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CONTROLLING INFLAMMATION

Vilobelimab in Severe COVID-19: PANAMO Phase III Study

Top Line Results

March 31, 2022

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About InflaRx

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary technology to discover and develop first-in-class or best-in-class, potent and specific inhibitors of C5a and C5aR. Complement C5a and C5aR are powerful inflammatory mediators involved in the progression of a wide variety of autoimmune and other inflammatory diseases. InflaRx was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information, please visit www.inflarx.com.

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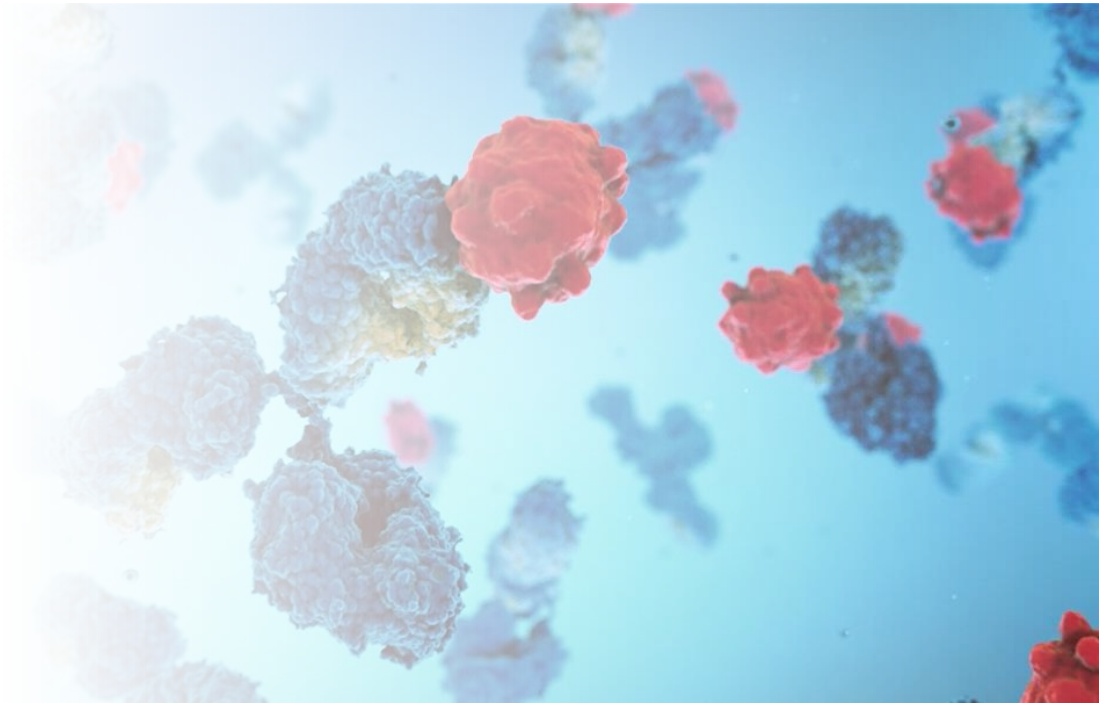
AGENDA

- INTRODUCTION & KEY MESSAGES
- VILOBELIMAB MODE OF ACTION IN COVID-19
- PANAMO TRIAL DESIGN AND PHASE II RESULTS
- PANAMO PHASE III RESULTS
- SUMMARY
- Q&A



INTRODUCTION & KEY MESSAGES

Introduction

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Introduction – Key Messages

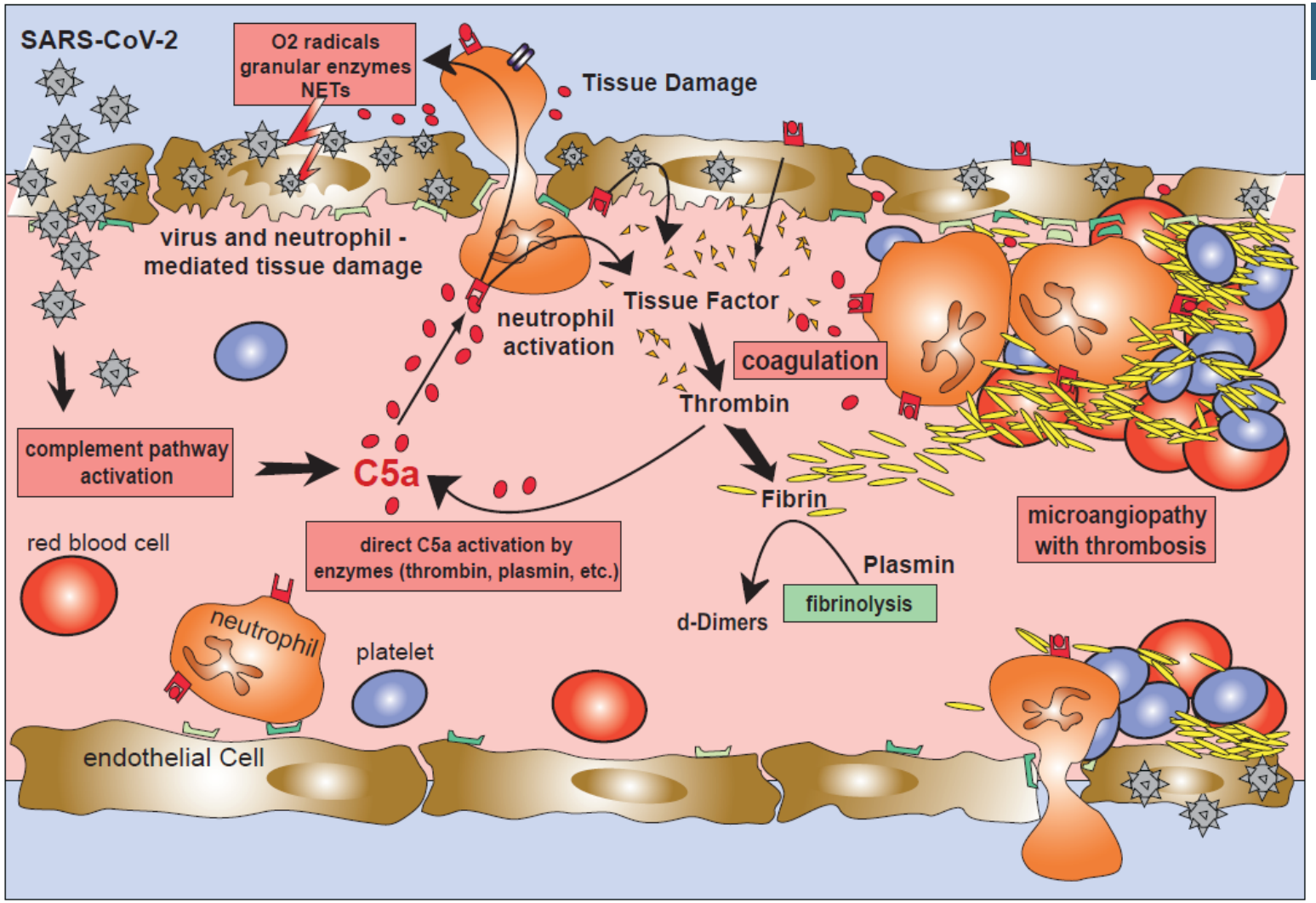
OVERVIEW

- Primary endpoint of 28-day all-cause mortality – clinically meaningful benefit in Vilobelimab arm, but missed statistical significance using pre-specified analysis method
- Other pre-specified analyses show significant improvement in 28-day all-cause mortality ($p<0.05$)
- Significant treatment benefit ($p=0.014$) in pre-defined analysis of Western European patient population with 43% relative reduction in 28-day all-cause mortality
- Significant treatment benefit ($p<0.05$) in all three pre-defined subgroup analyses of patients with higher disease severity at baseline
- Continued robust improvement in all-cause mortality up to day 60
- Favorable safety profile for vilobelimab confirmed in this critically ill patient population

VILOBELIMAB MODE OF ACTION IN COVID-19

COVID-19 induced Vascular Injury – Potential Role of C5a

Model for Proposed Mode of Action of C5a in COVID-19 induced vascular injury



Source: InflaRx GmbH

OUR HYPOTHESIS

- **Endothelial damage** is induced by SARS-CoV-2 infection which also activates the complement system leading to C5a generation.
- **C5a activates neutrophils** via C5aR, leading to increased adherence to endothelial cells and damage through generation of oxidative radicals, granular enzyme release and neutrophil extracellular traps (NETs).
- C5a induces **release of tissue factor** from neutrophils & endothelial cells, which promotes coagulation, leading to Fibrin formation.
- Thrombin, plasmin and other enzymes can further induce direct C5a activation (through direct cleavage of C5), which may establish a vicious cycle **leading to microangiopathy with thrombosis**.

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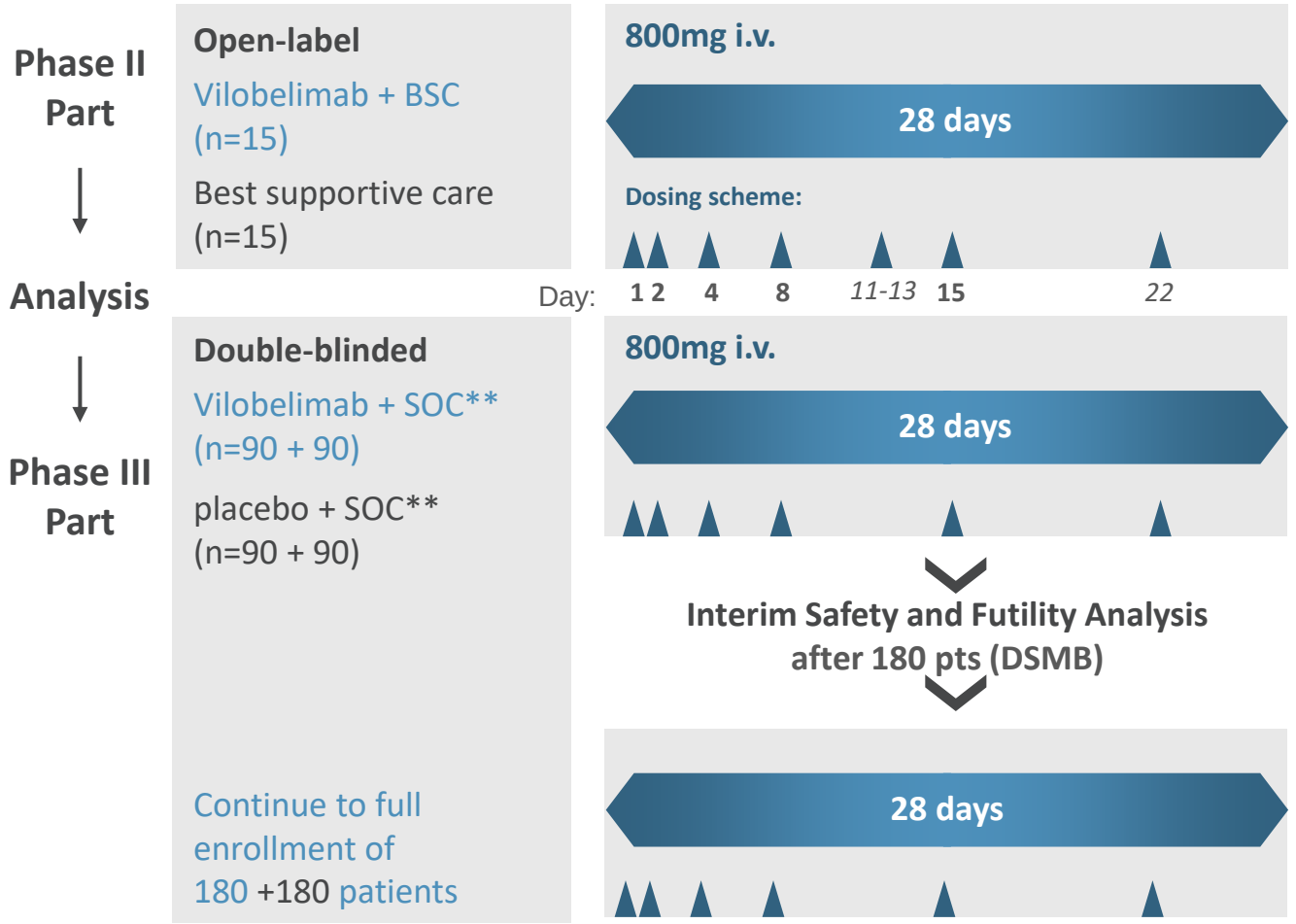
PANAMO TRIAL DESIGN AND PHASE II RESULTS

Design of PANAMO Phase II/III Study with Vilobelimab in Severe COVID-19

STUDY DESIGN

- Critically ill intubated* patients with COVID-19 induced pneumonia
- Phase III primary endpoint:
  28-day all-cause mortality
- Key secondary endpoints
  - 60-day all-cause mortality (proportion of patients deceased until Day 60)
  - Proportion of patients with an improvement in the 8-point ordinal scale (Day 15, Day 28)
  - Proportion of patients developing acute kidney failure during ICU stay and at Day 28
  - Proportion of patients free of any renal replacement therapy within 28 days upon randomization
  - Frequency, severity, and relatedness to study drug of serious and non-serious TEAEs



* In Phase III part, eligible patients were required to have been early intubated. In the Phase II part, patients were enrolled if either early intubated or dependent on oxygen delivery.
** SOC includes venous thromboembolism prophylaxis at a minimum and may include other specific recommended treatments for COVID-19 per the locally adopted treatment recommendation. 97% of patients received corticosteroids.

Phase II Part Results

Overview

PHASE II STUDY RESULTS

Primary endpoint:

- No difference detected in improvements between groups in PaO2/FiO2 ratio
- High variability between patients
- Conclusion: Endpoint not suitable as response parameter

Key secondary and other endpoints - Observed effects with vilobelimab compared to best standard of care:

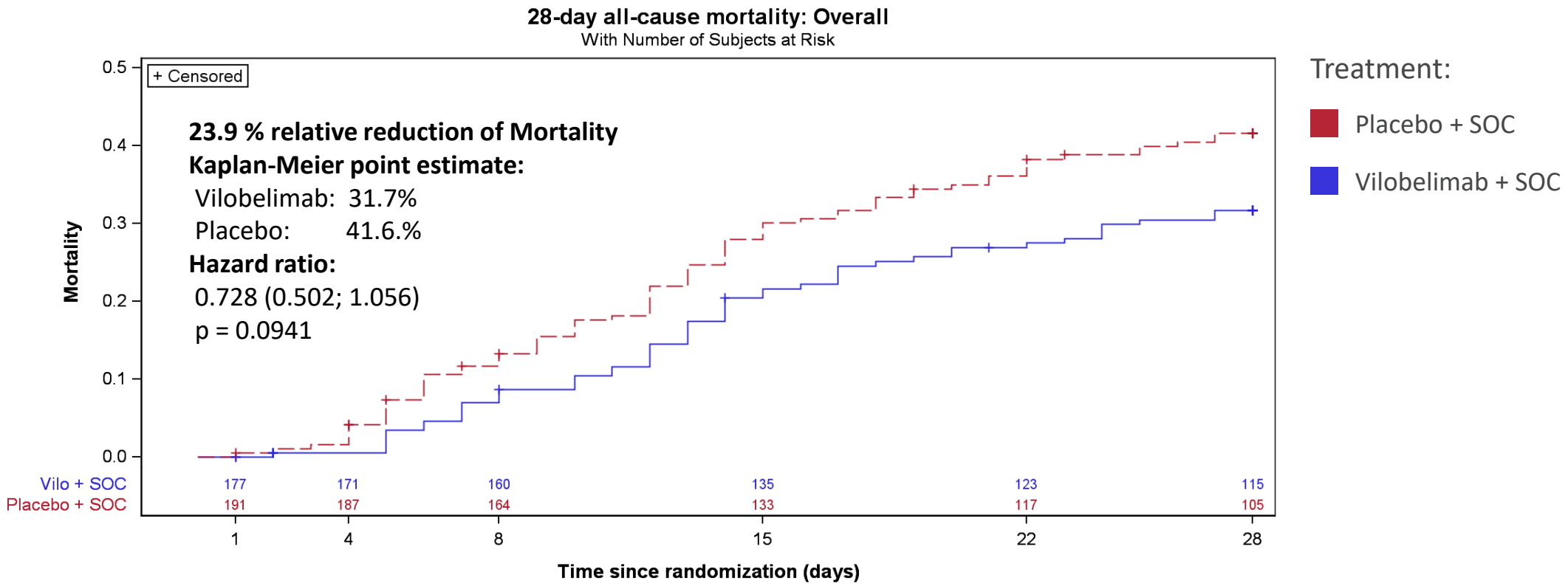
- **50% lower all-cause mortality rate** (13% in vilobelimab group vs 27% for control group)
- **Fewer patients experienced renal impairment** assessed by estimated glomerular filtration rates
- **Faster reversal of blood lymphocytopenia**
- **Reduction in tissue damage**: Greater lowering of lactate dehydrogenase concentrations
- Temporary but **statistically significant increase in D-dimer levels** in first days after vilobelimab administration - **potential signal of induction of blood clot lysis**

Source: Vlaar, A et al. *Lancet Rheumatol 2020*. https://doi.org/10.1016/S2665-9913(20)30341-6

PHASE III TOP LINE RESULTS

Phase III Top Line Results

PRIMARY ENDPOINT: 28-DAY ALL-CAUSE MORTALITY



One additional life was saved for every 10 vilobelimab-treated participants, compared with placebo at day 28

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Phase III Top Line Results

SUPPLEMENTARY ANALYSES OF PRIMARY ENDPOINT 28-DAY ALL-CAUSE MORTALITY

Cox regression approach	p-value	Hazard ratio	Comment
Stratification by site	0.0941	0.728 (0.502; 1.056)	Pre-specified primary endpoint analysis method
No stratification	0.0266	0.674 (0.476; 0.955)	Original protocol-defined analysis method
“Frailty” model with random effect for site	0.0181	0.648 (0.453; 0.929)	Post hoc analysis
Stratification by country	0.0067	0.613 (0.430; 0.873)	Post hoc analysis
Simple Log-Rank test	0.0407		Post hoc analysis

Phase III Top Line Results

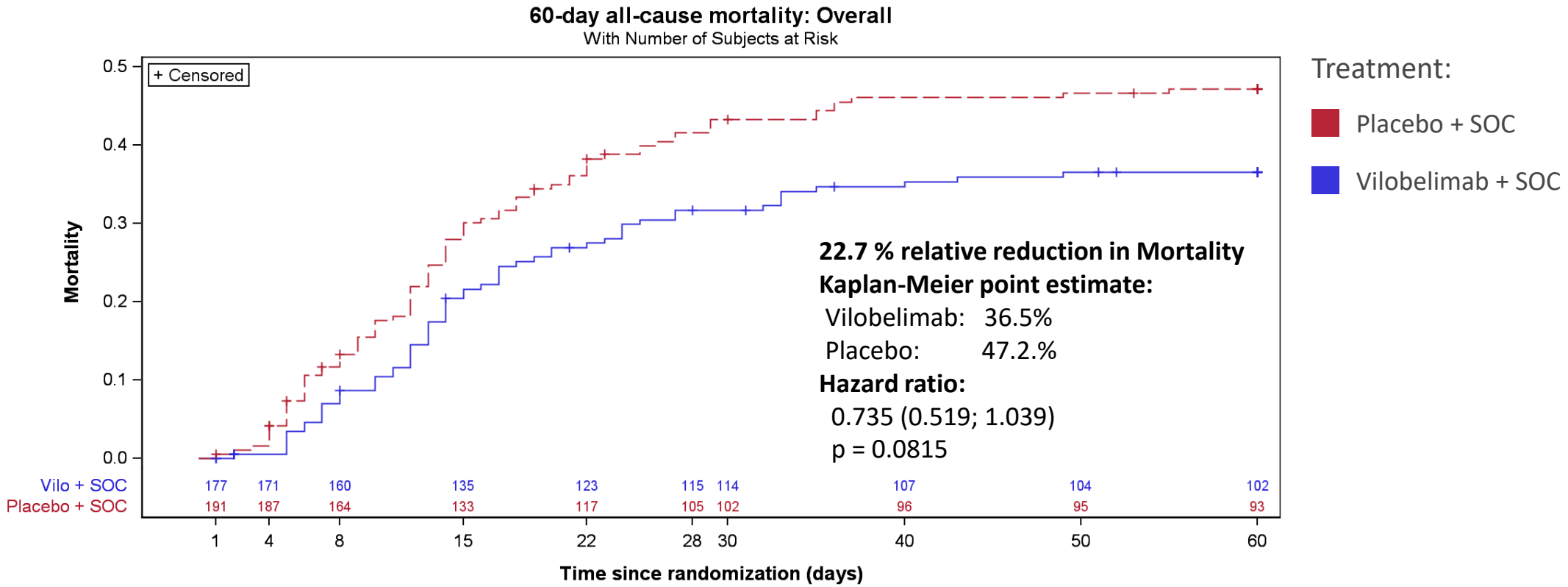
PRIMARY ENDPOINT: PRE-SPECIFIED SUPPLEMENTARY ANALYSES WITH LOGISTIC REGRESSION

Day 28 survival status	Vilo + SOC (N=178)		Placebo + SOC (N= 191)	
	Pat. n	(Pat. %)	Pat. n	(Pat. %)
Dead	54	(30.3%)	77	(40.3%)
Alive	115	(64.6%)	105	(55.0%)
Missing/Imputed*	9	(5.1%)	9	(4.7%)

*Imputation Method for patients who could not be followed until day 28	p-value based on logistic regression	Risk difference 28-day mortality based on logistic regression
"Worst case" in favor of placebo	0.2772	-5.4% (-15.1%; 4.3%)
All alive	0.0340	-10.4% (-19.9%; -0.9%)
All dead	0.0446	-10.1% (-19.9%; -0.3%)
Multiple imputation	0.0293	-11.0% (-20.8%; -1.2%)

Phase III Top Line Results

SECONDARY ENDPOINT: 60-DAY ALL-CAUSE MORTALITY



One additional life was saved for every 9 vilobelimab-treated patients, compared with placebo at day 60

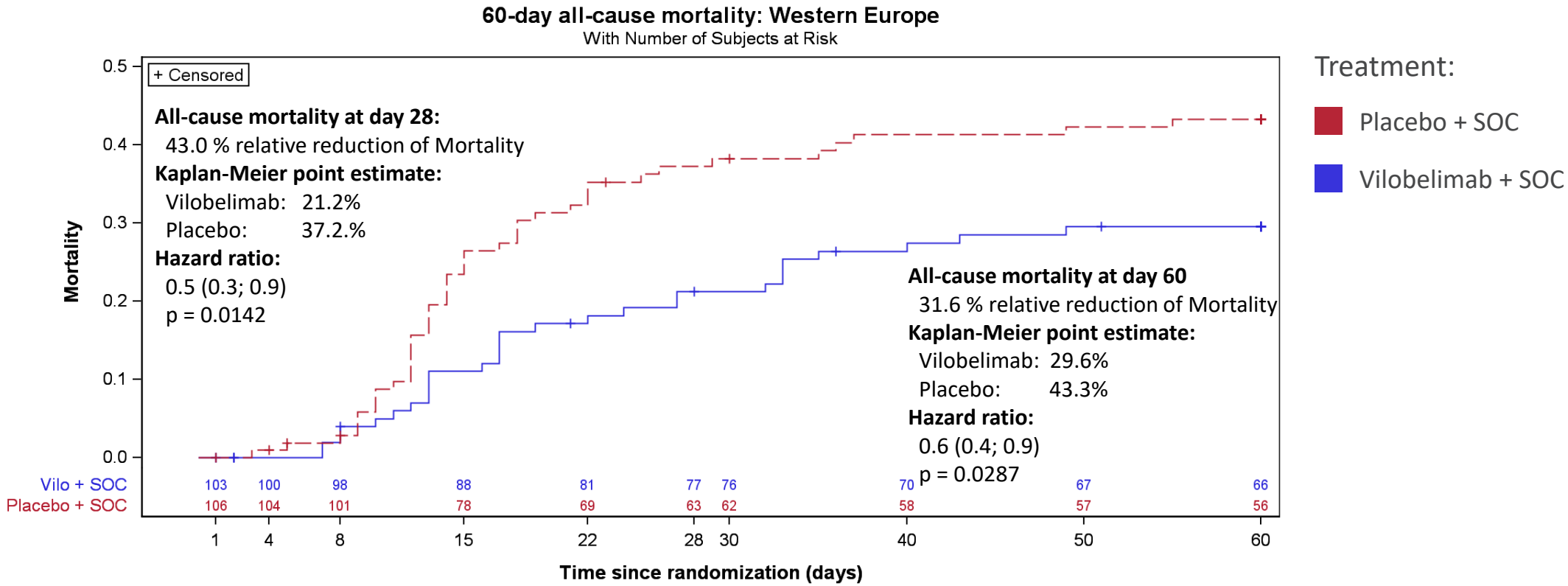
Phase III Top Line Results

SUPPLEMENTARY ANALYSES OF SECONDARY ENDPOINT 60-DAY ALL-CAUSE MORTALITY

Cox regression approach	p-value	Hazard ratio	
Stratification by site	0.0815	0.735 (0.519; 1.039)	Pre-specified analysis method
No stratification	0.0163	0.670 (0.484; 0.929)	Original protocol-defined analysis method
“Frailty” model with random effect for site	0.0104	0.644 (0.460; 0.901)	Post hoc analysis
Stratification by country	0.0042	0.616 (0.442; 0.858)	Post hoc analysis
Simple Log-Rank test	0.0315		Post hoc analysis

Phase III Top Line Results

MORTALITY – WESTERN EUROPE PRE SPECIFIED SUBGROUP ANALYSIS



In Western Europe, one additional life was saved for every 6 patients at day 28 and for every 7 patients at day 60 who were treated with vilobelimab compared to placebo

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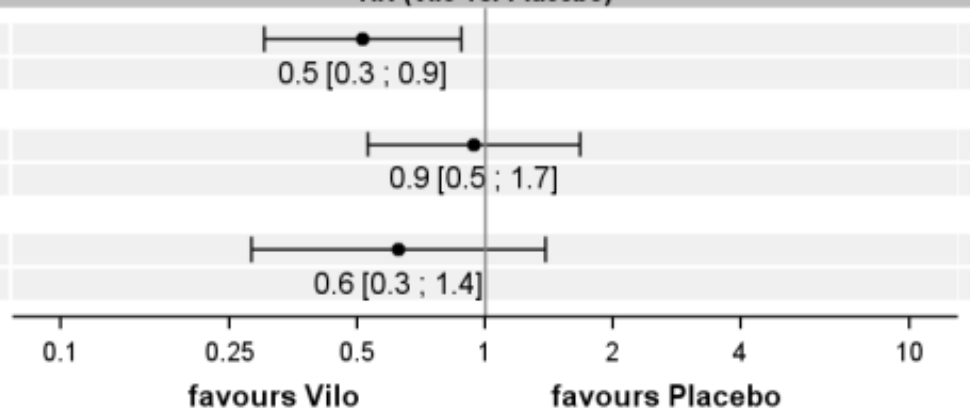
Phase III Top Line Results

PRE-SPECIFIED SUBGROUP ANALYSES BY REGION

Region	Treatment	n	Mortality (KM-Estimate)	p-value
Western Europe*	Vilo + SOC	103	21.2% (14.4% - 30.7%)	0.0142
	Placebo + SOC	106	37.2% (28.7% - 47.4%)	
South America**	Vilo + SOC	58	39.6% (28.1% - 53.7%)	0.8337
	Placebo + SOC	68	37.3% (26.9% - 50.0%)	
South Africa/Russian Federation	Vilo + SOC	16	68.8% (46.4% - 88.6%)	0.2450
	Placebo + SOC	17	87.3% (66.7% - 97.9%)	



*Belgium, France, Germany, Netherlands

**Brazil, Mexico, Peru

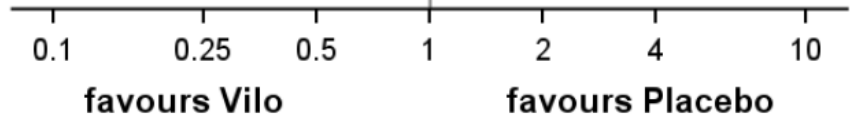
Phase III Top Line Results

PRE-SPECIFIED SUBGROUP ANALYSES

The following subgroup analyses point towards a stronger treatment effect on 28-day all-cause mortality in more severe patients:

- Ordinal scale at baseline
- ARDS severity at baseline based on PaO2/FiO2<100
- eGFR category at baseline

Subgroup	Treatment	n	Mortality (KM-Estimate)	HR (Vilo vs. Placebo) *	p-value
Baseline Ordinal Scale = 7	Vilo + SOC	105	32.1% (24.0% - 42.1%)		0.0279
	Placebo + SOC	132	43.7% (35.6% - 52.7%)	0.6 [0.4 ; 0.9]	
Baseline ARDS: Severe (PaO2/FiO2 <= 100 mmHg)	Vilo + SOC	43	40.0% (27.1% - 56.2%)		0.0441
	Placebo + SOC	55	59.5% (46.8% - 72.6%)	0.5 [0.3 ; 1.0]	
Baseline eGFR < 60 mL/min/1.73m²	Vilo + SOC	47	41.5% (28.8% - 57.1%)		0.0358
	Placebo + SOC	61	59.4% (47.0% - 72.1%)	0.5 [0.3 ; 1.0]	



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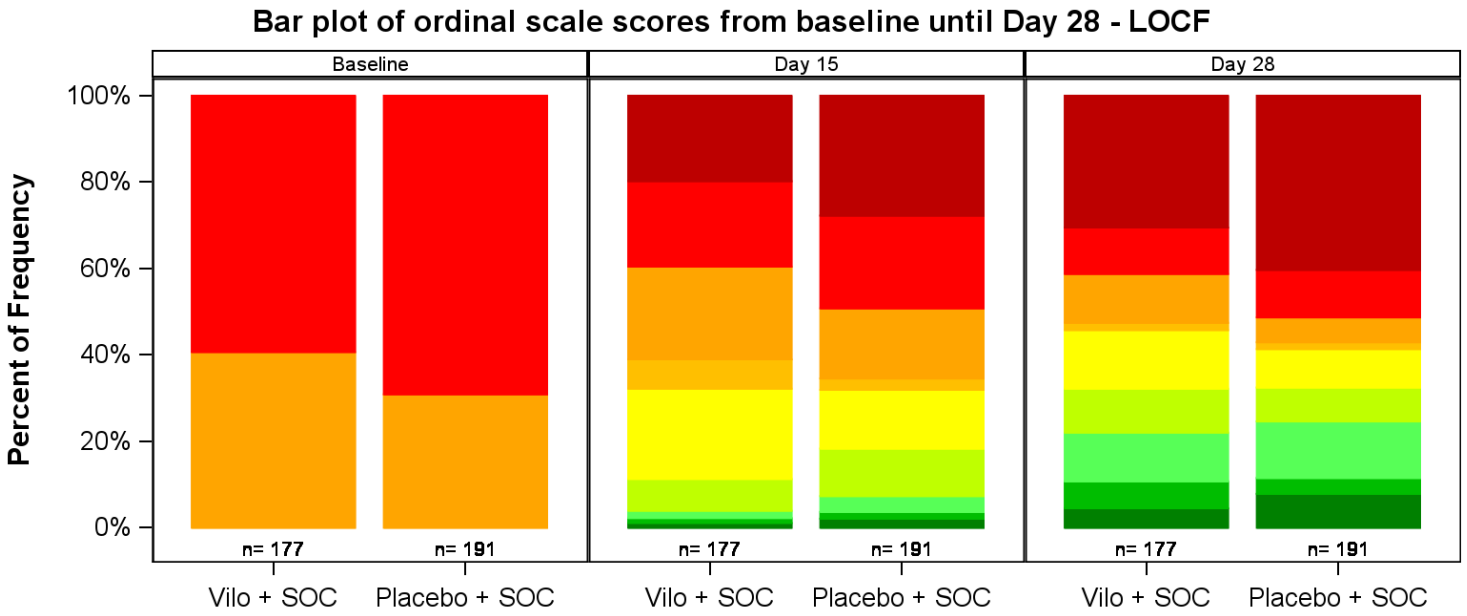
Phase III Top Line Results

SECONDARY ENDPOINT

Proportion of patients with an improvement in the 8-point ordinal scale (Day 15, Day 28)



Variable	p-value	Risk difference
Ordinal Scale at Day 15	0.1553	7.4% (-2.8%; 17.5%)
Ordinal Scale at Day 28	0.1181	8.1% (-2.0%; 18.1%)

Ordinal scale score:

- 0 – No clinical or virological evidence of infection
- 1 – No limitation of activities
- 2 – Limitations of activities
- 3 – Hospitalized, no oxygen therapy
- 4 – Oxygen by mask or nasal prongs
- 5 – Non-invasive ventilation or high-flow oxygen
- 6 – Intubation and mechanical ventilation
- 7 – Ventilation + additional organ support – pressors, RRT, ECMO
- 8 – Death

Phase III Top Line Results

SECONDARY ENDPOINT

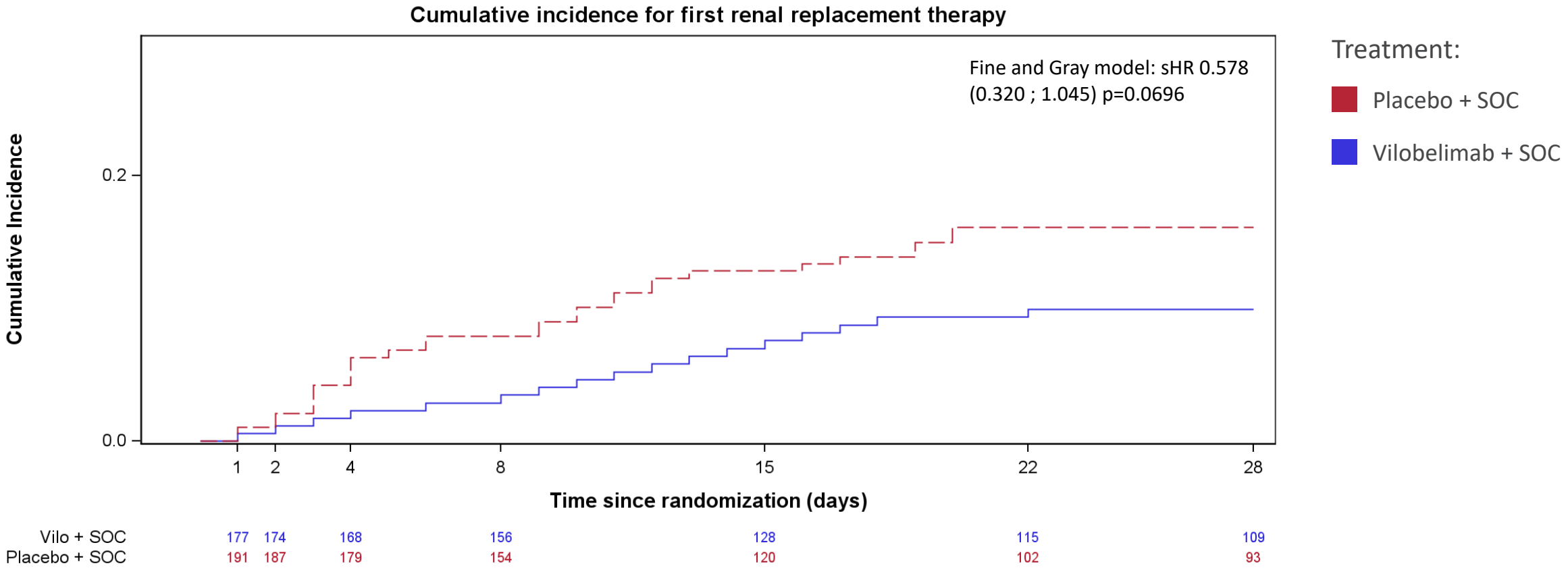
Proportion of patients developing acute kidney failure at Day 28

Acute kidney failure at Day 28 (based on eGFR)	Vilo + SOC (N=177)		Placebo + SOC (N= 191)	
	Pat. n	(Pat. %)	Pat. n	(Pat. %)
Acute kidney failure	8	(4.5%)	12	(6.3%)
No acute kidney failure	158	(89.3%)	168	(88.0%)
Not evaluable	11	(6.2%)	11	(5.8%)

Phase III Part Top Line Results

SECONDARY ENDPOINT

Proportion of patients free of any renal replacement therapy within 28 days of randomization



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Phase III Top Line Results

SAFETY OVERVIEW

Adverse event category	Vilobelimab (N=175)	Placebo (N=189)
Any TEAE	159 (90.9%)	172 (91.0%)
Any related TEAE	20 (11.4%)	16 (8.5%)
Any serious TEAE	103 (58.9%)	120 (63.5%)
Any serious related TEAE	8 (4.6%)	9 (4.8%)
Any fatal TEAE*	62 (35.4%)	85 (45.0%)

*149 deaths were observed in all randomized patients but 2 patients did not contribute to fatal TEAEs. One patient died before receiving the first IMP infusion, and one patient died on Day 4 but the fatal AE started before the first IMP infusion.

Phase III Top Line Results

SAFETY OVERVIEW - INFECTIONS

MedDRA High Level Group Term	Vilobelimab (N=175)	Placebo (N=189)
Any TEAE in SOC infections and infestations	110 (62.9%)	112 (59.3%)
Infections – pathogen unspecified	91 (52.0%)	88 (46.6%)
Bacterial infectious disorders	68 (38.9%)	75 (39.7%)
Fungal infectious disorders	21 (12.0%)	15 (7.9%)
Viral infectious disorders	22 (12.6%)	14 (7.4%)
Ancillary infectious topics	4 (2.3%)	4 (2.1%)

Summary

KEY LEARNINGS

- Primary endpoint of 28-day all-cause mortality – **clinically meaningful benefit in vilobelimab arm** but missed statistical significance using pre-specified analysis method
- Pre-specified and post-hoc analyses suggest **robust reduction in mortality at day 28 and day 60** in vilobelimab treated patients compared to placebo
- **Significant treatment benefit (p=0.014)** in pre-defined analysis of Western European patient population with 43% relative reduction in 28-day all-cause mortality
- **Significant treatment benefit (p<0.05)** in all three pre-defined subgroup analyses of patients with higher disease severity at baseline
- **Favorable safety profile** for vilobelimab confirmed in this critically ill patient population

Company plans to discuss results with regulatory authorities


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