



# Humanigen

The Cytokine Storm Company

## Humanigen Reports Positive Phase 3 Topline Results Demonstrating That Lenzilumab™ Improves Survival Without Need for Mechanical Ventilation in Hospitalized Patients With COVID-19

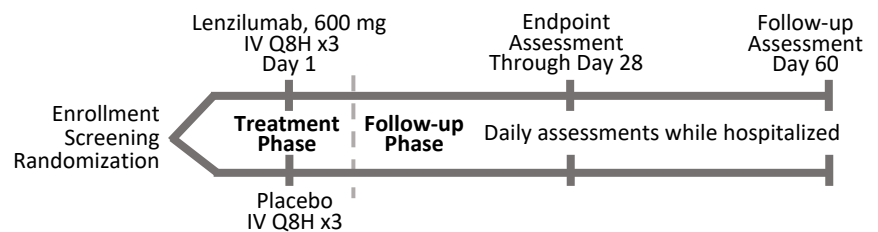
### Key Takeaways

- **54% improvement** in the likelihood of survival without the need for invasive mechanical ventilation, over and above other treatments including steroids and/or remdesivir, compared with placebo and other treatments
- **Safe and tolerable** with serious adverse event rates consistent with placebo

### Trial Characteristics

- Randomized, double-blind, placebo-controlled, multi-center
- 520 hospitalized patients, SARS-CoV-2 infection, aged at least 18 years
- Required SpO<sub>2</sub> ≤ 94% on room air and/or supplemental oxygen but not invasive mechanical ventilation
- Lenzilumab infused over a single day
- Lenzilumab could be used with other treatments including steroids (88%), remdesivir (62%), or both (57%)

### Trial Design



- Primary Endpoint: Ventilator-free survival through day 28
  - Key Secondary Endpoints through day 28:
    - Ventilator-free days\*
    - Survival
    - Duration of ICU stay\*
    - Time to recovery\*
- \*Pending final analysis

### Trial Results

Endpoint	Hazard Ratio (95%CI) Lenzilumab vs Placebo	Kaplan-Meier Estimate (95%CI)		p Value
		Lenzilumab	Placebo	
<b>Primary Endpoint</b>				
Ventilator-Free Survival	1.54 (1.03 – 2.33)	15.6 (11.5 – 21.0)	22.1 (17.4 – 27.9)	0.0365
<b>Key Secondary Endpoints</b>				
Survival	1.39 (0.82 – 2.39)	9.6 (6.4 – 14.2)	13.9 (10.1 – 19.0)	0.2287
<b>Serious Adverse Events</b>	<b>Lenzilumab</b>	<b>Placebo</b>	<b>Overall</b>	
Number of subjects (%)	63 (24.7)	76 (29.6)	139 (27.1)	

### Trial Conclusions

Lenzilumab, a dual-action therapy, is:

- For newly hospitalized patients with COVID-19 pneumonia
- A convenient IV infusion administered within a single day, to which other treatments can be added
- Safe and tolerable with serious adverse events balanced between treatment arms
- Potentially a new standard of care

