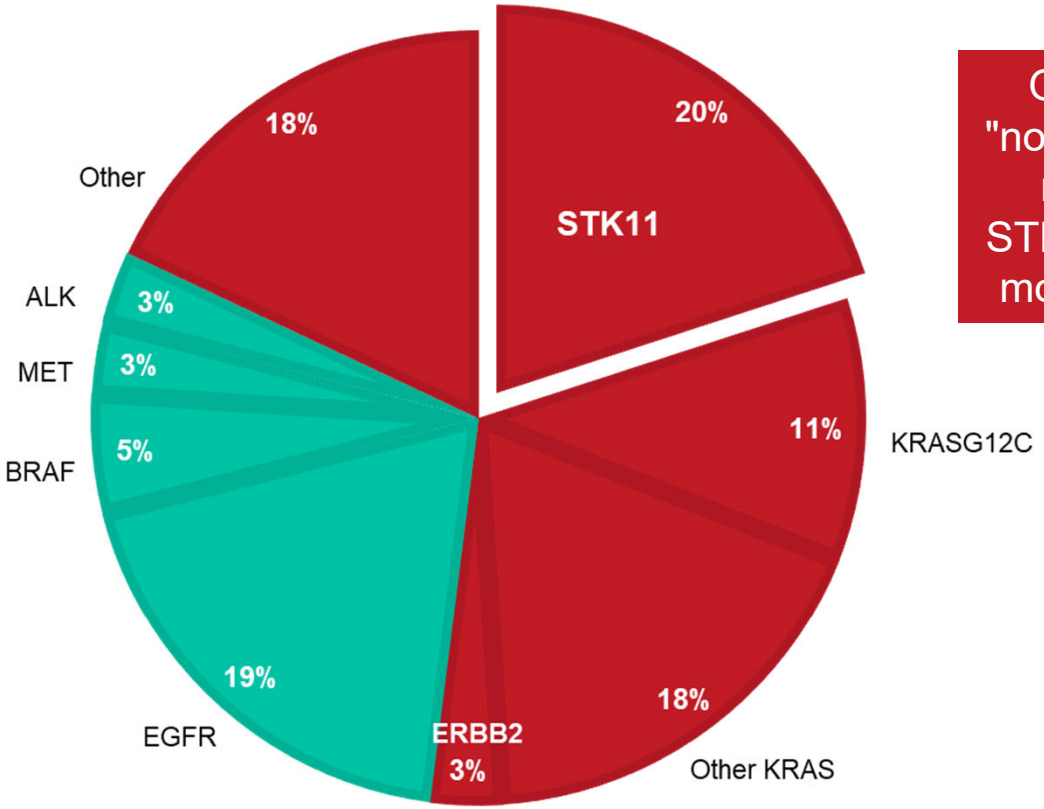
1L NSCLC treatment is based on molecular driver status; STK11 being the most common “non-actionable” mutation

Actionable 1L NSCLC mutations with currently approved therapeutics



Of currently "non-actionable" mutations, STK11m are the most prevalent

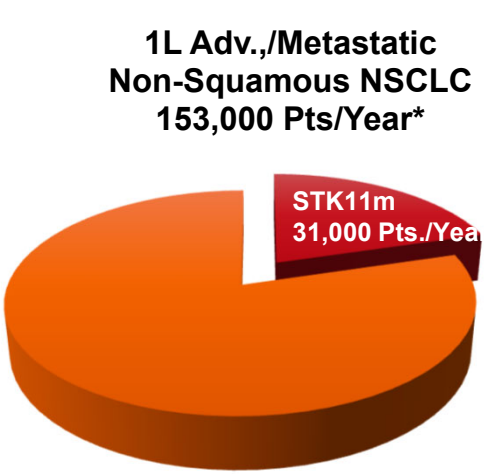
* Sources:Oncogenic driver mutations in non-small cell lung cancer: Past, present and future, World J Clin Oncol. 2021 Apr 24; 12(4): 217–237

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^) 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

^Source: Global Data estimate in US, UK, Fr, Gr, Sp, It
*ASCO 2022, Abstract 9021

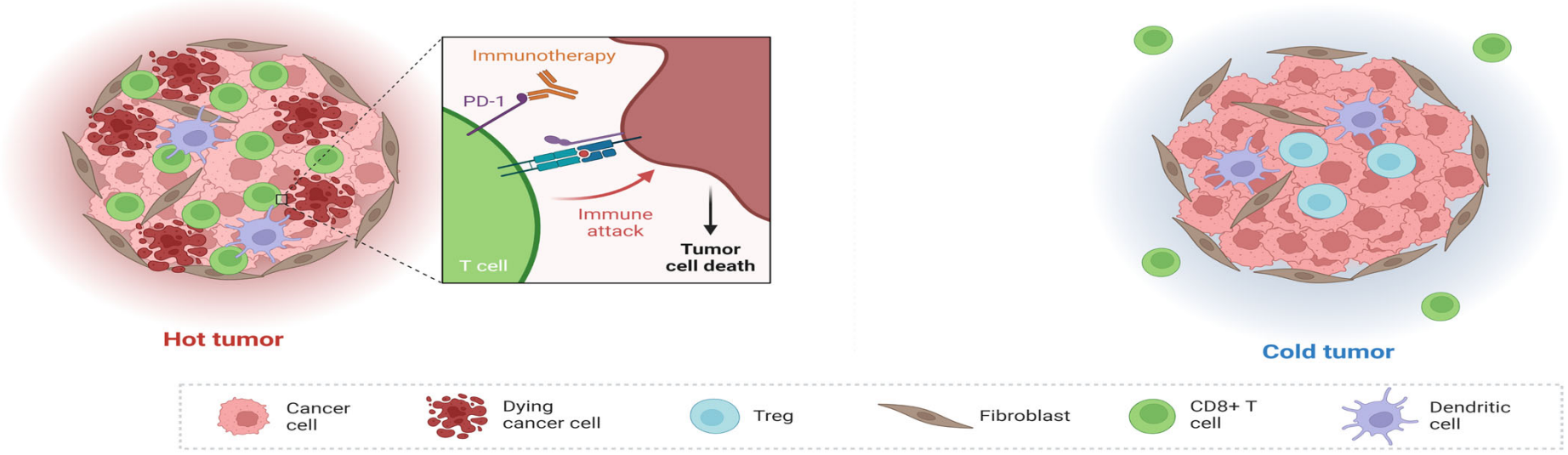
STK11 mutations create a more immunosuppressive tumor microenvironment limiting response to checkpoint inhibition

CHECKPOINT INHIBITION THERAPY IN NSCLC

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

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**



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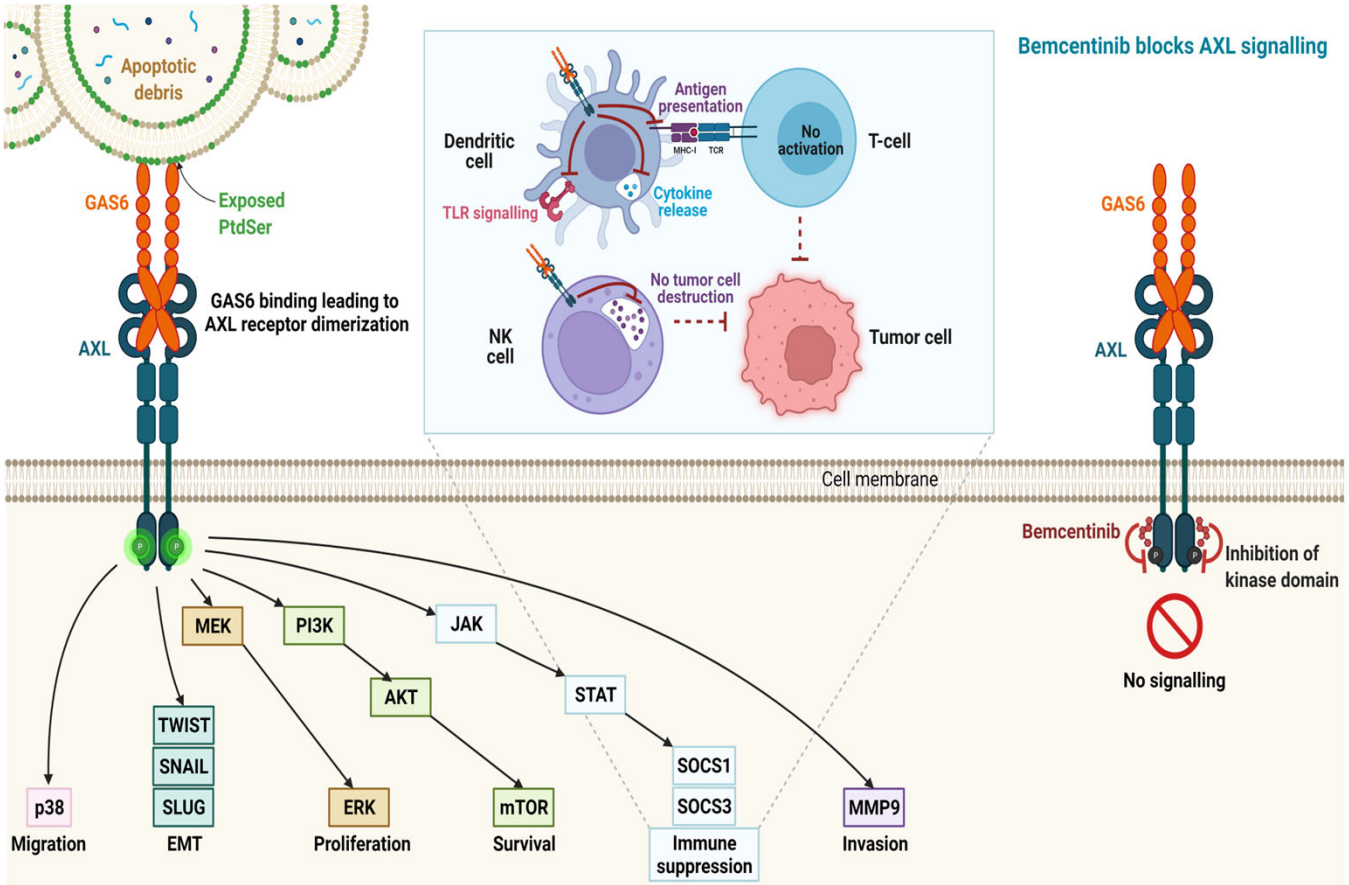
By selectively blocking AXL activation bemcentinib restore sensitivity to ICI therapy and potentiate chemotherapy



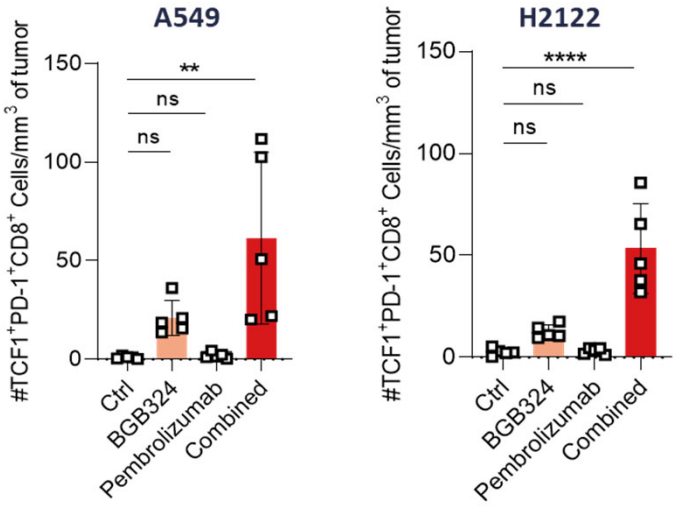
Bemcentinib has two key MOAs relevant for STK11m NSCLC

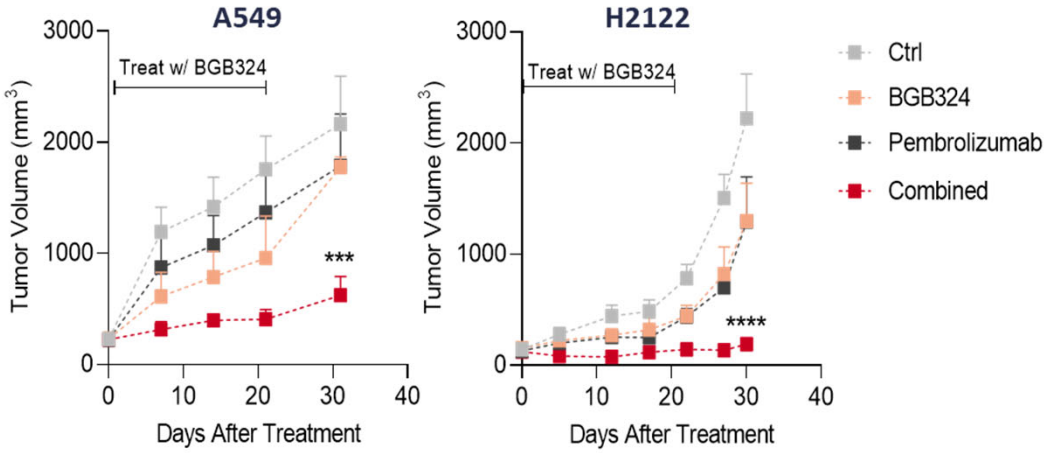
- Bemcentinib increases Type I interferon secretion from dendritic cells driving expansion of tumor-specific CD8+ T cells, restoring therapeutic response to PD-1
- Downregulation of AXL activation in chemo-resistant cancers, delaying resistance and/or potentiating effect of chemotherapies

Adapted from Gay *et al*., 2017

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

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Clinical data supporting role of AXL in NSCLC

Clinical data supports role of AXL and benefit of bemcentinib in combination with current standards of care (immune checkpoint inhibition + chemotherapy):

Bemcentinib + ICI

Benefit in combination with ICI
BGBC008 2L NSCLC w/ pembrolizumab

Onco-genotype	mPFS	mOS
STK11*mut (n=8) AXL+	**8.2**	**24.4**
STK11mut* (n=2) AXL -	1.3	3.7
Historical controls (all comers):		
Checkmate 057 (Opdivo)	2.3	12.2
Keynote 010 (Keytruda)	3.9	10.4

Bemcentinib + chemotherapy

Benefit in combination with Chemotherapy
BGBIL005 >2L NSCLC w/ docetaxel

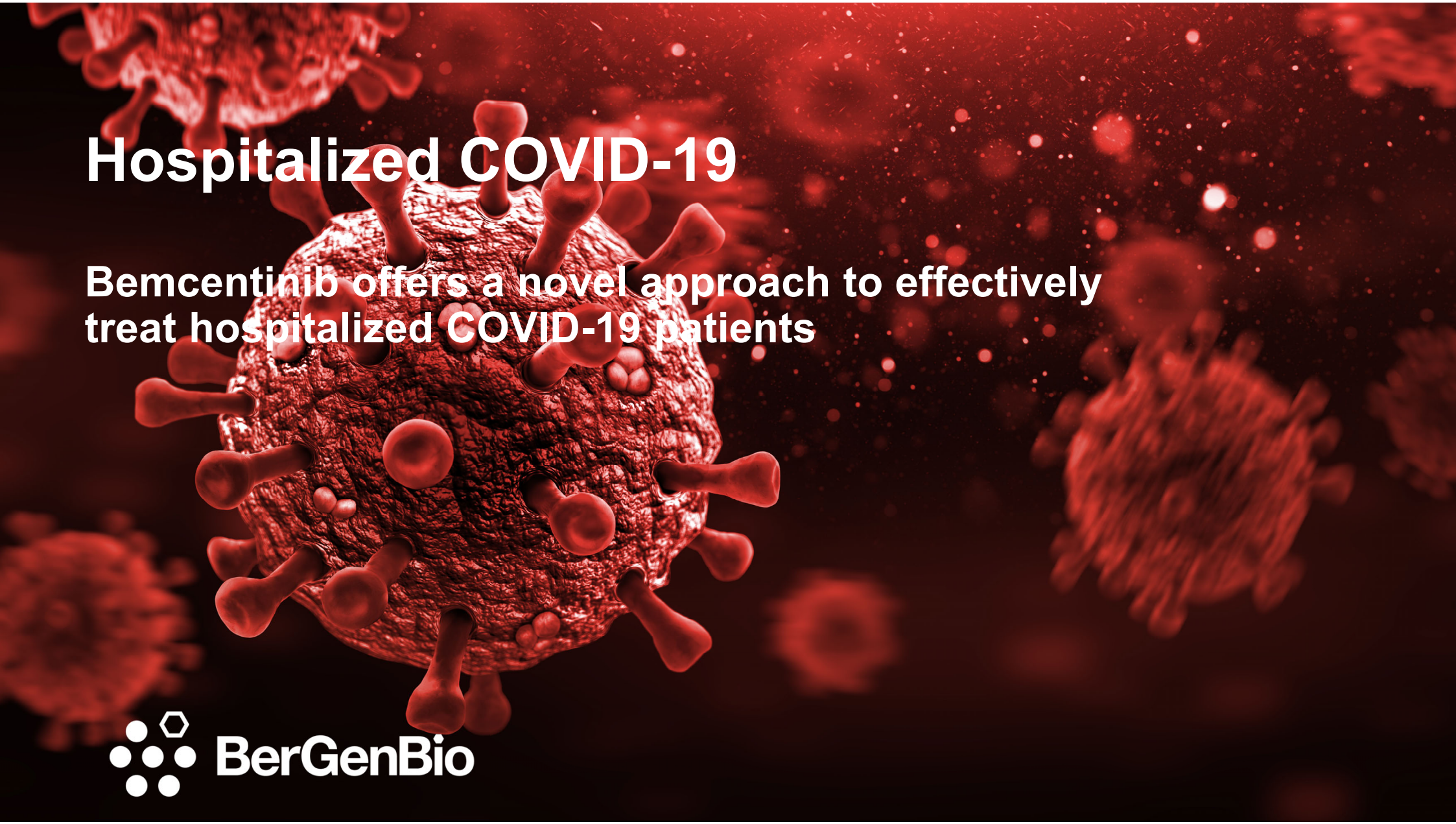
Treatment	ORR
Bemcentinib + docetaxel	**35%**
Historical control:	
2L docetaxel response**	Range 3-14%

* STK11m/STK11IPm (study on-going)
**Besse et al 2015

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+
1L Advanced/ Metastatic Non-Squamous NSCLC pts Newly diagnosed, Any PDL1 status, no actionable mutations STK11 or AXL status not required **Traditional 3+ 3 design**	**1L Advanced/ Metastatic Non-Squamous STK11m NSCLC pts**
Endpoints **Primary:** Safety/ Tolerability (DLT) **Secondary:** ORR, DCR, DOR, OS	**Endpoints** **Primary:** ORR **Secondary:** Safety, DOR, DCR, PFS, Time to Progression, OS, PK exposure

- Ph1b scheduled to start H2 2022 (in all comers)
- Bemcentinib combined with current standard of care in 1L NSCLC: pembrolizumab + doublet chemotherapy (pemetrexed + carboplatin)
- Ph 2a expansion in STK11m patients may start while last dose cohort is on-going in Ph 1b
  - Primary endpoint – efficacy ; safety secondary
- Data from Ph 1b expected to be available 2H23


Hospitalized COVID-19
Bemcentinib offers a novel approach to effectively treat hospitalized COVID-19 patients
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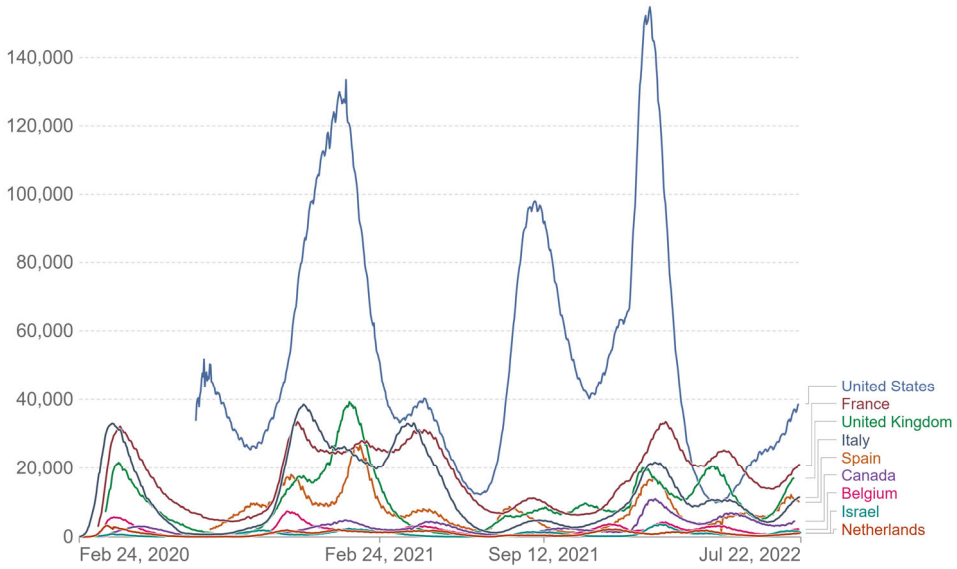
The need persists: hospitalizations and deaths continue even with “milder” variants

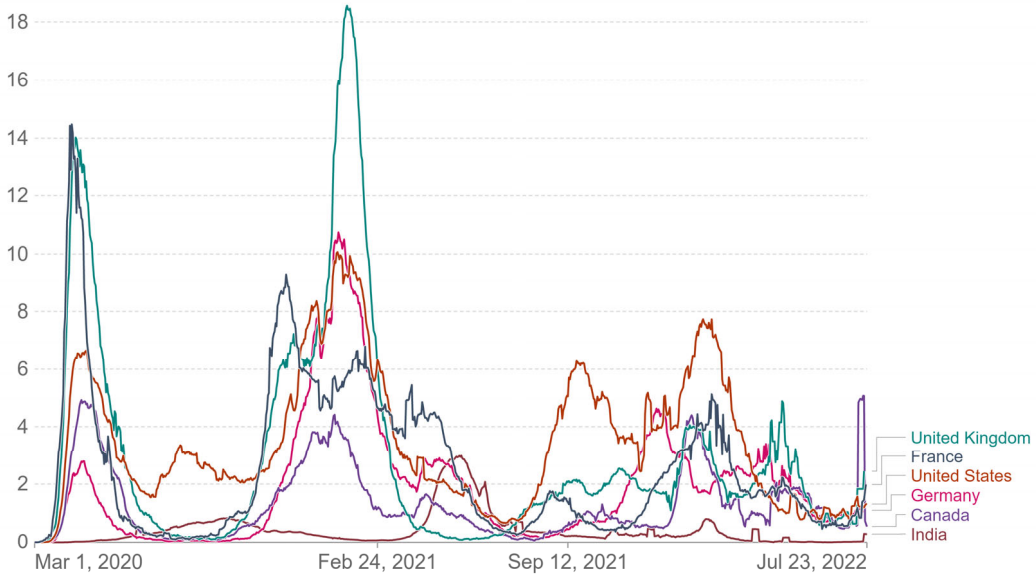
NUMBER OF COVID-19 PATIENTS IN HOSPITAL



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

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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[1]

Unvaccinated

- **120 million adults** at risk of hospitalization
- in US, EU[2]

Waning Immunity

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

[1]Prevalence of Immunosuppression Among US Adults, 2013, Rafael Harpaz, MD, MPH, JAMA Research Letter, December 20, 2016
[2]CDC, number of US adults who have received <2 vaccinations, June 2022; ecdc.europa.eu vaccination rates in EU adults >18

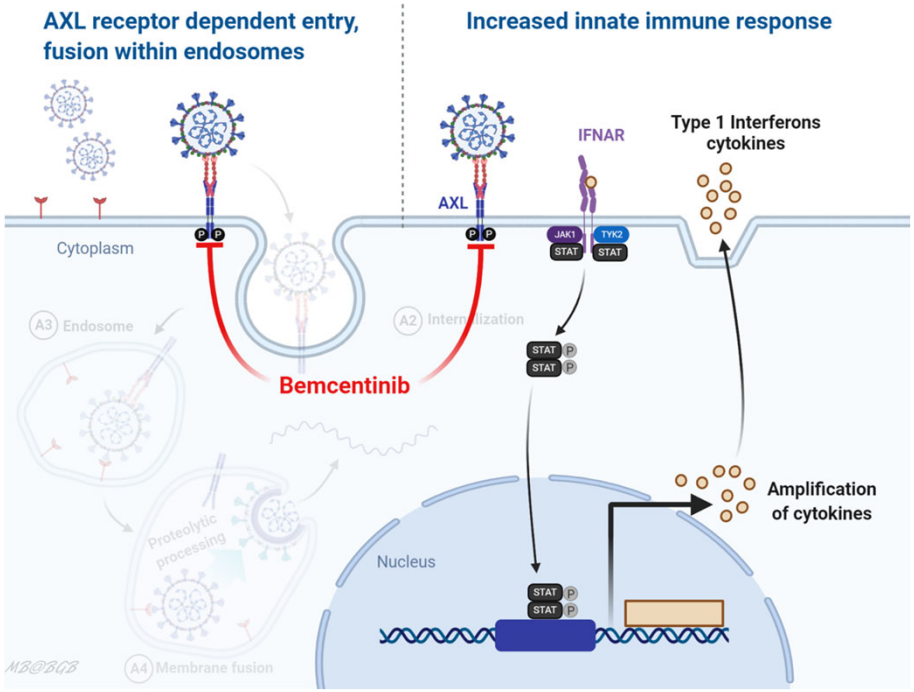
Unlike other anti-virals, bemcentinib acts through 3 mechanisms

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

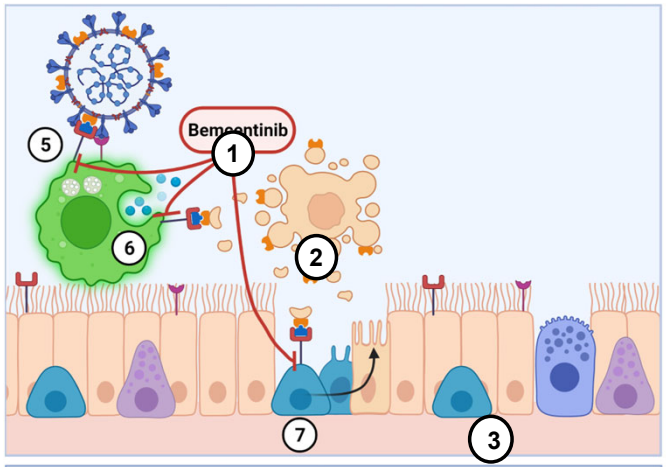
1

2

3



Repairs lung damage



Blocking AXL signalling:

5) Prevents endos[illegible] acidification. (1)

6) Restores media[illegible]roduction. (2)

7) Improves epithe[illegible]epair. (3)

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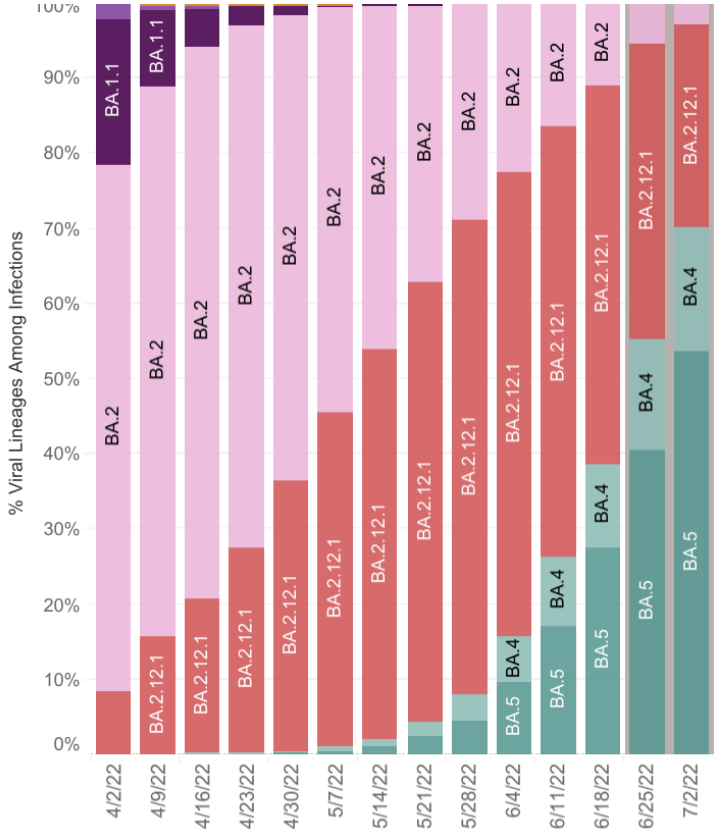
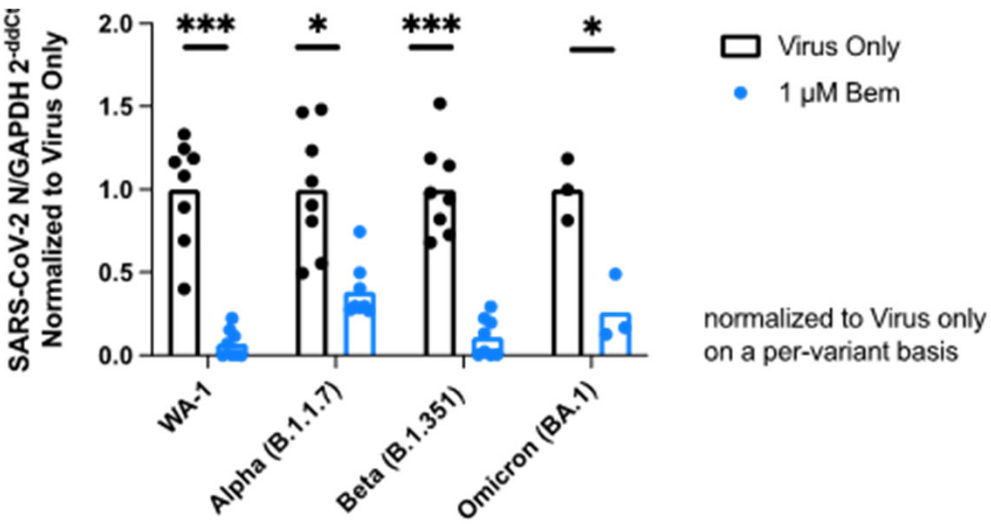
Bemcentinib's activity is agnostic to COVID-19 variant, positioning it for future pandemics

Variant evolution in past 3 mos. in US



Bemcentinib broad COVID-19 variant inhibition



Adapted from: ECCMID 2022

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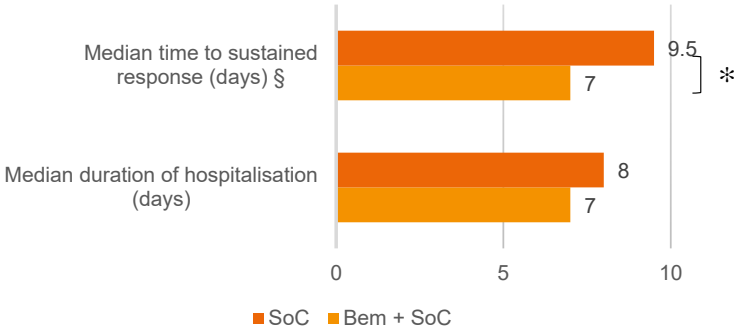
ACCORD2 bemcentinib + standard of care (SOC) in hospitalized COVID met primary and key secondary endpoints

PRIMARY ENDPOINT §



KEY SECONDARY ENDPOINTS

Endpoint	SoC + bemcentinib	SoC alone	Statistically significant*
Alive at day 29	97%	81%	✓
Alive at day 60	97%	75%	✓
% w/ sustained clinical benefit	90%	69%	✓

*, p-value ≤0.05

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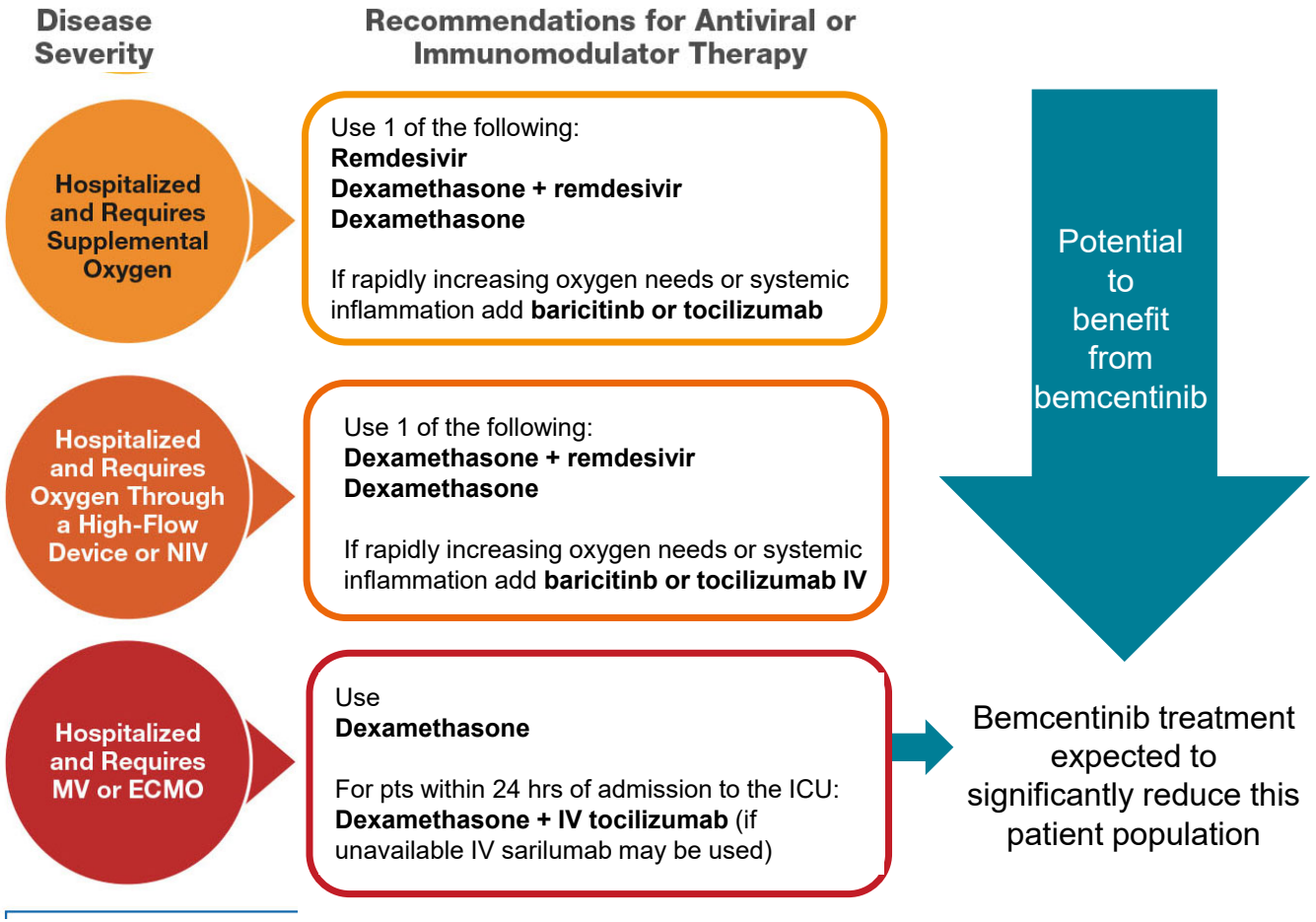
Current therapies are not positioned to treat across the spectrum of disease severity



23 August 2022: current NIH guidelines for hospitalized patients requiring oxygen

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

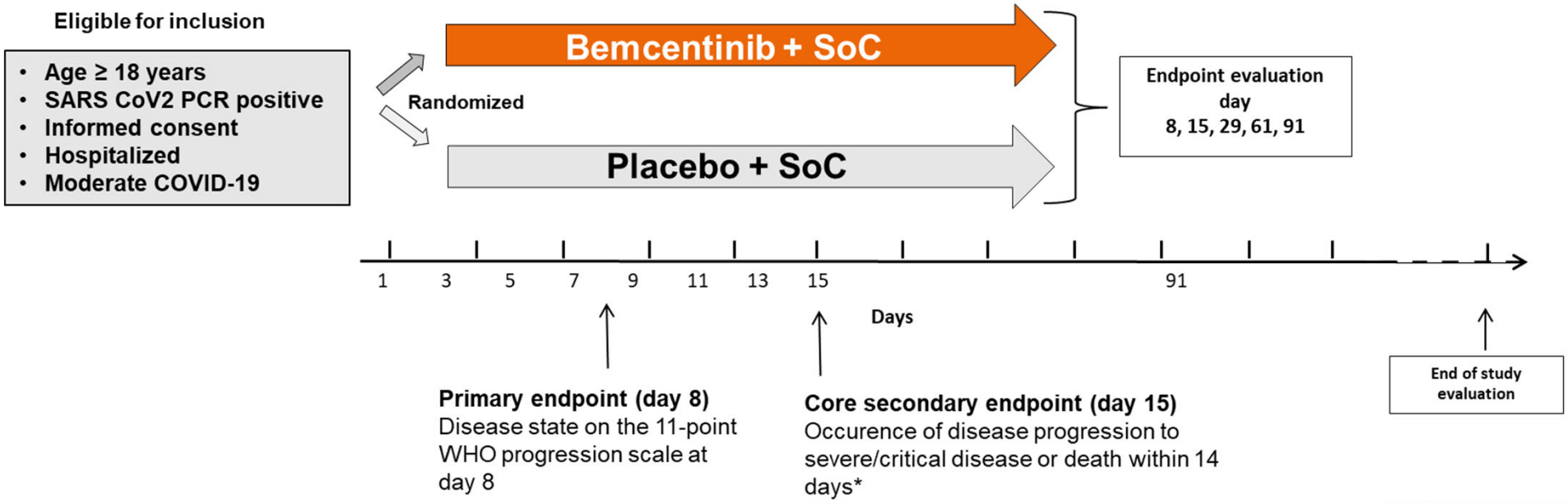
Established capability to recruit into hospitalized COVID-19 and captive study design

Platform

- Demonstrated ability to rapidly recruit hospitalized COVID-19 patients
- Baracitinib 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



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Key catalysts for bemcentinib in next 12-18 months

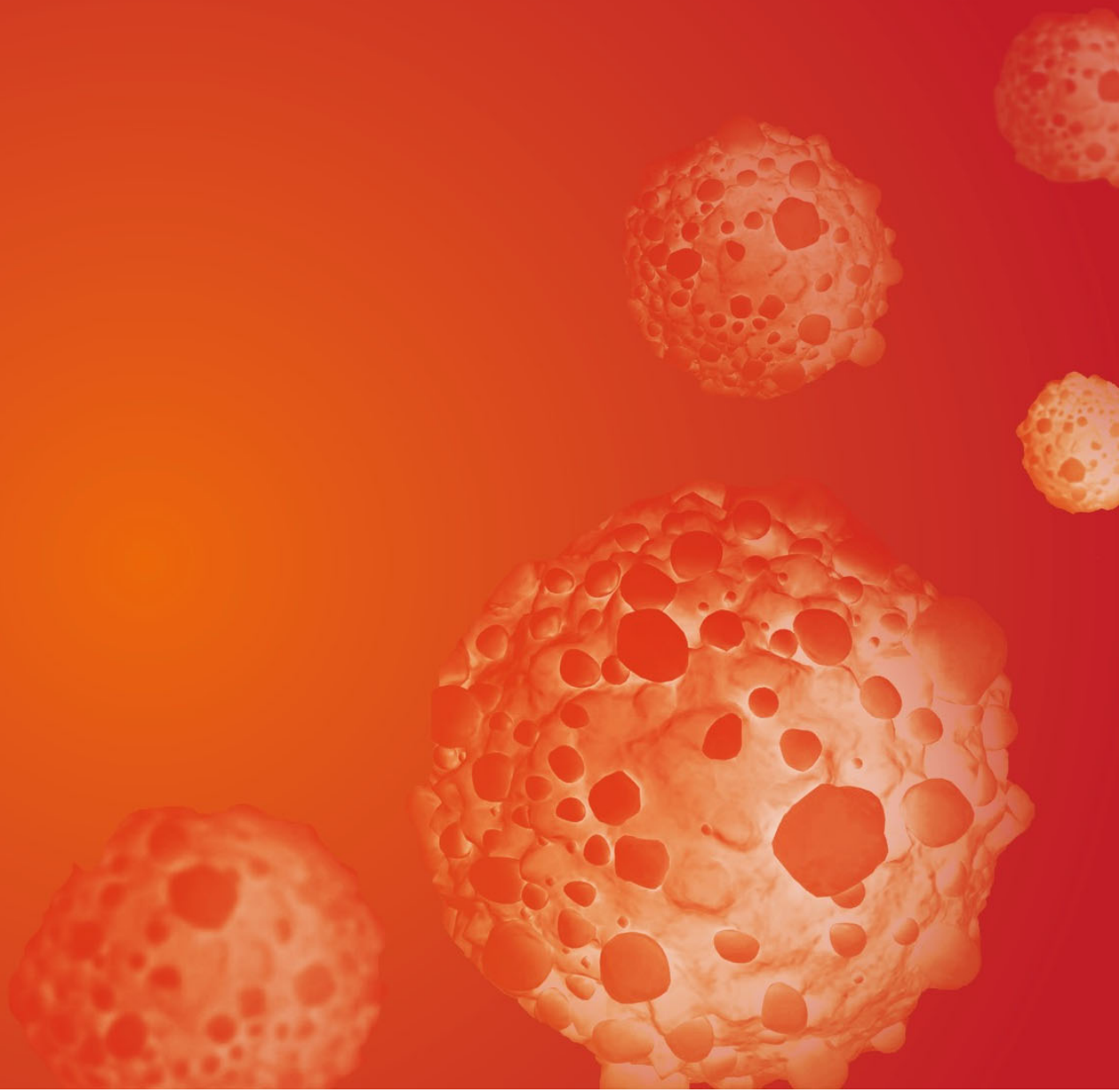
1L STK11m NSCLC

- 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

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

Thank you!



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