



**CERC-002: Double-blind, Placebo-controlled Phase 2  
Trial in Patients with COVID-19 Mild to Moderate  
ARDS – Final Data Analysis**

**March 2, 2021**



# Forward-Looking Statements

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# Executive Summary – Final Data Analysis

## Phase 2 Clinical Trial Met Primary Endpoint in Patients Hospitalized with COVID-19 ARDS

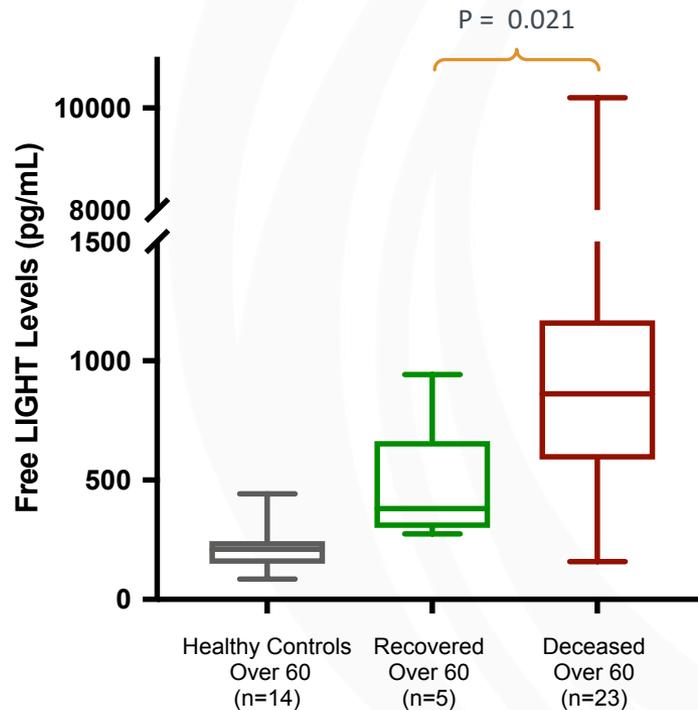
- CERC-002 significantly reduced respiratory failure and mortality in Phase 2 clinical trial in patients hospitalized with COVID-19 ARDS
  - This analysis updates the preliminary topline data reported on January 5, 2021, and is inclusive of 60-day safety data
  - Hospitalized COVID-19 patients treated with a single dose of CERC-002 demonstrated statistically significant improvement in the primary endpoint (proportion of patients alive and free of respiratory failure over the 28-day study period) compared to placebo (n=62, p=0.044)
  - Efficacy was highest in a prespecified subpopulation of patients over the age of 60 (n=34, p=0.042), the population most vulnerable to severe complications and death with COVID-19 infection
  - At both the 28-day and the 60-day final timepoints, an approximately 50% trend in mortality reduction (22.5% vs 10.8%) was observed
  - CERC-002 showed statistically significant efficacy on top of corticosteroids and standard of care in COVID-19 ARDS (>90% of patients in the trial received corticosteroids and >65% received remdesivir)
- CERC-002 was well tolerated with no appreciable differences in immunosuppression or other SAE between CERC-002 and placebo
- CERC-002 dramatically and rapidly reduced serum free-LIGHT levels
  - ~85% reduction in free LIGHT achieved in 1 day
- Cerecor has applied for Breakthrough Therapy and Fast Track Designations, and plans to meet with FDA to discuss potential path to Emergency Use Authorization
- Additionally, the company is exploring the applicability of CERC-002 in non-COVID-19 ARDS

# LIGHT is a Central Driver of COVID-19 Related Cytokine Storm

Clinical Trial Initiated After Compelling Biomarker Study Completed June 2020

Association Between Elevated LIGHT and Mortality  
Strongest in Patients Over 60

Key Implications



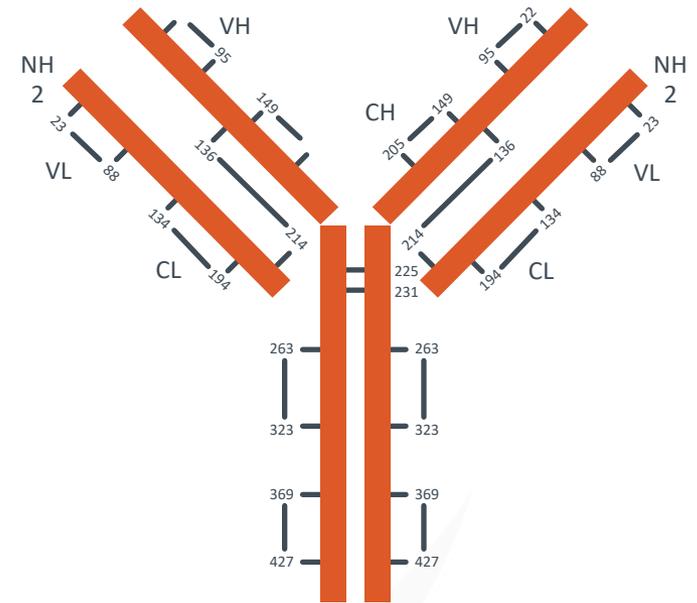
- In patients over 60, LIGHT levels were significantly higher in those that eventually died than in those patients that recovered ( $p=0.021$ )
- Observed mortality rate was higher for patients over 60 of age (82%) compared to patients <60 years (32%)

Elevated LIGHT levels in hospitalized COVID-19 patients were most strongly associated with mortality in patients over 60

# CERC-002: A Novel First-in-Class Anti-LIGHT (TNFSF14) mAb

## The Only Known Clinical Stage Anti-LIGHT Antibody

- In-licensed from Kyowa Kirin Co.
- Positive toxicology profile
  - 8-week monkey toxicology study was well tolerated up to 100 mg/kg per week with NOAEL at 60 mg/kg
- Phase I trial previously completed
  - Up to 1200 mg SQ in healthy volunteers (n=48) without significant toxicity
- Proprietary free LIGHT assay developed in collaboration with Myriad RBM enables a biomarker-based development approach



Discovered at La Jolla Allergy Institute  
and Licensed by Cerecor in 2016

# CERC-002 Treatment of Cytokine Storm-Induced COVID-19 ARDS

## Primary Endpoint: Respiratory Failure and Mortality Over 28 Days

### Proof-of-Concept Trial Design

Randomized, Double-blind, Placebo-controlled, Multi-Center, Proof-of-Concept Clinical Trial of CERC-002 in Adults with COVID-19 ARDS

#### Inclusion Criteria

Hospitalized Patients with Documented COVID-19 Infection and Clinical Evidence of Pneumonia with Mild to Moderate ARDS

Enrollment (N=83)

1:1  
Randomization

CERC-002 (16 mg/kg [maximum 1200 mg]) on Day 1 by SQ injection + Standard of Care at the site

Placebo-matched SQ injection + Standard of Care at the site

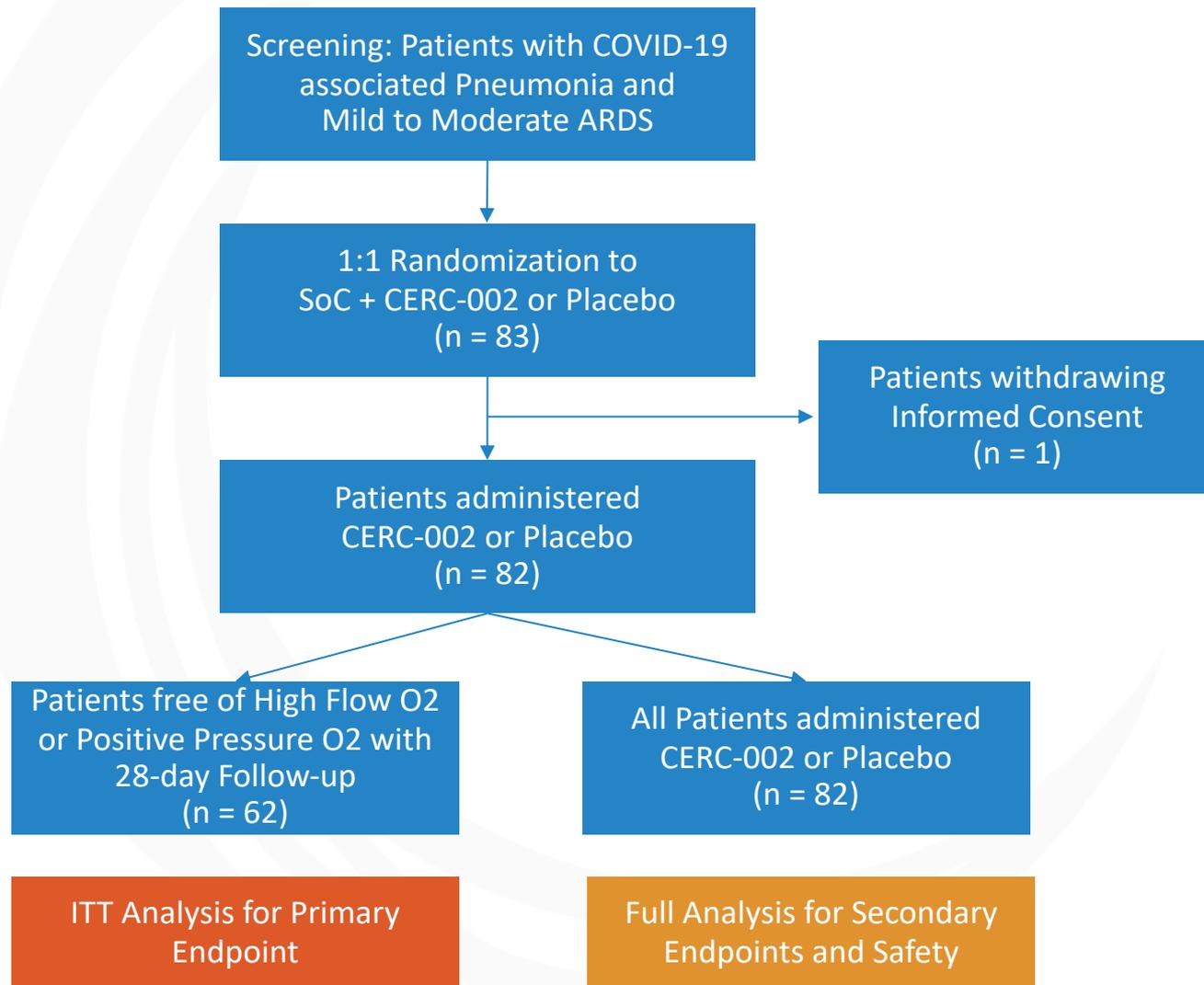
#### Primary Endpoint

- The proportion of patients treated with CERC-002 compared with placebo in addition to standard of care at site, alive and free of respiratory failure over 28 days
- 80% power to show an absolute difference of 25% between cohorts

#### Key Secondary / Exploratory Endpoints

- 1-month mortality
- Change in PaO<sub>2</sub>/FiO<sub>2</sub> ratio
- Time to and duration of invasive ventilation
- LIGHT levels and other biomarkers of inflammation
- Viral load

# Patient Disposition Chart



# Patient Demographics

Characteristic	CERC-002 (n=41)	Placebo (n=42)
Age, years Mean (SD)	59.2 (14.5)	58.1 (14.2)
Age Group		
<60 years (n, %)	20 (48.8%)	21 (50.0%)
≥60 years (n, %)	21 (51.2%)	21 (50.0%)
Gender		
Male	25 (61%)	32 (76.2%)
Female	16 (39%)	10 (23.8%)
Race		
White	31 (75.1%)	37 (88.1%)
Black or African American	7 (17.1%)	3 (7.1%)
Asian	2 (4.9%)	0 (0%)
Other	1 (2.4%)	2 (4.8%)
Free LIGHT Level at Baseline Mean (range) pg/mL	348 (63 - 1050)	273 (37 - 843)
Concomitant Medication Use at Baseline*		
Systemic corticosteroids	38 (95.0%)	37 (88.1%)
Remdesivir	26 (65.0%)	28 (66.7%)

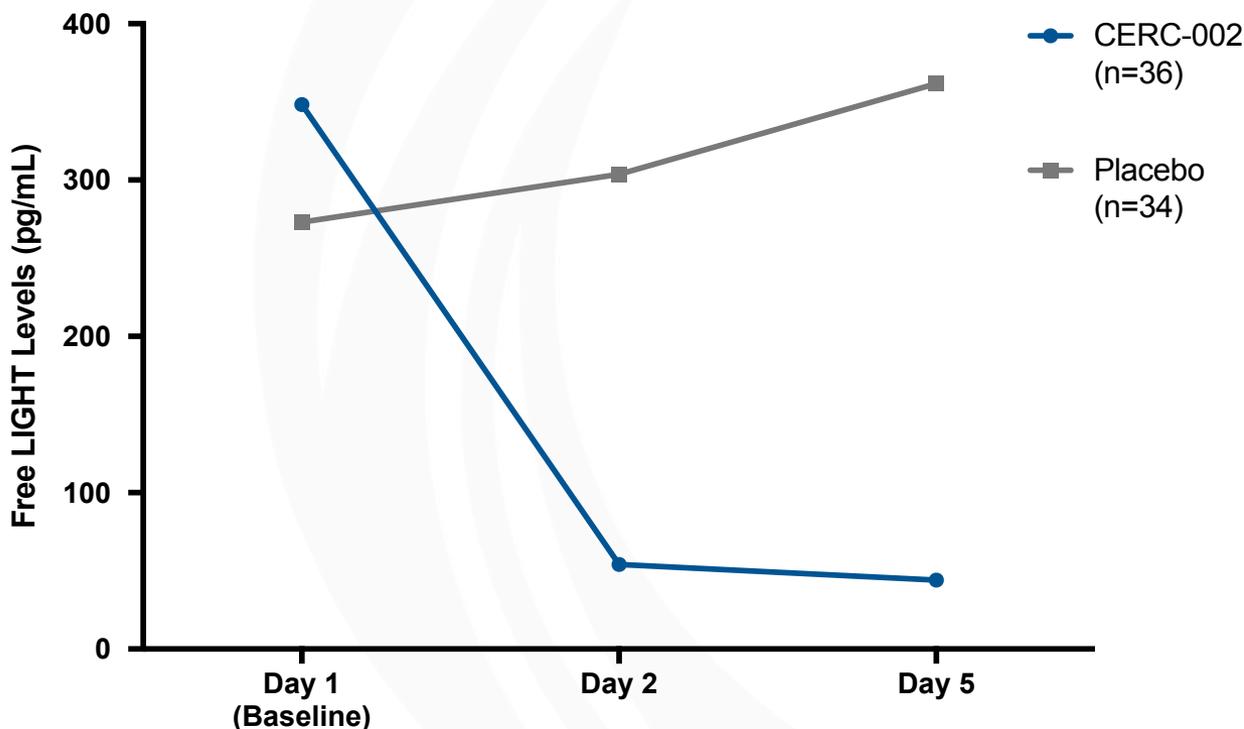
Data on file

\* Calculated from patients dosed (n=40 for CERC-002, n=42 for placebo)



# A Single Dose of CERC-002 Reduced Free LIGHT Levels Dramatically and Rapidly

## Free LIGHT Levels (pg/mL) Over Treatment Period

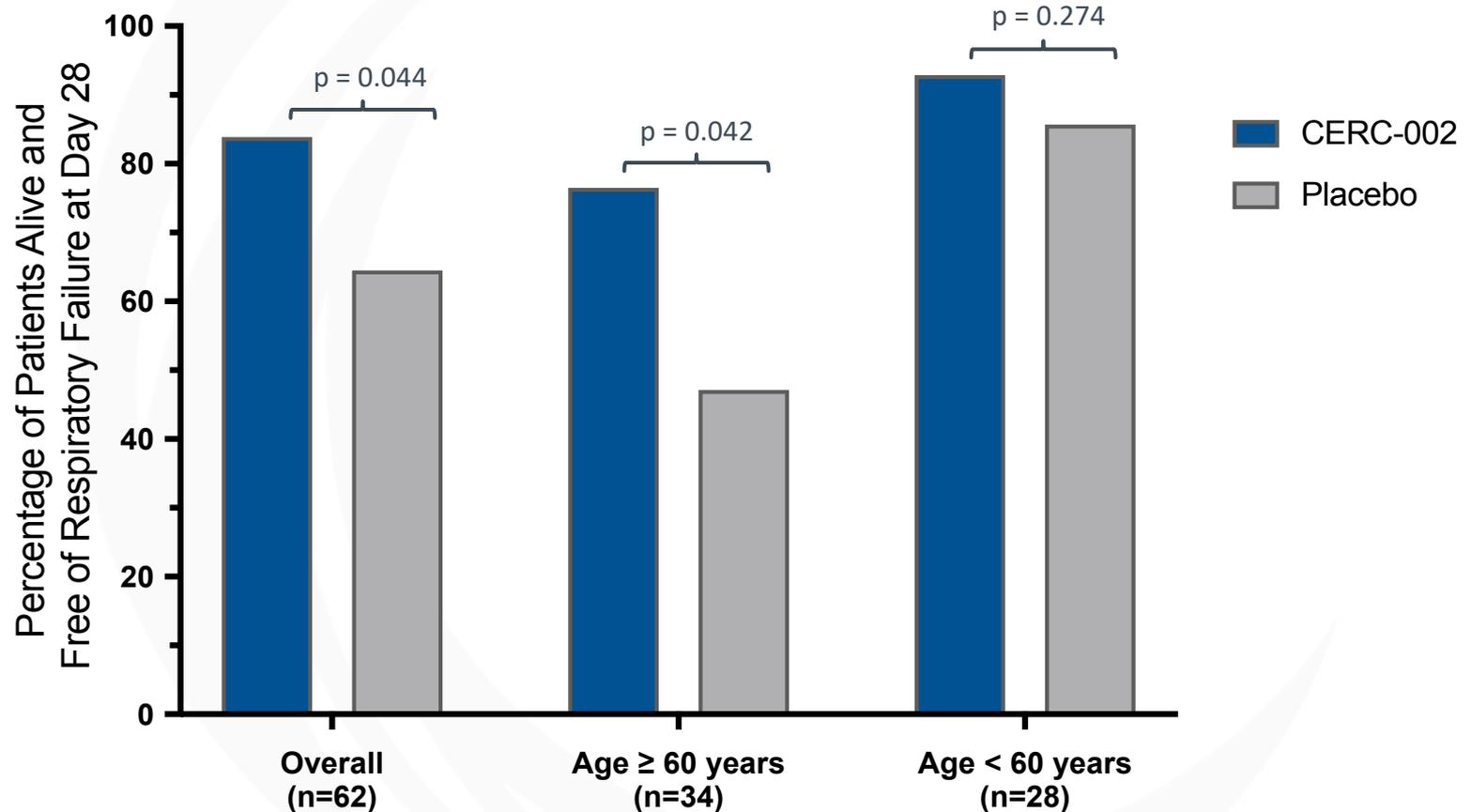


- Mean free LIGHT levels were comparable at baseline across cohorts
- Mean free LIGHT levels were about 100 pg/mL higher in the patients  $\geq 60$  years-old
- Free LIGHT levels reduced quickly in the active cohort and increased in the placebo cohort
- The pharmacodynamic effect was on top of standard of care where approximately 90% of patients received systemic corticosteroids

**Free LIGHT is inhibited by Day 1 and remains low**

# CERC-002 Significantly Reduced Respiratory Failure and Mortality in Phase 2 Clinical Trial in Patients Hospitalized with COVID-19 ARDS

Primary Endpoint: Percentage of Patients Alive and Free of Respiratory Failure at Day 28



Efficacy was highest in patients over the age of 60\* (n=34, p=0.042), the population most vulnerable to severe complications and death with COVID-19 infection

# A Single Dose of CERC-002 Reduced Mortality by ~50% in this Study

	CERC-002	Placebo
<b>28-day Mortality</b>	7.7%	14.3%
<b>60-day Mortality</b>	10.8%	22.5%

- A trend in ~50% reduction in mortality was observed at both the 28-day and the 60-day timepoints
- Efficacy observed is on top of corticosteroids and standard of care
  - (>90% of patients in the trial received corticosteroids and >65% received remdesivir)

## Safety and Tolerability

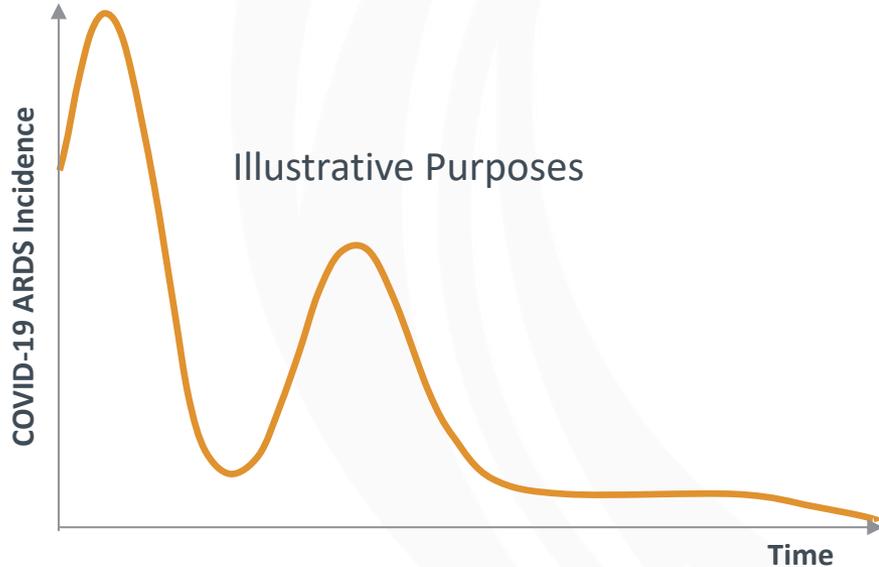
- CERC-002 was well-tolerated at a single dose of 16 mg/kg
- No serious adverse events attributable to CERC-002
- Majority of AEs judged to be mild or moderate
- No evidence of increased infections or adverse events related to immunosuppression

	CERC-002 (n=40)	Placebo (n=42)
Subjects with ≥1 AE (%)	16 (40%)	21 (50%)
Subjects with ≥1 Drug-related AE	8 (20%)	6 (14.3%)
AEs > 5%		
Leukocytosis	6 (15%)	4 (9.5%)
Anemia	4 (10%)	3 (7.1%)
Hepatic enzyme increase	4 (10%)	2 (4.8%)
Acute kidney injury	3 (7.5%)	2 (4.8%)
Respiratory failure	3 (7.5%)	3 (7.1%)

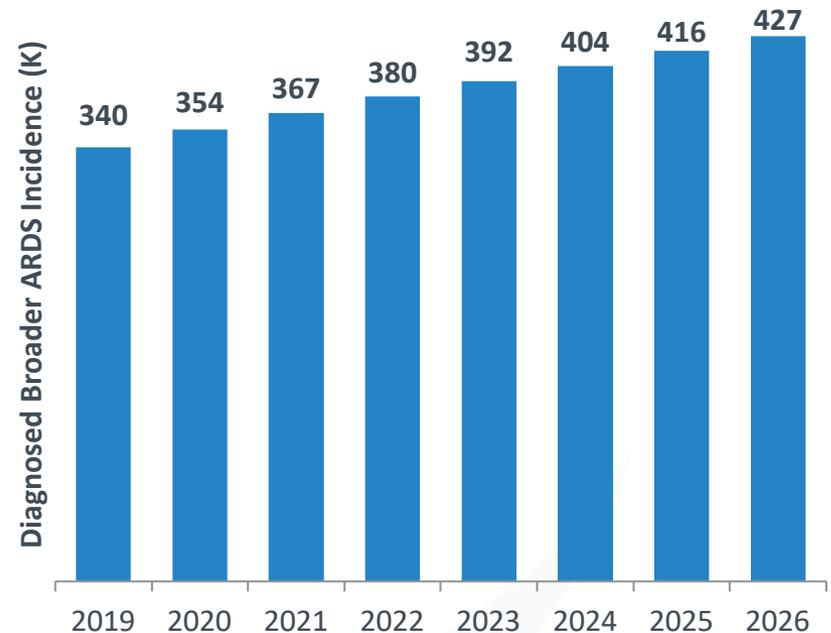
# COVID-19 and Broader ARDS Target Populations

**COVID-19 ARDS provides a potential path to treat a larger patient population in broader ARDS**

## U.S. COVID-19 Related ARDS Patients



## Estimated U.S. Broader ARDS Patients Excluding COVID-19

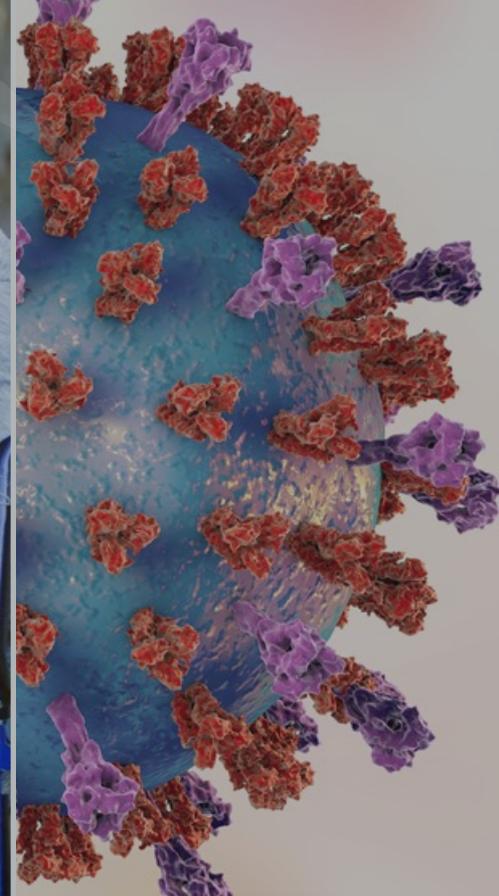
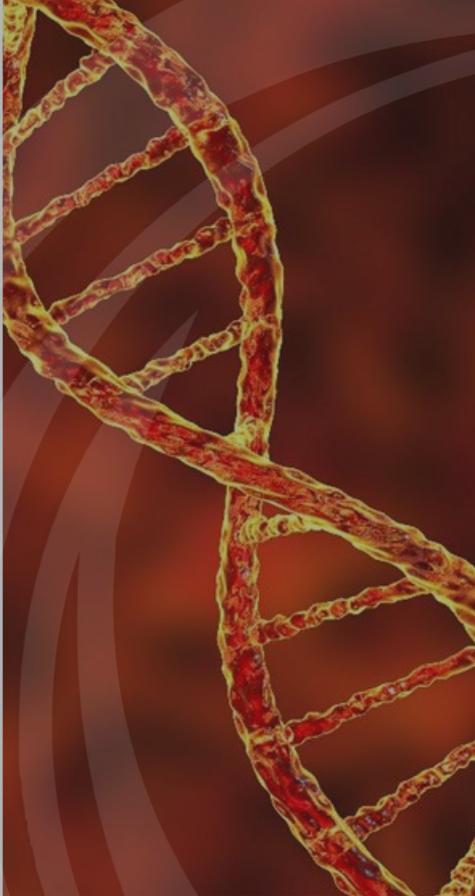


**There is a large market opportunity and high unmet need for effective therapy in cytokine storm induced ARDS beyond COVID-19**

## Next Steps

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- Applied for FDA Breakthrough Therapy and Fast Track Designations
- Plan to meet with FDA to discuss potential path to Emergency Use Authorization
- Manuscript in preparation with plan to present full data at a future scientific meeting
- Currently exploring the applicability of CERC-002 in non-COVID-19 ARDS



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**NASDAQ:CERC**

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