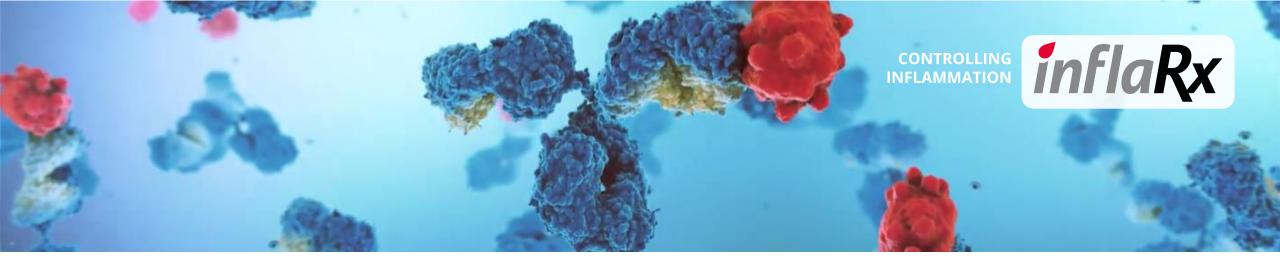


3-CT CRITICAL CARE TRIAL WORKSHOP – WASHINGTON D.C. USA LATE BREAKING SESSION: PANAMO PHASE III TRIAL DATA

A DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED PHASE III STUDY IN CRITICALLY ILL MECHANICALLY VENTILATED COVID-19 PATIENTS INVESTIGATING EFFECT OF VILOBELIMAB (MONOCLONAL ANTI-C5A ANTIBODY) ON 28-DAY ALL-CAUSE MORTALITY AS PRIMARY OUTCOME MEASURE

JUNE 25, 2022 - NIELS C. RIEDEMANN, CEO



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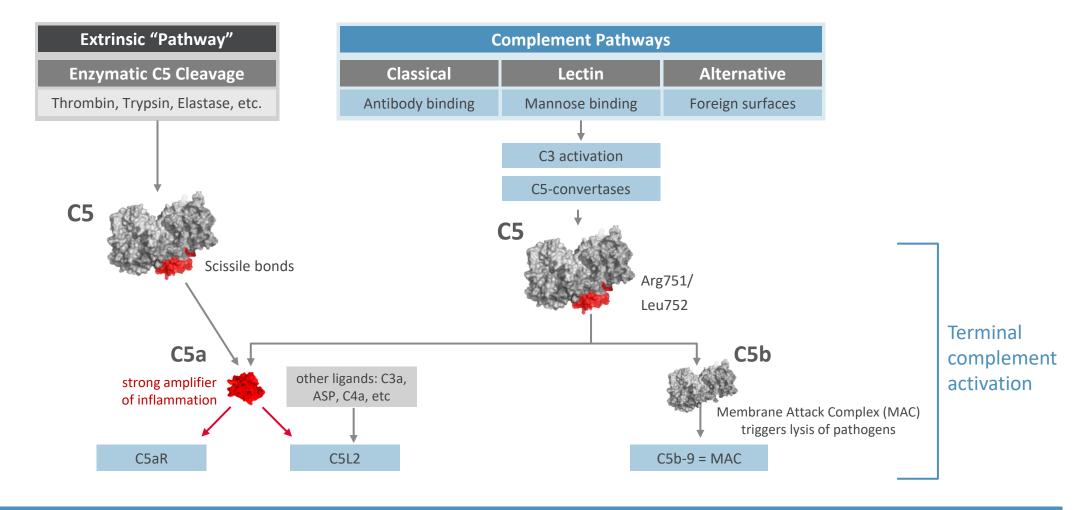
Information and Sources

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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.

The Complement System and C5a Activation

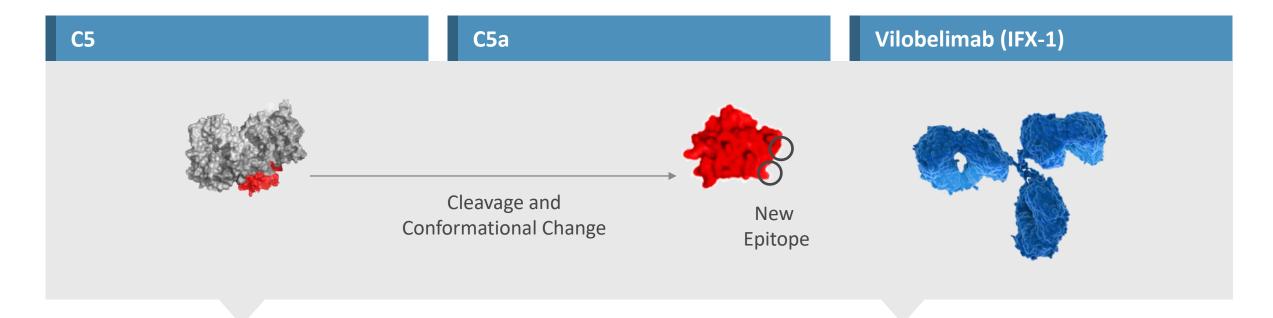




The extrinsic pathway represents an additional route, outside of the known complement pathways, to cleave C5a from C5



Vilobelimab Mode of Action



Cleavage of C5 through:

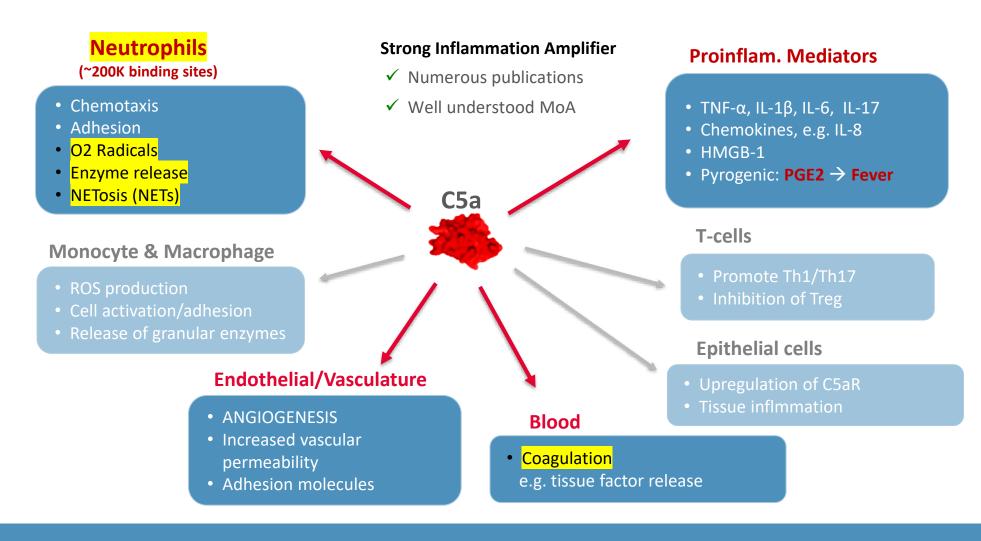
- complement pathway activation; or
- directly through enzymes via "extrinsic" pathway.

Vilobelimab Key Features

- ➤ Blocks C5a biological effects up to 100%
- ➤ Fully selective leaves MAC formation intact
- Binds with high affinity to a newly discovered epitope



Role of C5a in Inflammation





There are > 5000 publications on the role of the C5a / C5aR axis – C5a is an extremely well researched target

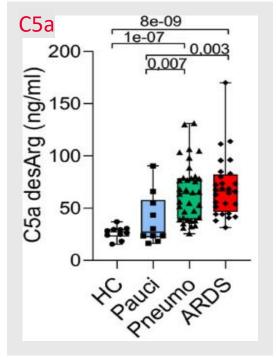
Why research C5a Inhibition in COVID-19?

Q C5A INHIBITION IMPROVED OUTCOME IN VIRAL ARDS MODELS

- ☐ In a monkey model of **H7N9-induced viral pneumonia**, Vilobelimab (IFX-1) markedly improved lung injury and reduced viral load (Sun et al, CID, 2015)
- ☐ In a mouse model of MERS-CoV-induced viral pneumonia, anti-C5aR mAb remarkably improved lung pathology and reduced viral titer. (Jiang et al., Emerging Microbes & Infections, 2018)

Q EARLY EVIDENCE FROM COVID-19 PATIENTS

□ C5a levels in critically ill COVID-19 patients were extraordinarily high and were correlated with disease severity (Carvelli et al, Nature, July 2020)

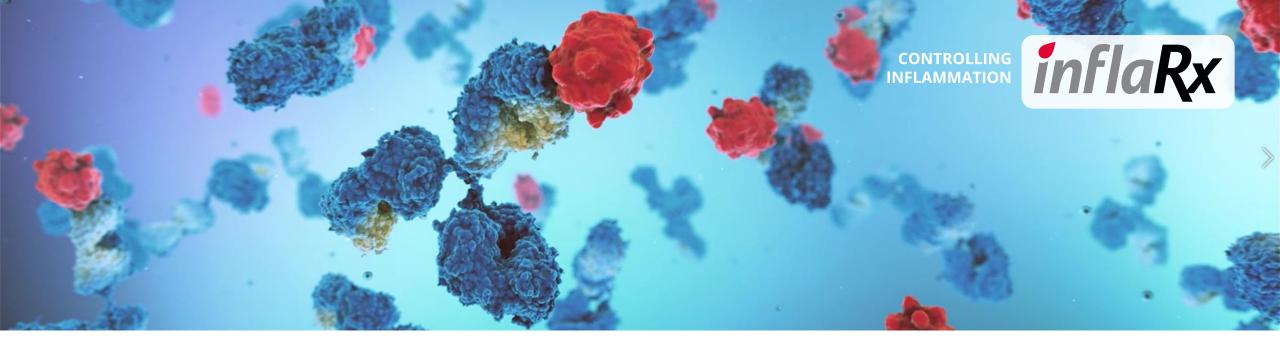


Carvelli et al, Nature, July 2020: doi: 10.1038/s41586-020-2600-6



C5a-induced neutrophil activation is a major pathogenic event in both bacterial and viral Sepsis





Vilobelimab Critical COVID-19

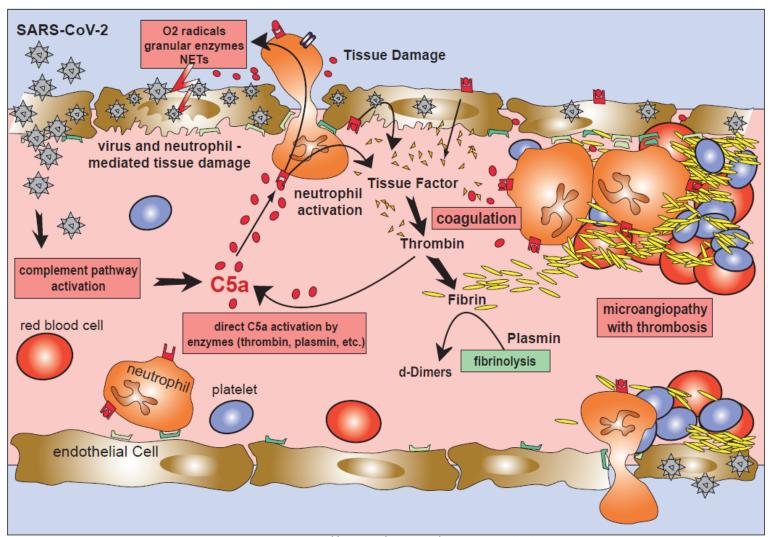


PANAMO STUDY – PHASE II PART

COVID-19 induced Sepsis with Vascular Injury – Potential Role of C5a

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





OUR HYPOTHESIS

- SARS-CoV-2 induces endothelial damage and activates the complement system (C5a)
- C5a activates neutrophils causing tissue damage by O2-radicals, granular enzyme release and neutrophil extracellular traps (NETs).
- C5a promotes coagulation through tissue factor release)
- Thrombin, plasmin and other enzymes can further induce direct C5a activation = vicious circle

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





Vilobelimab Critical COVID-19



PANAMO STUDY – PHASE III PART

Design of PANAMO Phase III Study Part

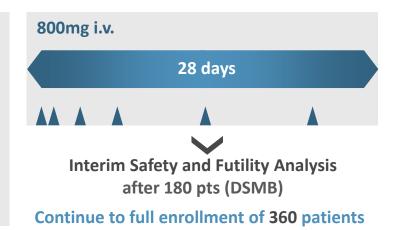


Double-blinded

Vilobelimab + SOC* (n=90 + 90)

placebo + SOC* (n=90 + 90)

Total Enrollment: n=360



STUDY DESIGN

- Double blind, placebo-controlled, randomized
- Powered 90% to show 28-day mortality difference
- Critically ill intubated patients only (within 48h of intubation)
- "global study": Planned to enroll in Western Europe, US, Mexico, Brazil, Peru, South Africa, Russia

Note: Originally planned potential interim stop for efficacy after 180 patients was eliminated upon advice from both, EMA and FDA

STUDY ENDPOINTS

Primary endpoint: 28-day all-cause mortality

• **Key secondary:** 60-day all-cause mortality

• **Secondary:** Improvement on Ordinal Scale (day 15, day 28)

• **Secondary:** Acute kidney injury development until day 28

• **Secondary:** Free of renal replacement therapy within 28 days

• **Secondary:** Safety: Frequency, severity, and relatedness serious and non-serious TEAEs

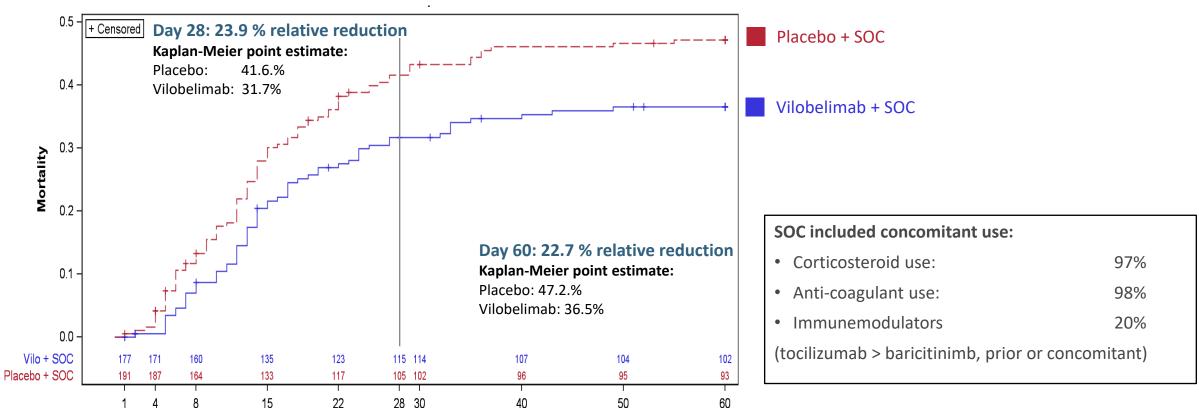


^{*} SOC includes venous thromboembolism prophylaxis at a minimum, recommended corticosteroid use and may include other specific recommended treatments for COVID-19 per the locally adopted treatment recommendation

PANAMO Trial: Phase III – Primary Endpoint







One additional life was saved for every 10 vilobelimab-treated patients at day 28 One additional life was saved for every 9 vilobelimab-treated patients at day 60

Time since randomization (days)



PANAMO Trial: Phase III – Primary Endpoint – Analyses 28-day all-cause Mortality



Analysis Method for 28-day all-cause mortality	p-value	Hazard ratio (95% CI) or Risk Difference for logistic regr.	No. patients "factually contributing"	Plan for Analysis	
Cox regression incl. stratification by site	0.0941	0.728 (0.502; 1.056)	313	Pre-specified primary endpoint analysis method	}
Cox regression incl. no stratification	0.0266	0.674 (0.476; 0.955)	368	Original protocol-defined analysis method	
Cox regression using "Frailty" model (random effect for site)	0.0181	0.648 (0.453; 0.929)	368	Post hoc analysis	
Cox regression incl. Stratification by country	0.0067	0.613 (0.430; 0.873)	368	Post hoc analysis	_
Logistic Regression (multiple imputation of missing values)	0.0293	-11.0% (-20.8%; -1.2%)	369*	pre-specified sensitivity analysis	
Simple Log-Rank test	0.0407		368	Post hoc analysis	

55 patients from 17 sites with no events (death) are not contributing within this analysis

All 368/369 patients enrolled are considered for these analyses

Vilobelimab shows a survival benefit (p<0.05) in all statistical analysis methods (pre-specified and posthoc) in which all available patient data (n=368) are considered/contributing to the analysis

Vilobelimab failed stat. sig. with site stratified Cox regression (55 patient not contributing) - chosen as the primary analysis method fixed in the stat. analysis plan (changed from planned non-stratified approach based on FDA recommendation)



^{*} One patient was randomized in error – this patient is part of the sensitivity logistic regression analysis

PANAMO Trial: Phase III – Key Secondary Endpoint – Analyses 60-day all-cause Mortality



Analysis Method for 28-day all-cause mortality	p-value	Hazard ratio (95% CI) or Risk Difference for logistic regr.	No. patients "factually contributing"	Plan for Analysis
Cox regression incl. stratification by site	0.0815	0.735 (0.519; 1.039)	331	Pre-specified primary endpoint analysis method
Cox regression incl. no stratification	0.0163	0.670 (0.484; 0.929)	368	Original protocol-defined analysis method
Cox regression using "Frailty" model (random effect for site)	0.0104	0.644 (0.460; 0.901)	368	Post hoc analysis
Cox regression incl. Stratification by country	0.0042	0.616 (0.442; 0.858)	368	Post hoc analysis
Logistic Regression (multiple imputation of missing values)	0.0162	-12.2% (-22.0%; -2.4%)	369*	Post hoc analysis
Simple Log-Rank test	0.0315		368	Post hoc analysis

^{*} One patient was randomized in error – this patient is part of the sensitivity logistic regression analysis

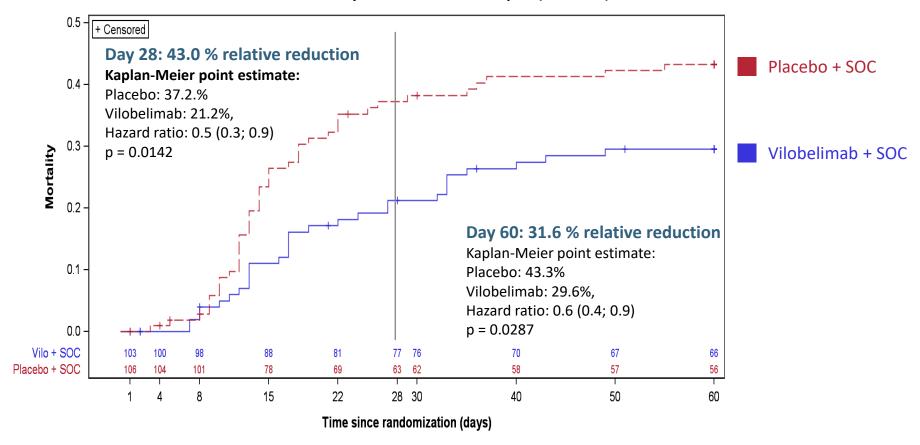
All comparable day 60 analyses confirm the day-28 findings with even lower p-values The treatment benefit of vilobelimab is preserved at day 60!



PANAMO Trial: Phase III – Outcome of pre-specified Western EU Region



All-cause mortality: Western Europe (n=209)



One additional life was saved for every 6 vilobelimab-treated patients at day 28 in Western EU One additional life was saved for every 7 vilobelimab-treated patients at day 60 in Western EU



PANAMO Trial: Phase III – Survival Outcome of pre-specified Supgroups



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PRE-SPECIFIED SUBGROUP ANALYSES

Subgroup	Treatment	n	Mortality (KM-Estimate)	HR (Vilo vṣ. 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]	
					
				0.1 0.25 0.5 1 2 4 10	
				favours Vilo favours Placebo	

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All three pre-specified subgroup analyses for more severe patients suggest a significant treatment benefit by vilobelimab



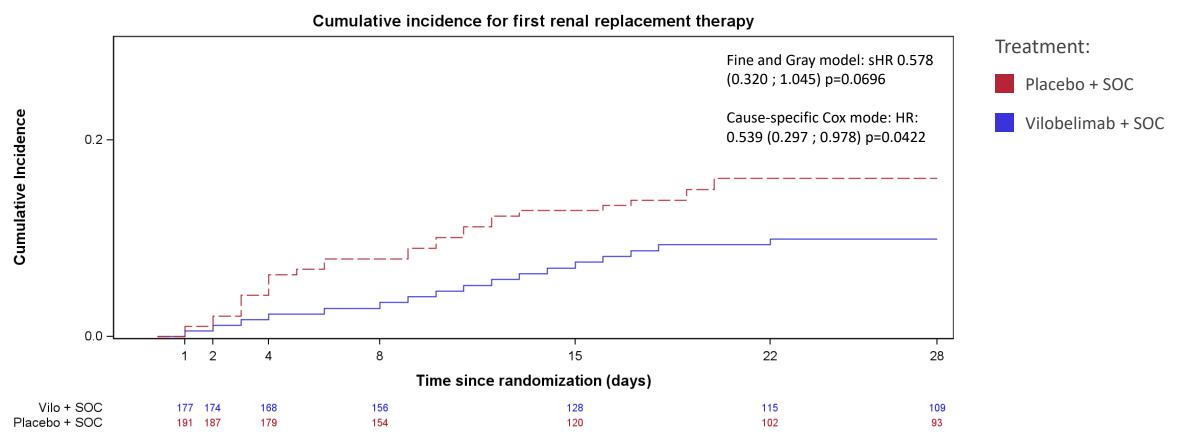
Phase III Part Top Line Results





SECONDARY ENDPOINT

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



Phase III Safety Results



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SAFETY OVERVIEW

INFECTIONS

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%)

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%)

^{*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.



Summary

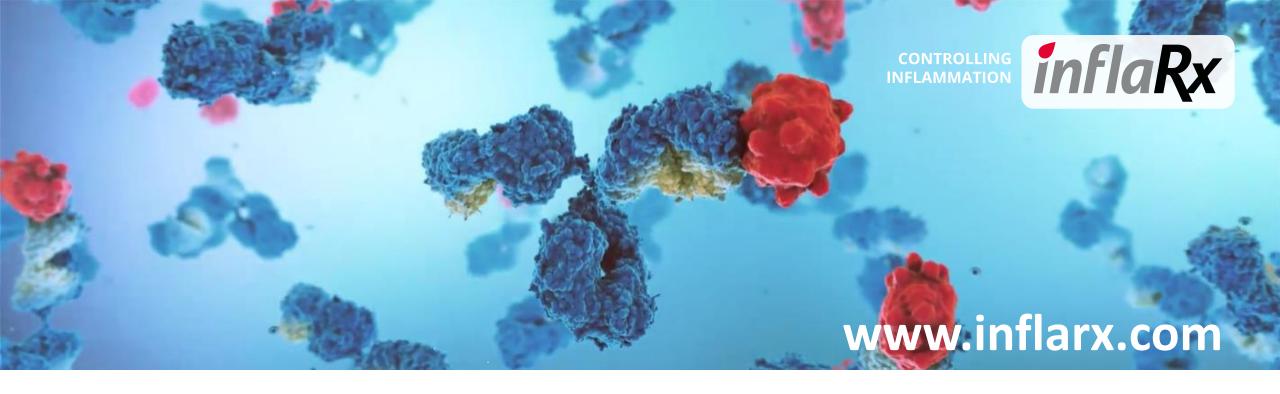


KEY LEARNINGS FROM PHASE III RESULTS

- Vilobelimab treatment led to a robust survival improvement on top of SOC confirmed by the day-60 all-cause mortality results (key secondary endpoint)
- 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

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Company in discussions with regulatory authorities on next steps towards potential approval



INFLARX N.V.

Winzerlaer Str. 2 07745 Jena, Germany

Email: info@inflarx.com

Tel: +49-3641-508180

Fax: +49-3641-508181