TOP LINE DATA FROM PHASE II TRIAL ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

Mr Richard Godfrey – Chief Executive Officer

Dr Akil Jackson PhD – Medical Director

Professor emeritus Stener Kvinnsland – Director of BerGenBio ASA and former Chair of Norwegian Korona Commission

BerGenBio

18th May 2021

Forward Looking Statements

Certain statements contained in this presentation constitute forward-looking statements. Forward-looking statements are statements that are not historical facts and they can be identified by the use of forward-looking terminology, including the words "anticipate", "believe", "intend", "estimate", "expect", "will", "may", "should" and words of similar meaning. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. Accordingly, no assurance is given that such forward-looking statements will prove to have been correct. They speak only as at the date of the presentation and no representation or warranty, expressed or implied, is made by BerGenBio ASA or its affiliates ("BerGenBio"), or by any of their respective members, directors, officers or employees that any of these forward-looking statements or forecasts will come to pass or that any forecast result will be achieved and you are cautioned not to place any undue influence on any forward-looking statement. BerGenBio is making no representation or warranty, expressed or implied, as to the accuracy, reliability or completeness of this presentation, and neither BerGenBio nor any of its directors, officers or employees will have any liability to you or any other person resulting from the use of this presentation.

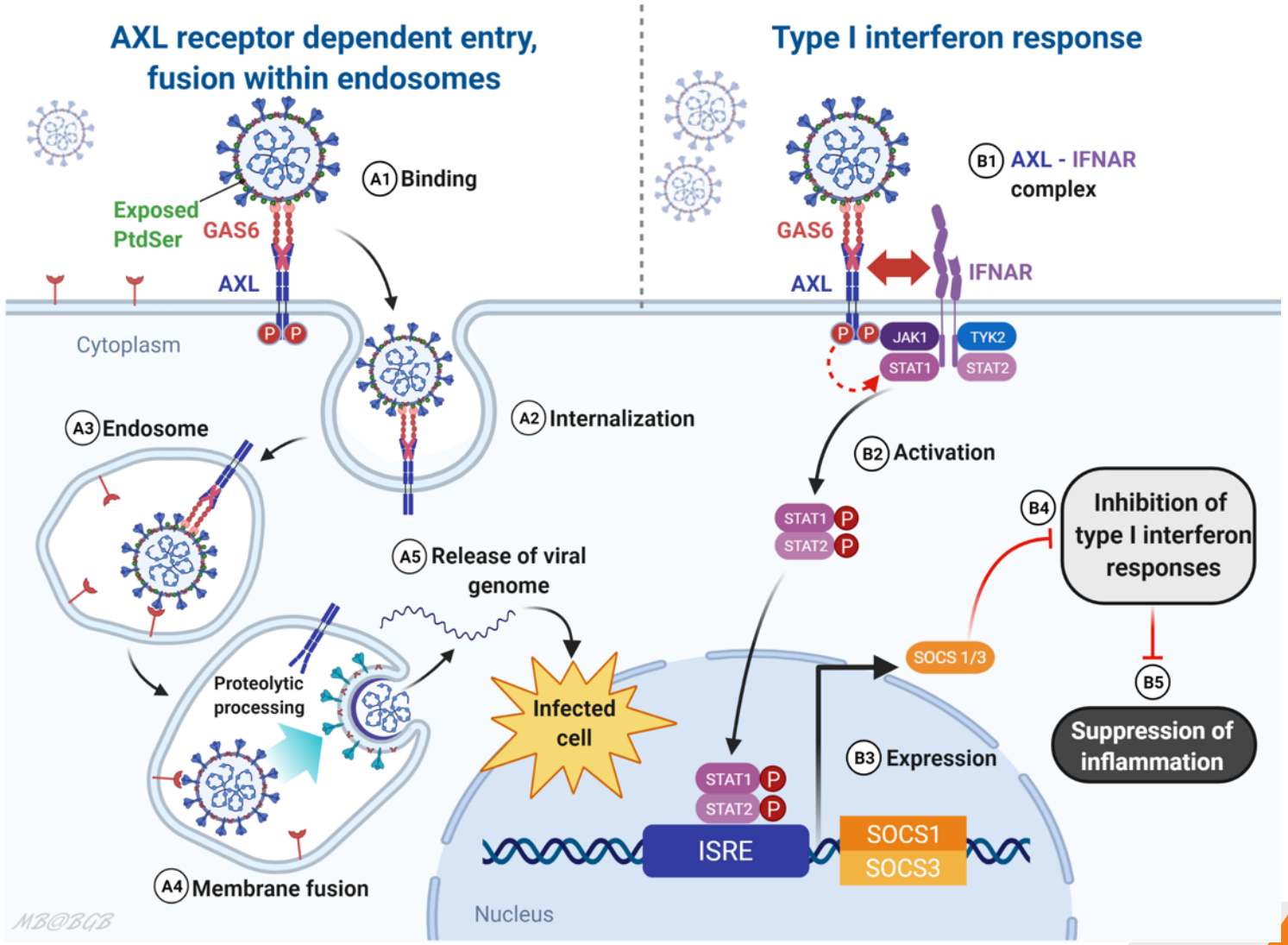
Executive Summary

The trial BGBC020 shows that Bemcentinib has the potential to increase the rate of ventilator free survival in more than 50% of hospitalised COVID-19 patients, addressing the greatest challenge faced by hospitals worldwide fighting the pandemic.

- Top line data from BGBC020, a randomised Phase II clinical study evaluating the efficacy and safety of bemcentinib in hospitalised COVID-19 patients
- Study conducted from October 2020 in 115 patients across sites in South Africa and India
- Ventilator Free Survival 90% in bemcentinib group vs 72% in standard of care
- Subgroup of COVID-19 patients identified with increased disease severity, representing more than 50% of hospitalised patients on the study.
- Analysis of overall survival in the BGBC020 study was combined with UK ACCORD2 study with analogous phase 2 design
- Survival benefit was numerically greater in the bemcentinib treated patients
- Bemcentinib was well tolerated throughout
- BerGenBio continues discussions with international governments and regulators regarding next steps

AXL is targeted by enveloped viruses to enter cells and dampen the viral immune response

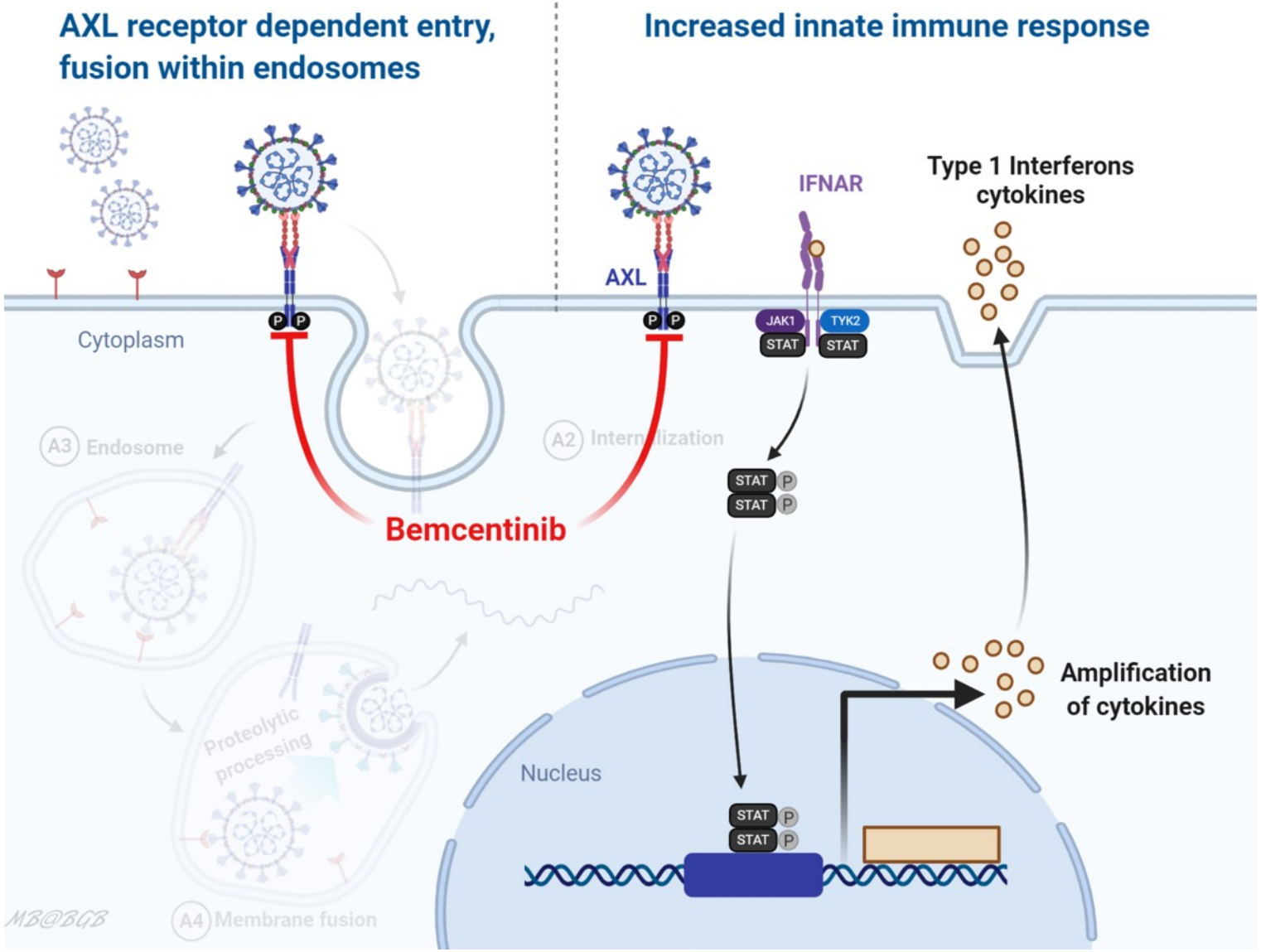
Enveloped viruses display phosphatidylserine that is recognized by GAS6, the AXL receptor ligand, that mediates viral entry through “apoptotic mimicry”.



Viral-mediated AXL receptor activation dampens type I interferon responses, a key anti-viral defence mechanism for all cells

Meertens L *et al. Cell Host & Microbe* 2012, *12*:544 / Chen J *et al. Nat Microbiol* 2018 *3*:302

Bemcentinib acts on two host pathways
Prevents viral infection and promotes innate immunity

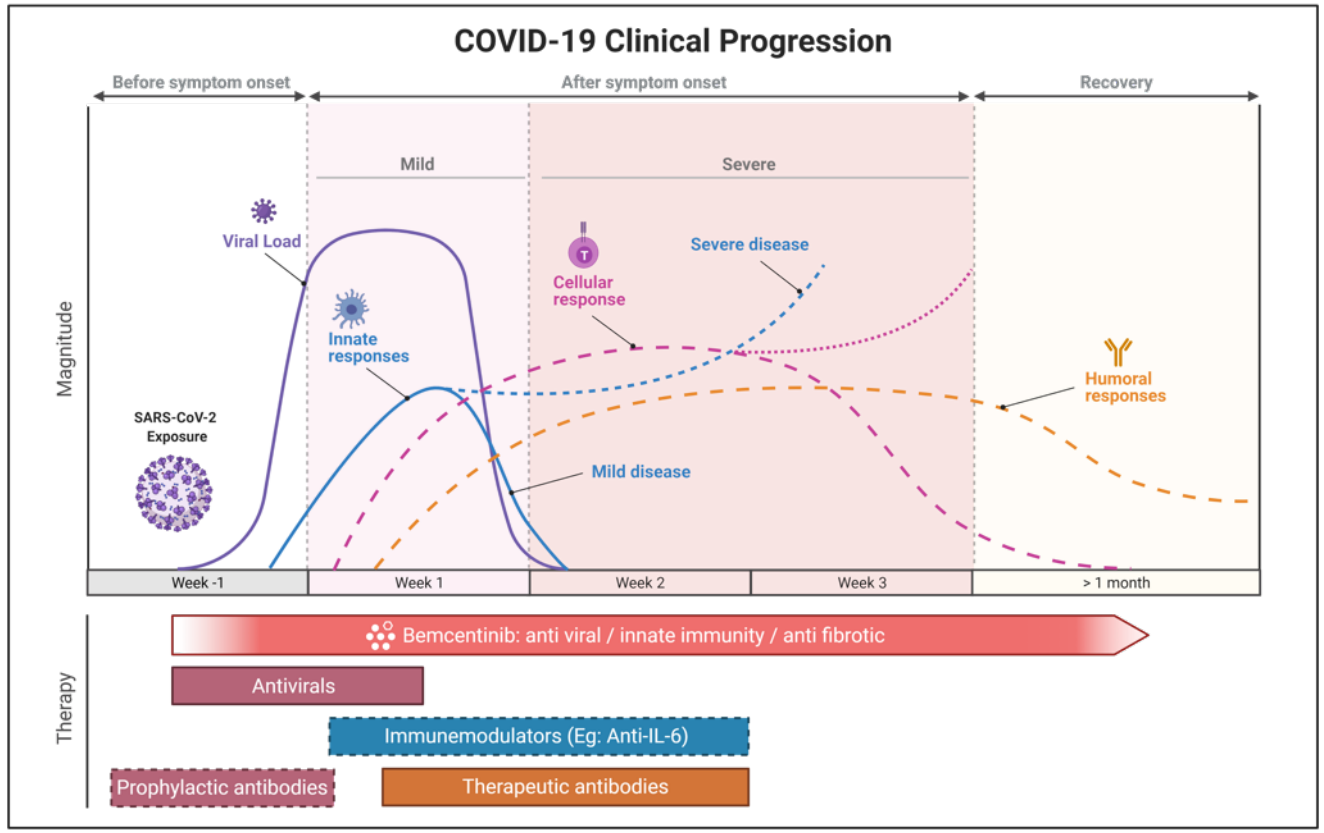


Bemcentinib:

- **blocks AXL-dependent viral entry**
- **enhances anti-viral interferon response**
- **Mode of action is independent of spike protein (or mutations)**

BerGenBio

Summary of bemcentinib as a COVID-19 therapy

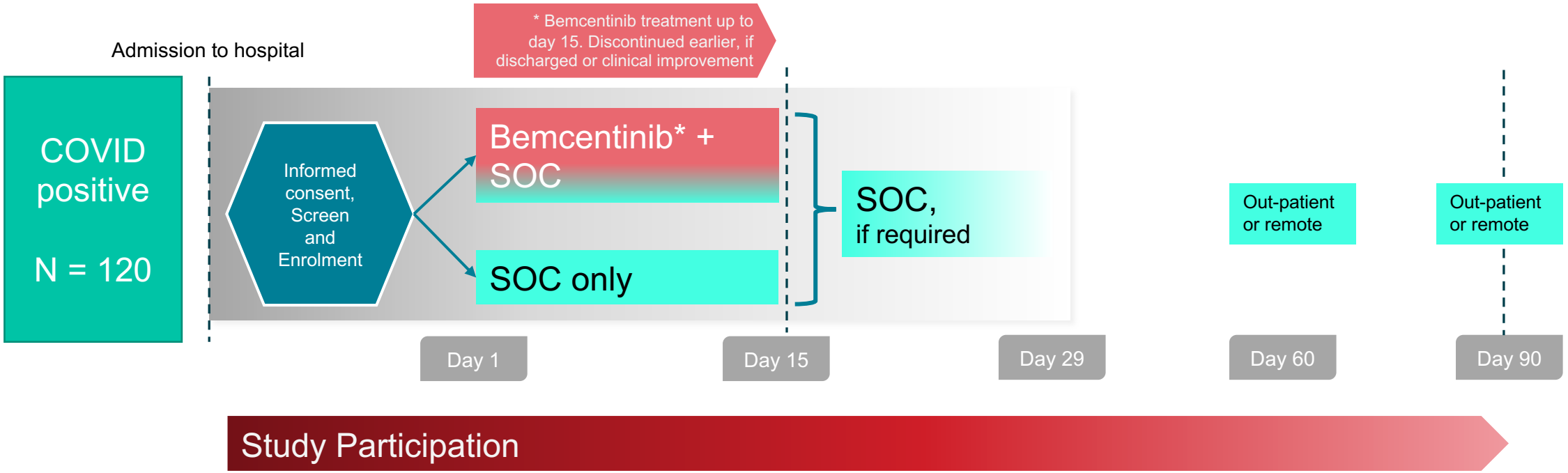


- **Bemcentinib acts on two host pathways**
  - Prevents viral infection
  - Promotes innate immunity

- **Bemcentinib inhibits viral entry by inhibiting AXL**
  - AXL is independent of viral spike protein and should remain effective against current and future variants
  - Ongoing work will confirm viral genome sequencing of clinical trial samples

BerGenBio

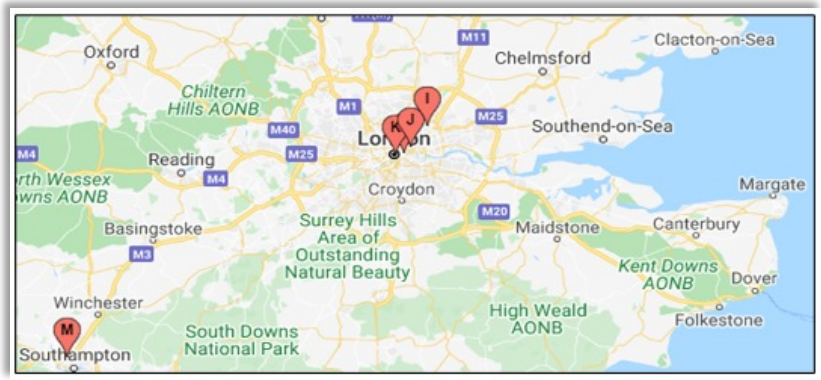
Study Schematic - BGBC020 and ACCORD2 share identical design



BerGenBio

Bemcentinib studied in COVID-19 across 3 countries

Patient Accrual 3/24	India	South Africa	UK	Total
Bemcentinib	30	28	30	88
SoC	30	27	32	89
				177



SoC- standard of care therapy

BGBC020 Enrolment – strata and arm

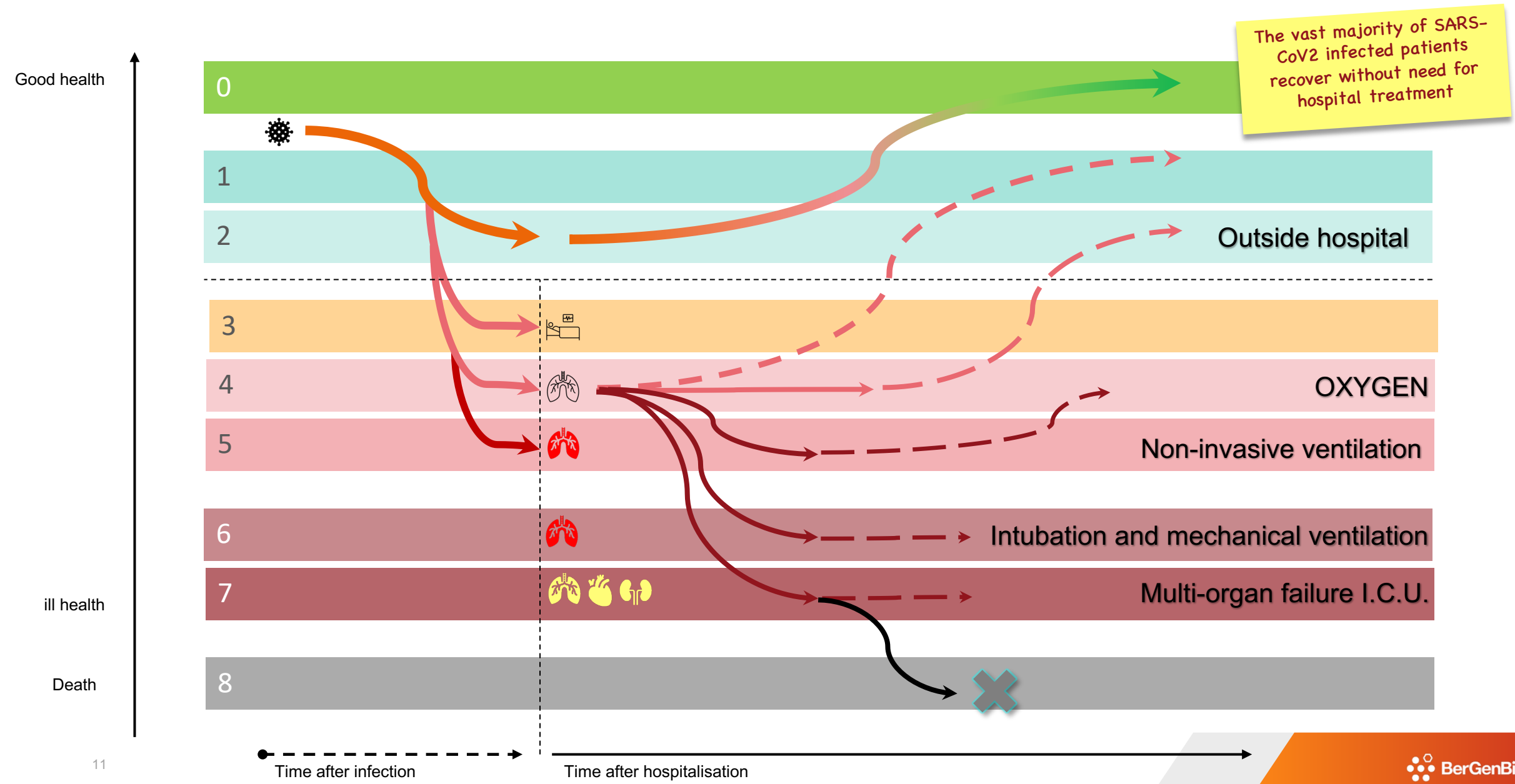
Baseline WHO OCS	Baseline Intent to use steroid	Bemcentinib	SOC	Total
3	**N/A**	6	5	**11**
4	**No**	11	10	**21**
	Yes	36	36	**72**
5	**No**	1	1	**2**
	Yes	4	5	**9**
	Total	**58**	**57**	**115**

Baseline intention to treat with steroids - 81 patients (70%);
On-study use of steroids - 87 patients (76%)

Inclusion based on WHO COVID19: 9-point ordinal category scale (OCS)

	Setting	Severity	Supportive intervention	BGBC020 ACCORD2	Dexamethasone	IL-6 receptor antagonists	Remdesivir
0	Uninfected	no clinical or virological evidence of infection					
1	Ambulatory	no limitation of activities					
2		limitation of activities					
3	Hospitalised	mild	**no oxygen therapy**	except India			
4			**oxygen by mask or nasal prongs**				
5		severe	**noninvasive ventilation or high-flow oxygen**				
6			intubation and mechanical ventilation				
7			ventilation and additional organ support – - vasopressors - renal replacement therapy (RRT) - extracorporeal membrane oxygenation (ECMO)				
8		Death					

WHO 9-point scale – graded increase in pulmonary support



BerGenBio

Post-hoc exploratory analysis identified subset of patients affected by more severe disease, benefit from bemcentinib

PATIENT Subset: (Grade 4 & 5, CRP>30mg/L)

A. Grades 4 and 5 patients

Grade 3 patients (not on oxygen)

- Rarely admitted (not eligible in India)
- Did not usually progress to require oxygen
- Shorter stay in hospital (4-5 days)

B. C-reactive protein

- bemcentinib benefit is greater in patients with higher baseline inflammation
- CRP is an acute phase blood based biomarker in routine clinical use
- 30 mg/L threshold identified

VENTILATOR-FREE SURVIVAL (VFS)

GOALS of COVID19 therapy

1. Preventing death
2. Preventing progression to require ventilation
    1. Non-invasive
    2. Intubation and mechanical ventilation

Ventilator Free Survival is an endpoint derived from studies in Acute Respiratory Distress Syndrome

- Being alive at day 29

AND

- not deteriorating to require ventilation

Clinically meaningful endpoint for:

1. Individual Patient health – both acute, and long-term
2. Healthcare system; resource constraints

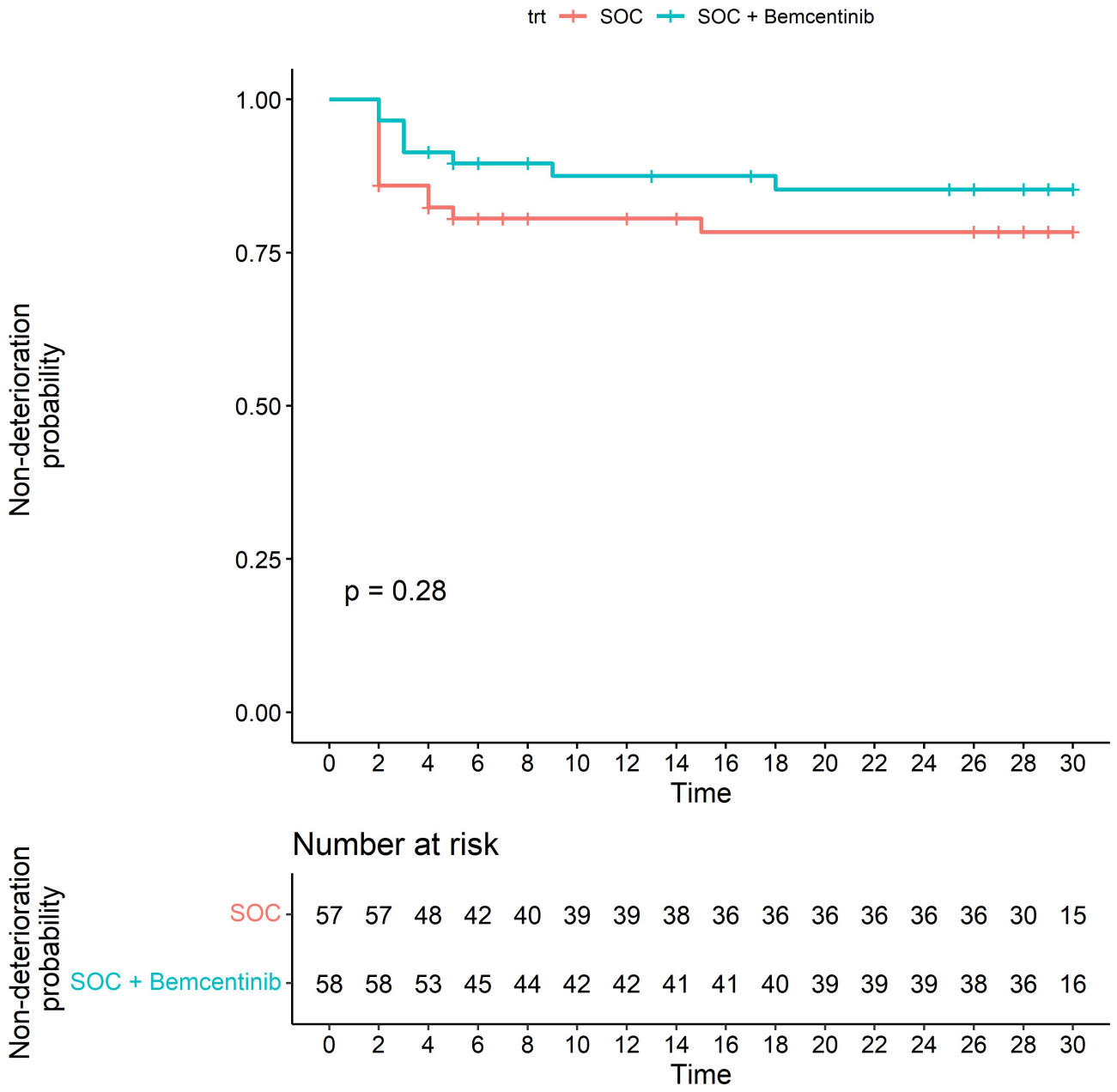
End Point: Time to deterioration

Deterioration defined as increase from baseline WHO ordinal scale by ≥1 grade (including progression to grade 8 – death)

When evaluating Grade 4 or 5 patients, this endpoint assesses the avoidance of any increased ventilation requirement, this is equivalent to **VENTILATOR-FREE SURVIVAL**, over 29 days after admission to hospital.

Time to deterioration: BGBC020

all patients (115)



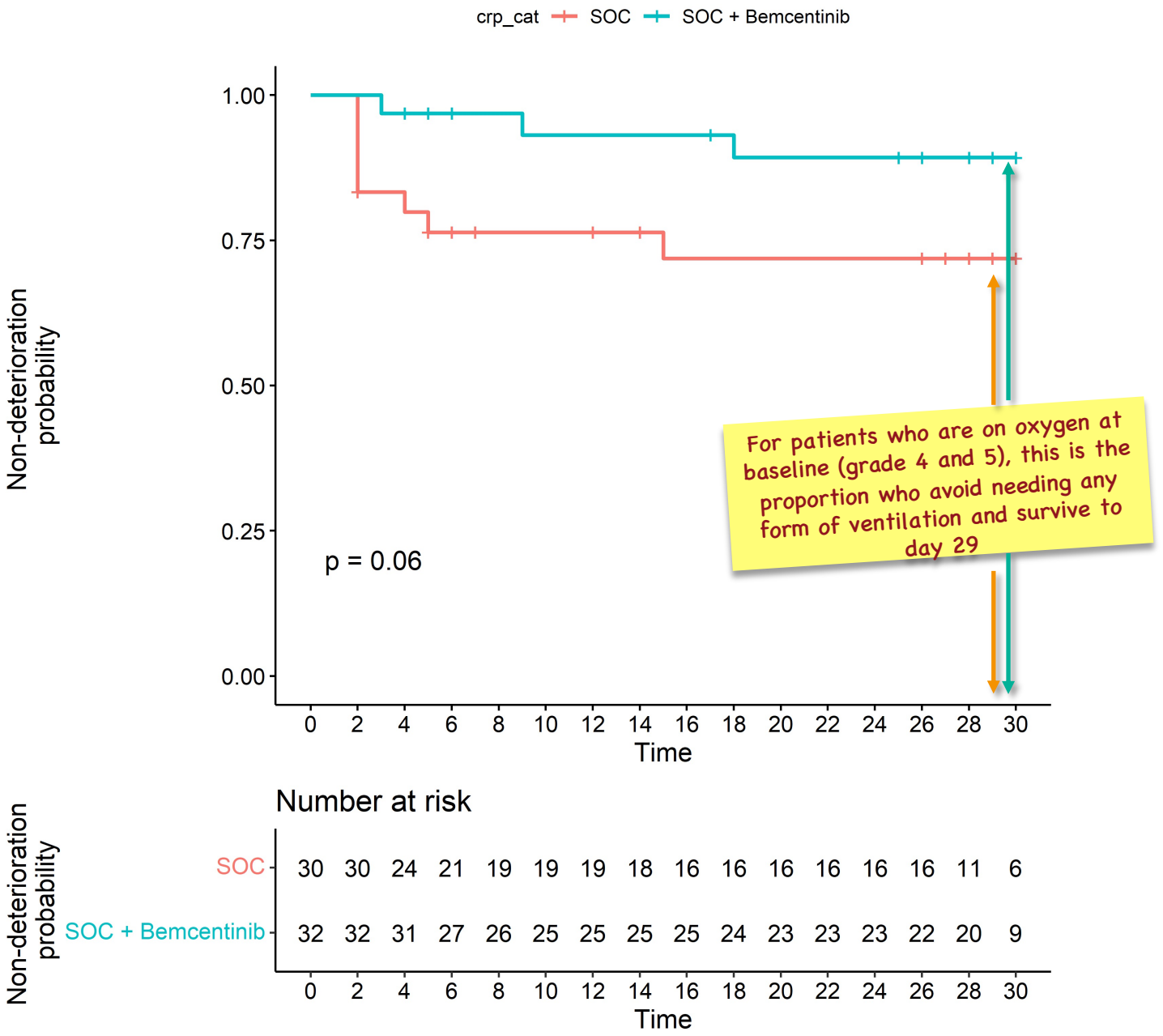
BerGenBio

Time to deterioration: BGBC020

Grades 4, 5 with CRP>30mg/L (62 Patients)

Ventilator Free Survival

- Defined as the proportion of patients that survived to day 29 day without admission to ICU and the need for ventilator assisted breathing
- A sub-group of patients treated with bemcentinib appeared to be protected from an early deterioration, at day 2 or 3, compared to patients on SOC
- This effect was maintained through 29 days
- In sub-group of patients, ventilator free survival was higher (90%) with bemcentinib treatment compared to SOC only (72%)



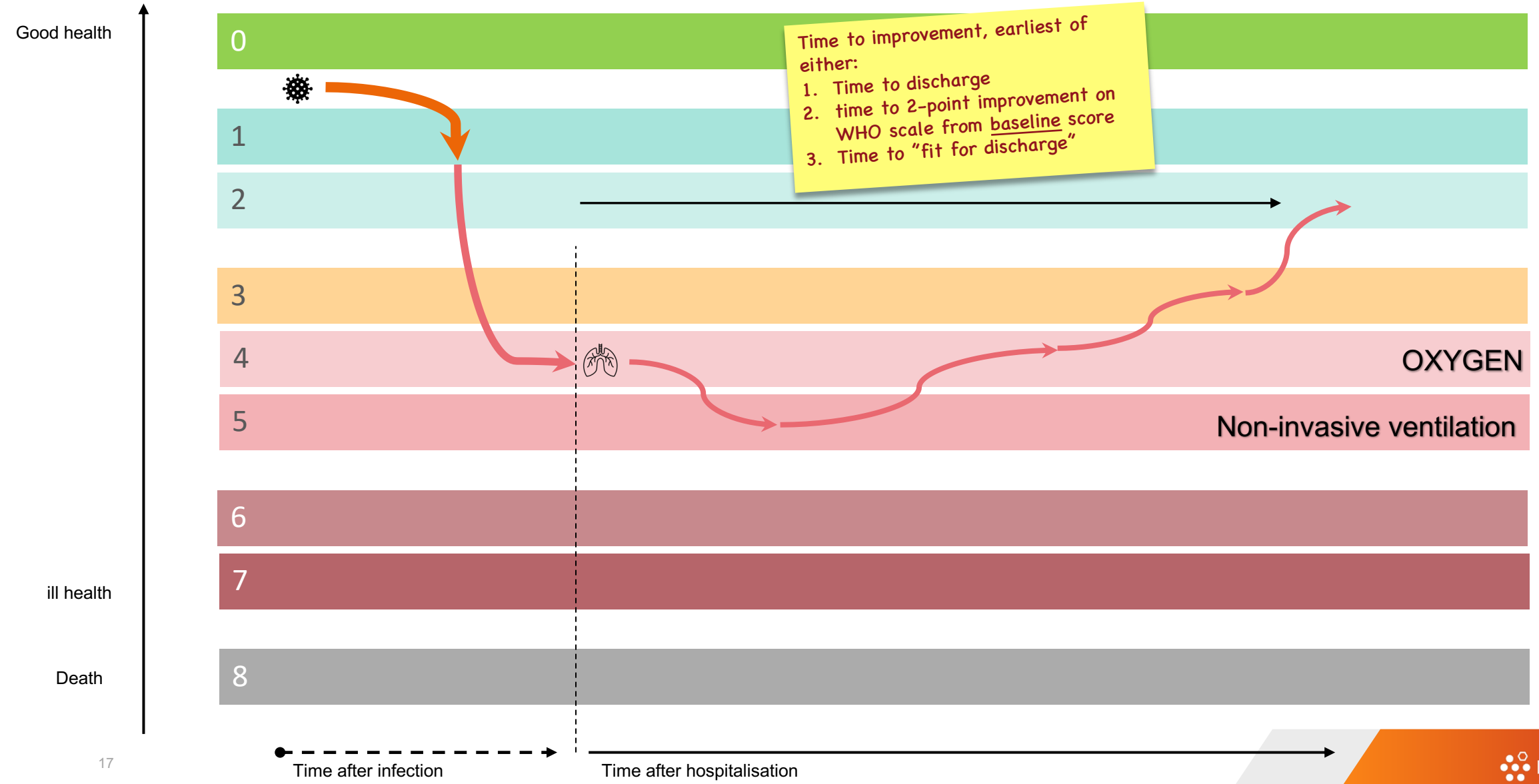
BerGenBio

Primary endpoint – time to improvement (WHO 2-point) or discharge

This endpoint, is subject to a broad range of subjective factors, including variation in clinician practice, local epidemic case rates, ensuing demand for bed occupancy in hospital, and resource availability.

Therefore this endpoint may not directly measure the individual patient's health, or the benefit from bemcentinib.

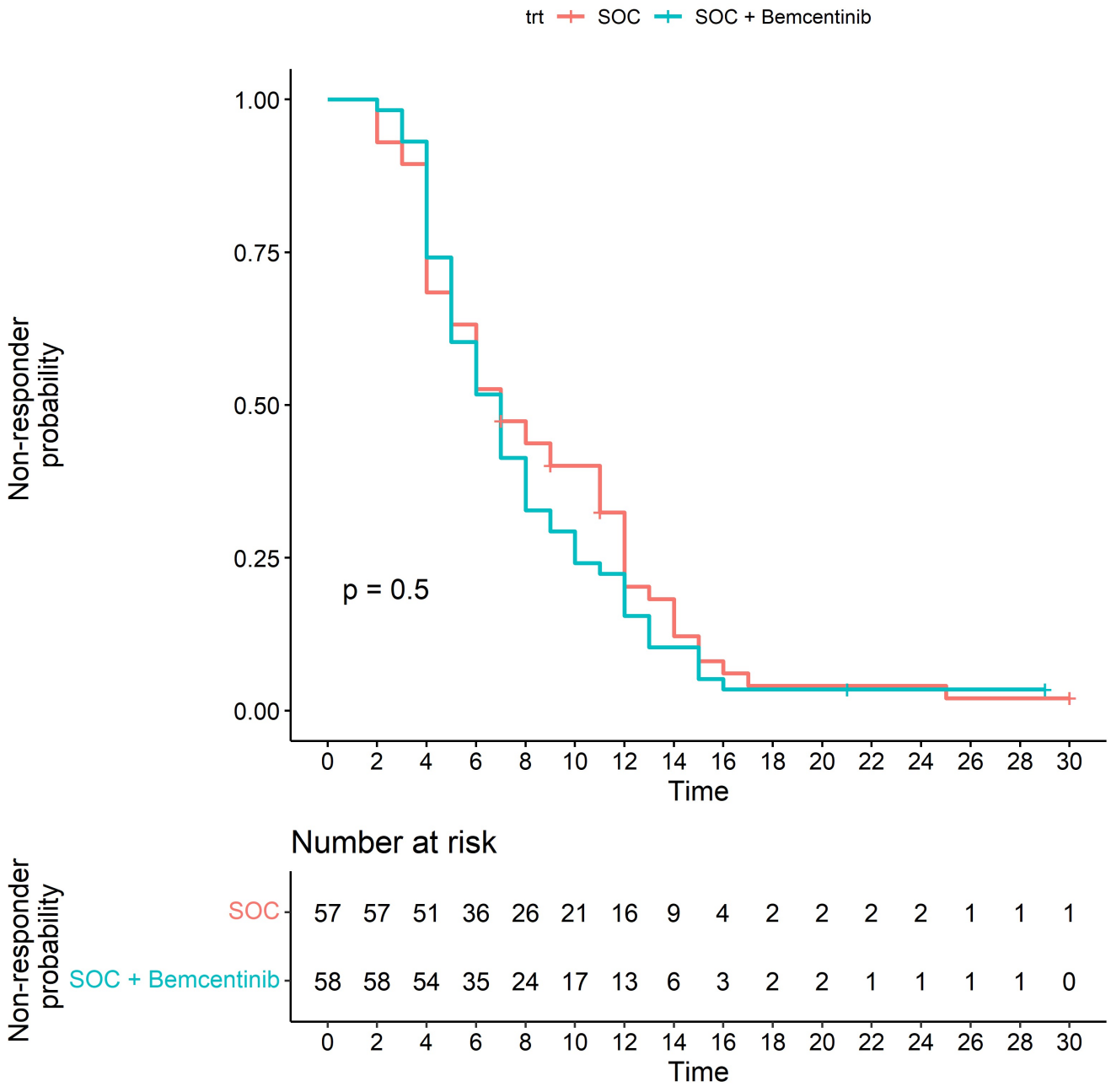
Primary endpoint – time to improvement



BerGenBio

Primary endpoint: time to improvement or discharge BGBC020

all patients

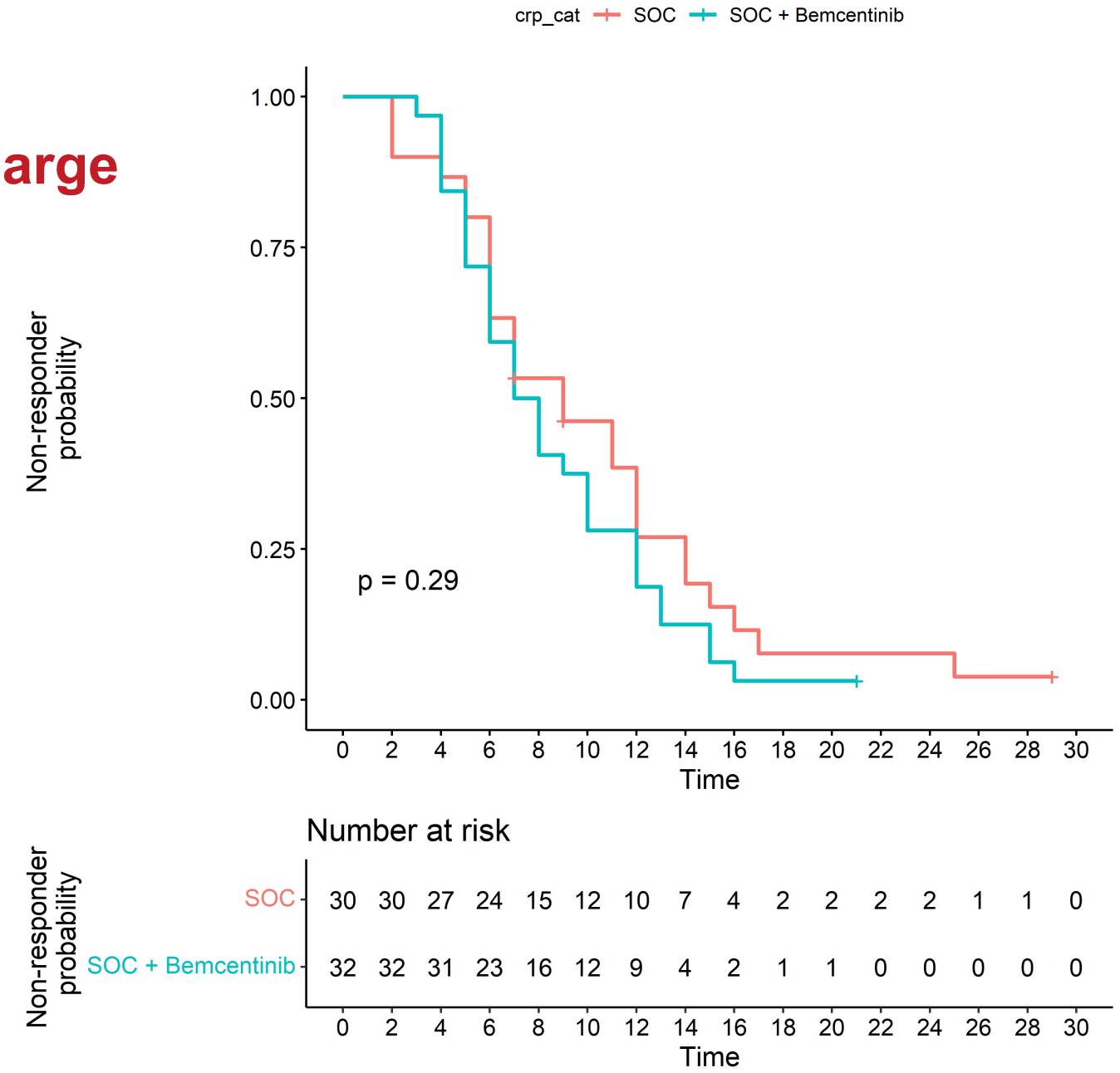


BerGenBio

Primary endpoint: time to improvement or discharge BGBC020

Grades 4, 5 with CRP>30mg/L

- The primary endpoint (time to improvement by two WHO grades, from baseline, or time to discharge marginally favoured bemcentinib treatment over SoC
- Difference was not statistically significant



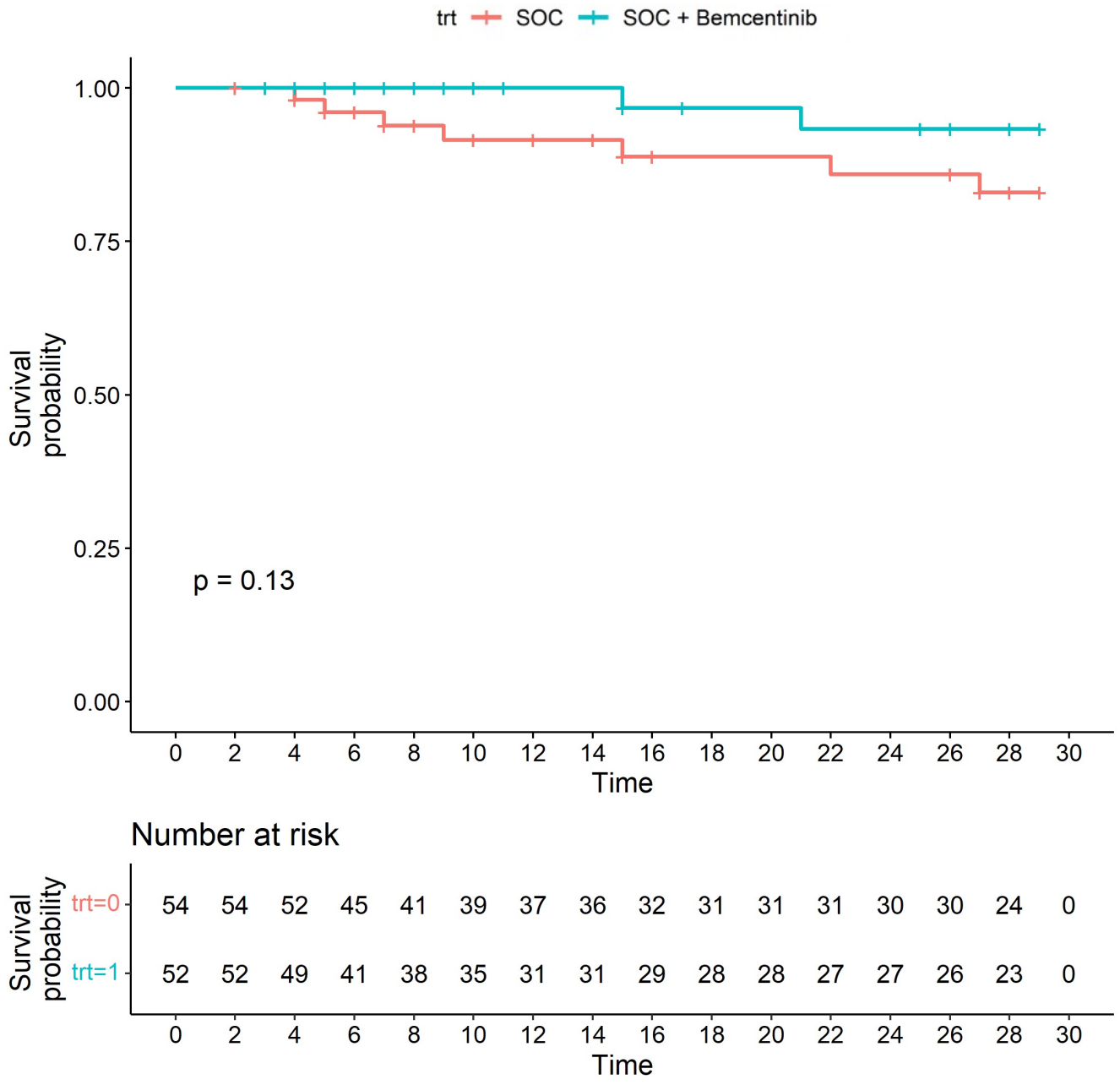
BerGenBio

End Point: Survival

Time to mortality event

Survival
BGBC020 + ACCORD2
Grades 4,5 with CRP≥30mg/L

- Mortality rates in ACCORD2 SOC treated patients were higher than those in BGBC020 at day 29; (5 of 32 patients (16%) in ACCORD2, versus 3 of 57 (5%) in BGBC020.
- Overall in the combined studies, survival to day 29 was 96.5% (83 of 86 evaluable patients) in bemcentinib arm versus 91.0% (81 of 89) treated with SoC alone.



BerGenBio

Summary statements

- Ventilator Free Survival observed to be 90% in bemcentinib treated patients vs 72% in SOC treated patients, in a sub-group of patients with increased disease severity
- Sub-group of patients with increased disease severity (grade 4 & 5) and a blood biomarker for inflammation (CRP>30mg/ml), represented more than 50% of hospitalised patients on the study
- Primary endpoint, although favourable for bemcentinib, did not reach statistical significance
- Survival benefit was numerically greater in the bemcentinib treated patients
- Bemcentinib was well tolerated throughout both studies

Conclusion and Next Steps

- Full scientific analysis of BGBC020 will be combined with the ACCORD2 dataset in a meta-analysis for presentation at a scientific conference and publication in a peer-reviewed journal.
- The totality of data clearly informs a benefit from bemcentinib in treating a substantial subset of hospitalised COVID-19 patients
- Post-hoc data analysis suggests that bemcentinib treatment results in few patients progressing to ICU, the avoidance of ventilator assisted breathing and increased survival
- This data will support ongoing engagement with regulatory agencies, Governments and industry partners.

Questions